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**Clinical measurement of functional outcomes of pulmonary
rehabilitation**

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A thesis submitted in partial fulfilment of the requirements of
Sheffield Hallam University
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Abstract

Chronic Obstructive Pulmonary Disease "COPD" is a chronic condition characterised by progressive deterioration in the lung function. COPD co exists with other clinical conditions resulting into complex cases. People with COPD suffer from progressive functional limitations and participation restrictions.

Pulmonary Rehabilitation "PR" is a multidisciplinary intervention designed to improve functional outcomes in people with COPD. Despite the established effectiveness of PR, a number of clinical problems in the provision of PR services remain unresolved. In order to address these problems an outcome measure that is appropriate for implementation in clinical settings is required.

The aim of this thesis was to develop a clinical tool for the measurement of functional outcomes of PR in people with COPD. The research process included three phases. A "conceptualisation" phase, the phase of "development", and a "clinical testing" phase.

During the phase of conceptualisation a critical review of the literature was performed. This resulted in the development of a framework for the measurement of functioning in people with COPD, and the identification of the specifications for a clinical outcome measure.

The phase of development resulted in the selection of the TELER method of measurement and the development and validation of TELER "function" indicators using extensive qualitative research that used indepth interviews and focus groups methods.

The final phase was testing the indicators in clinical PR settings. This resulted in providing evidence of the usefulness of the TELER "function" indicators in producing informative data appropriate for full clinimetric analysis. The clinimetric analysis of TELER data developed new insights about the provision of PR.

This thesis has contributed to the development in the measurement of the functional outcomes of PR, by providing a new clinical tool that is underpinned by sound theoretical, clinical and empirical knowledge. The tool is appropriate for use in clinical evaluation, and has the potential to resolve clinical problems in the provision of PR.

Acknowledgement

I would like to take this opportunity to thank all those who have made the thesis and its completion possible. I particularly wish to thank my Director of studies Professor Sue Mawson for all her support, thoughtfulness, caring, help and patience during the years it took from start to completion of this thesis. I would also like to thank Dr Angela Tod for her precious advice and support. I would like to express my sincere appreciation to Mr LeRoux who has graciously fielded all my questions and was invaluable in blazing the trail. I remain grateful to the CLAHRC COPD Theme steering group for their support and invaluable feedback. It would also have not been possible without the patients and the support group members, who took the time to be interviewed and complete the TELER "function" indicators.

I would like to dedicate this thesis for the unconditional love, support, and infinite patience, for mum and dad. For the best mother in the world your tears on the day I left have been such an inspiration. And for the best father in the world, your wisdom, advice, and faith have lightened the darkest nights. I remain indebted for the relentless emotional and financial support from my father and mother in law; it is you who made the completion of this journey possible and peaceful. I would like to express my gratitude for dearest uncle Okasheh for the financial and expressive sponsorship of this journey.

For all those who, just by being there, has been an inspiration and encouraged me to complete this work. For lovely sister Rand thank you for being there to care when everybody else was busy. My sweetheart Hani and Gaith, thank you for all the lovely jokes that picked me from the deepest lows. I would like to single out Mohammed and Ala'a for being such a great family and beloved friends. For dearest Dania, Bashar, Faisal and Yara your presence literally made life away from home much easier. As much as it is for those who have been around, it is for those who left this world. For my grandmother and aunt Thuraia, I'm sorry I was not around to pay a tribute, but I hope this stands. May your souls rest in peace.

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Abbreviations list

| | |
|-----------------------|--|
| ATS | American Thoracic Society |
| BTS | British Thoracic Society |
| CAT | COPD Assessment Test |
| CCQ | The Clinical COPD Questionnaire |
| CRQ | The Chronic Respiratory Questionnaire |
| COPD | Chronic Obstructive Pulmonary Disease |
| CSP | Chartered Society of Physiotherapy |
| ERS | European Respiratory Society |
| GOLD | Global Initiative for Chronic Obstructive Lung Disease |
| NHLBI/WHO | National Heart, Lung and Blood Institute/World Health Organization |
| NICE | The National Institute for health and Clinical Excellence |
| NIHR CLAHRC SY | The National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care, South Yorkshire |
| PR | Pulmonary Rehabilitation |
| SGRQs | The St. George's Respiratory Questionnaire |
| LACDL | The London Chest Activities of Daily Living Questionnaire |
| MRADL | The Manchester Respiratory Activities of Daily Living questionnaire |
| QIPP | Quality Innovation Productivity and Prevention challenge |
| RCTs | Randomized Controlled Trials |
| TELER | Treatment Evaluation by the LERoux method |
| WHO | World Health Organization |
| PFSDS | The pulmonary functional status Dyspnoea scale |
| PFSS | The pulmonary functional status scale |

Introduction

The prevalence of chronic diseases¹ is escalating, presenting an increased economic burden nationally and worldwide (WHO 2008)². Chronic diseases are defined by the department of health as those diseases that could be controlled, but at present not cured (Department of Health 2004). The increased prevalence is explained by the aging of the population, and the increased exposure to risk factors resulting from behavioural, societal and environmental changes (Rosen *et al.* 2007).

Chronic respiratory diseases were identified amongst the four leading causes of disability worldwide (WHO 2008). There is growing evidence that Chronic Obstructive Pulmonary Disease “COPD” coexists with other chronic conditions creating complex cases (Yawn and Kaplan 2008) and (Barnes and Celli 2009). Such a complex disease requires a complex multidisciplinary intervention to target it. Pulmonary rehabilitation “PR” is currently accepted as a standard component of the integrated care for people with COPD (NICE 2010)³. Physiotherapists are key to the design and delivery of PR programmes, and frequently involved in leading the program (CSP 2011)⁴. Delivery of PR occurs at clinical, community, and home settings. Moreover, physiotherapists facilitate concordance with the exercise program and maintenance of the long term benefits by contributing to the education and self-management components of PR. The overall aim is to improve functional status of the individual patient (BTS 2001)⁵.

NICE produced two documents containing various sources of evidence supporting the effectiveness and efficiency of pulmonary rehabilitation (NICE 2006, and NICE 2010). Moreover, evidence from randomised controlled trials “RCTs” suggests that intensive multidisciplinary pulmonary rehabilitation resulted in decreased length of hospital stay (Griffith *et al.* 2000) (Griffiths *et al.* 2001) and reduction in readmission with evidence of cost effectiveness (Seymour *et al.* 2010) .

¹ The terms chronic, life long, long term, non-communicable diseases/ conditions, are used interchangeably.

² The World Health Organization.

³ The National Institute for health and Clinical Excellence.

⁴ The Chartered Society of Physiotherapy.

⁵ The British Thoracic Society.

A number of studies reported improved exercise capacity following pulmonary rehabilitation (Nici and ZuWallack 2010), (Laccasse *et al.* 2009), and (Ries *et al.* 1995). However, there is no evidence to show that improvement in exercise capacity translated into improved functional performance at home and in the community (Pitta *et al.* 2008) (Bourbeau 2010). One explanation of this could be that functional performance is influenced by factors other than those influencing functional capacity. Therefore, it should be measured separately (Nici *et al.* 2006). However, an “appropriate” outcome measure of functional performance currently does not exist.

An appropriate outcome measure should be able to trace changes in functional performance. Moreover, the outcome measure should be appropriate to the context and the population within which it will be implemented. Clinicians working in PR setting are critical of the appropriateness of functional status outcome measures used in RCTs for use in clinical settings. Despite the ability of existing outcome measures to provide evidence of improved functional outcomes at the level of the population, when used in clinical setting at the level of the individual these outcome measures have two main problems. Firstly, they fail to reflect all clinically significant changes experienced by the patient. Secondly, although they include a comprehensive set of items that make a good assessment tool, they fail to inform the decision making process during treatment (Greenhalgh *et al.* 2005).

The evaluation of functional outcomes in a clinical setting is an integral component of care (Higginson and Carr 2001). Appropriate measurement of outcomes improves the quality of care delivered to the individual patient. This is particularly relevant to people with chronic conditions, who suffer from progressive functional limitations that interfere with their daily life functions. It is proposed that the appropriate measurement of outcomes would provide informative clinical data. It might be assumed that this could enhance the experience of care of the individual patient, facilitates clinical reasoning and decision making, and ultimately improves the efficiency and effectiveness of care provided to the whole group of patients (Lakeman 2004).

Therefore, this PhD program set out to develop a clinical tool for the measurement of functional outcomes during PR. The thesis suggests that an appropriate outcome measure for use in a clinical setting should be a valid, reliable and responsive tool that enables the translation of improvements realised from the intervention at the level of the individual patient into informative clinical data. Moreover, the aggregation of the data generated at the level of the individual could provide information at the level of a group of patients. It is expected that this would provide informative data for managers.

In order to develop such a measurement tool a review of the theoretical, clinical and empirical knowledge underpinning the disease and the interventions implemented is required. It has been highlighted that PR is a multidisciplinary complex intervention. The development of outcome measures for complex interventions requires thoughtful awareness of the relevant theory and clinical knowledge about the progression of the disease. This ensures clarity about what should be measured, and how should it be measured (MRC 2008).

While it is customary in a thesis to “perform a literature review, identify the gap in the knowledge, formulate research questions, design a study to answer questions followed by a discussion of the results”, this thesis is constructed in a different way. The rationale for this being that during the literature review a critical lack of theoretical knowledge and standardised definitions about the disease and the intervention was identified. Subsequently a critical review of the literature was required to synthesise existing literature into a framework of measurement that would guide and inform the following steps in development.

To define this preliminary critical review of the literature, the term “conceptualisation”, that is traditionally used to refer to the definition of the construct to be measured, was expanded to refer to a number of conceptual activities. The term “conceptualisation” used in this thesis refers to a set of conceptual activities that included a critical literature review, a synthesis of clinical and theoretical knowledge and empirical and pragmatic research evidence, and a development of a framework for the measurement of functioning.

Moreover, in response to the problem of a lack of knowledge about the progression of COPD, this program of research also examined the experience of people with COPD and clinicians undertaking PR of COPD. The development of the measurement tool was underpinned and guided by the knowledge generated from the phase of conceptualisation, the patients' perspectives and the clinicians' clinical knowledge. Following development the tool was tested in clinical setting to explore the usefulness of the indicators, and to provide new knowledge about the delivery of the program and the outcomes.

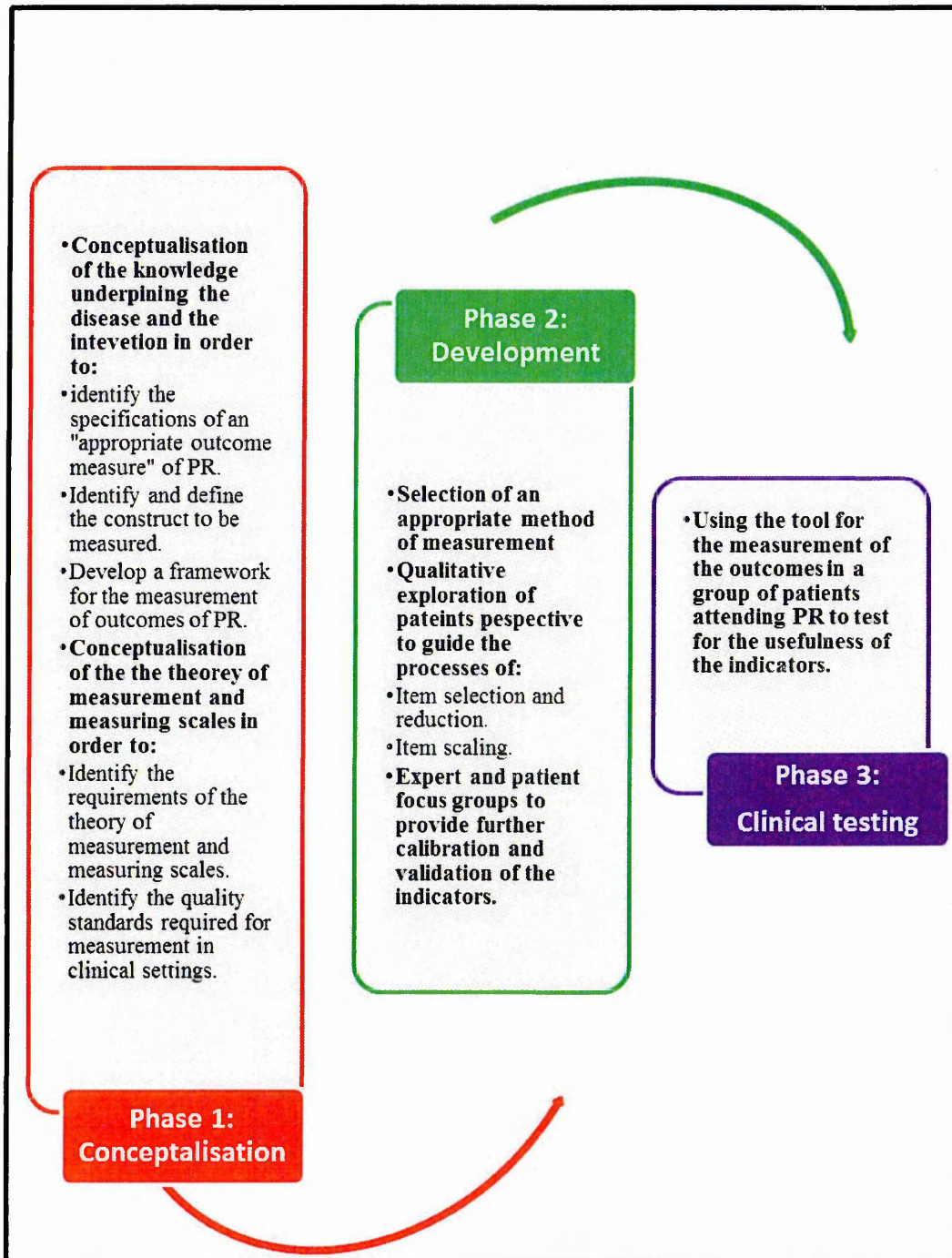
The process of outcome measure development was divided into three phases. The first phase is the conceptualisation. During this phase the theories and knowledge derived from existing literature about COPD, PR, models of functioning, measurement theories and principles of measurement in clinical settings, were used to provide the specifications of an appropriate outcome measure of functional outcomes for implementation in clinical PR setting. This phase constituted an integral component upon which the design and the conduction of the second phase were based.

The second phase was the development of the outcome measure. This involved the selection of a method of measurement that fulfilled the specifications of an appropriate outcome measure for implementation in clinical PR setting, a qualitative exploration of patients' experiences of the functional limitations resulting from COPD, and validation and calibration of the outcome measure with reference to clinicians' clinical knowledge and patients' perspectives.

The third phase was testing the indicators in clinical PR settings. The aims of the different phases and research questions were formulated at the outset of each phase of the process of development. They were continuously developed and reviewed according to the development of knowledge and understanding resulting from the previous phases. Each phase was followed by a discussion to verify the findings and link the knowledge generated to the next phase. Figure 1 presents the Phases of the process of development.

A mixed method approach that used a triangulation of qualitative and quantitative methods was employed to achieve the aim of this research process. This included a critical review of the literature, an indepth qualitative exploration of the patients' perspectives and clinician's experiences, and a quantitative and qualitative evaluation in clinical PR settings.

Figure 1 The Phases of developing the measurement tool



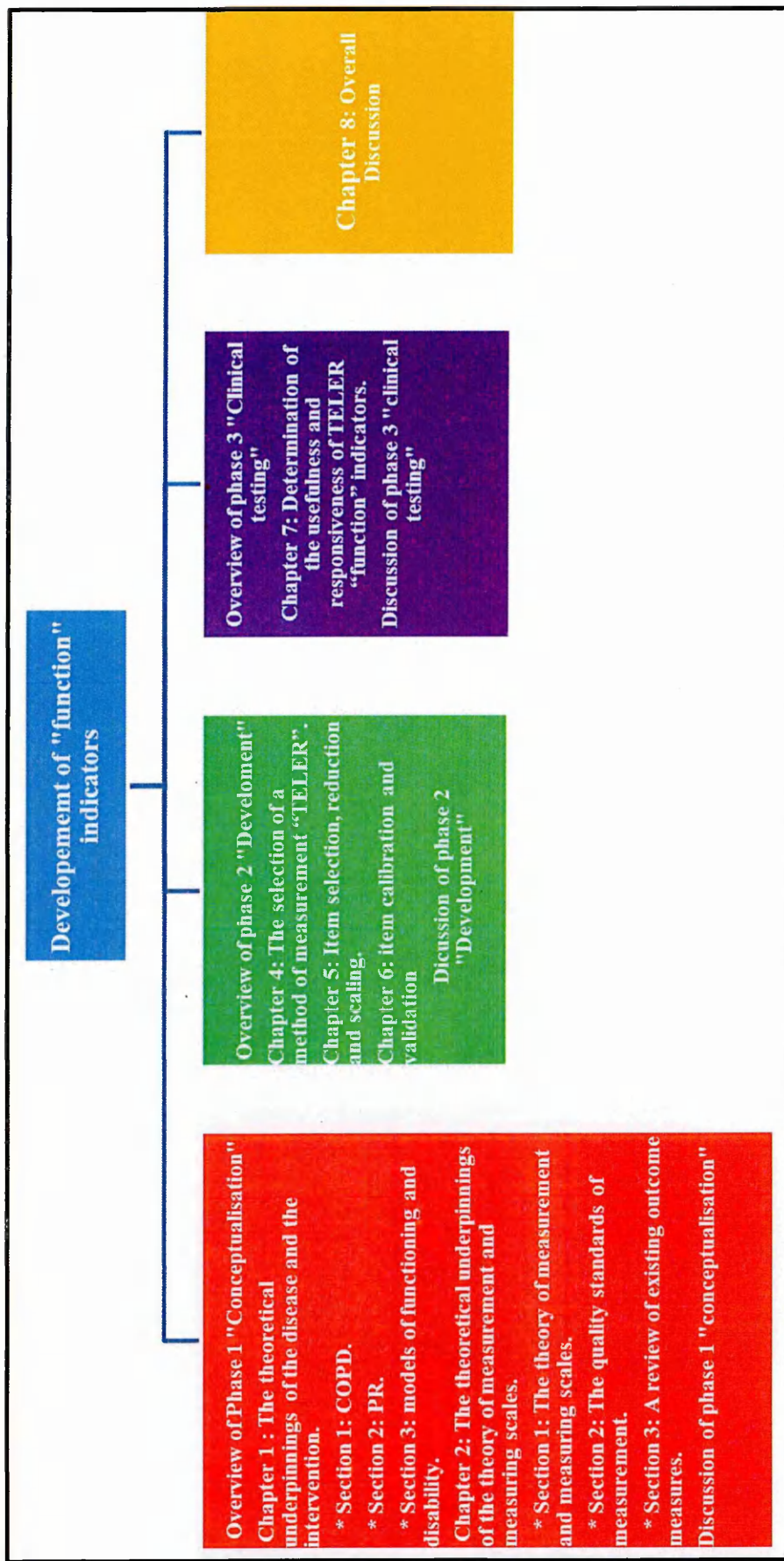
The thesis presents a novel process of developing a new outcome measure of “functional outcomes” of PR for people with COPD followed by an overall discussion.

The outcome measure developed during this PhD research is the only outcome measure that is based on comprehensive conceptualisation and synthesis of clinical and theoretical knowledge, and empirical and pragmatic research evidence. The process of development was guided by the knowledge and the theoretical framework developed during conceptualisation. The definitions of the construct and the categories of the outcome measure are clinically significant and grounded into patients’ narratives. It is also the only outcome measure that was formally evaluated in a clinical PR setting.

The overall discussion is presented in two parts. The first part is concerned with identifying the need for the measurement of health outcomes in clinical settings. The second part is a discussion of the contribution of this thesis to the knowledge in the area of developing outcome measures for implementation in clinical settings. This includes a reflection on the suitability of the methodologies used and its impact on the quality of the outcome measure that was developed.

The discussion also highlights the contribution of the new outcome measure to solving clinical problems in PR settings, by providing informative data to the patients, clinicians, and managers. A discussion of the new clinical knowledge that has emerged about the provision of PR is also provided. This is followed by a reflection on the limitations of this research and a discussion of future research. Figure 2 shows a diagram presenting the overall structure of the thesis.

Figure 2 The overall structure of the thesis



Phase 1: Conceptualisation

Chapter 1: The knowledge underpinning the disease and the intervention

- Section 1: Chronic Obstructive Pulmonary Disease (COPD).
- Section 2: Management of COPD.
- Section 3: Models of functioning and disability

Chapter 2: The theoretical underpinnings of measurement

- Section 1: The theory of measurement and measurement scales.
- Section 2: The quality standards of measurement.
- Section 3: A review of existing outcome measures.

Overview of phase 1: “Conceptualisation”

The aims of the literature review are to:

1. Identify the complex and progressive nature of COPD and how this influences the design of complex interventions, particularly Pulmonary Rehabilitation.
2. Identify the functional outcomes of PR that should be measured in people with COPD.
3. Identify the specifications of an “appropriate outcome measure” of functional outcomes of PR, based on the current empirical and pragmatic research evidence, and the theoretical and clinical knowledge of COPD and PR.
4. Establish a framework for the measurement of the outcomes of PR in people with COPD.
5. Identify the criteria of outcome measures, which would result in the generation of informative data in clinical settings, and have the potential to be implemented as self-management tool at home and in the community.

Research questions of the phase “Conceptualisation”

1. What are the functional outcomes of PR that should be measured in people with COPD?
2. What are the specifications of an “appropriate outcome measure” of the functional outcomes of PR in people with COPD?
3. What are the principles of measurement in clinical settings, required to ensure the generation of informative data?
4. Do existing outcome measures fulfil the specifications and the criteria required of “an appropriate outcome measure” of PR in people with COPD?

Methods of the literature review

To achieve these aims a critical literature review was performed. Grant and Booth (2009) provided a typology of literature reviews and associated methodologies. A critical literature review aims to synthesise and conceptually analyse the literature from diverse resources. The aim is not to provide answers but to create a multidimensional model that represents the current knowledge and theory on the topic. Therefore, while acknowledging the quality standards required for the evaluation of research reports, this type of reviews does not exclude materials based on a pre-specified criteria.

In the literature review logical decisions are made on the conceptual contribution, provided by empirical and pragmatic research evidence, review articles, expert opinions and theories, to the development of knowledge and theories underpinning the disease and the intervention. However, the author maintained a thoughtful consideration to the strengths and weaknesses of each source of information.

Scope of the literature review

The critical review of the literature is split into two main sections. The first section is a review of the knowledge underpinning the disease and the intervention and includes:

1. Chronic obstructive pulmonary disease.
2. Pulmonary rehabilitation.
3. Models of functioning and disability.

The second section is a critical literature review of the theoretical underpinnings of measurement and includes:

1. The theory of measurement and measuring scales.
2. The principles of measurement in clinical settings.
3. Existing outcome measures currently used in PR.

Chapter 1: The knowledge underpinning the disease and the intervention

1 Chronic Obstructive Pulmonary Disease “COPD”

This is the first section of the critical literature review of the disease “COPD” and the intervention “PR” to be researched in this thesis. This section is presented in three parts. The first part is a review of the burden of the disease. The second part is a critical review of the factors that influenced the lack of knowledge about COPD. The third part is a presentation of the current knowledge on COPD derived from national and international guidelines, expert opinion, and pragmatic and empirical research evidence.

1.1 The burden of COPD

Chronic obstructive pulmonary disease (COPD) is an umbrella term suggested by Burrows *et al.* (1966) to provide a unified definition of a group of disabling conditions that affect the function and structure of the pulmonary system, clinically known as chronic bronchitis and emphysema (Burrows *et al.* 1996) and (Department of Health 2010b). Globally, COPD is a leading cause of morbidity and mortality with a substantial and escalating burden. According to the WHO, 80 million people have severe and moderate COPD worldwide. It was estimated that death from COPD amounts to 5% of all deaths globally, with 90% of the deaths resulting from COPD occurring in the low and middle income countries where accurate prevalence data is lacking (WHO 2008).

The World Health Organisation (2008) ranked COPD as the fourth leading cause of death worldwide that is projected to become the third in 2020. This is largely due to changes in smoking behaviour that is significantly increasing in the developing world, and the aging population in the developed countries with more people living longer, and reaching the age when COPD develops (WHO 2008) and (The Global Initiative for Chronic Obstructive Pulmonary Disease “GOLD” 2010).

1.1.1 Prevalence and mortality of COPD

Prevalence data varies substantially. This is due to the variation in the exposure to risk factors. It is further compounded by the variation of survey methods which include, but not limited to: Self report of a doctor diagnosis, Spirometry and Questionnaires asking about respiratory symptoms. The GOLD report suggests that prevalence data based on self report of doctor diagnosis are the lowest, constituting (6%) of prevalence data. This reflects the widespread under diagnosis and under recognition of the disease (GOLD 2010).

Halbert *et al.* (2006) conducted a systematic review of population based studies of COPD globally and reported 9-10 % prevalence in adults above the age of 40. However, Demarco *et al.* (2004) estimated prevalence based on GOLD (GOLD 2010) definition of COPD, and reported this to be 2.5% for stage 1 COPD, and 1% for stage 2 or 3 COPD in adults under 45 years living in Europe. They suggested that the prevalence of the disease in the UK is about average when compared to other European countries (Demarco *et al.* 2004).

Stang *et al.* (2000) estimated 3 million people living with COPD in the UK. However, only 900,000 people were correctly diagnosed (British Lung Foundation “BLF” 2003). In the year 2004, COPD resulted in the death of 27,478 men and women in the UK. The majority of those were above the age of 65 (Burney and Jarvis 2006). Interestingly, as about twice this number have COPD either in part I or part II of their death certificate, this is because COPD usually co exists with other conditions such as ischemic heart disease and lung cancer (Burney and Jarvis 2006). This reflects the complexity of the clinical condition of people with COPD.

Health inequality that might result from a disparity in the distribution of COPD across socioeconomic groups, ethnicities and gender is another important aspect of the disease. There is a strong urban rural gradient in mortality rates in England with higher rates in the north of England (Hansell *et al* 2003). Moreover, there is a major social inequality with unskilled men employed in manual occupations being 14 times likely to die from the disease (British Thoracic Society “BTS” 2001). Ethnic and gender disparities also exist with growing evidence suggests that black men living in urban areas and female gender (BLF 2005, and GOLD 2010) are more susceptible to the disease.

1.1.2 Social and economic burden of COPD

The potential for severe disability in COPD results in a substantial social and economic burden that is reflected by days lost from work, early retirement and the time and effort of family members caring for people with COPD. These aspects of the economic burden are not adequately acknowledged when calculating the direct and indirect costs of COPD, where emphasis is being placed on the costs of health care utilization, which is on its own substantial (Pauwels and Rabe 2004). This also reflects the dearth of research about an important aspect of COPD that is the functional limitations and participation restrictions associated with COPD.

The Department of health (2005) reported 1.4 million primary care consultations for COPD which is four times more than angina. Within respiratory diseases COPD is the most common cause for hospital emergency admissions, and ranked the second just after pneumonia for total beds per day (BTS 2001). The direct health costs of COPD are reported by the Chief Medical Officer (Department of Health 2005) to account for more than £800 million. However, the indirect health costs are substantial and very difficult to quantify, with an estimated 24 million lost days from work per year (Department of Health 2005).

The escalating burden of COPD resulting from high mortality rate and progressive disability, taken together with health inequality implications makes COPD a health priority as stated by the vision of the new white paper on public health (Department of Health 2010c). The strategy of this white paper is developed to tackle social determinants of health inequalities and help people live longer and healthier (Department of health 2010c).

The burden of COPD is described in the literature in terms of data on prevalence, mortality, morbidity, direct and indirect health costs, the existence of co morbidities and quality of life. It is worth noting that this data is variable and greatly underestimates the actual burden of the disease (Pawels and Rabe 2004). This variation could be explained by two main factors. The first is the differences in the reporting and research methods used to collect these data (Mannino *et al.* 2002). The second factor is scarcity of knowledge about COPD and inconsistent definitions of the disease.

1.2 The factors that influenced the lack of knowledge about COPD

Lack of knowledge about COPD is related to certain attributes of the disease such as multiple risk factors, and the progressive natural history that has adverse impact on the life of people with the disease. The risk factors of COPD are naturally diverse and include environmental exposure and behavioural factors “smoking”. The result is a heterogeneous distribution of the disease across geographical areas, socioeconomic classes, and gender (Pawels and Rabe 2004).

The heterogeneous distribution of the disease results in heterogeneous population. This should be thoughtfully considered when designing and evaluating interventions for this population. Conclusions drawn from a certain group of people with COPD might not be relevant for implementation in another context and within another group. This highlights the pressing need for shifting from a disease oriented approach to a patient centred approach when designing and evaluating interventions (Higginson and Carr 2001). It might be suggested that this shift should be supported by tools that facilitate individualised delivery and evaluation of care. Therefore, an outcome measure that enables measurement of outcomes at the level of the individual patient is required.

The onset of the symptoms of COPD was described in the literature as “insidious” where clinical signs and symptoms are not recognised until the disease is moderately advanced (Kornmann *et al* 2003) and (Mannino *et al.* 2002). Even when the disease is clinically evident the stigma of the self inflicted disease and the misconception of symptoms as aging rather than COPD has resulted in reluctance of patients to seek medical advice, this is known in the literature as “under reporting”.

The slow and silent progression of the disease resulted in a lack of knowledge about the early stages of the disease and its development. This was further complicated by the scientific conception that once the disease is moderately advanced it is "irreversible" (Hansen *et al.* 1999). The result was a broad negligence that contributed to the shortage of knowledge about the disease, its mechanisms and its impact (Barnes and Kleinert 2004). It is suggested that the lack of the clinical and theoretical knowledge underpinning the disease has prohibited the development of valid outcome measures that are based on sound theory and knowledge (Ninci *et al.* 2006). It might be suggested that this gap in the knowledge could be filled by involving the perspectives and experiences of the patients when developing new outcome measures.

The slow and progressive course of COPD as well as persistent disability has implications on how health outcomes should be identified and measured. It is suggested that it would be more informative to measure changes in the pattern of the disease at a number of points in time, rather than one clinical end point. This will provide more information about the changes experienced by the patient as a result of treatment. This will also enable the clinician to implement changes in treatment when no change or deterioration occurs (Higginson and Carr 2001).

Next is a critical review of the literature on the definition and symptoms of COPD. Risk factors and co morbidities are presented with their impact on the development of complex interventions. This will inform the identification of the specifications of an outcome measure for this population.

1.3 A review of the current knowledge on COPD

1.3.1 Definition of COPD

The definition of Chronic Obstructive Pulmonary Disease (COPD) continues to evolve as our knowledge about the disease advances. This continuous reform is due to the development of new laboratory technologies, expanding research, and the publication of a number of guidelines that are applauded for increased awareness of the impact of the disease and its burden (ATS/ERS, GOLD, NICE, the COPD national strategy, and an Outcomes Strategy for Chronic Obstructive Pulmonary Disease (COPD) and Asthma in England).

1.3.1.1 Physiological definition of COPD

Current COPD guidelines Highlighted airflow limitation as the main characteristic of COPD (ATS/ERS, GOLD, NICE). Airflow limitation results form a combination of airway obstruction and parenchymal damage. This is defined and classified based on two main spirometric measures, the FEV₁: Forced Expiratory Volume in 1 second, and the FEV₁/FVC: Forced Expiratory Volume in 1 second/ Forced Vital Capacity (Table 1).

Table 1 GOLD classification of spirometric definitions of COPD. Adapted from GOLD (2010)

| GOLD stage | Characteristics |
|------------------------|--|
| 0: At Risk | <ul style="list-style-type: none"> • Chronic symptoms. • Exposure to risk factors. • Normal spirometry. |
| I: Mild | <ul style="list-style-type: none"> • $FEV_1/FVC < 70\%$. • $FEV_1 > 80\%$. • With or without symptoms. |
| II: Moderate | <ul style="list-style-type: none"> • $FEV_1/FVC < 70\%$ • $50\% < FEV_1 < 80\%$ • With or without symptoms |
| III: Severe | <ul style="list-style-type: none"> • $FEV_1/FVC < 70\%$ • $30\% < FEV_1 < 50\%$ • With or without symptoms |
| IV: Very Severe | <ul style="list-style-type: none"> • $FEV_1/FVC < 70\%$ • $FEV_1/FVC < 30\%$ or $FEV_1/FVC < 50\%$ with presence of chronic respiratory failure or right heart failure |

The guidelines provide different standards for defining COPD based on spirometry. While it is scientifically established that airflow obstruction is best measured by FEV1/FVC, establishing a diagnosis of COPD using spirometric criteria is currently questioned with a plea for revising current guidelines arising from a number of editorials (Miller *et al.* 2009, Townsend 2007, Marco 2008 and Culver 2006) and emerging new research evidence (Vaz Fragoso 2009; and Vaz Fragoso 2010).

Conventionally, establishing a threshold for defining people with the disease has been based, in medical research, on studies that compare the distribution of markers of the disease in the clinically diagnosed and healthy controls (De Marco 2008). Another method to establish this threshold is by conducting longitudinal studies that follow up the development of risks or complications related to the disease (De Marco 2008). Existing definitions of COPD are not based on such evidence and there is an urge to validate or redefine physiological thresholds of COPD (Miller *et al.* 2009), (Townsend 2007), and Culver 2006).

This suggests that there is a lack of appropriate research evidence to validate existing physiological definition. This has implication on the potential availability of clinical knowledge to inform the development of new outcome measures. This further emphasises the importance of the inclusion of knowledge generated qualitatively from patients and clinicians to formulate an adequate understanding about the disease.

1.3.1.2 Pathological characteristics of COPD

Recent literature is adopting a pathological perspective of the definition. A literature review by Cazzola *et al.* (2007) defined COPD as "a chronic inflammatory process in the pulmonary tissue". COPD is a complex disease process that is not fully understood. The slowly progressive course precludes easy validation of targets, and significant pathological changes are already evident by the time the disease is diagnosed.

Our current knowledge about the pathogenesis of COPD is derived from observational studies of the pathology and its interaction with host etiological factors, and from in vivo and in vitro disease models (Sabroe *et al.* 2008). The study of the pathology of COPD started recently and evidence is still emerging. A detailed review of the pathogenesis is beyond the scope of this thesis and has been extensively reviewed elsewhere (MacNee 2005) (Barnes and Kleinert 2004). However, it can be seen that unlike cardiovascular diseases there are no lifelong population based study looking at the natural history of COPD and the development of irreversible loss of lung function (Kohansal *et al.* 2009)

Currently there is a lack of appropriate research evidence to define physiological and pathological parameters. Accurate knowledge about physiology and pathology of COPD is still emerging and might be difficult to achieve due to the progressive nature of the disease and the insidious onset of clinical signs and symptoms. Moreover, there is a long subclinical phase that could not be defined. This notion implies that currently there is not enough clinical knowledge upon which to base the development of standardised measurement tools. Due to this significant gap, it is suggested that outcomes of treatment in terms of the impact of the disease on patients' life, rather than physiological and pathological outcomes, might provide more information and enhance the knowledge about the disease.

1.3.2 The natural history of COPD

A World Health Organization document (2007) defined COPD as "a heterogeneous disease, with various clinical presentations". COPD is a disease process; each stage is characterised by distinctive clinical manifestations and symptoms. It is well known that people with COPD present with varying severities and seek medical advice at various stages of the disease.

During the course of the disease some symptoms become more prominent at a certain stage. Mannino *et al.* (2002) suggests that the heterogeneous nature of the disease is well evident, with different potential interventions still emerging. On the other hand a new approach to understanding COPD views the disease as a network of a number of components. The nature of key components varies within the disease overtime, but this variation follows a certain pattern, that is not explored yet (Sabroe *et al.* 2008).

The National Heart, Lung, and Blood Institute/World Health Organization workshop (2001) described COPD as "a disease state". COPD presents as a disease status that is resistant to treatment, it is actually resulting from the interaction of multiple active processes that perturbate "health status" and operate against the immunity and body defence mechanisms resulting in the new status quo (Sabroe *et al.* 2008).

Petty (2006) described COPD as "a disease spectrum" reflecting the progressive nature of the disease and the varying characteristics of different stages. The word "spectrum" reveals the multi component nature of the disease. Current evidence suggests that the progression of COPD is influenced by the interaction of a number of pathological, personal and environmental factors resulting in a downward spiral where persistent and progressive pathological and physiological changes give rise to a number of clinical presentations that is signs, symptoms, and functional limitations that develop over time and contribute to disease severity (Sabroe *et al.* 2008).

Current knowledge about the natural history of COPD is incomplete. Moreover, COPD is currently defined from a medical perspective only; viewing the patient as a complex deposit of anatomical components and physiological systems (Aggleton & Challmers 2000). This has resulted in devising concepts that are inadequate to encompass the full process and impact of the disease. An example is provided in the latest GOLD report (2010), where "Emphysema" and "chronic bronchitis" have been frequently used in the definition of COPD.

The report highlighted the flawed use of these terms in the definition of COPD. The report suggested that Emphysema is a pathological term that has been used clinically and it describes only one of a number of structural changes in the alveoli. On the other hand chronic bronchitis is a useful clinical term, but it only describes two clinical symptoms "cough and sputum production", and does not reflect the full impact of these symptoms on the disease progression, the clinical endpoints (GOLD 2010), and the functional status. The limited physiological and pathological knowledge about the natural history of COPD, and the chronic progressive disease that interferes with day to day life highlights the importance of adopting a biopsychosocial perspective when identifying the progression and the clinical endpoints of the disease.

1.3.3 Symptoms of COPD

Symptoms of COPD have a pronounced impact on patients' everyday life and interfere with most functional activities, resulting in functional limitations and participation restrictions (International Classification of functioning disability and health "ICF" 2001). The updated GOLD document (2010) highlighted the importance of educating patients, health care professionals and the community in which people with COPD live that breathlessness, cough and sputum production are not trivial symptoms and that they are significant public health problems that should be monitored and addressed. Thus the document identified relieving symptom as an essential aspect of the management of COPD. In order to identify the symptoms associated with COPD and its impact on functioning in daily life a presentation of symptoms most commonly reported by people with COPD is provided next.

1.3.3.1 Nasal symptoms “rhinorrhoea”

Although the inflammatory reactions associated with COPD occur mainly in the lower airways, a large proportion of people with COPD present with nasal symptoms. This is explained by the anatomical continuity of the upper and the lower airways, and their mutual function (Hurst *et al.* 2004). The most commonly reported upper airway symptom is rhinorrhoea (Hurst *et al.* 2004). This is particularly significant because nasal symptoms were found to result in impaired quality of life in 88 % of a cohort of 65 patients with COPD as assessed by the 20-item Sino-Nasal Outcome Test (SNOT-20) (Hurst *et al.* 2004).

Objective assessment of upper airway symptoms is very difficult due to poor correlation between nasal symptoms, clinical makers and radiological changes (Hurst *et al.* 2004). Moreover, there was a poor correlation between SGRQ score, a disease specific quality of life measure in COPD, and SNOT-20 scores in a cohort of people with COPD (Hurst *et al.* 2004). The authors explained this by the significant impact of the lower airways' symptoms assessed by the SGRQ that have masked the impact of symptoms of the upper airways.

This highlights the need for moving from attempting to measure symptoms to measuring the impact of symptoms on activities of daily life that could be observed and properly reported by patients themselves. The SNOT-20 Items questionnaire claims to measure the impact of nasal symptoms on quality of life, however, the way questions are formulated seems to enquire answers about "how much problematic is a certain symptom". These ill defined questions probably do not provide sufficient information about the concept "quality of life"; rather it is descriptive of the symptoms themselves. There is a pressing need for reviewing measurement tools used in the literature, in the light of the principles of the theory of measurement, and sound definition of the concepts being measured. This review is presented in section three of the second chapter of this thesis.

1.3.3.2 Cough and sputum production

Cough is usually the first sign, and might be unproductive initially. However, it is usually misinterpreted as normal aging process, or a usual smoker cough, thus patients do not seek medical advice at this stage of the disease (Pauwels and Rabe 2004). Regular sputum production for three months in two consecutive years is clinically defined as chronic bronchitis. However, patients present with varying patterns of sputum production which makes it difficult to use the clinical definition for characterising people with COPD (Pauwels and Rabe 2004). This emphasises the need for adopting an individualised approach to the evaluation and management. This also further emphasises the need for shifting from the evaluation of symptoms to the evaluation of the impact of symptoms on function.

1.3.3.3 Dyspnoea and fatigue

Dyspnoea and fatigue are the most commonly reported symptoms, and result in exercise intolerance which is the main factor limiting activity and participation (Nici *et al.* 2006). Exercise intolerance is associated with anxiety and poor motivation resulting into further activity limitations and participation restrictions (Nici *et al.* 2006). This highlights the importance of evaluating the impact of symptoms on activities in people with COPD.

Dyspnoea or shortness of breath on exertion usually drives patients to seek medical help. It interferes with patients' ability to perform daily activities before the disease progress to more severe stage (Pauwels and Rabe 2004). The actual mechanism by which dyspnoea develop is not fully understood (Jolley and Moxham 2009). The most accepted mechanism proposes central sensitisation as mediator of perceived breathlessness, emphasising the role of personal factors in influencing dyspnoea (Undem and Nassensteina 2009) and (Manning and Mahler 2001).

Fatigue is identified as a factor limiting exercise tolerance in people with COPD. The mechanism of the development of fatigues has not been investigated (Saey 2003). Although it might be expected that fatigue is related to muscle wasting and peripheral muscle weakness, a qualitative exploration of patients' experiences of fatigue linked fatigue to laboured breathing (Small and Lamb 1999). Further investigation of the mechanisms of fatigue and its impact of the performance of daily life functions is required.

Breathlessness and fatigue, which are frequently reported clinical symptoms of COPD are subjective in nature and best defined with reference to people's experience of the symptoms and their impact on their lives. The knowledge about the disease could not be developed without adopting a holistic approach and involving the perspectives of patients when attempting to research and describe the processes of development of functional limitations in people with COPD. A qualitative exploration is an integral component for developing enhanced understanding of the impact of COPD on functioning in people with COPD. This will consolidate current knowledge and provide empirical qualitative evidence that would inform the development of new outcome measures. Outcomes should be formulated in terms of patients' needs and priorities, and in the light of the multidimensional impact of the disease.

1.3.3.4 Systemic manifestations of COPD

Systemic symptoms are present when the disease has progressed to the severe stage, these include: weight loss, loss of muscle mass, anorexia, and fatigue (Pauwels and Rabe 2004). The reality that COPD is a long term condition with progressive detrimental effects on functioning, resulting in activity limitations and participation restrictions; invites anxiety and depression. These psychological symptoms have been reported to be prevalent in 50% of people with COPD (Mikkelsen *et al.* 2004).

It is worth noting that the symptoms of COPD are not only respiratory but extend to involve other systems as the disease progresses, this emphasizes the significance of adopting a holistic approach to the management of COPD (Bellamy *et al.* 2006) and a multidimensional framework for evaluating interventions used in the management of COPD (MRC 2008).

A number of studies reported that symptoms are strongly related to quality of life, and this relation is stronger than that existing between quality of life and the severity of the disease as defined by GOLD based on physiological parameters (FEV1). Quality of life is directly influenced by functional limitations experienced by the individual (Victorson *et al.* 2009).

One of the purposes of the measurement of health outcomes is to diagnose causes of functional limitations (Duncan and Velozo 2007). Thus when identifying the outcomes of interventions, the relation between quality of life and symptoms institute symptoms as a more credible parameter than disease severity. However, objective assessment of symptoms is difficult due to their subjective nature and poor correlation with clinical markers. Hence measuring the impact of symptoms merits consideration.

The impact of symptoms on daily life activities is evident early in the disease progression (Pauwels and Rabe 2004), it might be more appropriate to evaluate the impact of symptoms on activities, rather than attempting to evaluate the symptoms. This is because symptoms of COPD are subjective “dyspnoea and fatigue”, and difficult to quantify, while the impact of symptoms on daily activities could be observed and reported by the patients themselves.

The impact of symptoms on daily life activities is best described by the patients' perspective of the disease. This perspective could be scientifically investigated using rigorous qualitative research (Ritchie and Lewis 2003). The knowledge emerging from this qualitative research could then be used to inform the development of measurement tools. There are a number of questionnaires that were developed to evaluate the impact of symptoms on daily life of people with COPD; however there are lots of issues in these questionnaires. A review of existing outcome measures is provided later.

1.3.4 Risk factors of COPD

Identification of risk factors is essential for developing strategies for preventing and managing diseases (GOLD 2009). This is particularly important in COPD as the disease result from the interaction of a number of risk factors most of them could be modified and avoided. Although smoking is frequently reported as the main risk factor for COPD, emerging evidence suggest that COPD result from the interaction between host risk factors and environmental exposure.

Smoking is generally accepted as the main risk factor (Mannino and Buist 2007). The main preventative strategy of COPD is based on "smoking cessation"(Viegi *et al.* 2007); this implies a behavioural component involved in the disease progression. Other risk factors include biomass exposure, outdoor pollution, environmental exposure, childhood respiratory infections, genetic and developmental abnormalities of the respiratory system (Mannino and Buist 2007), (Viegi *et al.* 2007) (ATS/ERS 2004), (GOLD 2010) and (NICE update 2010); all implying personal, environmental, and socioeconomic components of the disease. This complex set of risk factors necessities a holistic and patient centred approach to management as the limited focus on the medical basis of the disease is very unlikely to result in interventions that would modify the progression of COPD.

The interaction of multiple of risk factors and the coexistence of other co morbidities has implications on the experience of living with the disease. Qualitative studies exploring patients' experiences of living with the disease reported a detrimental impact because of the chronicity and the multidimensional nature of the condition. Leidy and Haase (1999) suggested that living with COPD has created challenges for preserving individual integrity and the efficacy of managing the long term disability resulting from the disease.

The British Thoracic Society (2001) has recommended the incorporation of behavioural components in the long term management of this group of people. This has resulted in the development of complex management programmes; however this was not accompanied by the development of outcome measures that are appropriate for the measurement of the outcomes of such complex interventions.

1.3.5 Co morbidities

There is emerging evidence that COPD co exists with other diseases resulting in complex cases. The most commonly reported co morbidities are: Age, anxiety and depression, lung cancer, coronary artery disease with arrhythmias, and venous thrombo-embolism. Most of the evidence on COPD and co morbidities investigated cardiovascular conditions and COPD. Longitudinal studies, matching participants with COPD with non COPD participant and identifying the prevalence of cardiovascular conditions in both groups were conducted. All studies concluded that the prevalence of cardiovascular diseases was higher in patients with COPD (Mapel *et al.* 2005), (Sidney *et al.* 2005), (Suellen *et al.* 2006). Marquis *et al.* (2005) reported that patients with COPD usually have one or more components of a metabolic syndrome, including diabetes. The evidence of the relationship between COPD and lung cancer is still emerging (Strange 2010)

However, the growing body of evidence supporting the fact that COPD co exists with other chronic conditions creating complex cases has opened a new realm of investigations. the scientific community is currently advocating a new hypothesis based on pathological and clinical knowledge that view the coexistence of COPD and other comorbidities as a new syndrome characterised by a systematic inflammation in response to a triggering stimulus. The triggering stimulus has been frequently reported as smoking and biomass fuel (Sabroe *et al.* 2008), (Fabbri *et al.* 2008) and (Yawn and Kaplan 2008). However, recent guidelines adopt a more holistic approach identifying the triggering stimulus as a combination of risk factor (GOLD 2010) and (WHO 2008).

Proponents of the new systemic inflammation theory are calling for a new approach for the management of COPD, advocating a shift from an organ multi pharmacological treatment based approach to a patients centred approach, that emphasise is oncontrolling risk factors, particularly smoking. However, in order for this movement to succeed it is important to support it by appropriate research evidence based on realistic clinical evaluation of complex interventions (Pawson 2003), and the measurement of outcomes at the level of the individual. This implies that outcomes of the interventions should be patient centred and defined from the perspective of patients. Moreover, an outcome measure that is appropriate for the measurement of clinical outcomes at the level of the individual and is appropriate for implementation in clinical settings should be developed.

1.4 Summary

In order to be able to identify the specifications of an appropriate outcome measure for people with COPD, it is important to understand the complexity of the disease. A critical review of the literature on the current knowledge on COPD has identified a number of important issues.

1. COPD is a leading cause of mortality and morbidity with a substantial and escalating burden that affects the individual and the society.
2. The potential for severe disability results in a substantial social and economic burden that is not fully captured because of the paucity of research on the impact of COPD on functioning in daily life.
3. Currently there is a significant lack of knowledge about the physiology and pathology of the disease and the natural history of the progression of the disease. This lack of knowledge has been attributed to a number of factors related to the nature of the disease and its progression. Amongst these factors are the heterogeneous population which result in a difficulty with the generalisation of research evidence from one context to another. Other factors are related to the insidious onset of the disease, the stigma of the self inflicted disease, and the confusion of symptoms of COPD such as breathlessness and fatigue with natural ageing processes resulting into lack of knowledge about the early stages of the development of the disease.
4. The symptoms of COPD are multiple and extend from respiratory symptoms to systematic manifestations. Amongst the most commonly reported symptoms are dyspnea and fatigue. These are subjective symptoms perceived differently by different patients. The mechanisms of development of these symptoms are not fully understood.
5. New approaches to understand COPD adopt a theory of systematic inflammation that is triggered by a number of risk factors resulting into the development of co morbidities.

All of these issues have implications on the knowledge required to the development of new measurement tools for the measurement of clinical outcomes of COPD.

1. There is a need to shift from a medical model of management to a bio psychosocial model. This requires the measurement of functional outcomes of interventions rather than physiological and pathological outcomes.
2. There is a need to shift from a disease oriented approach of measurement to a patient oriented approach. This requires the measurement of outcomes at the level of the individual.
3. Due to the lack of knowledge about the natural history of COPD, it is required to measure changes in the pattern of the disease at multiple follow up points and not clinical endpoints.
4. Due to the subjective nature of symptoms and the lack of knowledge about the underlying mechanism, measurement should emphasise the impact of symptoms on functioning from the perspective of patients.

Having identified the knowledge underpinning the disease, it is important to identify the knowledge underpinning the intervention. This is undertaken in order to enhance the understanding about the potential outcomes of the management approaches in COPD, and how these outcomes should be measured. The next section is a critical literature review of the management of COPD.

2 Management of Chronic Obstructive Pulmonary Disease

In the last section it was identified that COPD is a chronic condition resulting in progressive physiological and pathological impairments, and functional limitations that follow a downward trajectory. Moreover, COPD usually co exists with other chronic conditions such as ageing, cardiovascular diseases, osteoporosis, depression and anxiety. This creates complex cases that require complex interventions. Therefore, the acute care model, which focuses on a cure, is deficient in meeting the complex needs of the individual patient (Nici *et al.* 2009). Appropriate management of COPD requires a new chronic care model that implements effective communication and collaboration across disciplines. This model should adopt an integrated multidisciplinary provision (Nici *et al.* 2009).

This section provides an introduction to the model of integrated care, the aims of integrated care in the management of COPD, and the contribution of PR to the integrated care of people with COPD. However, this PhD set out to respond to the clinical problem of the measurement of outcomes in clinical PR settings. Therefore, the literature on PR will be critically reviewed with a focus on identifying the specifications of an outcome measure appropriate for implementation in clinical PR settings. The specifications will be identified in terms of:

- The clinically significant outcomes of PR that contribute to the delivery of integrated care.
- The current clinical problems in the provision of PR services and the specifications of an outcome measure required to inform clinical practice in order to resolve these problems.

2.1 The integrated care model

The world health Organization defined integrated care as "*a concept bringing together inputs, delivery, management, and organization of services related to diagnosis, treatment, care, rehabilitation, and health promotion*" (Grone and Garcia-Barbero 2001, p:7). The application of the concept of integrated care to the management of COPD should be performed with considerable attention to the natural progression of COPD. This requires designing and delivering lifelong care plans.

Current evidence suggests that COPD is influenced by the interaction of a number of pathological, personal and environmental factors resulting in a downward spiral of functional loss. Persistent and progressive pathological and physiological changes give rise to various clinical presentations (Sabroe *et al.* 2008). This implies that efficient integration of care in the management of COPD should be guided by reasonable decisions about the effective and the timely provision of the right therapy that is appropriate and specific to the individual patient (Nici *et al.* 2009).

Management of COPD includes a number of therapeutic options such as: smoking cessation, promotion of healthy life style by increasing activity and adherence to regular exercise, collaborative self-management strategies, optimal pharmacotherapy, palliative therapy, and end of life care (Ries *et al.* 2007). Due to the wide variation in therapeutic options available for COPD, integrated care should be provided collaboratively at a system wide multidisciplinary level. However, it should be tailored to the individualised needs of the patients. People with COPD should also be involved in making choices about their own care (Troosters *et al.* 2005).

The ultimate aim of adopting an integrated care paradigm for the management of COPD is three folds. Firstly, is to address the lifelong functional limitations and participation restrictions, and facilitate the integration of the individual in the community. Secondly, is to facilitate early discharge while ensuring that the individuals are fully supported in their homes and in the community. Thirdly, is to facilitate the delivery of care closer to home enabling early detection of deteriorations and the prevention of hospital readmissions (Seemungal and Wedzicha 2006).

Pulmonary rehabilitation programmes are individualised by definition and encompass a multidisciplinary provision of a number of therapeutic options. Therefore, they fulfil the assumptions of the WHO concept of integrated care. However, pulmonary rehabilitation should be viewed as one component of the integrated care of COPD patients, while integrated care has a broader system wide emphasis.

Although some patients who are severely limited may not be eligible for the complete pulmonary rehabilitation program, its components such as activity promotion, self-management strategies, and education should be provided as part of the integrated care of COPD (Nici *et al.* 2009). This suggests that the decision on which components to deliver should be guided by patients' needs and clinical problems presented.

A caveat is that in order for PR to be established as an effective component of the integrated care it is important that the benefits resulting from PR contribute to the aims of the integrated care in people with COPD. It might be suggested that PR should contribute to the improvement of functioning in daily life, improving self-management and patients' control of the clinical condition, and the reduction of hospitalisation in order to fit effectively within the integrated care model.

Next is an exploration of pulmonary rehabilitation, this will include: the definition of PR, the benefits of PR, and the clinical problems in the provision of PR.

2.2 Pulmonary Rehabilitation

Pulmonary rehabilitation is now a standard of care and has been recommended in national and international guidelines such as the American Thoracic Society/ European Thoracic Society statement on pulmonary rehabilitation "ATS/ERS" (2004), Nici *et al.* (2006), the British Thoracic Society Standards of Care Subcommittee on Pulmonary Rehabilitation "BTS" (2001), the Global initiative for chronic obstructive lung disease "GOLD" (2010), and the National Institute for Health and Clinical Excellence "NICE" (2010). Efforts should now be directed towards improving the effectiveness of the intervention in clinical settings, increasing awareness and recognition of its importance amongst patients and health professionals, improving access and enhancing patients' concordance with the program (Nici *et al.* 2009).

2.3 Definition of Pulmonary Rehabilitation

The American Thoracic Society/ European Thoracic Society statement on pulmonary rehabilitation defined pulmonary rehabilitation as "*evidence based, multidisciplinary, and comprehensive intervention for patients with chronic respiratory diseases who are symptomatic and often have decreased daily life activities. Integrated into the individualized treatment of the patient, PR is designed to reduce symptoms, optimize functional status, increase participation, and reduce health care costs through stabilizing or reversing systematic manifestations of the disease.*" (P: 1391, ATS/ERS 2004).

The definition identifies three important features of the PR program (Ries *et al.* 2007):

- The program adopts a multidisciplinary, individualised approach to delivery. The program is tailored to fulfil the patient's needs, with focus on physical and social function.
- PR programs for patients with chronic lung disease are well established as a mean of enhancing standard therapy to control and alleviate symptoms and optimise functional capacity.
- The primary goal is to restore the patient to the highest level of independent function, this is accomplished by improving patient's knowledge about the disease, the treatment, and coping strategies.

It is worth noting that pulmonary function testing using spirometry is a gold standard for the diagnosis of COPD. However, it is not considered a selection criterion for PR. Referral to PR is based on the individual's report of compromised functional status presented as functional limitations and participation restrictions despite optimal medication and stabilised clinical condition (Nici and ZuWallack, 2010). This highlights the importance of researching the impact of COPD on functional status, and how improvements realised from PR translate into improved functioning. This also emphasises the importance of the measurement of functional outcomes of PR.

2.4 Aims of Pulmonary Rehabilitation

The short term aims of PR are to control symptoms, enhance exercise capacity, and improve Health Related Quality Of Life. Its long term aims are to maintain gained improvements following the program and to ensure that the benefits of PR are translated into improved functioning in daily life and improved self management and disease control. The ultimate goal is to reduce health care resources utilization, especially through hospital admission prevention, reduced length of hospital stay and limiting dependence on professional health care (NICE 2010). It could be seen that the long term goals of PR conform to the aims of the integrated care of COPD. Therefore, long term benefits of COPD will be explored in further details.

Whilst the effectiveness of a PR program in achieving its short term goals is well established, evidence of achieving the long term goals is controversial. In order to investigate this controversy and identify the causes, a summary of current evidence on short term benefits and a critical review of the literature on the long term benefits of PR are presented next.

2.4.1 Benefits of Pulmonary Rehabilitation

There is now high level evidence from randomised controlled trials “RCTs”, meta-analyses (Salman *et al.* 2003) and systematic reviews of RCTs (Lacasse *et al.* 2002) that PR improves exercise capacity, symptoms and quality of life (Nici *et al.* 2009). Emerging evidence suggests that it also reduces health care utilisation. Established benefits of PR include controlling and alleviating the impact of symptoms, particularly dyspnoea and fatigue, improved functional capacity, and improved health related quality of life (Mador *et al.* 2001) (Nici *et al.* 2010), (Laccasse *et al.* 2002),(Ries *et al.* 1997) and (Ries *et al.* 1995).

A number of issues should be recognised while interpreting current evidence on the effectiveness of PR in order to make clinical inferences.

Firstly, despite established effectiveness of PR in improving functional capacity, alleviating symptoms and improving HRQOL, these improvements did not translate into improved functional independence in daily life (GOLD 2010). This could be explained by the following.

- It might be suggested that improvements in daily life functions is independent from the short term benefits of PR, therefore these should be measured separately (Nici *et al.* 2009).
- It might be suggested that there are other factors that influence performance in the patients' environment that are not existent in the clinical PR settings. Therefore, functional outcomes vary in response to these factors and become difficult to maintain.
- While evidence form RCTs suggest that PR work for people with COPD, at the level of the population, there is no evidence of the optimum method of delivery for the individual patient in clinical settings. It might be suggested that the evidence that has come from RCTs has not addressed existing clinical problems in the provision of PR. This has resulted in a suboptimal delivery of clinical PR programmes which have prevented patients from experiencing the long term benefits of PR.

Secondly, while there is evidence to support the effectiveness of PR in achieving its short term goals, the evidence is inconsistent. This inconsistency should be thoughtfully considered when attempting to implement the findings in the clinical context. A number of factors have contributed to this inconsistency.

- The first factor is related to the study sample. During the literature review on COPD, it was highlighted that the population of COPD is heterogeneous, and the disease has various clinical presentations. Evidence on the effectiveness of PR is mainly drawn from a quantitative research paradigm that strives to control bias by controlling confounding variables. The result is a research population that is homogenous and does not reflect the heterogeneous presentation of patients in clinical settings.
- The second factor is related to the protocol of PR implemented within the research studies. This is related to the definition of PR as an individualised intervention (Lacasse *et al.* 2002). This has resulted in a lack of standardisation in the protocol in different research studies. While this might be theoretically the “optimal” method of delivery in clinical settings (Higginson and Carr 2001), it hinders the generalisability of results from one context to another. What works for one group of patients does not necessarily work for another. Moreover, none of the studies has undertaken a clinical evaluation of an individualised delivery at the level of the individual, using an appropriate research design.
- The third factor is related to the outcome measures used. This is not only related to the lack of standardisation of outcome measures used but also to the measurement of different outcomes (Troosters *et al.* 2005). This suggests that there is a lack of consensus on the appropriate outcome measure and what constitutes a significant outcome of PR.

It might be suggested that in order to overcome these problems a realistic clinical evaluation of the provision of PR in clinical settings is required (Cazzola 2009). Moreover, the optimum method of delivery at the level of the individual within the clinical context should be established. In order to achieve this, new research methods should be implemented, full guidance on the selection and implantation of research methods to evaluate clinical complex interventions is provided by the MRC (2008). These new methods should be supported by the appropriate outcome measures.

Therefore, the next part of this review is concerned with identifying the significant outcomes of PR and the current problems with the provision of the service in order to identify the specifications of an appropriate outcome measure of PR, for implementation in clinical PR settings.

2.5 Identifying the significant outcomes of PR

For the purposes of this literature review the significant outcomes of PR are defined as the long term benefits of PR that contribute to the aims of integrated care of people with COPD. Based on the literature on PR these outcomes are identified as improving function and the maintenance of the short term benefits of PR. It is suggested that improved functioning and maintenance of the benefits of PR will ultimately result into facilitated early discharge and reduced hospital admissions (BTS 2001).

2.5.1 Improve functioning

The central aim of PR is to improve functioning (BTS 2001). This highlights functioning as an important outcome of PR. PR has no direct effect on airflow limitation, such as forced expiratory volume in 1 sec (FEV₁); nonetheless its established effectiveness is explained by ameliorating the systemic effects and the co morbidities of the disease (Nici *et al.* 2009).

Evidence shows that patients with COPD have decreased exercise capacity and substantial limitations in their daily activities. The American lung association (2002) showed that 51 % of all COPD patients report limitations in their ability to work, 70% in normal physical exertion, 56% in household chores, 53% in social activities, 50% in sleeping, and 46% in family activities. These findings are supported by direct measurements of physical activity at home (Pitta *et al.* 2005). Decreases in functional exercise capacity and physical activity appear to be related to increased health care utilisation and mortality in COPD (Gosselink *et al.* 1996).

Observational data link higher levels of physical activity with better outcomes, including a lower risk of hospitalisation, a lower rate of decline of lung function and improved survival (Ries *et al.* 2007). This highlights the importance of improving functional activity levels in people with COPD.

Steele *et al.* (2008) found that an intervention designed to enhance adherence to exercise programme did improve adherence and exercise capacity, but did not result into improved activity levels. They explained these results by the "disappointing" measurement

characteristics' of the accelerometer Steele *et al.* (2008). Other studies showed increased activity levels after the PR intervention (Sewell *et al.* 2005 and Pitta *et al.* 2008).

It should be noticed that activity monitors reflect changes in the level and intensity of activities performed over a specific period of time. However, they do not specify the type of the activity performed, the difficulty associated with performing the activity, and the factors influencing performance. Therefore, the information generated by activity monitors is limited in terms of providing data informative for making clinical decisions. This highlights the need for a clinical outcome measure of functioning that is able to reflect the translation of physiological benefits of exercise into improved functioning in daily life. This outcome measure should provide informative clinical data.

Nici *et al.* (2009) suggested that improvements in physical activity may not necessarily be related to improvements in exercise capacity. This is because of the multidimensional input of pulmonary rehabilitation that is not limited to exercise training. Non exercise components may also promote activity, independent of improvements in exercise capacity. For example, improved pacing and increased self efficacy directly contribute to the enhanced functioning. Further investigation of the effect of PR on functioning and the factors influencing functioning is needed Nici *et al.* (2009). A multidimensional outcome measure of functioning that is designed based on qualitative narratives of patients' on the factors influencing functioning such as exercise habits, self efficacy, and internal and external barriers is required.

Moreover, although Sewell *et al.* (2005) provided evidence for improved activity levels following exercise program they failed to provide evidence for the superiority of the individually targeted exercise training. This could be explained by the limitation imposed by the outcome measures and the study design they used. An individualised measurement tool that could trace changes in the individual patient over time is required to establish the effectiveness of the intervention at the level of the individual.

PR is a multidisciplinary individualised treatment plan that addresses all aspects of the disease over time and is incorporated in the life long integrated care of patients with COPD (Nici *et al.* 2009). Therefore, if delivered and measured appropriately, evidence of the effectiveness of PR in the improvement functioning in daily life in people with COPD could be established.

2.5.2 Maintenance of the benefits of rehabilitation

Maintenance of the benefits of PR is an important goal. Bourbeau (2010) suggested that one of the criteria of a successful PR program is its ability to implement behavioural changes in physical activity that could be maintained. Lack of exercise maintenance following PR, resulted in a controversial evidence of the long term benefits of PR (Brooks *et al.* 2002) and (Ries *et al.* 2003).

Maintenance of the effects of PR on functional performance requires vigilant attention to barriers and facilitators to performance, and the implementation of methods that could influence them on the long run (Bourbeau 2010). Currently there is no empirical evidence describing the factors influencing functional performance of people with COPD. It is suggested that those are best described from the perspective of patients living with the disease.

In order to ensure maintenance of the benefits of PR it is important that patients concord with a self-managed exercise program or remain functionally active during daily life. Strategies that ensure maintenance of effect following PR should be an integral part of the program. Moreover, patients should be equipped with skills and knowledge that enable them to maintain maximum functioning following PR. They should also be equipped with knowledge and tools that enable them to monitor and self-manage changes in functioning (Nici *et al.* 2009).

An important factor to consider in the evaluation of the maintenance of benefits gained is the occurrence of clinical exacerbation. Currently the most clinically acceptable definition of COPD exacerbation is *“a sustained worsening of the patient's condition, from the stable state and beyond normal day-to-day variations, that is acute in onset and necessitates a change in regular medication in a patient with underlying COPD”*. (Rodriguez-Roisin 2000, P: 398S).

COPD exacerbations result in clinical and functional deterioration beyond that experienced by the natural progression of COPD. This suggests that exacerbations significantly contribute to the functional loss and lack of maintenance following PR (Cote *et al.* 2007). Therefore, a patient reported outcome that enables the patients to detect initial deterioration in clinical and functional status before it develops into full exacerbation is required.

Having identified the significant outcomes of PR in terms of improving function and maintenance of gained benefits, the next part of this review examines the current clinical problems in the delivery of PR. This is performed in order to identify the specifications of an appropriate outcome measure that would enable the provision of informative clinical data. It is proposed that informative clinical data would enable the resolution of these clinical problems.

2.6 Current clinical problems in the provision of PR

These are problems in identifying the optimum mode of delivery. It is important to highlight that the provision of PR should be individualised and tailored to the needs and clinical problems of the individual patient. This requires making evidence based decisions on the effective components, the optimum duration, the optimum settings of the program, and the prediction of response to PR. Below is a review of research evidence on the optimum provision of PR.

2.6.1 Components of pulmonary rehabilitation

Pulmonary rehabilitation programs involve patient assessment, exercise training, self-management intervention, nutritional intervention, and psychosocial support. PR programmes are viewed as a continuum of intervention strategies incorporated into the lifelong management of patients with chronic respiratory disease and involve multidisciplinary input from the health care providers and the involvement of the family, and the wider community of the patient (Nici *et al.* 2009).

In this review two components directly related to the significant outcomes of PR which are improving functioning and the maintenance of the benefits gained are examined. These components are exercise training and self-management.

2.6.1.1 Exercise training

The overall aim of exercise training in COPD is to improve functional capacity and physical fitness by reducing the impact of symptoms particularly breathlessness and fatigue. Although the loss of lung function in COPD is irreversible the rationale for the inclusion of exercise in PR programmes is to increase functional capacity by inducing physiological adaptation in peripheral muscles, and improving the efficiency of the cardiovascular system (Bourbeau 2010). Exercise training could improve functional capacity without altering lung function. For example exercise training and oxygen therapy could improve exercise tolerance by delaying the onset of ventilatory limitation resulting from hypoxia and deconditioning. Physiological responses to exercise in people with COPD and their impact are presented in (Appendix A.1).

Physiological factors limiting exercise performance have been widely investigated (ATS/ERS 2004); however factors limiting exercise from the perspective of the patient were not studied. This highlights the importance of identifying the factors limiting performance by exploring the experience of people living with the COPD.

Moreover, it remains unknown whether these physiological improvements translate into improved functional performance of daily life activities. An appropriate outcome measure of functional performance is required to demonstrate changes in this construct during and following PR. An appropriate outcome measure should measure the construct “functional performance” and fulfil the requirements of the measurement theory (Stevens 1946). A review of existing outcome measures in the area of PR is presented in the third section of chapter 2 of this thesis.

Another problem with the exercise component is adherence to exercises during and after PR. Due to the progressive nature of COPD Physiological benefits gained during PR gradually diminish after the end of the training program (Wedzicha *et al.* 1998). In order to maintain benefits of exercise, an exercise behaviour change should be induced. Studies performed in chronic disease populations reported self efficacy and expectations of

beneficial outcomes as predictors of adherence to exercise (Brassington *et al.* 2002) and (McAuley *et al.* 1993).

Confusion and depression were reported as predictors of poor adherence (Brassington *et al.* 2002). Moreover, Rhodes *et al.* (1999) reported that education level and past exercise behaviours were positively correlated with regular exercise behaviour, while self-perception of fatigue and poor health were reported as barriers to the adoption and maintenance of exercise.

Qualitative studies on adherence to exercises in COPD population reported progression of the disease, associated co morbidities (Nault *et al.* 2000), and frequent exacerbations as reasons for exercise non adherence (Brooks *et al.* 2002). Moreover, Soicher *et al.* (2009) reported previous exercise habits and 6 min walk test as factors differentiating compliers from non-compliers to exercise program. This implies the inclusion of maintenance interventions in PR programmes.

Concordance with the exercise program is a new term that emphasises the importance of involving patients in setting the goals of treatment and taking charge of their own care. It might be suggested that concordance could be improved if patients are provided with appropriate feedback that enables them to realise the beneficial impact of exercise on outcomes important to them. Evidence suggests that an individualised exercise program that is designed based on mutually agreed treatment goals might improve concordance (Bourbeau and Bartlett 2008). However, this should be supported by a patient reported outcome measure that measures clinically significant outcomes. These clinically significant outcomes should be defined from the perspective of the patients in order to provide them with meaningful feedback.

The concept of concordance was introduced to facilitate a shift in the dynamics of the relationship between the patients and health professionals to support the patients move from passive recipients of care to active collaborators in the provision of their own care. Self management techniques were introduced to facilitate this new approach to care delivery (De Silva 2011). While the aim of this thesis is to develop a clinical measurement tool, it is proposed that an outcome measure of functional outcomes of PR might have the potential

to be used a self management tool by providing meaningful feedback to the patients about their clinical condition. An exploration of self management is presented next.

2.6.1.2 Self-management

The introduction of the expert patient program to the NHS in 2001 has driven consequent self management and disease prevention initiatives. Recently the “generic long term condition model” was introduced advocating a case management approach, patient centred long term planning, and equipping patients with resources to support self care (Department of Health 2001).

Self management techniques include a continuum of interventions that range from passive education to more proactive techniques of self monitoring and implementing treatment. The components of the self management intervention vary from one chronic condition to another. The need for specific components also varies between individuals. Therefore, an individually targeted intervention program should be designed (Jones 2006).

The design of effective and appropriate self management interventions should involve the patients’ experience and needs, other stakeholders and collaborators through systematic user centred designs (De Silva 2011). An example of such comprehensive design was presented by Nasr *et al.* (2010), who reported an interdisciplinary user centred approach using empirical and theoretical knowledge in the development of a set of concepts for the design of a self management system for stroke patients. It might be suggested that such research should be reviewed and implemented in the area of PR.

The proposed benefits of incorporating self-management in PR is to enhance independence in functional performance and boost health behaviours resulting into improved coping and control of the disease (Bourbeau 2010). Moreover, it is thought that self-management education is the best method to ensure maintenance of the beneficial outcomes of PR, by preserving optimum functioning (Bourbeau 2010).

In a Cochrane review Self-management interventions have shown a reduction in COPD related hospital admissions (Effing *et al.* 2007). Another systematic review showed a positive impact of an integrated self-management intervention in the chronic care model on health care utilization (Adams *et al.* 2007). However, there is limited research in COPD on the impact of self-management on the maintenance of physical activity and functional status (Bourbeau 2010). Developing a patient reported outcome measure of functioning that could be used as a self-management tool would enable generating such evidence.

The ultimate goal of self-management education should be shifting responsibilities of management from health care to patient (Bourbeau 2010). This implies helping the patient to acquire knowledge of the disease, and action planning strategies. Action planning includes monitoring and controlling symptoms, initiating appropriate medication and seeking medical help in crisis or exacerbation (Bourbeau 2010).

To achieve optimal monitoring and control of the disease the patient should have an objective method of recording changes in health status that could be communicated effectively to health care professionals. Although a number of general and disease specific health status measures were developed for use by people with COPD, none was a purposely developed self-management tool. In order to facilitate self-management the outcome measure should be patient reported, it should also provide informative and meaningful data to the patients about their current clinical condition.

Self-management should be integrated in PR and should be tailored to ensure concordance with medication and exercise, symptom control, mastering breathing techniques, and energy conservation techniques. Currently the provision of self management in COPD is delivered with focus on information provision and self efficacy improvements. Providers of pulmonary rehabilitation programmes should ensure that self-management interventions are operationalised in an effective way to induce a change in health behaviour that could be maintained and monitored following PR (Bourbeau 2010). This could be achieved by the inclusion of technical skills and technology in the design of self management interventions.

Effective self-management requires ongoing collaboration between the patient and the health professionals. This could be achieved by mutual development and implementation of an individualised action plan. This action plan should be supported by tools that enable the patient to recognise early changes in their health status and implement self-care strategies or seek professional help (Bourbeau *et al.* 2003). A self reported outcome measure that is responsive to early changes in functional status might be a valuable tool for such a purpose.

2.6.2 Duration of pulmonary rehabilitation

Designing the optimal PR program is influenced by available resources and how to best allocate them. This raises the question of the optimum duration of the program to induce long term changes in functional status (Nici *et al.* 2009).

Currently the standardised provision of PR is in the form of short courses ranging from (6 to 12) weeks (Troosters *et al.* 2005). The ERS/ATS (2004) Guidelines recommended a minimum of 20 sessions given at least 3 times per week. Clinical trials that have followed participants up to (12 to 18) months post intervention found that beneficial effects of PR gradually decline, but remain above baseline (Ries *et al.* 1995, Strijbos *et al.* 1996, Engstrom *et al.* 1999, Griffiths *et al.* 2000, Guell *et al.* 2000, Ries *et al.* 2003, and California Pulmonary Rehabilitation Group 2004).

While some components of the PR program should be maintained after the end of the program, such as self-management and psychological support, the length of exercise programmes studied varied with longer programmes yielding larger training effects. However, the minimum duration that would result in the maximum potential improvement is not established yet (ATS/ERS 2004).

Studies that examined the effect of several follow up programmes following the initial intervention, reported variable effects (Foglio *et al.* 2001, Brooks *et al.* 2002, and Wijkstra *et al.* 1995). This could be explained by different study protocols, baseline characteristics of participants and outcome measures used.

Foglio *et al.* (2001) reported that the main benefit of additional PR is reduced exacerbations represented by reduced number of hospitalisations. The authors reported no impact of additional PR on physiologic outcomes (Foglio *et al.* 2001). This finding could be explained by the progressive nature of the disease, especially that authors compared intervention group with the control group a year after the additional rehabilitation program, a time period that is sufficient for the beneficial outcomes to diminish naturally (Wedzicha *et al.* 1998).

This raises the question of the appropriateness of the pre-post experimental design for the evaluation of PR programmes. It could be that the pre post method of measurement was not able to detect the change that was detected by looking at the number of hospital admissions. Frequency of hospital admissions provide information on the number of occasions patients were admitted to hospital over time. Although this is not a direct measure of change over time, it highlights the importance of measuring change over time when evaluating PR programmes.

COPD is of progressive nature, where patients experience multiple exacerbations and continuous decline in health status. Moreover, PR is a complex intervention that is tailored to induce behavioural change through multidimensional modalities. These factors imply that a research design based on pre- post measurement will hide lots of valuable information about the changes in the disease trajectory and patients' status over time. This inappropriate method of evaluation has led to conflicting judgments on the long term benefits of PR.

It is suggested that in order to provide accurate measurement of the long term benefits of PR, measurement should be performed at regular intervals during and following PR. it should be expected that functional status is going to decline naturally. The purpose of measurement should be to identify the time at which a follow up PR is required.

In order to establish the minimum duration of the program that would result in maximum clinical benefit, and identify the time for referring the patient for a follow up PR, an appropriate outcome measure is required. This should be an individualised, outcome measure that could trace changes in functional performance as well as reflecting no change when a plateau in functional performance has occurred. The outcome measure should be able to detect the point when that patient has achieved maximum potential clinical improvement and maintained it for a clinically significant period of time. An outcome measure that has the ability to detect clinically significant changes and no changes over a period of time is the TELER.

TELER is an acronym for Treatment Evaluation by the LeRoux method. The TELER system is a concept of evaluation developed during the 1980s by Le Roux. It is based on the concept of using clinically significant change over clinically significant time periods as a measure of effective and efficient intervention (Mawson, 2002). Currently there are no TELER function indicators developed for use in people with COPD to evaluate the outcome of PR.

2.6.3 The settings of PR

Bourbeau (2010) suggested that providing PR at various settings that is tailored to the individual's needs improves accessibility and concordance. Evidence for effectiveness of PR has been provided in various settings; inpatient/outpatient hospital based programmes, community based programmes, and home based programmes. Home based programmes are usually confused with community based programmes. The difference is that community based programmes require direct patient supervision and entails, a consumption of health care resources that is equivalent to hospital based programmes. Home based rehabilitation is a self monitored training (Puente-maestu *et al.* 2000) and (Bourbeau 2010).

Benefits of PR will gradually wear out due to the progressive nature of the disease (Wedzicha *et al.* 1998). Maintenance of benefit requires continuous input at home after discharge. The delivery of the service at home setting should be investigated further. However, the delivery of PR at home should be supported by an appropriate patient reported outcome measure to facilitate the communication of changes in the clinical condition between the patients and the health professionals.

2.6.4 The prediction of response to PR

Whilst the effectiveness of pulmonary rehabilitation has been supported by significant research; analysis of response to PR showed that there is a portion of patients who are not responding to PR. Previous studies that have stratified patients according to baseline airflow limitation were inconclusive regarding differences in patients' response. It has been shown earlier that COPD is a progressive disease that has a multidimensional impact on patient's life. The experience of disability resulting from COPD is unique and experienced differently by each patient (Sabroe *et al.* 2008).

It is suggested that in order to differentiate responders from non-responders an outcome measure that measures changes at the level of the individual should be implemented. Current methods of evaluating the outcome of PR provide an average score that is not specific to any individual patient in the group. Developing an outcome measure that is able to detect changes within the individual patient is a necessity. This will enable identifying non responders, and altering the treatment delivered to them in order to induce a response. This will eventually save wasting resources resulting from delivering a treatment that is not specific and ineffective for these patients.

2.6.5 Limited delivery of PR

Another issue that remains unresolved despite established effectiveness of PR is limited access (Bourbeau 2010). A report by the Health care commission showed that only 64 % of 326 hospitals included in the audit had a formal rehabilitation unit, many of which have a very small capacity for patients, and did not have secured funding (Commission for Healthcare Audit and Inspection, 2006). Although NICE Guidelines recommended that all patients experiencing functional disability as a result of COPD should be referred to PR, only 3% of patients with COPD are being referred for PR (National Statistics 2006). The National Statistics (2006) suggested that GPs should be encouraged to refer patients to PR; however more services need to be commissioned.

To address this issue it is important that outcome measures used to evaluate PR provide data that is informative for managers and commissioners. The outcome measure should be able to provide data that could be analysed at different levels to provide such evidence. A method of measurement that provides such data is the TELER. This emphasises the need for developing TELER function indicators for use in people with COPD in PR.

2.7 Summary

- The integrated care model provides the basis for bridging the gap between health and social care. It places the patient and the context within which the patient live at the centre of the process of care delivery. It aids specific and effective care for complex cases and long term conditions such as COPD. The aims of integrated care in the management of patients with COPD are:
 1. To manage the chronic functional limitations and participation restrictions in people with COPD, and facilitate the integration of this group in the community.
 2. To facilitate early discharge by providing full patients' support in the community.
 3. To enable early detection of deteriorations in order to prevent hospital admissions.
- PR is a multidisciplinary intervention that is part of the integrated care for people with COPD. The long term goals of PR contribute to the provision of integrated care to people with COPD through the improvement of functioning and the maintenance of the benefits gained from PR.
- The effectiveness of PR in inducing short term changes in the control of symptoms, the improvement of functional capacity, and the improvement of HRQOL is well established. However, these changes do not translate into improved functional independence and are difficult to maintain.
- A qualitative exploration of patients' perspectives on the factors influencing functioning in their own environment is required.
- At this stage of the thesis the significant outcomes of PR were identified as the improvement of functioning and the maintenance of the benefits of PR.
- During the review of the role of PR in the improvement of functioning in people with COPD a number of issues were identified.
 1. Evidence suggests that patients with COPD have reduced levels of physical and functional activities.
 2. Reduced levels of physical and functional activities were linked to higher health care utilisation in this group of people.
 3. Studies that evaluated physical activity in people with COPD used most frequently activity monitors for the measurement of activity levels.

4. Activity monitors provided limited information that does not inform clinical decisions.
- During the review on the maintenance of the outcomes of PR a number of issues were identified.
1. It was suggested that the maintenance of the benefits of PR could be achieved by equipping the patients with self-management skills and a patient reported outcome measure that could provide informative feedback for the patients about their clinical condition.
 2. Maintenance of the benefits requires early detection of COPD exacerbation and preventing them.
- A number of clinical problems in the provision of PR were identified. These included:
1. Identifying the appropriate components and the optimum delivery of those components. It was identified that optimum delivery of the exercise components requires establishing patients' concordance with exercise. While optimum delivery of the self-management component requires equipping the patient with the tools to self monitor their condition.
 2. Identifying the optimum duration of the program. This requires the identification of when improvements occur and when to provide a follow up PR.
 3. Identifying the optimum setting for PR. It was shown that the effectiveness of PR is established at hospital and community settings. However, maintenance of the benefits requires establishing the effectiveness of PR at home settings.
 4. Identifying response to PR. This requires the identification of non-responders in order to change the treatment and induce a response.
 5. Limited delivery of PR was influenced by limited commissioning. An outcome measure that is informative to clinicians and commissioners is required to facilitate the commissioning of PR.
- To resolve the above problems, it is required to shift from the RCTs to a new research paradigm that implements methods of clinical evaluation such as the realistic evaluation (Pawson 2003). It is also required to shift from the pre-post measurement designs to the longitudinal measurement of outcomes at the level of the individual. However, this transition should be supported by appropriate clinical tools. Currently a clinical tool that measures change at the level of the individual, and provide informative clinical data does not exist. In order to

develop such a tool it is important to identify the specifications of an appropriate outcome measure for implementation in clinical settings.

- From the findings of the literature review on PR, a number of specifications were identified. These are:
 1. The outcome measure should trace changes in the patients' condition over clinically significant time periods.
 2. The outcome measure should provide informative data to the patients, to the clinicians and to the managers and commissioners.
 3. The outcome measure should be patient reported.
 4. The outcome measure should be a multidimensional outcome measure of functioning.

The central aim of rehabilitation is to improve functioning, which is a multidimensional concept influenced by a number of factors. Full definition of the construct "functioning" requires the incorporation of theoretical knowledge as well as patients' perspective. Therefore, the next section is a critical review of the literature on the models of functioning in order to define the construct "functioning", and identify a framework for the measurement of the domains of functioning.

3 Functioning/Disability: Models and definition

3.1 Introduction to the construct “functioning”

In the previous chapter functioning was identified as the central aim of PR. An important outcome of PR was to reduce the disability resulting from COPD (BTS 2001). GOLD (2010) suggested that health status is an important area of evaluation following PR. In the national and international guidelines on PR, recommended areas of evaluation appeared to reflect aspects of functioning or a broader health status and quality of life concepts. However, there was no consensus on the recommendation of a particular outcome measure for a certain area of evaluation. A standardised definition of functioning was not provided by major guidelines, and research in the area lacked consensus on the definition (Leidy 1994). This was evident by the wider range of linguistic expressions used to refer to aspects of functioning.

This ambiguity around the construct "functioning" could be explained by the fact that "functioning" is a multidimensional concept that is used to represent a humanistic phenomenon (Macdonald and Friedman 2002). Therefore, it is important to define the construct “functioning” based on theoretical background and clinical knowledge. This decision was made to ensure that subsequent qualitative enquiry is guided by sound theoretical knowledge that conceptualise the complex dimensions of the phenomenon. Moreover, the eventual aim of this enquiry on "functioning" is to identify the specifications of an appropriate outcome measure. This mandates appropriate theoretical definition to ensure construct and content validity (Ware 1987). Ware (1987) suggests that the "definition is the blueprint underlying the construction of health measures" (Ware 1987, P: 473).

Development of outcome measures of abstract concepts has started in the early twentieth century, when psychologists attempted the development of outcome measures of personal traits (Bartholomew 1995) and (Williams *et al.* 2003). The first step in operationalisation, i.e. the definition of a construct according to how it is measured, is a theoretically sound definition of the construct that identify the dimensions and the factors influencing it (Macdonald and Friedman 2002).

Appropriate Definition of the construct being measured is important to standardise understanding and ensure the validity of the measurement tool. An important criterion of scientific measurement is that the meaning inferred from the outcome measure should be “singular” i.e. that the measurement tool measures one thing and one thing only (Stevens 1946). This mandates identifying the dimensions of the construct. Moreover, the measurement tool should account for all of the factors influencing the construct being measured. This is particularly important in a chronic disease such as COPD that is progressive, incurs multisystem manifestations, influenced by multiple factors, and results in multiple functional limitations, and participation restrictions (WHO/ International Classification of Functioning Disability and Health “ICF” 2001).

In order to be Realistic in identifying all possible factors influencing the construct, it was decided to limit this investigation to a specific group of people. That is people with COPD eligible for PR. The reasoning for this selection; first is the huge burden of the disease and its impact on functional status, second is that a patient report of being functionally limited is the main criterion for referral to PR.

3.2 Definition of functioning

In the Oxford Dictionaries functioning was derived from the origin “function”: an activity that is natural to, or the purpose of a person or thing. This definition has three main components; first "activity" denoting action and involvement. Second is "natural" denoting daily involvement. Third is the "purpose of person" denoting value and fulfilment of roles. In the literature the entire domain of functioning is referred to as “Functional status” (Leidy 1994). It was not possible to identify the linguistic difference between "functioning" and "functional status" except that the word status in the Oxford dictionary is interpreted as the relative position in relation to other indicating some sort of ranking item. For the purpose of standardising language this thesis will espouse the term "functioning" unless the concerned literature has stated otherwise.

Improvement in functional status has frequently been referred to as an important outcome of patient centred care (ATS/ERS 2004). Despite this importance there was a proliferation of terms “health status, functional status, quality of life etc.” that were used interchangeably and lacked standardisation (Leidy 1994). It is important to highlight that Quality of life is a socially constructed concept that could be equally applied to people with or without a health condition (Engel 1977). While it is recognised that functioning is a dimension of quality of life, the focus of this thesis is the definition and measurement of functioning.

Health status is another generic concept that has sometimes been used interchangeably with quality of life. However, a number of authors who studied the concept quality of life believed that health status constitutes a dimension of quality of life (Ware 1987) and (Guyatt *et al.* 1993). Health is a multidimensional concept that encompasses physical, mental and psychological health. Similar to quality of life, health is a socially constructed concept. It is also a personally constructed perception of being ill or healthy manifested by seeking professional help (Engel 1977).

Functioning was identified by Ware (1987) as an aspect of health. This is in agreement with more recent classifications of health status such as the International classification of functioning, disability and health (WHO/ICF 2001). An important notion is that most existing outcome measures place greater emphasis on the negative aspect of health. This has resulted in quantitative loss of information when the measurement tool was not able to reflect the interindividual variation. A qualitative loss of information is also manifested by measuring disability on the account of functioning. Therefore, any attempt to define constructs for the purpose of developing measurement tools should identify positive as well as negative aspects of the construct. The ICF has conquered this dichotomous presentation of concepts and to comply with this, "functioning/disability" will be both presented in thesis.

Leidy (1994) suggested that previous models and definitions of functioning had problems. They were very broad and too encompassing to guide specific treatment planning and outcome measurement. On the other hand sometimes the definitions were too constrained. Therefore, they failed to account for all aspects influencing functional status, and to reflect how physiologic improvements in performance translate into improved day to day performance. Existing models also failed to demonstrate an important distinction between functional capacity and functional performance.

Moreover, Leidy (1994) criticised the inclusion of a number of constructs under a single label. It was suggested that this inclusion has resulted in the use of terms interchangeably leading to further terminology misuse. Other authors suggested that the practice of including a number of constructs under one label is not harmful. Actually it is necessary when one general construct like quality of life is multidimensional and should be analysed (Ware 1974). What is needed is a standardised use of the constructs and classifications. An example of models and definitions on each of the previous problems is provided in (Table 2).

Table 2 Examples of problems in models and definitions of functional status, cited in (Leidy 1994)

| Problems identified | Impact | Example | Reference |
|---|--|--|----------------------------------|
| Too broad | Could not guide and inform treatment planning , study design and outcome measurement | Their concept of psychological and social functioning included cognition, affect, psychiatric illness, social interactions, adaptations to the environment, spiritual fulfilments, and subjective wellbeing. | Meyboom-de Jong and Smith (1992) |
| Too constrained | Do not account for all factors influencing functional performance | Their work is based on the premises that there are six activities of daily living that are "basis" or of "sociobiologic primacy": bathing, dressing, feeding, continence, toileting, transferring. The work was translated into a questionnaire that asks about the ability to perform the tasks giving a vague notion of the capacity to perform without clarifying the importance of the tasks to patients | Kats and Stroud (1989) |
| | Do not show how physiologic improvements translate into improvements in activities of daily living. | Developed a conceptual model that addresses the concept functional capacity from a physiologic perspective. It provides insight into the physiologic factors that contribute to functional capacity defined as the product of cardiac output and the skeletal muscle arterio-venous difference following myocardial infarction. | Folta and Metzger (1989) |
| Inclusion of a number of different constructs under one label | The use of different constructs included under one label interchangeably, resulting in absence of refinement and loss of information. | The inclusion of "Health health status, functional status and quality of life" under the global construct Health related quality of life. | Guyatt et al. (1993) |
| No differentiation between capacity and performance | Development of outcome measures containing items that measure two different constructs. No explicit identification of the domain being studied. | Functional status was defined as the level of actual performance or capacity to perform, both in the sense of self care and in the sense of being able to fulfil a task or role at a given moment or during a given period. | (WONCA) ¹ |

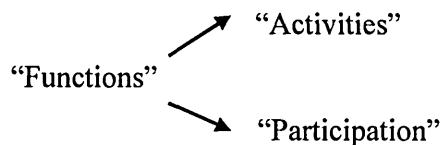
The literature also presented different descriptions of the term, with some overlapping, such as role functioning, physical functioning, psychological functioning, cognitive functioning, etc. This confirms that the concept is multidimensional. Therefore, this thesis adopts a comprehensive definition of functional status "functioning" provided by (Leidy 1994, p: 2).

“Functional status is a multidimensional concept characterizing one’s ability to provide for the necessities of life; that is, those activities people do in normal course of their lives to meet basic needs, fulfil usual roles, and maintain their health and wellbeing. Necessities include, but are not limited to, Physical, psychological, social, and spiritual needs. There are four dimensions of functional status: Capacity, performance, reserve, and capacity utilization.”

To ensure a systematic approach to the definition, so that it could inform the development of outcome measures, it was decided to support this definition by a theoretical framework. This will be achieved by developing an “analytical/classification” framework” that provides a classification of the “necessities of life”, factors influencing the “necessities of life” and analysis of the dimensions of the concept functioning.

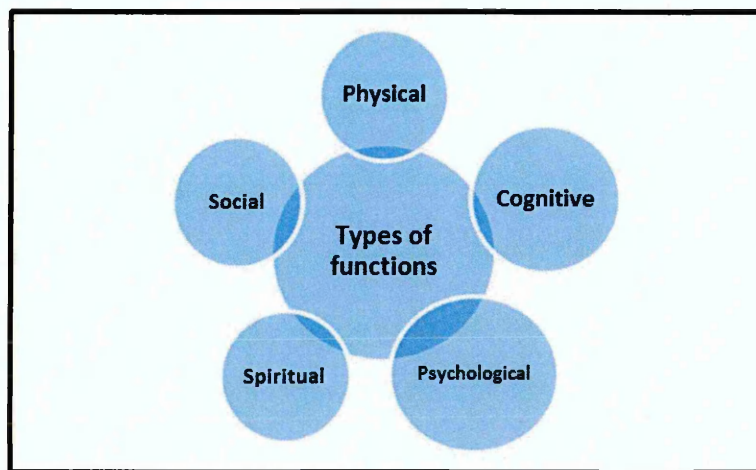
The following statements provide the set of standardised terms that will be used to ensure consistency:

- Although Leidy (1994) used the term functional status, this will be substituted by the term “functioning”.
- Necessities of life are activities people do in the normal course of their lives to meet basic needs, fulfil usual roles, and maintain their health and wellbeing. These will be referred to as “functions” of any type, including physical, cognitive, psychological, spiritual, and social (Leidy 1994). These are classified by the ICF (WHO 2002) into “activities and participation”. That is:



- Figure 3 shows different types of functions as proposed by Leidy (1994).

Figure 3 Types of functions



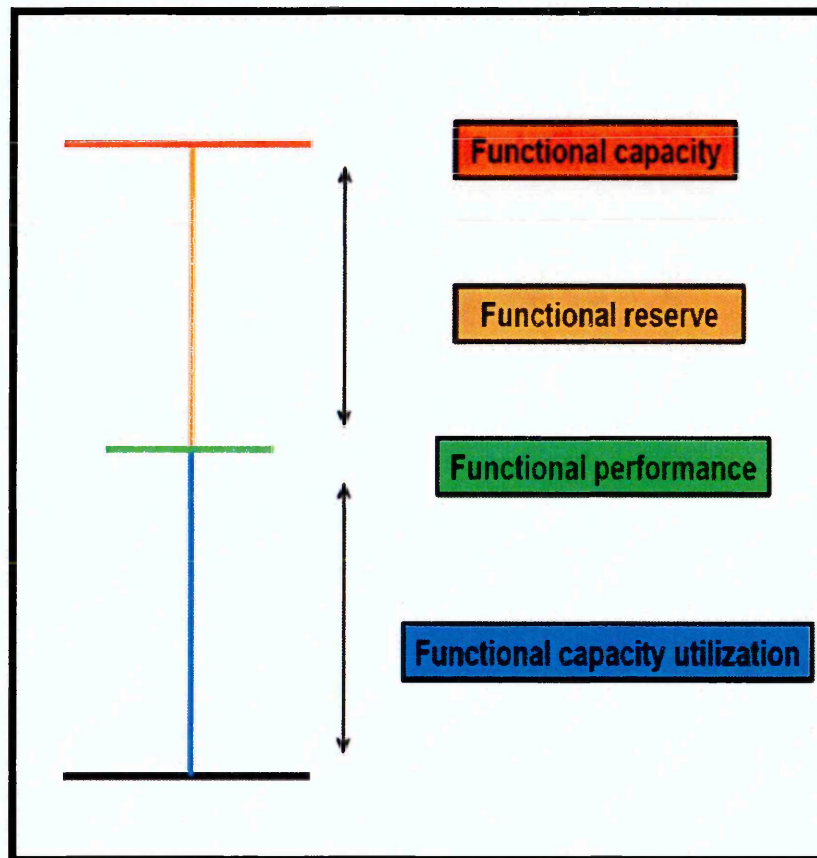
It is worth mentioning that

Figure 3 is not a classification of the types of functions, neither an exhaustive list. It is just to show how these concepts provided by other definitions fit within the adopted definition of functioning.

3.2.1 Defining the dimensions of functioning

Leidy (1994) suggested that a complete analysis of functioning requires a simultaneous consideration of all dimensions. This is consistent with Duncan and Velozo (2007) view of the measurement of the outcomes of rehabilitation. Duncan and Velozo (2007) suggested that a full evaluation of the outcomes of rehabilitation requires using a tool box of a number of outcome measures, each of which is specific for the purpose of measuring one dimension. However, meaningful measurement requires separate consideration and measurement of one dimension at a time. Leidy (1994) identified four conceptual dimensions of functional status: functional Capacity, functional performance, functional reserve, and functional capacity utilisation (Figure 4).

Figure 4 Conceptual dimensions of functioning. Adapted from Leidy (1994).



3.2.1.1 Functional capacity

"Functional capacity is defined as one's maximum potential to perform those activities people do in the normal course of their lives to meet basic needs, fulfil usual roles, and maintain their health and wellbeing. The term refers to potential in any domain, including physical, cognitive, psychological, spiritual, and sociodemographic." (Leidy 1994, P: 198).

Leidy (1994) highlighted a number of outcome measures that have been used to measure capacity in different domains such as physical, psychological, spiritual, cognitive etc. The author ascertained that the capacity of the person to perform certain functions is influenced by resources available. A person with a given potential to perform might not choose to perform up to capacity (Leidy 1994). Whilst functional capacity provides the maximum potential to perform, the actual level of performance is influenced by a number of contextual factors that either facilitate or hinder performance (WHO/ICF 2001). It is important to notice that capacity is implied by appropriate functioning of body structures and organs.

3.2.1.2 Functional performance

"Functional performance is defined as the physical, psychological, social, occupational, and spiritual activities that people do in the normal course of their lives to meet basic needs, fulfil usual roles and maintain their health and wellbeing." (Leidy 1994, P: 198).

The level of functional performance is influenced by a number of factors mainly patients' perception of what is important and available capacity implied by optimal functioning of body structures and organs (Leidy 1994). Measurement at this level should be directed by patients' goals, and clinical determination of what is achievable. This suggests that an appropriate outcome measure of functional performance should be based on functional goals mutually selected by patients and clinicians. This notion points out the importance of a qualitative investigation of patients' perspective. The study should find out factors influencing functional performance, as well as patients' functional goals. This should also be verified by clinical experts.

Leidy (1994) classified functional performance into components "domains"⁶ depending on the domain of activities. For example the physical domain includes activities of daily living, the psychological domain includes hobbies or favourite past time such as reading or music, the social domain includes attending parties and family gathering, and the spiritual domain includes meditation and worship services. An important notion here is that the performance of activities in a certain domain is influenced by the collective potential and resources available to the person in all domains of life. That is the performance of a certain function like shopping requires a combination of physical, cognitive and psychological capacity to perform it. Moreover, the performance of a certain function is influenced by contextual factors such as environment, assistive devices, and support from others.

3.2.1.3 *Functional reserve*

"Functional reserve is the difference between capacity and performance, one's functional latency and dormant abilities that can be called upon in time of perceived need." (Leidy 1994, P: 199).

Leidy (1994) suggested that functional reserve constitutes the difference between functional capacity and functional performance. The author used that difference to propose an empirical relationship between capacity and performance that is synchronised by the amount of perceived exertion. That is, the closer the level of performance to capacity the more exertion the person will experience. Thus to move for the next level of performance without increasing exertion, capacity should be increased. It is thought that this is an over simplification of a complex relationship that is regulated by a number of factors that are not fully investigated.

It is believed that Leidy's conclusion has resulted from assuming a liner modelling of interaction between the dimensions of functioning. Actually this linear model and the empirical relationship suggested by Leidy (1994) do not explain why benefits gained by people with COPD following PR are not related to improvement in lung function which

⁶ Leidy used the word "component", but it was replaced by "domain" to ensure standardisation throughout the thesis.

is an outcome measure of physiological capacity. It also does not explain why people with COPD with the same level of capacity have different levels of performance.

Finally, it does not explain why improvements in capacity do not translate into improved functional performance (Ninci *et al.* 2009). However, Leidy's model partially explained the later issue by introducing the concept "functional capacity utilization".

3.2.1.4 Functional capacity utilization

"This term refers to the extent to which functional potential is called upon in the selected level of performance". (Leidy 1994, P: 199). However, Leidy's model does not show what factors influence the utilization of capacity. This means measurement tool based on this model alone will lack the ability to reflect changes in the construct measured resulting from all the multidimensional factors influencing the construct.

While the framework suggested by Leidy (1994) provides an analytical tool for identifying dimensions of functioning, defining them and standardising concepts. It fails to provide a classification system for the wide ranging types of functions "necessities of life" i.e. physical, psychological, occupational, etc. It also lacks the ability to reflect the impact of disease on functioning. Particularly complex chronic conditions such as COPD, where a linear model fails to identify the multidimensional impact on functional status. Whilst this linear model provides a good analytical framework, it doesn't accommodate for the multiple factors influencing functioning. A multidimensional framework that provides a classification system for functioning is the International Classification of Functioning, Disability, and Health (WHO/ICF 2001). This presented next.

3.3 The International classification of functioning disability and health "ICF"

3.3.1 Introduction to the ICF

One important point to highlight at the beginning of this part is that the ICF claims that the classification system classify health and health states. However, based on the foregoing literature review it is believed that concepts provided by the classification represent functioning as influenced by the health of the individual rather than being a comprehensive classification of the overall health of the individual. Although it is logical to propose that overall functioning is a reflection of health, it was found more appropriate to use the ICF framework as a classification of functioning and

how it is related to the presence or absence of a health condition rather than a classification of health states.

It is believed this is a justified decision given that in the WHO (2001) document the proposed classification provided definitions of functioning and aspects of functioning, but not a single definition of health. Moreover, the concepts offered in the classification represent "functioning" as defined by (Leidy 1994). Therefore, the term "health" was replaced by "functioning".

3.3.2 Characteristics of the ICF

The development of a multidimensional measurement tool of functioning requires standardised definition of the construct and identifying all the factors influencing it (Ware 1974). The ICF (2001) defines "Functioning" as "an umbrella term encompassing all body functions, activities and participation; similarly, disability serves as an umbrella term for impairments, activity limitations or participation restrictions" (WHO 2001, P:7). This presents a classification rather than a standardised definition of the construct. The International classification of functioning, disability and health provides a unifying framework for classifying functioning in relation to health status.

The framework provides a model of interaction between different aspects of functioning as influenced by "health", this facilitates identifying factors influencing certain aspects of functioning and the impact of health condition on functioning. On the other hand Leidy (1994) provided a comprehensive definition supported by analytical framework resulting in standardised construct identification, which could guide outcome measures development.

The WHO family of international classification provides assessment tools to describe and classify the health of the population in an international context. While the ICD-10 provides information on mortality, the ICF provides classification of the functional outcomes of health (WHO 2001). Of interest to this thesis is the ICF.

The ICF provides a systematic representation to the various aspects of functioning. This provides a standardised framework for identifying aspects of functioning where outcome measures should be developed. This ensures a holistic evaluation of functioning. This could be accomplished by developing outcome measures for each aspect of functioning.

The ICF is a valuable tool for the assessment of functioning in chronic conditions. It facilitates the identification of aspects of functioning that are not addressed by current interventions, so that new strategies are incorporated in management programs supporting the provision of integrated care (IMPRESS 2008).

An important feature of the ICF is that it reflects individuality by considering contextual factors “environmental and personal” as factors influencing functioning. Two individuals with the same diagnosis and the same functional capacity might have different functioning profiles. This is particularly significant in chronic conditions like COPD where the progression and the experience of the disease are unique to each individual (Sabroe *et al.* 2008). This also facilitates the delivery of patient centred care and the development of individualised outcome measures.

To be scientific a classification system should state clearly three main properties: the universe of the classification, the scope, and the units of the classification.

3.3.3 The universe of the ICF

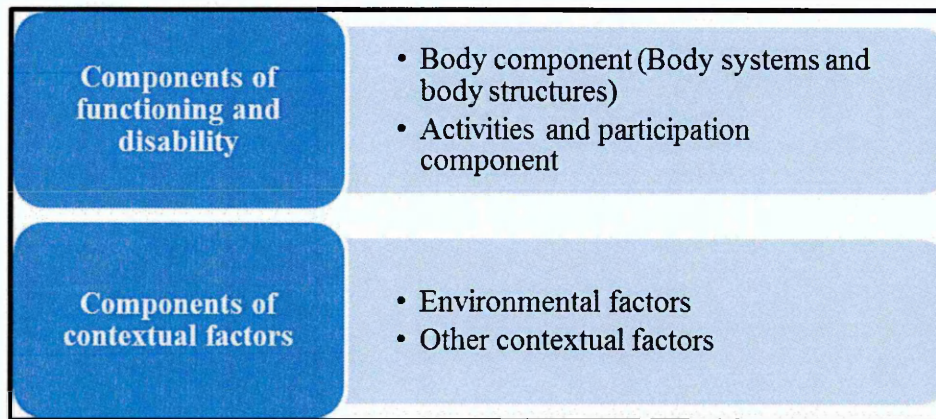
The classification includes all aspects of functioning in relation to the health of the person. It classifies those aspects into functioning domains and functioning related domains. From outcome measurement perspective functioning domains are viewed as the areas that constitute the primary outcomes of care delivered, while functioning related domains constitutes factors that influence functioning domains “facilitate or hinder”. The classification reflects the broad context of health. However it does not include domains that might influence persons’ functioning but are not health related; such as socioeconomic factors. For example participation restrictions because of race are not included in the classification (WHO 2001).

An important feature of the universal application of the ICF is that it provides a classification system for all people whether they have a disability or not. This facilitate the use of positive language, prevent the stigma inflected by the disease, and provides common grounds for comparing functioning profiles of people (WHO 2001). This is particularly relevant in a disease such as COPD, where the stigma of the self inflected disease is one of the main factors restricting participation (Okasheh *et al.* 2010).

3.3.4 The scope of the ICF

The ICF provides a framework for organising information on human functions and its restrictions. Information is organised in two parts. Part 1 functioning and disability, and part 2 contextual factors. Each part has two components (Figure 5) (WHO 2001).

Figure 5 The components of the ICF



A list of the definitions applicable to the above components is provided in the text box below (Adapted from WHO 2001):

Definitions

In the context of health:

Body functions are the physiological functions of body systems (including Psychological functions).

Body structures are anatomical parts of the body such as organs, limbs and their components.

Impairments are problems in body function or structure such as a significant deviation or loss.

Activity is the execution of a task or action by an individual.

Participation is involvement in a life situation.

Activity limitations are difficulties an individual may have in executing activities.

Participation restrictions are problems an individual may experience in involvement in life situations.

Environmental factors make up the physical, social and attitudinal environment in which people live and conduct their lives.

Although personal factors constitute a component of the contextual factors a classification of personal factors is not provided by the ICF, because they are highly variable and individualised nature.

The components of functioning and disability can be described to indicate a problem related to health condition that is impairment, activity limitation, and participation restriction or absence of problem “body function and structure, activity and participation” (WHO 2001). This feature enables identifying aspects of functioning influenced by the health problem. This is important in a progressive disease that has a multidimensional impact such as COPD. This is because it aids identifying functions where individuals were able to cope with the disease and maintain optimal performance, and functions that were lost as a result of the disease.

3.3.5 Unit of classification of the ICF

The unit of classification is categories within functioning and functioning related domains (WHO 2001). An important issue is that persons are not the unit of classification, but it provides a classification of functioning of each individual. This highlights the individualized nature of the classification and its usefulness in guiding the development of outcome measures that measures functioning at the level of the individual. The description of functioning is provided within the context of personal and environmental factors (WHO 2001). This is particularly relevant to patients with COPD, where studies reported the impact of environmental factors such as weather on exacerbations (Nault *et al.* 2000) and personal factors such as anxiety and depression on functional outcomes (Kim *et al.* 2000).

3.3.6 Overview of the ICF classification

3.3.6.1 *Body functions and structures and impairments*

Body refers to the human organism as a whole. Body functions constitute the basic human functions, while body structures constitute the structures responsible for performing the function. Therefore, the classifications of body functions and structures are designed to be used in parallel (WHO 2001). The classification of body functions and structures is guided by knowledge at the sub cellular or molecular level. However, this level is not presented in the classification. Impairment represents an anomaly, defect, loss, or significant deviation from the generally accepted populations' standard of biomedical status. This classification is recorded using codes, the nature of the impairment "temporary, permanent; progressive, regressive; static, intermittent" is verified using qualifiers after the code (WHO 2001).

It is worth noting that impairment is different from the underlying pathology and is the manifestation of the pathology. Moreover, impairment is not dependent on aetiology. This is important in a disease like COPD where the manifestations of the disease appear to be an exaggerated response to an initially trivial stimulus (Sabroe *et al.* 2008) Moreover, COPD might coexist with other health conditions resulting in impairments that are not directly related to COPD (Curtis *et al.* 1997).

3.3.6.2 Activities and participation/ activity limitations and participation restrictions.

One list is used to provide the domains for all activities and participation. These are qualified by performance and capacity qualifier. Figure 6 shows a list of the domains.

Figure 6 The domains of the activities and participation. Adapted from (WHO 2001)

| Domains | | Qualifiers | |
|---------|--|-------------|----------|
| | | Performance | Capacity |
| d1 | Learning and applying knowledge | | |
| d2 | General tasks and demands | | |
| d3 | Communication | | |
| d4 | Mobility | | |
| d5 | Self-care | | |
| d6 | Domestic life | | |
| d7 | Interpersonal interactions and relationships | | |
| d8 | Major life areas | | |
| d9 | Community, social and civic life | | |

The performance qualifier is described in relation to the current environment of the person. It represents “involvement in a life situation” or “the lived experience” of people (WHO 2001, P: 15). This highlights the importance of considering contextual factors when attempting to create a framework for the measurement of functional performance.

The capacity qualifier is described as the ability of the person to perform a certain task or function in a standardised environment, which is a neutral environment that has no impact on performance. This allows for assessing the impact of the person's current environment on performance and allow for modifications to enhance performance (WHO 2001). However, it is questionable whether this standardised environment is achievable, and whether there is an international standard for creating such environments to allow universal comparisons.

The ICF identifies capacity as a qualifier of activities and participation, and is described as "*an individual's ability to execute a task or an action*". *It is the highest probable level of functioning that a person may reach in a given domain at a given moment. It is assessed in a standardised environment.*" (WHO 2001. P: 15). The concept of capacity provided in Leidy's framework is totally different to that provided by the International classification of functioning, disability and health (ICF). The reason for this conceptual difference is that Leidy's framework is an analytical framework that identifies dimensions of functioning, while the ICF is a classification system that provides a description of functioning.

It might be suggested that capacity as defined by the ICF is a loose concept. It is believed to be a replication of the definition of performance, but in a standardised environment. Whilst this is important in identifying environmental impact on functioning, it lacks the ability to provide meaningful information for clinicians and managers on targeting interventions, or developing outcome measures. That is whether the individual patient would benefit from interventions that target capacity in terms of impairment of body structure and functions, or performance in terms of the ability to execute certain tasks or functions.

This is particularly relevant in the case of COPD where PR programmes resulted in physiological improvements that did not translate into improved functioning in daily life. Moreover gained improvements were found to be not related to pulmonary function (Nici *et al.* 2009). This highlights the importance of the distinction between capacity and performance in terms of interventions and outcome measurement.

3.3.6.3 Contextual factors

Contextual factors include two components: environmental factors and personal factors. “*Environmental factors make up the physical, social and attitudinal environment in which people live and conduct their lives*” (WHO 2001, P: 16). Environmental factors influence the individual’s functioning by facilitating or hindering functioning. Environmental factors are organised into two levels: the individual level which constitutes the direct environment of the person “home environment” and close family interaction. The societal level which is the community or society settings and all interaction and services provided in the community.

Personal factors are the individual’s inherent characteristics, psychological assets and behavioural features such as gender, age, race, fitness, lifestyle, self efficacy, experiences etc. these vary widely between people and are not classified in the ICF. The identification of personal factors and their impact on functioning requires in-depth qualitative inquiry of people’s perspective. Figure 7 provides an overview of the ICF parts, components, domains, and constructs.

Figure 7 Overview of ICF. Adapted from (WHO 2001)

| | Part 1: Functioning and Disability | | Part 2: Contextual Factors | |
|-----------------|--|--|---|---|
| Components | Body Functions and Structures | Activities and Participation | Environmental Factors | Personal Factors |
| Domains | Body functions Body structures | Life areas (tasks, actions) | External influences on functioning and disability | Internal influences on functioning and disability |
| Constructs | Change in body functions (physiological) Change in body structures (anatomical) | Capacity Executing tasks in a standard environment Performance Executing tasks in the current environment | Facilitating or hindering impact of features of the physical, social, and attitudinal world | Impact of attributes of the person |
| Positive aspect | Functional and structural integrity | Activities Participation | Facilitators | not applicable |
| Negative aspect | Functioning | | Barriers / hindrances | not applicable |
| | Impairment | Activity limitation Participation restriction | | |
| | Disability | | | |

3.4 Framework for the measurement of functional status based on models of functioning and disability

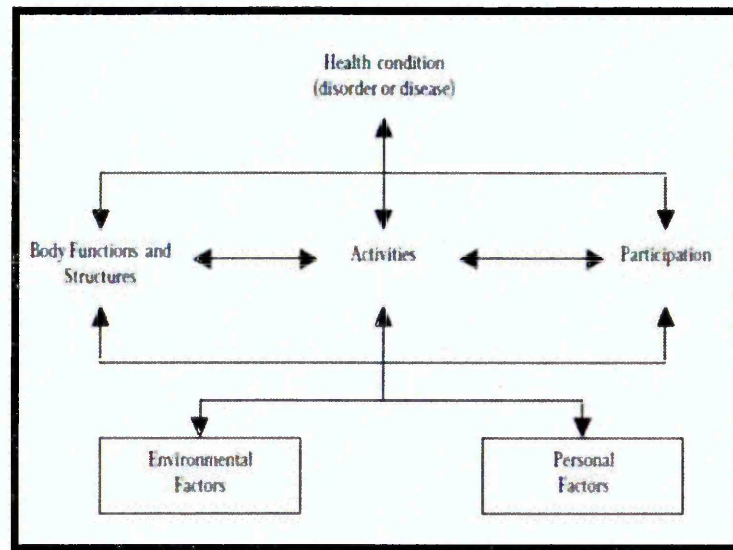
The emergence of a phenomenon that is socially disruptive or individually distressing, is associated by pressing needs for understanding the phenomenon and reversing its impact (Engel 1977). One way of understanding a certain phenomenon is by devising a model to describe it and study it. A model is defined as "*a belief system utilised to explain natural phenomena, to make sense of what is puzzling or disturbing.*" (Engel 1977, P: 130). In health the belief system could adopt a reductionist perspective where conceptual and experimental tools that illustrate and analyse biological systems are of physical nature (Engel 1977). Another belief system is based on the biopsychosocial approach that employs a dynamic interaction between physiologic, psychologic, and psychosocial factors that perpetuate health status and results in disability (WHO 2001).

Fundamental to the conflict between advocates of the biomedical model and those supporting new holistic model is what aspects of the health status resulting from disease should be treated. The biomedical model implies that patient care is summarised in reversing the systematic manifestations resulting from pathological disease process. That is our interventions should be tailored to target impairments of body function and structures. This exclusion of the psychosocial components could distort the whole process of care. A good example is problems such as "functioning/disability" in chronic conditions, which is a central aspect of health status, and is influenced by both biomedical and psychosocial factors. "functioning/disability" has been highlighted earlier as the central outcome of rehabilitation, therefore a framework that could inform the development of outcome measures in this area is required.

In the previous section the international classification of functioning, disability and health was presented (WHO 2001). It was evident that this classification system was comprehensive and adopted a multidimensional approach to the classification of functioning. The classification reflected how activity limitations and participation restrictions result from the multidimensional interaction between disease processes, resulting in impairment of body functions and structures, and the environment within which the person is functioning, as well as personal and behavioural factors. Therefore, the biopsychosocial model presented by the ICF will be adopted as a basic framework for the study of functioning in people with COPD. Figure 8 presents the bio

psychosocial model of functioning, disability and health provided by the ICF (WHO 2001).

Figure 8 The ICF model of disability and functioning. Adapted from (WHO 2001).

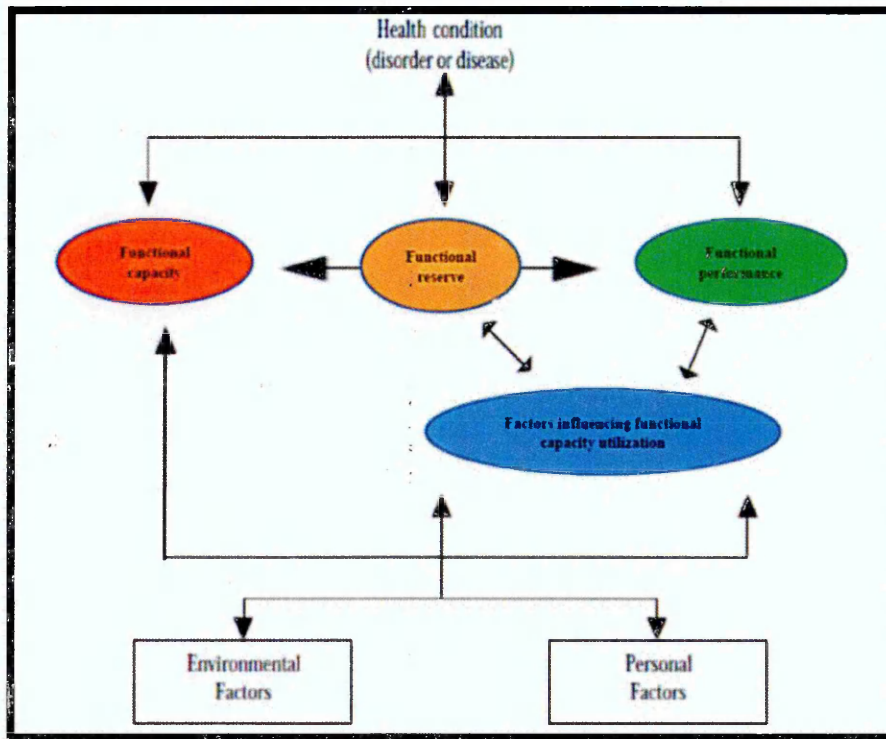


A caveat here is that the above model provides an explanation of the phenomenon "functioning/disability". It is a descriptive model that provides a dynamic presentation of the factors influencing functioning. Whilst this model could serve a good function as an assessment tool it lacks an important feature that would enable it to inform the development of outcome measures in the area. That is the scientific analysis of the dimensions of the construct "functioning" and precise definition of the dimensions.

Such an analytical framework was provided by Leidy (1994) and described earlier in this section. However, this framework was linear and lacked the ability to account for various factors influencing functioning. It is suggested that a comprehensive framework that could inform the development of outcome measures that have construct validity could be achieved by merging Leidy's analytical framework in the multidimensional ICF model.

The question here is where to fit the framework. On the ICF model it could be seen that the central part of it represents the phenomenon "functioning/disability" while the upper and the lower part represents factors influencing "functioning/disability". Therefore, the proposed framework is presented in (Figure 9).

Figure 9 A proposed framework for the measurement of functioning



It is clear that functioning is a multidimensional construct, thus it is imperative to determine which dimensions should be measured. Looking at the model above “functional performance” is the construct that should be measured to represent “activities and participations”. Functional capacity represents “body functions and structures”. Thus functional capacity is measured in terms of physiological outcome measures. Impairment of body functions and structures results in a number of symptoms such as breathlessness, fatigue, coughing, and sputum production in the case of COPD.

Leidy (1994) described symptoms as precursors of performance or a result of performance at a certain level rather an element of performance i.e. a breathless patient might not be able to go upstairs because of his breathlessness. Or going upstairs might induce breathlessness. In both cases the patient is unable to perform or complete the activity. Similarly, psychological symptoms such as anxiety and depression are a result of impairment and precursors to performance i.e. anxiety resulting from breathlessness might stop the patient from performing certain function, or result in a lower level of performance.

The biomedical model has dominated the health care system for a long time (Engel 1977). This has resulted in positive advances in the physiological outcome measures i.e. measures of impairment representing functional capacity (Alder 2009). However, these outcome measures failed to show how improvements in functional “exercise” capacity resulting from PR translate into improved Performance (Bourbeau 2010). Functional performance constitutes what people actually do in their daily life and thus represent meaning and value for them. Therefore, it is proposed that while a comprehensive profile of functioning could not be achieved with measuring outcomes representing all dimensions of functioning. Functional performance is a key dimension that should be measured.

One of the problems associated with quantifying functional performance is with identifying relevant functions “activities and participation”. These could be activities limited by symptoms; particularly those that are perceived as important to the individual. One way of identifying these activities is by asking patients about the activities in which they experience limitations, because of the disease and to rank those in terms of importance (Guyatt *et al.* 1987b).

3.5 Identifying the “functions” and factors influencing them

Central to the proposed definition of functioning, is the persons' ability to provide for the necessities of life. Necessities were defined as basic needs, usual roles and maintenance of health and wellbeing. An important question here is who defines basic needs, usual roles and health and wellbeing. In an era of patient centred care it is believed that patients' perspective is a key aspect of the definition (IMPRESS 2008).

Full identification of the impact of health condition “COPD”, what functions are affected, the values attached to those functions and what are the factors hindering the functions could not be achieved without accounting for patients' perspective. It might be suggested that a qualitative study guided by the proposed framework is required to consider these issues. This will provide a comprehensive profile of functioning in people with COPD. This profile will suffice to guide the development of outcome measures of functioning because it poses two qualities. First, the theoretical background based on the definitions and models of functioning generated from the literature. Second, an empirical knowledge derived from the qualitative inquiry.

However, before investigating patients' perspectives and developing the outcome measure, two main issues should be verified. First, what are the criteria required by the measurement tool other than accurate definition of the construct measured. This mandates a literature review on the theory of measurement and measuring scales and the principles of measurement in clinical settings. Second, what is the content of existing outcome measures of functioning? And do they fulfil the criteria required by the measurement theory and the principles of measurement in clinical settings?

The next chapter provides a review of the literature on the theory of measurement and measuring scales and the principles of measurement in clinical settings in order to identify the criteria required by a clinical outcome measure of functioning. This is followed by a review of the existing outcome measures in the light of the identified criteria.

Chapter 2: The theoretical underpinnings of measurement

4 Section 1: The theory of measurement and measurement scales.

The aim of the following section is to identify the criteria required by the scientific measurement scale and an appropriate outcome measure of functional performance following PR for people with COPD.

4.1 Introduction

The fact that functional performance is a qualitative attribute implies thoughtful consideration to Psychological measurement in the next literature review on measurement. This is due to the discussions and concerns expressed by scientists regarding the quantification of qualitative attributes in the area of psychological measurement. The literature on the theory of measurement and measuring scales is reviewed to identify the criteria required to construct a scientific measurement scale. Scientific scale means it could be falsified, i.e. it could be tested empirically by experiment or observation to be rejected or accepted (Kerry *et al.* 2008).

4.2 Definition of measurement

Historically, the definition of measurement was the focus of argument between advocates of different epistemological perspectives. This discussion became prominent in the mid-20th century, when Campbell and other physicists of the time described psychological measurement as short of fulfilling the requirements of scientific quantification. Measurement was then described as a form of empirical quantification that could be accepted or rejected experimentally (Campbell 1928, cited in Luce and Suppes 2001). At the time Stevens, a leading psychologist, responded by contending that this was rather narrow definition that disheartens the scientific status of psychology. He then proposed a new definition of measurement:

“Assignment of numerals⁷ to objects or events according to rules-any rule”
(Stevens 1946, P: 677).

⁷ Numerals, by which is meant simply a group of conventional signs or marks on a piece of paper, obtain their order by convention (Campbell 1928).

Stevens (1946) stated that measurement could be achieved at different levels determined by the process of measurement, and the formal mathematical properties of the relations established between empirical observations and mathematical structures. This has resulted in four types of measurement scales (nominal, ordinal, interval and ratio). Although Michels (1983) argued that nominal scales satisfy the logical requirements of measurement, there was an apparent consensus in the literature that nominal scales are classifications rather than measurement scales (Luce and Suppes 2001). However, ordinal scales created most of the confusion and debate (Luce and Suppes 2001).

Michell (1997) presented a critique of measurement in psychology condemning the quantification of attributes that are not quantitative in nature. He used this argument to validate an exclusive reference of the term "measurement" to "quantification". Michell (1997) suggested a highly restrictive definition of measurement:

"The estimation or discovery of the ratio of some magnitude of a quantitative attribute to a unit of the same attribute." Michell (1997, P: 29).

The implication that scientific measurement is only restricted to measurement of quantitative attributes is deficient. It pays no heed to a whole paradigm of scientific evidence that deals with the study of qualitative attributes. Whilst the author totally concurs with the logic of "the estimation of ratio of a quantitative attributes" Michell (1997, P: 29). This logic could not be used to undermine the scientific qualitative enquiry. Thorndike (1904) cited in Michell (1997) contended that measurement of qualitative attributes "by relevant position" is different to measurement of quantitative attributes "by amount of some unit". He states:

"Measurement by relative position in series gives as true, and may give as exact, a mean of measurement as that by amount" (Thorndike 1907, P:19) cited in Michell (1997).

Morgan provided a coherent debate of Michell's notion of scientific measurement:

"Michell has little time for ordinal scales, and presents them as desperate inventions of S. S. Stevens to deflect attention from the failure of ratio scales. I do not follow the reasons for this severity. Other sciences have worked quite happily with scales that are not continuous, and which therefore fail to satisfy the Holder axioms. For example, classical genetics used a unit called (as it happens) the morgan or centimorgan. This was the distance apart between two genes measured by the probability of recombination. The fact that centimorgans turned out in many cases to be additive was taken as evidence for the linear arrangement of genes on chromosomes. But it is clear that this scale never had a hope of being continuous, since genes are discrete. Similarly, molecular biologists now happily measure the genome in kilobases. Again, this cannot be continuous because the number of bases is discontinuous. The requirement of continuity for a scientific measurement scale is far too restrictive." (Morgan1997, P: 399,340)

Stevens (1946) ascertained that in order for measurement scales to be scientific the following should be made explicit: First, the rule of assigning numerals. An important point to highlight here is that representational measurement is not just representation via numerals. It is how components of the observed structure and the mathematical structure relate to one another according to scientific theories and knowledge (Luce and Suppes 2001). Second, the mathematical properties of the resulting scales. Third, the use of appropriate statistical operations. Failing to account for the above requirements resulted in the faulty assumption that numerals represent numbers "implying quantities". This has led to the misuse of Stevens's definition to legitimise absurd acts of measurement (Michels 1983).

The broad concept of measurement provided by Stevens implies that measurement is a process that includes a number of steps ranging from simple classification and ending with the more complex quantification. The process aims to generate data from observations. This is achieved by establishing relationships between the observation and a mathematical system.

To ensure scientific quality of the resultant measurement scale one should be able to provide a scientific evidence for the isomorphism between the observation and the assigned mathematical structures. A definition that adequately represents this process was provided by Michels (1983):

"Measurement is the act of converting observations into data, and includes classifying, counting, ranking, and quantifying." (Michels 1983, P: 210).

Michels (1983) identified three logical requirement of measurement. First is identifying a dimension of interest, in the case of this thesis "functioning". Second, operationally define the dimension; this includes conceptualisation and modelling the dimensions and the factors influencing the construct. Third, define two or more categories of the unit so that they are mutually exclusive and exhaustive. Michell (1997) referred to those requirements as instrumentalisation. It follows then that the assignment of numerals to categories on the scale should follow a rule that does not change under different conditions (Ellis 1986 cited in Michels 1983). It is worth mentioning that all previous requirements should be underpinned by theoretical, clinical and empirical knowledge. The only arbitrary aspect of scale development is the choice of the unit (Campbell 1927 cited in Luce and Suppes 2001).

Next is a presentation of the appropriate type of scales for the measurement of "functioning" and the mathematical relation of the numeral system implied by that scale.

4.3 Scales of measurement and the theory of measuring scales

In the previous chapter "functioning" was defined and a model was developed to identify the dimensions of the construct. "Functional performance" was identified as one dimension of functioning and was highlighted as an important outcome of pulmonary rehabilitation. Functional performance is a qualitative attribute that varies between individuals and within the individual with varying conditions and influencing factors. Functional performance of an individual could be observed and categorised in different levels of performance depending on the existing functional capacity and influencing factors.

Levels of functional performance “categories” could be rank ordered in a hierarchical structure. The unit of measurement is an arbitrary unit that reflect clinically significant changes in functional performance, resulting from clinically significant amount of treatment “Pulmonary rehabilitation”. This unit by convention is “clinically significant change”. Representational measurement is achieved by collecting data from empirical observations and arranging them logically in terms of familiar mathematical structures (Luce and Suppes 2001). This raises two questions. First what is the logic of arrangement? Second what is the appropriate mathematical structure?

What is the logic of arranging categories?

In identifying the logic of arrangement the author refers to previous work on measurement in physiotherapy. Mawson (2002) suggested that measurement of clinical change should be supported by clinical knowledge. Reflecting on COPD, the way we order the observed components of performance of a certain function should be underpinned by theoretical and clinical knowledge of the disease process and the development of disability resulting from the disease.

It has been highlighted earlier that COPD is a progressive disabling disease that usually co exists with other conditions creating complex cases. This suggests that theoretical and clinical knowledge is not sufficient on its own. In order to provide an exhaustive definition of the categories on the scale, patients' experiences of the development of disability should be incorporated.

What is the appropriate mathematical structure?

In order for the outcome of measurement to be meaningful, an appropriate measurement scale should be selected (Stevens 1946). Clearly there are only few qualities that could be claimed about the construct functional performance. First it is qualitative. Second it could be observed providing empirical evidence, in terms of qualitative description, about a certain level of performance. Different levels of performance (categories) could be arranged in a hierarchal structure ranging from lack of ability to perform to optimum performance. A mathematical structure that represents relative order of categories in relation to each other is the ordinal scale (Stevens 1946).

A measurement scale results from numerical relation system and a mapping from the empirical to the numerical relation system, which preserves the observed order of categories (Luce and Suppes 2001). However, Stevens (1946) identified three properties that should be imposed by an empirical observation that is measured by an ordinal scale. This ensures that the resultant measurement scale is a scientific measurement scale⁸. These properties are transitivity, asymmetry and connectivity⁹.

Mawson (2002) suggested that definition of categories based on clinical knowledge ensures that the resulting empirical structure satisfies the requirements of the theory of measuring scales, the author states:

"The concept that clinical change is significant only if it can be supported by clinical knowledge ensures that the definition of the points of the ordinal scale fulfil the requirements specified by the theories of measuring scales (Stevens 1946), i.e. that they have the properties of transitivity, asymmetry and connectivity. This concept also ensures that the indicator has face validity." (Mawson 2002).

Stevens (1946) suggested that the real concern should be the meaning of measurement. It follows that any statistical manipulation of data generated by any scale should ensure that the scale remain invariant, thus preserving meaningfulness. Therefore, data generated by an ordinal scale are only ordinal numbers and could not be subjected to operations of algebra (Michels 1983). Nunnally asserted this principle by stating:

"In the use of descriptive statistics, it makes no sense to add, subtract, divide, or multiply ranks" (Nunnally 1967, P: 18) cited in (Michels 1983).

It is worth mentioning that some statisticians highlighted this issue of using appropriate statistics as a misconception resulting from the confusion between measurement theory and statistical theory (Lord 1953). In a statement on statistical tests of null hypothesis Lord (1953) states:

"The numbers do not know where they came from" (Lord 1953, P: 751)

⁸ Scientific scale means it could be falsified, i.e. it could be tested empirically (experiment or observation) to be rejected or accepted (Kerry *et al.* 2008)

⁹ Transitivity means that if measurement "a" is larger than measurement "b", and measurement "b" is larger than measurement "c", then measurement "a" is larger than measurement "c".

Connectivity means that if measurements "a", "b" and "c" have meanings that are unique and different, then they can be ordered.

Asymmetry means that "a" is related to "b", but "b" is not related to "a".

It is believed that this is confusion between numbers and numerals. Numerals on the ordinal scale do not denote anything more than a rank order. They fall short of satisfying the properties of quantification (Campbell 1927 cited in Luce and Suppes 2001). Therefore, any statistical manipulation beyond that permitted by the theory of appropriate statistics will render the results meaningless and difficult to interpret (Stevens 1946).

4.4 Summary

Three logical requirements of measurement should be ensured before embarking on measuring a certain construct these are:

1. Identifying the dimension of interest and verifying whether it is a quantitative or a qualitative attribute. If it was claimed to be quantitative then it should be proved that the construct fulfils the Holder's axioms (Michell 1997).
2. Operationally define the construct and factors influencing the construct.
3. Define categories of the construct so that they are mutually exclusive and exhaustive.

Functional performance is a qualitative attribute, and concerns were reported in the literature on the quantification of qualitative attributes. To overcome this problem Stevens (1946) proposed a new definition of measurement that revolutionised the approach to the measurement of qualitative attributes. He ascertained that measurement is not restricted to the act of quantification.

Stevens (1946) defined measurement as assigning numerals to events or observations according to rules. However, to ensure that this wider concept of measurement does not undermine the scientific basis of measurement, the following standards should be ensured:

1. The rule for assigning numerals should be made explicit. This could be achieved by identifying how the components of the observed structure and the mathematical structure relate to each other.
2. Identifying the level of measurement and the mathematical properties of the resulting scale. This could be achieved by providing evidence of the isomorphism between the observed structure and the assigned mathematical structures.
3. The use of appropriate mathematical and statistical operations.

Finally, three qualifiers of the process of measurement should be ensured, these are:

1. Ensuring that the meaning of measurement is always preserved, from the stage of calibration, through to implementation and analysis of data generated by the scale.
2. Defining an arbitrary unit of measurement.
3. Appropriately use numerals or numbers on the scale depending on the level of the measurement.

This section has identified the logical requirements, the standards and the qualifiers of measurement imposed by the theory of measurement and measurement scale to ensure that an outcome measure is a "scientific measurement scale". The next section is concerned with establishing the principles of measurement in clinical settings to ensure the outcome measure is an "appropriate outcome measure" for the clinical context.

5 Principles of measurement in clinical settings

5.1 Introduction to measurement in clinical setting

There is a national drive for the provision of efficient, patient centred care. Measuring the outcomes of interventions using "appropriate outcome measures" that reflect quality and efficiency is a cornerstone in addressing such a demand.

When performed appropriately, measurement in clinical practice provides informative data for the clinician and the patient to trace changes in response to treatment. It serves as a feedback tool for clinicians to facilitate informed decisions about managing patients, thus improving patients' experience of care. Additionally, when accompanied with appropriate documentation, measurement provides legitimate and legal credentials that justify practice and assist clinical reasoning (Roach 2006).

The aim of this section is to identify the criteria required by an "appropriate outcome measure" of functional performance for use in people with Chronic Obstructive Pulmonary Disease "COPD" attending Pulmonary Rehabilitation "PR". The word "appropriate" is defined in the online Oxford Dictionary as "suitable or proper in the circumstances". This implies that in order to claim appropriateness of an outcome measure; one should identify the setting "contextual factors" and the population within which the outcome measure will be implemented (Kirshner and Guyatt 1985).

5.2 The rationale for developing clinical outcome measures

Health care systems are facing continuous reorganisations, with the aim of developing new integrated health care models. The new health care model places the patient at the centre of the process of care (Fitzpatrick *et al.* 1998). This has resulted in a proliferation of measurement tools that were tailored to measure patient centred outcomes such as quality of life, health status and functional status (Fitzpatrick *et al.* 1998). It was highlighted earlier that COPD coexists with other conditions creating complex cases that are best targeted by adopting an integrated health care model (Kruis *et al.* 2010). Therefore, a number of generic and disease specific quality of life outcome measures were developed in the area, for example chronic respiratory questionnaire, St. George's respiratory questionnaire, and others.

Moreover, the proliferation in patient centred outcome measures was accompanied by an increasing demand on physiotherapists and other health professionals to provide convincing scientific evidence in the form of quantitative data (Feinstein 1983). This has moved the focus of the scientific community from developing analytic tools that aid clinical reasoning and facilitate communication between patients and health professionals (Lakeman 2004). The dominant attitude was to develop measurement tools for research purposes with less focus on the appropriateness for clinical, home and community settings (Patient reported outcome measurement group, Oxford 2009).

It is thought that such distraction has resulted from the belief system created by the prevailing scientific policy that regards clinical data as "soft" and short of fulfilling the requirements of scientific evidence (Feinstein 1983). Ultimately there is a significant lack of measurement tools that translate clinical observations into meaningful scientific data.

The need for the measurement of patient centred outcomes using tools appropriate for use in clinical settings is justified by the following facts. Firstly, there was an impressive development of scientific measurement tools that assess clinical parameters of COPD, such as the measurement of pulmonary function using spirometry, x-ray, and oxygen saturation monitors. However, researchers were not able to provide evidence of a relation between these parameters and patient centred outcomes such as symptoms, and functional performance (Nici *et al.* 2009). This could be explained by the lack of scientific rigour in describing, analysing and measuring patient centred outcomes in clinical settings.

Secondly, improvements in clinical parameters of COPD were not translated into improved performance in daily life (Steele *et al.* 2008). This could be explained by the inappropriateness of the measurement tools to account for changes implied by the home environment.

Thirdly, a measurement tool that has adequate psychometric properties at the level of the group and performs satisfactorily in the measurement of outcomes in clinical research is not necessarily appropriate for the evaluation of clinical outcomes at the level of the individual in the clinical settings (Greenfield and Nelson 1992).

Physiotherapists and other health professionals were resistant to accept clinical tools that have not been tested in clinical trials, due to the fears of losing the intellectual status of the quantitative experimental science (Michels 1983). Moreover, practice guidelines have always been formulated in the light of the hierarchical evidence pyramid, placing randomised controlled trials at the top (Mant 1999). This has resulted in ignorance not in the "instrumental methods" they use in terms of the techniques of data collection and analysis, although this happens quite often, but more importantly in the "logic" of research practice and understanding the relevance of research finding to the clinical environment (Michelle 1997).

The ignorance of logical inferences in a clinical practice and even in research has detrimental effect on the progression of the profession of physiotherapy. This is particularly relevant when the research evidence does not provide adequate rational justification of the effectiveness of the costly and lengthy treatment of complex cases that physiotherapists face at the rehabilitation units such as people with COPD attending PR. It might be suggested that in order to provide evidence of the quality and effectiveness of treatment in clinical settings, a clinical tool that conforms to the principles of measurement in clinical settings is required. Moreover, the tool should provide informative data to support clinical decision making in the clinical context.

This highlights the urgent need for developing and evaluating new outcome measures of patient centred outcomes such as functioning, which are appropriate for use in the clinical setting, and have the potential to be transferred to home and community settings. However, in order to develop such tools it is important to identify the principles of measurement in a clinical setting.

5.3 A framework for the measurement in clinical settings

Clinimetrics emerged in the eighties of the last century to provide an intellectual framework for the process of providing scientific clinical data (De vet *et al.* 2003). Similar to biometrics and psychometrics, clinimetrics has developed as a methodological discipline focusing on the quality of measuring human clinical phenomena. This is achieved by developing clinical measurement scales appropriate for the demands of clinical setting (Feinstein 1983). A clinical phenomenon include the types, severity, and impact symptoms, progression of illness, co morbidities, health status including functional status, adherence to therapy, or any other subjective clinical experience that requires identification, analysis and measurement (Feinstein 1983).

Feinstein (1983) suggested that the quality of clinical measurement mandates the assurance of the quality of the measurement tool and the quality of the measurement process. This could only be achieved by an iterative process from development to implementation in clinical settings. If the measurement tool was found to lack reliability for example then it should be modified and items revised to ensure reliability in the context of implementation (Feinstein 1983).

It is worth noting that there has been some criticism of Clinimetrics. Streiner (2003) suggested that the term was an unnecessary distinction and probably a harmful invention of terminology. The author viewed Clinimetrics as an attempt to reinvent the wheel, suggesting that it might cut off scale development from an established literature on developing and evaluating measurement scales in psychometrics (Streiner 2003).

The author concurs that the literature on psychometrics is well established. However, it has been highlighted earlier that, particularly in pulmonary rehabilitation, current practice in scale development does not give appropriate consideration to the purpose of the tool and the context of implementation. Psychometrics developed as a methodological science for the evaluation of the rigour and quality of the measurement tool at the level of the group. However, measurement in clinical settings requires establishing the rigour and quality of the measurement tool at the level of the individual. This necessitates a scientific framework to refocus attention particularly to the clinical relevance and meaningfulness of measurement in clinical practice (Kirshner and Guyatt 1985).

In order to provide clinical measurement that would contribute to resolving clinical problems and provide evidence based practice, it is important that the development of measurement tools and evaluation of its quality and rigour be performed in the light of the principles of measurement in clinical settings. The ultimate goal is to preserve the meaning of measurement and clinical relevance throughout the process of development and testing (Hinds *et al.* 2002).

For the purposes of this thesis the following definition is suggested for clinimetrics.

Clinimetrics is a methodological framework for the development, evaluation and implementation of clinical measurement tools. The framework should be informed by adequate conceptualisation of the knowledge underpinning the clinical condition, the intervention, and the clinical phenomenon being measured, and the principles of measurement in the clinical settings.

Next is a review of the requirements of measurement in clinical settings.

5.4 Principles of clinimetrics

5.4.1 Clinical assessment versus evaluative measurement

It is important to determine at the outset of the process of developing any tool whether it is an evaluative measurement tool or an assessment tool. The clinical assessment of patient is different from evaluative measurement. The aim of a clinical assessment is to identify clinical problems and propose solutions. Measurement observes whether the clinical status of the patients has changed in response to the intervention and the pattern of the change. The purpose of assessment is different to the purpose of evaluative measurement, although measurement could be performed as part of the overall process of assessment. In pulmonary rehabilitation the focus of clinical assessment is to identify current activity limitations and participation restrictions, to identify underlying impairments, set treatment goals and design appropriate rehabilitation program (British Thoracic Society Statement 2001).

Roach (2006) suggested that a fundamental aspect of measurement in clinical settings is identifying the purpose of the tool, as this enables the definition of the set of rules that will control the measurement process.

Measurement tools could have either diagnostic (discriminative and predictive) or evaluative purposes (Kirshner and Guyatt 1985). Evaluative measurement tools could be used for research purposes, routine clinical practice, or by patients as a self-management tool in the community and home settings (Dekker 2005). Evaluative measurement tools should demonstrate certain attributes based on the context and the population within which they would be implemented. Evaluative measurement tools or "evaluative indexes" as reported by Kirshner and Guyatt (1985) are defined as a measurement tool that is used to:

"Measure the magnitude of longitudinal change in an individual or group on the dimension of interest." (Kirshner and Guyatt 1985, P: 28).

If the measurement tool is to be used for research purposes then the specifications required by measuring tools vary with the study design (Guyatt *et al.* 1989). However, when the tool is to be used in clinical settings then the specifications of the tool vary with the nature of the clinical condition treated, the nature of the intervention, the nature of the clinical outcome being measured, and the clinical characteristics and the needs of the patient mix attending that clinical settings.

Attempts to combine assessment with measurement are not always easy and maybe misleading. Considering the COPD Assessment Test "CAT", the tool was developed to assess the overall impact of COPD on overall health (Jones *et al.* 2009). The items on the tool might serve a good function in providing comprehensive and simple representation of potential clinical problems in people with COPD. However, scaling each item on the questionnaire and generating an overall score has resulted in measurement tool that do not fulfil the logical requirements of the theory of measurement and measuring scales.

5.4.2 Measurement at the level of the individual patient

When measuring at the level of the individual patient the requirements for the quality of the instrument are higher than in the research settings (Dekker *et al.* 2005). Measurement in clinical settings requires the collection of data at the level of the individual (De vet *et al.* 2003). Measurement at the level of the individual inflicts high demand for reliability and responsiveness. When measurement is done at the level of the group, a common practice is to average the results to reduce measurement error. This is not attainable at the level of the individual (De vet *et al.* 2003). Moreover, the measurement tool should be highly responsive to subtle changes in functioning that might be clinically significant and meaningful to the patient (Guyatt *et al.* 1987a).

Another important issue when measuring at the level of the individual is that researchers usually differentiate between the significance of change scores of a certain magnitude in the individual as compared to the same magnitude in the mean score of a group. A classical example is a change of 2 mmHg in blood pressure. While this is considered trivial and within the range of measurement error at the level of the individual, it was shown that a change of 2 mmHg in the average blood pressure in a group of patients was associated with reduced numbers of stroke in that population (Guyatt *et al.* 1987a).

Reflecting on the measurement of functional performance, it has been shown that functional performance is a highly individualised experience and extremely variable even within the individual patient in COPD. Therefore, it should be measured at the level of the individual. Considering the high variability in individual responses (Guyatt *et al.* 2002), and the qualitative nature of the attribute "functional performance" implies that calculating the mean is both unscientific and meaningless. The generated value does not reflect the clinical condition of any individual in the group.

5.4.3 Measurement of individualised outcomes

Functional performance is a qualitative attribute that is experienced by each patient differently. The impact of COPD on functional performance resulting in activity limitations and participation restrictions is best described by patients' narratives. Adequate analysis and understanding of the phenomenon “functional performance” and the factors influencing it could not be achieved without involving patients' perspective. Therefore, adequate construct validity could not be achieved unless the items are generated and the pattern of functional loss is described by patients themselves (De vet *et al.* 2003).

It is important to ensure that the patient's perspective is included using a systematic and rigorous qualitative research methods. Moreover, the requirements of the theory of measurement and measurement scales should be addressed to ensure that the resultant measurement tool provide valid and reliable scientific data.

5.4.4 The feasibility of measurement in clinical setting

If the measurement tool is to be used in routine clinical practice then contextual factors such as small sample size, patient characteristics, and time and resources limitations should be considered (Whitty *et al.* 1996). This suggests that certain factors should be considered, such as the time required for measurement, ease of administration, staff training implications, and acceptability by patients and clinical staff (Patient reported outcome measurement group, Oxford 2009).

Another important aspect of feasibility that is not reported when providing evidence of the feasibility of the measurement tool is the value of time required for measurement. The time required for the performance of measurement should not be at the expense of treatment. Also an important question to ask is whether patients benefit from outcome measurement. Outcome measurement in clinical practice should be used in the context of quality improvement and not only for management and research purposes (Dekker *et al.* 2005). This suggests that the measurement tool should provide clinical data to inform clinical decision making and improve the care provided to the patient.

Lakeman (2004) cautioned that routinely collected outcome measures in its current form fail to capture the richness of the experience of care of individuals. He suggested that reducing clinical data to a meaningless aggregate of numbers is very seductive and simplistic and does not inform clinical decision making.

Moreover, Lakeman (2004) warned that simple and short outcome measures that claim feasibility do not necessarily reflect a valid outcome of care. There should not be a trade-off between simplicity, and informative and in depth approach to the analysis of the experience of care. A feasible clinical outcome measure should account for the process of care and not a predetermined end point (Lakeman 2004).

5.4.5 Meaningfulness¹⁰ of measurement

Meaningfulness of measurement is the degree to which one can assign meaning to scores (Dekker *et al.* 2005). A definition that pays attention to the intended audience defined meaningfulness as a quality of the measurement tool that ensures:

"The intended audience must understand the magnitude of the effect" (Guyatt *et al.* 2002).

In order for the measurement tool to provide meaningful data, it should be developed by reference to the measurement theory and the definition of measurement: *"assigning numerals according to rules"* (Stevens 1946, P: 677). It has been highlighted earlier that the rule should make explicit the isomorphism between the empirical observations, the mathematical structure, the arbitrary unit of measurement, and the mutually exhaustive and exclusive definition of categories (Michel 1983). Moreover, the process of development should involve patients, clinicians and decision makers to generate categories that describe meaningful changes to them. The definition of the categories on the measurement scale should be performed using statements that provided singular¹¹ meanings. Finally the measurement system should allow the analysis of data at the level of the individual and at the level of the group, thus outcomes are meaningful to patients, clinicians, and managers.

¹⁰ The literature used interpretability and meaningfulness to refer to the same construct. For the purposes of standardisation meaningfulness will be used in this thesis.

¹¹ Singular means that the statement describing the category has one meaning and one meaning only.

Guyatt *et al.* (2002) highlighted the widespread scope of the clinical context, and that it should not be confined to the clinicians. Therefore, an endeavour to make outcomes meaningful should address patients, clinicians, and managers.

Measurement should be meaningful to the patients by providing feedback about their clinical conditions and the changes in the clinical condition in response to the treatment or to the progression of the disease. For clinicians, meaningful measurement should provide information about the patient's response to treatment and whether a change in the treatment should be implemented. Moreover, the measurement should inform clinicians about when the patient has achieved the maximum potential benefit, when to discharge the patient and whether the clinical condition of the patient is successfully maintained (Greenfield and Nelson 1992).

Commissioning services is the requirement of all managers. In order to inform decisions about the impact of resource allocations on patients, the measurement should provide meaningful data to managers.

Guyatt *et al.* (2002) proposed a number of statistical manipulations in order to assign meaning to scores. This thesis contends that whilst it is important to devise methods for assigning meaning to scores, this has two main problems. First using statistical manipulation brings us back to the initial problem of clinical versus statistical significance. (Beaton *et al.* 2001). Second a significant conflict emerged in the literature on interpreting the meaning of statistical processes aimed at interpreting the meaning of scores. It is suggested that instead of attempting to assign meaning to scores, it could be more fruitful to develop outcome measures that generate meaningful scores (Lakeman 2004), if they do not exist.

5.4.6 The definition of clinical significance

This requires identifying clinically significant outcomes and clinically significant change.

5.4.6.1 Identifying clinically significant outcomes

Kazdin (1999) defined clinical significance as:

“The practical or applied value or importance of the effect of an intervention—that is, whether the intervention makes a real (e.g., genuine, palpable, practical, noticeable) difference in everyday life to the clients or to others with whom the client interact.” (Kazdin 1999, P: 332).

Identifying clinically significant outcomes is important because the way the outcome of the intervention is presented influence the inclination of clinicians to intervene or not. For example; when data from clinical trials suggests that the increase in life expectancy and mortality benefits are trivial, then clinicians are less enthusiastic to intervene. This is particularly critical when the intervention reported not to have an effect on mortality could actually improve the quality of life or the functional status of the individual patient in clinical settings. Moreover, it is worth noting that patients appreciation of certain benefits vary considerably. Additionally, the same patient may place a different value on the same benefit with varying circumstances. In the context of clinical settings or clinical trials, for the outcomes to be useful they should be meaningful to the intended audience that is patients, clinicians, and policy makers (Guyatt *et al.* 2002).

The values attached to outcomes are central in clinical management decisions. This has highlighted the importance of including patients in the decision making process. This inclusion should be performed in a systematic manner that involves presenting patients with available options and eliciting their response. A caution here is that patients should understand the meaning of benefits expected form treatment and the feasibility of achieving those benefits given the existing impairments (Kirshner and Guyatt 1985).

Kazdin (1999) suggested that an appropriate outcome measure of clinical significance should be developed based on a typology of abstract goals of treatment. These goals should be mutually developed between the patient and the therapist. A clinically significant outcome should be defined with reference to goals that are feasible, realistic and conceptually compatible with the proposed impact of treatment.

The central aim of PR is to improve functioning. Whilst the programme might have an impact on symptoms, improvements in symptoms are less likely to be reported as clinically significant outcomes (Okasheh *et al.* 2008). However, improved ability to control symptoms, cope with them and ultimately improved functional performance constitutes a clinically significant outcome that warrants appropriate measurement (Okasheh *et al.* 2008).

When attempting to identify the clinically significant outcomes it is important to refer to patients' perspectives and expectations. That is patients' goals of seeking professional help (Verrill *et al.* 2009). Much of the early symptoms of COPD such as coughing and breathlessness are related to aging or natural response to smoking. Therefore, patients do not seek treatment or professional advice until they become functionally limited as a result of symptoms (Okasheh *et al.* 2008). It follows that the clinical gain for patients is interpreted in terms of functional improvement rather than reversal of symptoms. Moreover, the lack of association between symptoms and functional ability has been frequently reported (Nici *et al.* 2009). This suggests that a clinically significant outcome of PR is best described by patients in terms of changes in functional performance.

Once the construct that constitutes clinically significant outcome is defined from the perspective of patients based on the goals of treatment, the clinically significant change should be established (Kazdin 1999).

5.4.6.2 Identifying clinically significant change¹²

The amount of treatment required to induce a clinically significant change is dependent on the type of problems treated and the progression of the disease. Kazdin (1999) asserted that clinically significant change as a result of treatment should be established apart from the statistical significance. It should capture the actual impact of treatment on everyday life with reference to the individual patient. Kazdin (1999) states:

"The question for any measure or index of clinical significance is the extent to which the measure in fact reflects a change that does have an impact on the individual's functioning in everyday life or a change that makes a difference" (Kazdin 1999, P: 336).

This prompts the question of how to establish the clinically significant change that has resulted from treatment. The usefulness of establishing the clinically significant change is due to the link it creates between the significant change and treatment decisions in clinical practice. It also highlights the importance of patient's perspective (Guyatt *et al.* 2002). Clinically significant change is defined as:

"The smallest difference in score in the domain of interest which patients perceive as important either beneficial or harmful, and would lead the clinician to consider a change in the patient's management". (Guyatt *et al.* 2002, P: 377).

Guyatt *et al.* (2002) argued that the clinically significant change represents significant improvement or deterioration as reported by the patient. He described that as "subjectively significant change". It is argued that it is not a subjective construct; rather the minimum clinically significant change is a "qualitative significant change". It could be measured objectively by creating a hierarchical structure of clinically important outcomes over time, based on clinical knowledge and patient experience. The unit of measurement should be calibrated so that it represents one clinically significant change.

¹² This is referred to in the literature as the minimum important difference. However, the author decided not to use this to avoid confusion by using the word minimum, as the clinically significant change might be a large change that requires large amount of therapeutic input, particularly in chronic conditions.

Anchor-methods to establish clinically significant change based on global rating have been frequently reported in the literature (Guyatt *et al.* 2002), (Beaton *et al.* 2001), (Jacobson and Traux 1991), (Wyrwich *et al.* 1999), and (Redelmeier *et al.* 1996).

Kazdin (1999) cautioned about the backward reduction of outcome measurement to global ratings that are not theoretically or scientifically established measurement tools. They ascertained the importance of establishing empirical connections between observed changes in clinically significant outcomes and standardised outcome measures.

Kazdin (1999) highlighted methodological issues in establishing clinical significance based on existing "validated" outcome measures using anchor methods and cut off points. Anchor methods are based on establishing relationships between global ratings and outcomes of experimentally established effective treatment (Guyatt *et al.* 2002). A caveat about using global ratings to establish clinically significant change is that the results represent perceived rather than actual change. It should be expected that patients might report themselves as "much better" while the construct measured has not significantly changed. Similarly patients might report themselves as not changed while the construct measured has changed as measured by the measurement tool. This is conceptually analogous to type I and type II error in experimental research (Kazdin 1999).

Kazdin (1999) highlighted two problems with establishing cut off point for normative data in order to establish clinically significant change. First, normative data is not based on data collected from the standardised sample on two separate occasions. Therefore they do not provide comparable pool of data to that collected using a pre post measurement study design. Second, a score within the normative range for someone in a community sample might not hold the same correlate or meaning for a score in the normative range for someone who has an impairment and received treatment.

Evidence of the improvement in daily life functioning following PR could not be provided unless functional outcomes of PR are measured using an appropriate measurement tool. This problem might be resolved by the development of an outcome measure that directly measures empirically observed changes in clinically significant outcomes. The unit of measurement should be “one unit of clinically significant change”. A measurement system located in the literature that enable such measurement is the Treatment Evaluation by the LeRoux “TELER” method (LeRoux 1993).

5.5 Quality standards of the measurement tool

In order to provide informative clinical data it is important to establish the quality and rigour of the measurement tool. This involves providing evidence of the validity, reliability and responsiveness of the measurement tool.

“Measurements are taken to provide information, but the result may be misinformation if the quality of measurements is not ensured”. (Task Force on Standards for Measurement in Physical Therapy 1991, P: 592).

A number of issues should be considered when providing evidence of the rigour and quality of the measurement tool. Firstly, a measuring scale has two components: the measurement scale, and the translating medium i.e. the mechanism that converts an attribute into a point on the measuring scale (LeRoux 2003). Secondly, a high quality measurement is the result of an interaction between the clinical knowledge of the rater and the refined design of the measuring scale.

5.5.1 Validity of the measurement

The validity of the measurement should be ensured during development by adequate conceptualisation of the knowledge underpinning the disease and the intervention, and the definition of the construct based on theoretical and clinical, and empirical and pragmatic research evidence to ensure appropriate translation of the construct into points on the scale. In COPD the translating medium is the perceived experience of the patient and the knowledge and experience of the clinician. Moreover, the theory of measurement and measuring scales should be considered to ensure the validity of measurement.

Kazdin (1999) suggested that outcome measures of clinical significance should be validated in relation to the conceptualised definition of clinical significance. Therefore face, content, and construct validity should be ensured during development of the tool by involving clinical and theoretical knowledge, perspectives of experts, and a representative sample of the population within which the outcome measure will be implemented.

The Task Force on Standards for Measurement in Physical Therapy (1991) ascertained that the best evidence of face, content and construct validity is provided based on logical argumentation of clinical and theoretical knowledge of the construct being measured and its dimensions. Further evidence of construct and criterion validity should be based on inferred meaningful interpretations of relations between the outcome measure and other outcome measures considering contextual factors “environment and population”. This highlights the importance of preserving clinical meaning while providing evidence of validity rather than reducing this to statistical tests and mathematical formulations (Kazdin 1999) and (poolman *et al.* 2009).

5.5.2 Reliability of measurement

Three important points should be highlighted when providing evidence that a measurement tool is reliable when used in clinical settings for the purpose of evaluating clinically significant changes. First is that measurement in clinical settings is performed at the level of the individual, thus the evidence should show that the tool is reliable for measurement of changes at the level of the individual patient (Kirshner and Guyatt 1985). Second, is that the clinical knowledge of the rater and the ability to identify and recognise change is an important factor to ensure the reliability of the measurement. The third point is related to the main purpose of the evaluative measurement tool which is detecting clinically significant changes in response to treatment. Therefore, the criteria required by the measurement tool to be reliable is to show small within subject variance in stable subjects, and a large change in score when the construct "functioning" has improved or deteriorated (Kirshner and Guyatt 1985).

Functioning in people with COPD is naturally variable and is influenced by a number of factors. Functioning changes from day to day and even diurnally. If the measurement tool is to be responsive enough to pick these changes, then this seems like a trade off between reliability and responsiveness. Therefore, the approach to provide evidence of reliability of a measurement tool that measures functional performance in this group of patients should be different. Reliability of such a tool is established by providing logical evidence that changes on the tool could be explained as changes resulting from a certain factor that is known to induce changes in functioning in this group of people (Guyatt et al. 1987a). Roach (2006) ascertained that reliability is not a stable characteristic of the measurement tool; rather it is influenced by the purpose of measurement, context of measurement and patient group.

Reliability of the measurement tool could be improved by improving the reliability of the measurement process. This could be achieved by a number of ways. Firstly, using language appropriate and understandable by the group of patients within which the tool is going to be implemented. Secondly, training the rater whether this is the clinician, the researcher, or the patient to correctly use and record changes using appropriate documentation. Scores could be documented using hospital databases or specialised software. Thirdly, if the outcome measure is to be implemented as a patient reported outcome in home or community setting, then appropriately designed patient diary that is user friendly should be implemented. Finally, to increase the reliability of measurement the documentation should make explicit the environment within which measurement occurred, and any potentially influencing contextual factors.

5.5.3 Responsiveness of measurement

An important characteristic of an evaluative instrument is its ability to correspond to clinically significant changes resulting from treatment (Guyatt and Kirshner 1985), (Guyatt *et al.* 1987a) and (De Bruin *et al.* 1997). Whitty *et al.* (1996) suggested that responsiveness is an important attribute of evaluative health outcome measures that should be tested early in the process of developing the instrument. Responsiveness is concerned with the study of the ability of the measurement tool to correspond to "change". Streiner and Norman (1991) suggest that the overall goal of any treatment is to induce "change".

The evaluation of the amount and quality of "change" induced influence clinical decisions about the effectiveness of treatment and rationing health resources without compromising patients' care. Thus the ability of the measurement tool to correspond to changes detected by the rater is an important quality of the measurement tool that should be evaluated.

Most of the studies on the psychometric properties of measurement tool are concerned with providing compelling evidence for reliability and validity but rarely for responsiveness. This has resulted in confusion on the definition and methods of providing evidence for responsiveness. The literature on the definition and the evaluation of responsiveness is controversial (Beaton *et al.* 2001).

Terwee *et al.* (2003) suggested that the confusion is mainly arising from varying descriptions of the type of change that the instrument is supposed to detect. In request to resolve this confusion "A taxonomy for responsiveness" was provided by Beaton *et al.* (2001), following an extensive review of the literature on the responsiveness of health status measures. They concluded that the confusion on the definition and interpretation of responsiveness could be alleviated by considering responsiveness as a contextualised attribute of the measurement tool. They suggested defining the context of the study of responsiveness by identifying who is being analysed, which scores are contrasted and what type of change is being measured. Considering a measurement tool that is appropriate for implementation in clinical settings, then the context of the study would be identified as follows:

- The analysis is at the level of the individual.
- The scores contrasted are within person change.
- The type of change measured is clinically significant change.

5.5.3.1 A proposed method for the evaluation of responsiveness at the level of the individual

The measurement tool should be constructed so that the unit of measurement is clinically significant change. Scaling of the measurement tool should be based on categories coded to represent clinically significant changes in the construct being measured. Definition of clinically significant changes should be determined based on clinical knowledge and patient experience. Each code on the scale should represent an observable patient centred treatment objective that it proposed to result from clinically significant amount of therapeutic input (Mawson 2002).

- Chi square goodness of fit

In order to establish the responsiveness of a measure, the chi square test could be used to test the association between true change in the construct and the random change. Theoretically a change could result from an effective treatment, the natural progression of the disease, or from changes in the parameters that influence the construct. One way of establishing responsiveness of the measure is to induce change, by for example introducing an intervention that is designed to influence the construct being measured and then assess the significance of the association between observed changes and the probability of random changes.

6 Summary

An increased number of measurement tools of quality of life have resulted in the provision of information on health status, well-being and functioning. Although evidence of appropriate psychometric testing was provided, these outcome measures did not inform the improvement of care or enhanced recovery (Liang 2000). This could be explained by a number of factors. Firstly, data provided by existing measurement tools are difficult to interpret by patients and clinicians; therefore it did not inform clinical practice. Secondly, a clinician doing a pre post measurement is actually assessing the patient at two time point rather than doing appropriate evaluation that could inform decision making. This would result in missing a significant number of critical changes occurring during treatment that would imply changing the provision. Thirdly, outcome measures used are usually designed to measure groups of individuals; therefore they are less responsive to changes at the level of the individual patient (Liang 2000).

To overcome these problems standards of developing or selecting measurement tools for clinical practice should conform to the principles of measurement in clinical settings

- Principles of measurement in clinical settings have been described in the literature on clinimetrics, this includes
 1. The distinction between assessment activities and evaluative measurement activities. The former enable the clinician to identify problems and needs, the latter are the actual tool for informing decision making and modifying management resulting in improved patients' experiences of care.
 2. Measurement at the level of the individual. In clinical settings clinicians are responsible for providing effective and efficient care for the individual patient. Therefore, an appropriate measurement tool should be able to detect within person changes. This demands high level of responsiveness.
 3. Measurement of individualised outcomes. Patients are considered as health customers. Therefore, outcomes should be described from their perspective and account for their needs. This is particularly important when the concept measured is

qualitative in nature such as functional performance. However, during the development of this type of outcome measures thoughtful consideration should be given to the logical requirement and the standards required by the theory of the measurement and measuring scales. This ensures that the resultant measuring scales are scientific. This means the generated data represents true reality removing the influence of guessing or memory.

4. Feasibility: this quality ensures that the outcome measure is appropriate given the limited time and resources at clinical setting. However, it should be ensured that there is no trade-off between validity and feasibility.
5. Meaningfulness: This quality implies that the data generated from measurement should be meaningful to the patient and the clinician without the need for statistical manipulations. The measurement tool should meet two requirements to ensure the results are readily meaningful to the patient and the clinician. First, direct measurement of clinically significant changes that is the unit of measurement should be one clinically significant change. Secondly, the ability to detect clinically significant change. Meaningfulness should be ensured during development and is actually the first qualifier of the measurement process required to ensure that the resultant measurement scale is scientific.

Quality standards required by the measurement tool are validity, reliability and responsiveness. These qualities should be evaluated considering contextual factors, that is the setting and the population within which the measurement tool will be implemented. Evidence of quality should be logical and based on scientific and theoretical inferences that preserve clinical meaning. To date evidence for the psychometric properties of measurement tools is provided in the form of statistical and mathematical models. This form of statistical evidence fails to provide evidence of the appropriateness of the tool to the purpose and context. It is also difficult to interpret.

Confusion in the interpretation of statistical tests has already been reported in the literature between researchers. To avoid this confusion the theory of measurement and measuring scales and the theory of appropriate statistics should be considered when performing psychometric tests. Lack of compliance with these theories has significantly hindered the ability of clinicians to select the appropriate outcome measure for clinical practice.

The next section is a review of outcome measures currently used in clinical practice.

7 Section 3: A critical Review of existing outcome measures

7.1 Introduction to the review of existing outcome measures

The aims of this chapter are: First, to identify the outcome measures of functional performance and outcome measures of quality life that include subscales measuring functional performance currently used in clinical practice in the area of pulmonary rehabilitation. Second, critically review them based on the criteria identified during the previous sections to find out whether or not they fulfil the requirements of a "scientific measurement scale" and an "appropriate outcome measure of pulmonary rehabilitation for people with COPD".

7.2 Identifying outcome measures for review

It is important to highlight the fact that due to the inconsistency in terminology used, for example: quality of life, functioning, functional status, health status, physical activity, physical functioning, and activities of daily life, it is very difficult to provide an exhaustive list of all outcome measures reported in the literature for use in people with COPD.

The aim of this chapter is not to systematically review all existing outcome measures. The aim is to identify a set of outcome measures that have been reported in clinical guideline, that "might have the potential" to be appropriate for the main purpose of measurement following pulmonary rehabilitation which is the measurement of clinically significant changes in functional performance.

To further clarify what is meant by "might have the potential" the following exclusion criteria were developed. Any outcome measure that does not meet the exclusion criteria is a potentially appropriate outcome measure.

1. The outcome measure is generic, i.e. not a disease specific outcome measure. The justification for the criteria is in two parts. First, there is accumulating evidence that a disease specific outcome measure is more responsive than a generic outcome measure (Guyatt *et al.* 1987b, and Jones *et al.* 1991). Responsiveness was highlighted in the previous chapter as an important quality standard in evaluative outcome measures. Second: the purpose of the outcome measure is to evaluate the changes in functional performance in people with COPD. There is evidence that the pattern of the development of functional limitations as a result of COPD is different to other health conditions and to functional limitations resulting from aging or sedentary life style in the healthy population (Eisner *et al.* 2011).
2. The outcome measure or sub domains of the outcome measure do not measure functional performance. That is it measures factors influencing functional performance such as functional capacity, symptoms, personal factors for example self efficacy, and environmental factors.
3. The outcome measure does not measure clinically significant change in functional performance, but attempts to quantify the construct by using factors such as time, speed, and energy expenditure.
4. The outcome measure does not measure clinically significant change in functional performance, but measures dependency in functional performance. That is how dependant or independent the patient is in performing the activity.

7.3 Searching for existing outcome measures of functional performance

It has been highlighted earlier that there was a proliferation of outcome measures of quality of life and functioning for people with COPD. As the focus of this thesis is implementation in clinical setting, the identification of outcome measures to include in the review was based on reviewing clinical guidelines rather than the literature. Moreover, four clinical inpatient and outpatient pulmonary rehabilitation services were approached and asked about the outcome measures currently implemented in their practices. This was further verified by networking and clinical contacts with physiotherapists and other clinicians at conferences and workshops.

A list of the clinical guidelines on the management of COPD and Pulmonary rehabilitation was identified by literature search of Google web, Google scholar, and Pubmed using the following combination of key words.

- COPD OR Chronic Obstructive Pulmonary disease AND clinical guidelines.
- COPD management OR Chronic Obstructive Pulmonary disease management AND clinical guidelines.
- Pulmonary rehabilitation AND clinical guidelines.

This has resulted in identifying seven guidelines and statements. None of the guidelines made an explicit recommendation of outcome measures. Some of the guideline the ATS/ERS, the BTS, the general practice airway groups and the consultation documents mentioned certain outcome measures and discussed their properties without making a recommendation. These are presented in Table 3.

Table 3 Outcome measures reported by major clinical guidelines on pulmonary rehabilitation and COPD

| Guideline or statements | Outcome measures of health related quality of life, health status, functioning, ADL (Activities of Daily Life) |
|--|--|
| Global Initiative for Chronic Obstructive Lung Disease | <p>The St. George's Respiratory Questionnaire (SGRQs).</p> <p>The Chronic Respiratory Questionnaire (CRQ).</p> <p>The medical outcome study short form (SF36).</p> <p>The primary care evaluation of mental disorders (PRIME MD) patient questionnaire.</p> |
| The joint American thoracic Society/European Thoracic Society on Pulmonary Rehabilitation. | <p>The St. George's Respiratory Questionnaire (SGRQs).</p> <p>The Chronic Respiratory Questionnaire (CRQ).</p> <p>Physical activity monitors.</p> |
| American Association of cardiovascular and pulmonary rehabilitation | <p>The St. George's Respiratory Questionnaire (SGRQs).</p> <p>The Chronic Respiratory Questionnaire (CRQ).</p> <p>Ferrans and Powers quality of life pulmonary version.</p> |
| The British Thoracic Society statement on pulmonary rehabilitation. | <p>The medical outcome study short form (SF36).</p> <p>The Quality of Well Being Scale (QWB).</p> <p>The Psychosocial Adjustment to Illness Scale-Self Report (PAIS-SR).</p> <p>The St. George's Respiratory Questionnaire (SGRQs).</p> <p>The Chronic Respiratory Questionnaire (CRQ).</p> <p>The pulmonary functional status scale.</p> <p>The pulmonary functional status Dyspnea scale.</p> <p>The London Chest Activities of Daily Living Questionnaire.</p> <p>The Manchester Respiratory Activities of Daily Living questionnaire.</p> <p>Physical activity monitors.</p> |
| The General Practice Airway Groups Opinion on pulmonary rehabilitation. | <p>Lung information needs questionnaire (LINQ).</p> <p>The Hospital Anxiety and Depression scale (HAD).</p> <p>The Clinical COPD Questionnaire (CCQ).</p> <p>The St. George's Respiratory Questionnaire (SGRQs).</p> <p>The Chronic Respiratory Questionnaire (CRQ).</p> |
| NICE clinical guidelines for COPD | No recommendations or reports on implementing outcome measures. |

| Guideline or statements | Outcome measures of health related quality of life, health status, functioning, ADL (Activities of Daily Life) |
|--|---|
| Consultation on a Strategy for Services for Chronic Obstructive Pulmonary Disease (COPD) in England. | The COPD Assessment Test (CAT). |
| Reported by clinicians | The COPD Assessment Test (CAT). The Medical Research Council Dyspnea scale (MRC). The Hospital Anxiety and Depression scale (HAD). The Clinical COPD Questionnaire (CCQ). The St. George's Respiratory Questionnaire (SGRQs). The Chronic Respiratory Questionnaire (CRQ). |

7.4 Selection of relevant outcome measures for review

Outcome measures reported in the guidelines were further reduced using the above exclusion criteria. Table 4 provides the reference and a basic description of the selected outcome measures. Selected outcome measures were reviewed based on the quality standards of outcome measures reviewed in the previous section. The aim is not to identify all problems in each outcome measure, but to use them as examples on problems in existing outcome measures.

Published reports on the development of the questionnaires were also reviewed. It is very difficult to evaluate the development process and the structure of the questionnaire separately. This is because problems in development would preclude the resultant structure from fulfilling the criteria of "a scientific measuring scale" and the quality standards of "an appropriate measurement tool".

Table 4 A descriptions of outcome measures selected for review.

| Outcome measure | Author (Ref) | Basic description | Important notes |
|---|------------------------------|---|--|
| The St. George's Respiratory Questionnaire (SGRQs). | (Jones <i>et al.</i> 1991) | The SGRQ is designed to measure health impairment in patients with asthma and COPD. It is in two parts. Part 1 produces the Symptoms score, and Part 2 the Activity and Impacts scores. A Total score is also produced. Of interest to this thesis is the second part. Part 2 (Questions 9 to 16) addresses the patients' current state (i.e. how they are these days). The Activity score measures disturbances to patients' daily physical activity. The Impacts score covers a wide range of disturbances of psycho-social function. | |
| The Chronic Respiratory Questionnaire (CRQ). | (Guyatt <i>et al.</i> 1987b) | The questionnaire examines four aspects of patient's lives: dyspnoea, fatigue, emotional function, and mastery (the feeling of control over the disease and its effects). The results of scoring are presented as mean score per dimension which is obtained by dividing the total score in each dimension by the number of questions in that dimension. | Designed for use in clinical trials. |
| The Clinical COPD Questionnaire (CCQ). | (Molen <i>et al.</i> 2003) | A questionnaire to measure clinical control in patients with COPD. It includes three main domains symptoms, functional state and mental state. The overall clinical COPD score and the scores of the domains are calculated by adding all scores together and dividing this sum by the number of questions. Thus the overall clinical COPD control score as well as the score on each of the domains vary between "0, very good control" to "6, extremely poor control". | Designed for clinical use (primary care setting) |

| Outcome measure | Author (Ref) | Basic description | Important notes |
|--|-------------------------------|--|--|
| The London Chest Activities of Daily Living Questionnaire (LACDL). | (Garrod <i>et al.</i> 2000) | The questionnaire is designed to assess dyspnea activities in daily living. It has 15 items classified into 4 components: Domestic, n=6; self care, n=4; physical, n=2; leisure, n=3. It was assumed that items were of similar weighting. The questionnaire was scored from 0, 'I wouldn't do anyway?' to 5 'someone else does this for me (or helps)', representing maximal disability. A value of 0 for 'I wouldn't do anyway' was used to indicate activities that do not represent handicap for the individual. | Only tested on persons with severe COPD. Focus on dyspnea |
| The Manchester Respiratory Activities of Daily Living questionnaire (MRADL). | (Yohannes <i>et al.</i> 2000) | Designed to assess respiratory disability in elderly outpatients with chronic obstructive pulmonary disease. It measures functional ability in four domains: mobility, 7 items; kitchen, 4 items; domestic tasks, 6 items; leisure activities, 4 items. A maximum score of 21 indicates no impairment. | Self completed and takes about 10 min to complete |
| The pulmonary functional status scale (PFSS). | (Weaver <i>et al.</i> 1998) | a self-administered, 56-item questionnaire That measures the mental, physical, and social functioning of the patient with COPD and takes 20 minutes to complete. Scaling of items: variable Likert-type scaling Scoring: Mean score for each subscale and total score, responses are weighted | |

| Outcome measure | Author (Ref) | Basic description | Important notes |
|---|--------------------------------|--|------------------|
| The pulmonary functional status Dyspnea scale (PFSDS). | (Lareau <i>et al.</i> 1994) | <p>A self administered questionnaire measuring functional status and dyspnea in pulmonary patients.</p> <p>Number of items: 164, Domains & categories: 2 domains 6 categories.</p> <p>Name of categories/domains</p> <p>Domains (functional status and dyspnea), categories (self care, mobility, home management, eating, recreation, and social)</p> <p>Scaling of items: Modified Likert 0 to 10 scale with verbal descriptors</p> <p>Scoring: Total scores of items on each domain (activity, and dyspnea), mean scores for each domain (total score divided by number of items rated), activity and dyspnea index (number of items rated 7, 8, 9 or 10), and individual scores on five general dyspnea scores. Higher scores indicate worse functional status or symptoms</p> | Focus on dyspnea |

7.5 Evaluation of existing outcome measures

Quality standards of outcome measures should be evaluated considering contextual factors, that is the setting and the population within which the measurement tool will be implemented. Evidence of quality should be logical based on scientific and theoretical inferences that preserve clinical meaning.

7.5.1 Measurement at the level of the individual

Existing outcome measures have been tested in a group of individuals. Their appropriateness for evaluating change within a specific individual patient has not been critically studied (ATS/ERS 2004). Measurement at the level of the individual inflicts high demand for reliability and responsiveness (Kelly *et al.* 2005).

7.5.2 Measurement of individualised outcomes

During the process of development items for the questionnaires reviewed were generated from qualitative work involving patients. Ideally this should result in items that are relevant to the individual patient. However, the reduction of items by experts, such as in the CCQ, or using statistical models, such as in the LADCL, implies that the decision on the importance and weighting of items were not individualised. Ideally the generation of items, the reduction, and the weighting should be performed by patients. Experts and clinicians should be consulted during the design of the theoretical framework of the construct being measured and to ensure scientific and clinical knowledge underpinning the resulting measurement tool (McDowell 2006).

The authors of the LADCL reported robust criteria for reducing items. However, one of the criteria for excluding items was association with demographic variables such as age. A caveat here is that COPD is a complex disease that develops later in life. Therefore, aging is an important factor that limits functional performance. It might be suggested that because functional performance is a multidimensional experience, it would be meaningless to the patient to exclude items that are associated with a certain age. There is no evidence that the items excluded are only influenced by age and not influenced by COPD.

Another criterion for item reduction in the LADCL was the exclusion of items that showed poor repeatability on repeat testing. It is suggested that due to the continuously changing functional status in people with COPD, this might have resulted in the removal of the more responsive items.

An important point to consider is that irrelevant or inappropriate items create burden on the patient. This could lead to lack of willingness on the side of the patient to respond in a focused and honest way adversely affecting the quality of resultant measurement (Kelly *et al.* 2005).

7.5.3 Feasibility

Feasibility is described in terms acceptability by patients and clinicians, ease of administration and scoring, and resources required for administration. Resources include time, cost, required equipment, and professional involvement. Questionnaires such as the PFSS and the PFSDS are very lengthy and less applicable in clinical setting. Therefore, a modified shorter version of both questionnaires was developed. An important question here is about the methods of item reduction. Only items that are problematic, relevant to the patient and have the potential to improve with the intervention administered should be retained (McDowell 2006). Unfortunately existing outcome measures have used strategies to reduce items, such as statistical models and expert opinions, which are unlikely to ensure the preceding three requirements (Lakeman 2004).

Another important point to consider is that feasibility has been described in terms of time required to complete the measurement. More importantly and less frequently discussed is the value of time required for measurement. This should be described in terms of the benefits the patient gain from the measurement process (Lakeman 2004). Existing outcome measures provide information that is more suitable for administration and managerial decisions not to inform clinical decision making. That is they do not inform the process of care. The value of measurement in informing the process of care is indicated by the meaningfulness of the measurement to the clinician and the patient. This is reviewed next.

7.5.4 Meaningfulness

This quality requires ensuring the meaningfulness of measurement. This is achieved by ensuring the following: first, the scoring system provides singular measurement. This is measurement that is unambiguous in the sense that it means one thing and one thing only (Kazdin 1999). Second, the meaning of measurement is maintained under any transformation or statistical and mathematical operations.

Scoring systems of existing outcome measures have resulted in the loss of the meaning of measurement. Hinds *et al.* (2002) states:

"It is possible to have a reliable and valid measure of a clinical phenomenon but to score the measure in a way that inaccurately represents the clinical meaning of the measured phenomenon" (Hinds *et al.* 2002, P: 345).

Three main problems were identified in the literature when using inappropriate scoring. The first is providing ambiguous measurement, the second is the dilution or the exaggeration of meanings on individual scales (Hinds *et al.* 2002). The third is that patients with different patterns of responses might have the same total score, resulting in initiating similar clinical actions for two different clinical profiles (Greenfield and Nelson 1992).

Next are examples of scoring systems of existing outcome measures that lack meaningfulness as a result of the scoring systems.

7.5.4.1 Example of scoring systems that resulted in ambiguous measurement

Unambiguous measurement is achieved by addressing the third logical requirement of measurement and the first requirement of the theory of measurement and measuring scale. These are "defining categories of the construct so that they are mutually exclusive and exhaustive" and "The rule for assigning numeral should be made explicit" respectively.

An example is provided using the scoring system of the MRADL (Figure 10). The instructions on scoring the MRADL indicate that: "much more slowly; quite a lot more slowly; most of the night; for 1–2 hours" are scored 0, and "a little more slowly; for 1/2 hours; not at all more slowly" are scored 1. This scoring system implies that there are three presumably different categories given the same score, resulting in three possible meanings for 0 and three possible meanings for 1.

Figure 10 Example of two questions from the MRADL

| | Much more slowly | Quite a lot more slowly | A little more slowly | Not at all more slowly |
|---|------------------|-------------------------|----------------------|------------------------|
| Do you have to eat more slowly than you would like? (*) | | | | |
| Does your breathing keep you awake at night? (*) | | | | |

7.5.4.2 Example of scoring system that resulted in the dilution or exaggeration of clinical problems

An example is provided using the LCADL (Figure 11)

Figure 11 Hypothetical scoring of the LACDL

Please tell us how breathless you have been during the last few days whilst doing the following activities.

| | 0 | 1 | 2 | 3 | 4 | 5 |
|---------------------------|---|---|---|---|---|---|
| SELF CARE | | | | | | |
| 1) Drying | 0 | 1 | 2 | 3 | 4 | 5 |
| 2) Dressing upper body | 0 | 1 | 2 | 3 | 4 | 5 |
| 3) Putting shoes/socks on | 0 | 1 | 2 | 3 | 4 | 5 |
| 4) Washing hair | 0 | 1 | 2 | 3 | 4 | 5 |
| DOMESTIC | | | | | | |
| 5) Make beds | 0 | 1 | 2 | 3 | 4 | 5 |
| 6) Change sheet | 0 | 1 | 2 | 3 | 4 | 5 |
| 7) Wash windows/curtains | 0 | 1 | 2 | 3 | 4 | 5 |
| 8) Clean/dusting | 0 | 1 | 2 | 3 | 4 | 5 |
| 9) Wash up | 0 | 1 | 2 | 3 | 4 | 5 |
| 10) Vacuuming/sweeping | 0 | 1 | 2 | 3 | 4 | 5 |
| PHYSICAL | | | | | | |
| 11) Walking up stairs | 0 | 1 | 2 | 3 | 4 | 5 |
| 12) Bending | 0 | 1 | 2 | 3 | 4 | 5 |
| LEISURE | | | | | | |
| 13) Walking in home | 0 | 1 | 2 | 3 | 4 | 5 |
| 14) Going out socially | 0 | 1 | 2 | 3 | 4 | 5 |
| 15) Talking | 0 | 1 | 2 | 3 | 4 | 5 |









0) Wouldn't do anyway
 1) I do not get breathless
 2) I get moderately breathless
 3) I get very breathless
 4) I can't do this anymore
 5) Someone else does it for me

Following the authors instructions the above questionnaire is scored as a total of 44. While the authors did not define a unit of measurement it is not known what this 44 means. The presence of two score 4 and 5 coded to give the same meaning which is the inability to perform the activity it is difficult to decide on the score that represents maximum disability. However provisionally this will be set as 5 multiplied by 15 items and the maximum disability is represented by a score of 75¹³. Assuming a maximum score of 75 representing maximum disability resulting from breathlessness interfering with functional performance, then this patient has approximately 60% loss of function as a result of breathlessness, which is suggested to have a significant impact on daily life.

Looking at the Responses to individual items, it is recognized that within the same domain "self-care" the level of disability varies considerably. That is the patient has no problem drying self "20 % loss of function", but gets very breathless putting shoes on "80 % loss of function", and is unable to wash hair "80% loss of function". This suggests that a total score of 44 "60% loss of function" has resulted in the dilution of 2 clinical problems and the exaggeration of one clinical problem.

7.5.4.3 Example of scoring system that results in one score for two different patterns of clinical problems

A theoretical example on this problem is provided from the CCQ and presented in (





















Figure 12). The figure shows that both patient  and  have a total average score of 3.3 indicating moderately poor control of clinical problems as indicated by the scoring instructions of the CCQ. Patient  reported being short of breath doing physical activities many times while patient  reported experiencing that almost all of the time. Patient  reported coughing and producing phlegm a great many times and many times respectively, while patient  reported this to happen a few times. This shows that the two patients were having different clinical problems. The predominant symptom that patient  has is breathlessness on exertion, while the predominant symptoms that patient  have appear to be coughing and producing phlegm.

¹³ The author is aware that these are not interval level measurement and therefore should not be summed to generate a total score; however this hypothetical example follows the instructions of calculating the score of the questionnaire.

The pattern of functional limitation is also different in the two patients. Patient O reported being slightly limited with moderate activities but totally limited in social activities. On the other hand patient O reported being extremely limited in moderate physical activities, but moderately limited in social activities.

While one might argue that one presentation or the other does not make sense. In practice the patient might give thousand reasons for contradicting scores, and the clinician could only accept. This is because the scale is unscientific and scoring could not be falsified empirically by observation or experimentation. Giving patients such a scale means that clinicians have to accept patients scoring as the ultimate truth. Else they are limited in interpreting the score, and identifying the type of clinical problems that limit the patient's functional performance.

Figure 12 Two clinical profiles on the CCQ with the same average score

| CLINICAL COPD QUESTIONNAIRE | | | | | | | |
|--|--------------------|---|---|---|---|---|---|
| Please circle the number of the response that best describes how you have been feeling during the past week. (Only one response for each question). | | | | | | | |
| On average, during the past week, how often did you feel: | never | hardly ever | a few times | several times | Many Times | a great many times | almost all the time |
| 1. Short of breath at rest? | 0 |  |  | 3 | 4 | 5 | 6 |
| 2. Short of breath doing physical Activities? | 0 | 1 | 2 | 3 |  | 5 |  |
| 3. Concerned about getting a cold or your breathing getting worse? | 0 | 1 |  |  | 4 | 5 | 6 |
| 4. Depressed (down) because of your breathing problems? | 0 |  |  | 3 | 4 | 5 | 6 |
| In general, during the past week, how much of the time: | | | | | | | |
| 5. Did you cough? | 0 | 1 |  | 3 | 4 |  | 6 |
| 6. Did you produce phlegm? | 0 | 1 |  | 3 |  | 5 | 6 |
| On average, during the past week, how limited were you in these activities because of your breathing problems: | not limited at all | very slightly limited | slightly limited | moderately limited | very limited | extremely limited | totally limited /or unable to do |
| 7. Strenuous physical activities (such as climbing stairs, hurrying, doing sports)? | 0 | 1 | 2 | 3 | 4 |  |  |
| 8. Moderate physical activities (such as walking, housework, carrying things)? | 0 | 1 |  | 3 | 4 |  | 6 |
| 9. Daily activities at home (such as dressing, washing yourself)? | 0 | 1 |  |  | 4 | 5 | 6 |
| 10. Social activities (such as talking, being with children, visiting friends/ relatives)? | 0 | 1 | 2 |  | 4 | 5 |  |

7.5.5 Validity of measurement

Unfortunately the authors of existing outcome measures did not provide a logical argument to support evidence of the face and content validity of the questionnaire. Involvement of experts was limited to generating and reducing the items and not systematically reviewing the structure of the questionnaire. Judgment of face and content validity should be based on the adequate representation of the construct being measures in the items of the questionnaire. This could not be achieved without providing a comprehensive definition of the construct and the factors influencing it (Hinds *et al.* 2002).

7.5.5.1 Defining the construct

Only the authors of the clinical COPD questionnaire provided a definition of the construct being measured (Molen *et al.* 2003). Appropriate definition of the construct and the factors influencing the construct is essential to ensure the face and content validity of the measurement tool. However, existing outcome measures failed to account for factors influencing the construct. For example the London Activity of Daily Living Questionnaire and the Pulmonary Functional Status Dyspnea Scale are concerned with impact of dyspnoea only on activities (Garrod *et al.* 2000).

Failure to provide a definition of the construct measured questions the construct validity of existing outcome measure. Moreover, it has detrimental impact on the meaning of measurement. An example from the MRADL is provided. MRADL was designed to assess "respiratory disability". However, without providing theoretical or logical evidence, the construct was reduced to asking questions about breathlessness and activities of daily life. Moreover, the questions were not designed appropriately to reflect how breathlessness impacted the performance of activities of daily life.

The MRADL lists a number of ADL and asks the patients to respond to each listed activity by choosing one of the following four categories: not at all, with help, alone with difficulty, alone easily. The design of the questions has two main problems. First it does not account for other factors that might influence the activity other than breathlessness. This is particularly important in a disease like COPD where impairments are multiple and many factors influence the performance of activities. Second it lacks uniqueness in the sense that each question asks about two things. That is whether the patient is independent in

performance indicated by the response "with help". And the difficulty of performance indicated by the responses "Alone with difficulty and alone easily".

Another important issue is the appropriateness of items “contents of the outcome measure” to provide valid clinical information. This is presented with an example from the PFSS (Figure 13)

Figure 13 An item from the PFSS

| 2. How much difficulty do you have getting dressed? | | | | | |
|--|--|------------------------------|-------------------------------|-------------------------------|--------------------------|
| (0) Cannot do this activity because of other health problems | (1) Cannot do this activity because of my lung problem | (2) Extreme difficulty | (3) Moderate difficulty | (4) A little difficulty | (5) No difficulty |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

This item provides three potential functional states: the patient is unable to perform the activity, the patient performs the activity with difficulty, and the patient has no problem performing the activity. Considering these information in the clinical context, the clinician would not have sufficient information to answer the following clinical questions: what is preventing the patient from performing the activity? What is the type of difficulties interfering with activity? Could these difficulties be eliminated with the type of treatment provided? This suggests that the information this item provides is invalid for informing clinical decision making.

7.5.5.2 Identification of the construct "Qualitative or Quantitative"

Adequate identification of the construct is in three parts. First is providing evidence of whether the construct quantitative or qualitative. Second is to operationally define the construct. Third is to define categories of the construct so that they are mutually exclusive and exhaustive. Existing outcome measures are all based on the assumption that the construct measured is quantitative without providing convincing evidence. Evidence that the construct is quantitative is provided by showing that the construct fulfils the Holder's axioms (Michell 1997).

An example is provided from the Chronic Respiratory Questionnaire (CRQ). The authors state the aim of the questionnaire as:

“A measure of quality of life for patients with chronic airflow limitation designed for use in clinical trials” (Guyatt *et al.* 1987b, P: 773).

Quality of life is a qualitative constructs, and items for the questionnaires were derived from literature review and qualitative interviews with patients. However, the scoring results are presented as mean score per dimension which is obtained by dividing the total score in each dimension by the number of questions in that dimension. Addition and division could not be applied to the level of data presented in the questionnaire.

Failure to recognise the qualitative structure of the construct “quality of life”, which is the first logical requirement of measurement, or using statistics appropriate to the level of data presented, precluded the fulfilment of the theory of measurement and measuring scales. The authors assumed that the 7 point scale they used to incongruously quantify items on the questionnaire is interval. This is not compatible with structure of the construct being measured which is qualitative. Moreover, the arrangement of the categories in the questionnaire is at best a classification of domains rather than being arranged in a hierarchy that poses the attributes of asymmetry, connectivity and transitivity, to create an isomorphism with an ordinal mathematical structure.

In its current structure the CRQ should be used as an assessment tool that provides an extensive list of items representing various domains of the construct “quality of life “ and classify them into four domains. It fails to fulfil the three scientific requirements of the theory of measurement and measuring scales.

Another example is presented in the structure of the PFSS and the PFSDS. Both use a likert type scale for measuring functional status assuming an interval level of measurement without providing evidence of an isomorphism between the structure of the construct “functional scale “ and interval level mathematical structure. No definition of the unit of measurement was provided.

Current reports on the validity of existing outcome measures focus on providing statistical evidence of significant negative and positive correlations with existing outcome measures. This practice reduces the ideally complex iterative process of providing evidence of face, content, and constructs validity to a statistical index. Accepting the fact that “this is what everybody does”, it still raises the question of the translational validity of the generated index. That is how “truly random” and representative is the sample, within which the correlations were studied, of the individual patient in clinical practice (Kelly *et al.* 2005). This also applies to the type of evidence provided for the reliability and the responsiveness of outcome measures (Kelly *et al.* 2005).

7.6 Summary

This review suggests that existing outcome measures of functional performance fail to fulfil the logical requirements of measurement, the standards required by the theory of measurement and measuring scales and the principles of measurement in clinical settings. Evidence of the psychometric quality of existing outcome measures is performed at the level of the group in isolation of the clinical context.

This has resulted in meaningless measurement that is incapable of informing clinical decision making and improving the process of care for people with COPD attending PR. This mandates a search for a measurement system that fulfil the preceding requirements and quality standards, and to develop new functional performance indicators for people with COPD attending PR. Next is a discussion of the conceptualisation phase.

Discussion of phase 1: “Conceptualisation”

The commonality of risk factors across most chronic conditions, such as COPD, asthma, diabetes, heart disease and stroke, as well as aging create complex cases with many older patients living with two or more chronic conditions (Department of Health 2004). This has a significant impact on the quality of life of individuals with chronic conditions, and their families (Department of Health 2010c). This highlights two important specifications of an appropriate outcome measure. First, it should be multidimensional to account for the multifactorial impact of the co-existence of multiple co morbidities. Second, the significant impact on quality of life suggests that the outcome measure should consider the measurement of constructs that constitute the dimensions of quality of life.

One proposed model of health care for chronic conditions that embrace the notion of enhanced recovery and facilitated early discharge, as well as high quality care is the integrated health care model. The integrated health care model places the patient at the heart of the process of care, and shifts the mode of delivery from “one professional” delivering care for “all”, to a system where all health professionals and social services integrate to deliver care to the “one”. The integrated care model responds to the changes in the needs for care, resulting from the complex cases created by the aging population with multiple chronic conditions (Lloyd and Wait 2005). Lloyd and Wait (2005) Stated:

“Integrated care seeks to close the traditional division between health and social care. It imposes the patient’s perspective as the organising principle of service delivery and makes redundant old supply driven models of care provision. Integrated care enables health and social care provision that is flexible, personalised, and seamless.” (Lloyd and Wait 2005, P: 7).

The integrated care model ensures that when the patients are discharged, they are fully supported in the community. In the chronic conditions, early discharge requires establishing patients' safety as well as the ability to cope and take charge of the management of the disease. Therefore, patients should be empowered by the knowledge and the tools that enable them to make decisions and take control over their own care. Patients should be assured that they are fully supported by the services at the community (Lloyd and Wait 2005).

However, this model of care delivery has resulted in the design and the delivery of complex interventions with multiple components. This mandates a thoughtful consideration to the evaluation of the process and outcomes of care to ensure the quality of care provided (Rosen *et al.* 2007). Outcome measures of such complex interventions should be able to detect small changes that might take long time to develop (Medical Research Council "MRC" 2008). Outcome measures should be able to trace changes in the status of the individual patient by providing informative data about when the patient has reached the maximum potential to improve and could be discharged. Moreover, these outcome measures should have the potential to be implemented in the community and be reported by the patient to facilitate self-management.

The phase of conceptualisation in this thesis provided the theoretical knowledge that resulted in a conceptual framework for the measurement of functioning in people with COPD. It also provided theoretical knowledge upon which the design and methods of the following phases were based. Hinds *et al.* (2002) suggested that a conceptual analysis of a clinical phenomenon identifies the dimensions of the phenomenon, and the personal and contextual factors influencing it. This can provide valuable indications of what dimension of the phenomenon should be measured and how to measure it (Hinds *et al.* 2002).

The conceptual analysis resulted in identifying functional performance as an important outcome of pulmonary rehabilitation. Functional performance was defined as:

"the physical, psychological, social, occupational, and spiritual activities that people do in the normal course of their lives to meet basic needs, fulfil usual roles and maintain their health and wellbeing." (Leidy 1994, P: 198).

It is important to highlight the fact that existing reports on the development of measurement tools of functional outcomes of PR for people with COPD lacked adequate conceptualisation. Guyatt and Kirshner (1985) ascertained that developing outcome measures of quality of life should start with appropriate definition of the construct to be measured. It is argued that quality of life is a multidimensional construct, and a standardised definition of it does not exist. Therefore, it is important that the conceptualisation is not limited to defining the construct but should extend to include the theoretical underpinnings of the disease and the intervention, and the models describing the construct. Conceptualisation should provide specifications that guide following phases of the development.

An important point that emerged during the review on the conceptualisation underpinning existing outcome measures of functioning is whether to measure symptoms or the impact of symptoms on activities.

Guyatt *et al.* (1993) suggested that symptoms should be measured separately in order to understand the dynamics between performance of activities and symptoms. The question is whether we could exclude the symptoms or the impact of symptoms when assessing performance in people with COPD. In the review of functional performance instruments performed by Stull *et al.* (2007) certain questions enquire about "ability" by asking "how limited were you, or how difficult is it for you to do? or have you had difficulty?". In this type of questions the assumption is implicit that the source of limitation is symptoms. Other questions ask "does your health now limit?" the use of the word health is an ambiguous replacement for symptoms. The SGRQ directly enquire about the impact of symptoms on

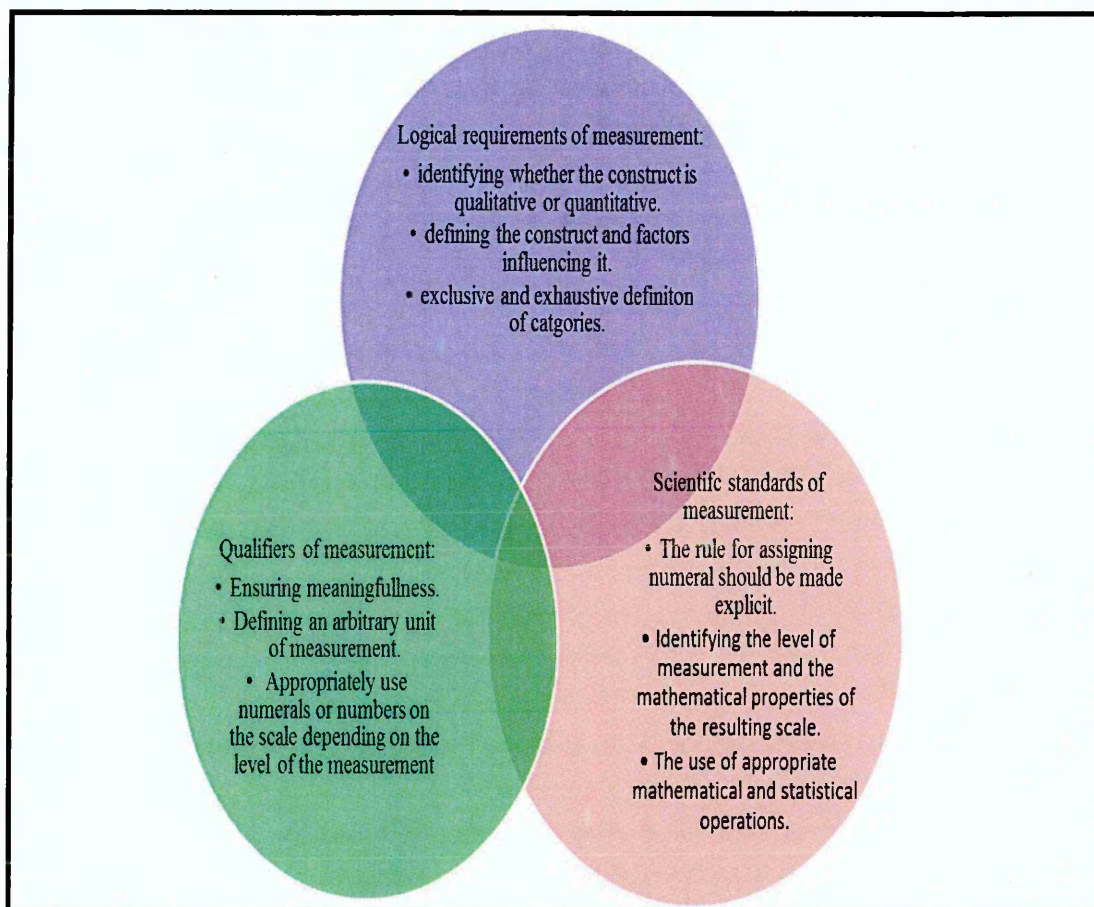
the activity by asking questions like “how your activities may be affected by your breathing problem?”

It is clear that measurement of functional performance is isolation from the impact of symptoms is impossible particularly in patients with COPD, where the main factor limiting performance is dynamic hyperinflation resulting in breathlessness (Eisner *et al.* 2011). It might be suggested that it would be more appropriate to measure changes in functional performance considering symptoms as an influencing factor.

Another problem in the conceptualisation underpinning existing outcome measures is that it provided no heed to the theory of measurement and measuring scales Figure 14, and to the quality standards of measurement in clinical settings. This has resulted in outcome measures that contravene the theory of measurement and are inappropriate for use in clinical settings. Evidence that existing outcome measures do not fulfil the requirements of the theory of measurement and measuring scales was provided with examples in “chapter 2/ section 3”.

Existing outcome measures were developed based on a fallible assumption that the construct being measured is quantitative. This has resulted in the incongruous use of interval or ratio structure to quantify a qualitative phenomenon. Moreover, even when the correct mathematical structure was used, the theory of measurement was contravened by using inappropriate statistics and mathematical operations. This has resulted in the loss of meaning of measurement particularly at the level of the individual.

Figure 14 A thematic presentation of the theory of measurement and measuring scales



Hinds *et al.* (2002) stated, that measurement should reflect the theoretical underpinnings of the construct being measured. This implies that the nature of the phenomenon whether it is qualitative or quantitative determines the mathematical structure that can be appropriately used in measuring the phenomenon, and the mathematical operations that could be performed on the data generated from the measurement. The phase of conceptualisation resulted in a theoretical framework that will guide the next two phases: development and clinical testing. This is presented next.

8 The Theoretical framework

The theoretical framework for this thesis is based on the following knowledge that emerged from the phase of conceptualisation:

- Our knowledge about COPD is incomplete. Therefore, the patients' lived experience of the disease and the clinicians' experiences and observation, constitute integral components of developing a new outcome measure. This is to ensure that the resultant outcome measure is underpinned by sound theory and clinical knowledge.
- The outcome measure should be informative to the patients, the clinicians, and the managers.
- An outcome measure informative to the patient should be patient reported. The items should be relevant and reflect the individual's experience of functional loss. The language and structure should be understood by and acceptable to the patient. Patients should be involved in generating the items, the categorisation, and the formulation of the codes of the measurement tool.
- An outcome measure informative to the clinician should facilitate clinical reasoning and clinical decision making. It should provide measurement that supports evidence based decisions about treatment provided, and changes implemented in treatment.
- An outcome measure informative to the managers should support the decisions on the quality of care delivered at the clinical department, the cost implications and the commissioning of resources.

- Goals of treatment should be negotiated rather than imposed, to ensure that the outcomes measured are individualised, meaningful to the patient and the clinician and clinically significant.
- PR is a multidisciplinary complex intervention designed to address the multidimensional functional limitations and participation restrictions resulting from COPD. This requires the use of multidimensional outcome measures. This is not attainable without adequate understanding of the factors influencing functional limitations and participation restrictions in people living with COPD.
- PR is designed to address the progressive functional limitations and participation restrictions “disability” resulting from COPD. This requires the use of an outcome measure that traces changes, and lack of changes, in functional performance. This is not attainable without adequate understanding of the development of functional loss in people living with COPD.
- The theory of measurement and measuring scales and the principles of measurement in clinical settings should provide the basis for the development and the evaluation of clinical outcome measures.

The next phase is a development of a new outcome measures based on the theoretical framework identified during the conceptualisation. The first chapter of the next phase is a review of a valid measurement system that was located in the literature on stroke rehabilitation, and the development of new indicators for pulmonary rehabilitation based on that system.

Phase 2: Development of “TELER” function indicators

Chapter 3: The selection of a method of measurement “TELER”.

Chapter 4: Item selection, reduction and scaling.

Chapter 5: item calibration and validation

Overview of phase 2:"Development"

The previous critical review of the literature identified the need for developing a new outcome measure of pulmonary rehabilitation that measures clinically significant changes in "functional performance". Therefore, the aim of the second part of this thesis is to develop this outcome measure. Following adequate conceptualisation of the construct, the process of development should start by the selection of an appropriate method of measurement¹⁴. The method of measurement should fulfil the following:

- The specifications of an outcome measure of functional performance for people with COPD following PR. These are: multidimensional, measure maintenance of effect, traces changes and lack of changes in functional performance, individualised, patient reported, informative to the patient, the clinician, and the managers.
- The requirements of the theory of measurement and measuring scales.
- The quality standards of measurement in clinical settings.
- The selection of the items of functional performance that should be measured is indicated by the patients' needs and the theoretical underpinning of the intervention. The steps of the process of developing the new outcome measure are based on the literature of developing outcome measures of quality of life. This is because functional performance was identified as an aspect of functioning, which is an integral component of quality of life.

The following steps are involved in constructing a measurement scale (Kirshner and Guyatt 1985):

1. Selection of a method of measurement.
2. Identifying clinically significant outcomes and the factors influencing them.
3. Selection of the item pool and item reduction.
4. Item scaling "categorisation and calibration".

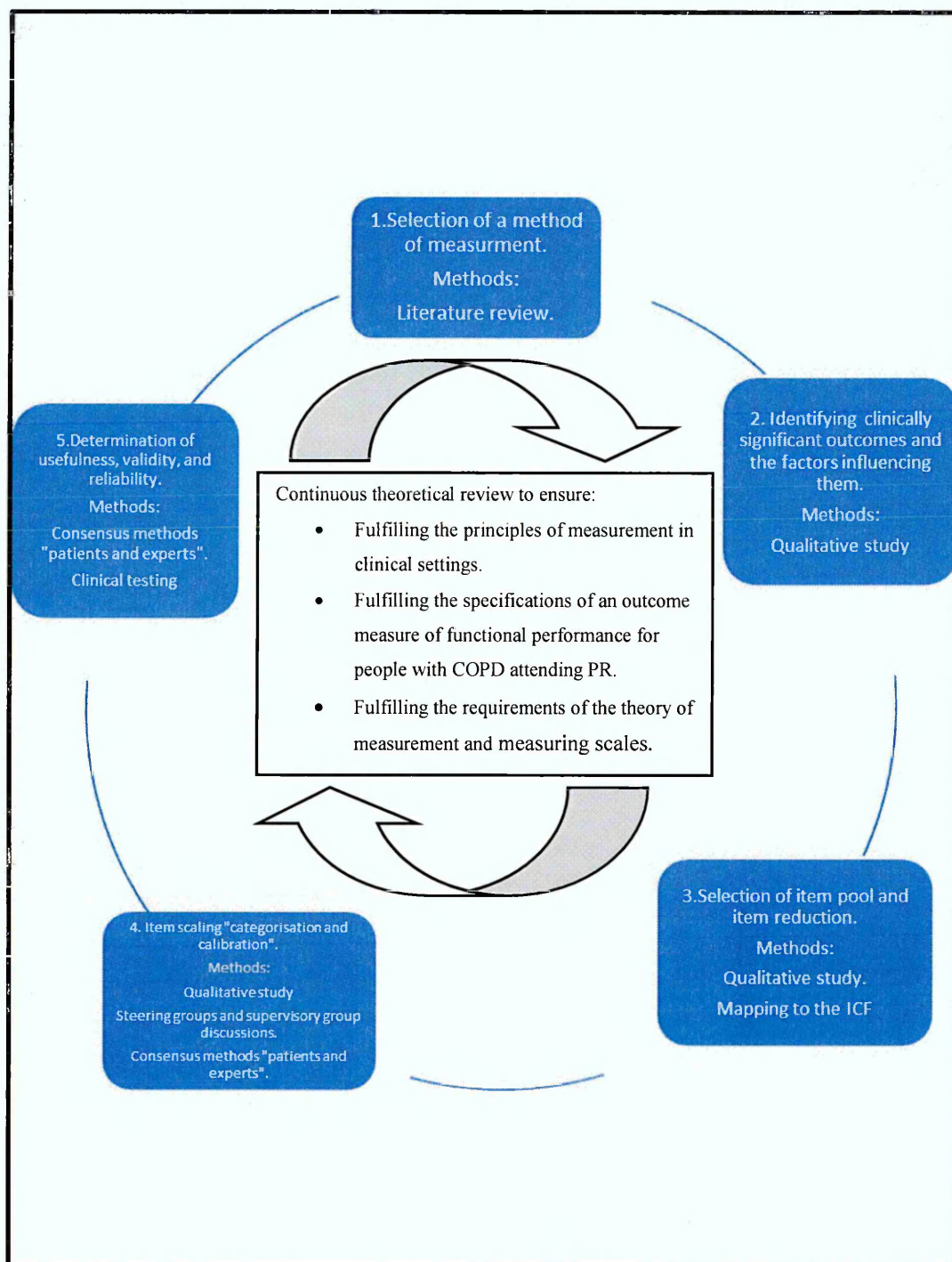
¹⁴ . Appropriate was defined in the literature review as "fit for purpose", an appropriate method of measurement ensures the usefulness of the measurement scale and the measurements generated by such scale.

5. Determination of usefulness.

Kirshner and Guyatt (1985) suggested that the reliability, validity and responsiveness of the outcome measure should be ensured during the development.

An overview of the process of the development of functional performance indicators and methods used is presented in Figure 15. A detailed description of the methods used is provided in relevant chapters on each step.

Figure 15 A diagram representing the stages of development of TELER function indicators



Chapter 3: The selection of a method of measurement "TELER"

9 The TELER method of measurement

The theoretical structure of a clinical phenomenon determines the appropriate mathematical structure to measure the phenomenon of interest (Narens and Luce 1986). Having defined "functional performance" and identified its qualitative nature, the next step is to decide on the best method of measuring it. Hinds *et al.* (2002) states:

"The selection of the method by which the phenomenon is measured, depends upon the clinical meaning of the measured phenomenon and the clinical interpretability of the resulting score". (Hinds *et al.* 2002, P: 346)

To ensure that the clinical meaning is preserved, the selected method of measurement should fulfil the specifications of the outcome measure of functional performance identified in the literature review, the requirements of the theory of measurement and measuring scales, and the quality standards of measurement in clinical settings. Fulfilling the preceding requirements ensures that the resultant outcome measure is a useful, valid, reliable and responsive outcome measure of functional performance for people with COPD attending PR. A method of measurement that was located in the literature on stroke rehabilitation, and fulfils the preceding requirements is the TELER method of measurement.

9.1 Definition of the TELER method of measurement

The acronym TELER stands for Treatment Evaluation by the LeRoux method. It is a concept of evaluation developed during the 1980s by Le Roux. The use of the TELER method was reported in areas such as wound care (Grocott 1997), stroke rehabilitation (Mawson 1993) and acquired, non-progressive neurological damage (Alderman *et al.* 1999). A common feature upon the three clinical areas is the complexity of the clinical condition and the intervention.

In COPD the complex nature of the clinical condition mandates the design of a multidisciplinary and an individualised interventions to target multiple and progressive disabilities. However, the evaluation of such complex interventions has been performed inappropriately resulting in the loss of information on the process of recovery at the level of the individual (Lakeman 2004). Evidence of the effectiveness of complex individualised interventions requires the implementation of high quality measurement methods.

The TELER method facilitates employing clinical expertise in the development of clinical indicators. This enables the clinicians to trace changes in functional performance at the level of the individual. The TELER indicators are used conjointly with a system of clinical note making. This aids the process of clinical decision making and changing the plan of treatment in response to clinical changes in patient’s status. The TELER software generates indices representing the effectiveness of care delivered to the patient. This facilitates the aggregation of data to provide informative inferences to managers about the quality of care delivered to a group of patients (Le Roux 2003).

The TELER method of note making provides a dynamic interface for recording clinical data. However, the completion of the TELER form requires the explicit use of formal and informal clinical knowledge. Clinical knowledge ensures that the appropriate indicators are used for the patient, and the deteriorations and the improvements are detected and acted upon without a delay (LeRoux 2003).

9.2 The structure of TELER

TELER has two components, the TELER method of clinical note making and the TELER method of measurement; the TELER indicator. The method of clinical note making uses a form that enables recording clinically significant information in a systematic manner. The form provides information such as the number of visits, the goals of treatment “in terms of the indicators titles” relevant to the patient, treatment plan, a record of changes and no changes on the TELER indicators, and indices representing the quality of care delivered to the patient (LeRoux 2003).

The TELER indicator is a six point ordinal outcome measuring scale that traces changes and no changes in different types of problems. Of interest to this thesis are functional problems. The TELER indicator has 6 reference points coded with numerals 0, 1, 2, 3, 4, and 5. The title of the indicator identifies the goal of treatment (LeRoux 2003).

Code 0 denotes a problem that is relevant to the patient and is amenable to change with the proposed intervention. Code 5 denotes the resolution of the problem in terms specific to the population in question. For example in people with COPD the full recovery of the functional problem is not attainable due to the limitation imposed by functional capacity as a result of persistent physiological impairments (Leidy 1994). Therefore code 5 represents the optimum possible improvement within the limit of persistent impairments. The remaining codes represent intermediate outcomes of the process of recovery. In order to provide a better understanding, the concept of TELER is reviewed and its relevance to the evaluation functional performance is highlighted.

9.3 The concept of TELER

"TELER" is based on the concept of using clinically significant change over clinically significant time periods as a measure of effective and efficient intervention (Mawson, 2002). TELER measures changes in the impact of symptoms on functional performance, rather than amount of symptoms (LeRoux 2003).

The TELER method is based on the following set of assumptions:

- The essential purpose of care is to induce or prevent change.
- The care provided must be specific to the patient.
- The care delivered must be grounded in theory.
- Change or lack of change occurs in clinically significant steps over clinically significant period of time.
- Change or lack of change can occur spontaneously, and the model for spontaneous change is constrained random walk.
- Change or lack of change which is unlikely to have occurred by chance was induced.

- The effects of clinically significant changes are not necessarily measurable on interval or ratio scale but can be observed.

9.4 TELER the “appropriate” method of measurement

The assumption that the aim of care is to induce or prevent change is in accordance with the central aim of pulmonary rehabilitation which is to improve functioning, and prevent progressive deterioration of functional status. The impairments, the activity limitations, and the participation restrictions resulting from COPD occurs progressively over a clinically significant period of time (Sabroe *et al.* 2008). This suggests that the reversal of the impact of the disease or the prevention of further loss as a result of the intervention would occur in clinically significant steps over clinically significant periods of time. The main purpose of measurement in rehabilitation setting is to trace changes in clinical and functional status at the level of the individual (Duncan and Velozo 2007). In that sense TELER fulfils the specification of an outcome measure of functional performance by tracing change and lack of change over a clinically significant period of time.

One of the assumptions of TELER is that the treatment provided to the patient should be underpinned by the theoretical and clinical knowledge. This includes the measurement of the outcomes of treatment. The formulation of treatment goals should be based on patients’ needs and clinical knowledge of the outcomes amenable to change with the treatment delivered. Moreover, theories of the intervention and the clinical knowledge enable the description of the process of recovery as a result of the intervention, and the definition of indicator codes that have face validity. Clinical knowledge ensures that the definition of codes fulfil the requirements of the theory of measuring scales. That is the codes have the properties of transitivity, connectivity and asymmetry (Stevens 1946).

TELER mandates the use of explicit clinical knowledge in the definition of the indicators. This ensures that the definitions are multidimensional and account for all possible factors influencing functional performance. TELER requires that care must be specific to the patient. This is relevant to pulmonary rehabilitation programmes which are designed to meet the needs and the abilities of the individual patients. Pulmonary rehabilitation is defined as a multidisciplinary individualised intervention (BTS 2001). This assumption also fulfils one of the quality standards of measurement in clinical setting which requires the measurement of individualised outcomes.

The definitions of the codes of the TELER indicator use a language that can be understood by the patients, the carers, the clinicians and the managers. The title of the TELER indicator identifies a treatment goal that is relevant to the patient. The goal of treatment is mutually selected by the patient and the clinician rather than imposed. Therefore, the TELER indicator is informative to the patient, and could be reported by the patient. Moreover, it has the potential to be used as a self-management tool, because it traces changes in functional performance using a language meaningful to the patient. The outcome of measurement using TELER could be easily interpreted by the clinicians and the managers. This is because each code on the indicator should be unique and measures one thing and one thing only.

The TELER form creates a critical link between clinical measurement on the indicators and the care delivered to the patient. It is informative to the clinician because it facilitates the process of clinical reasoning, evidence based treatment, and the justification for the implementation of a change in the treatment plan. The TELER indices provide quantitative summary of the treatment delivered to the patient. This informs the managers to make appropriate decisions on the quality of care delivered and the use of resources (LeRoux 2003).

An important point to highlight is that in clinical practice the treatment is delivered to patients with the belief that up to the knowledge of the clinician this is the best available evidence based treatment. Therefore, if using the TELER form the clinician could identify a correspondence between an observed pattern of change or lack of change, this could be taken as evidence that the care provided was effective. However, it remains unknown what aspect of the multidisciplinary care provided to the patient has resulted in the occurrence of change. An observed pattern of change or lack of change is unlikely to have occurred by chance if it is statistically significant. Nevertheless, accurate identification of the cause of an observed pattern of change or lack of change is only possible when TELER is used in an appropriate research design.

TELER fulfils the requirements of the theory of measurement and measuring scales (Stevens 1946). This is because it defines an arbitrary unit of measurement “a unit of one clinically significant change”. It uses an ordinal mathematical structure to measure qualitative attributes; therefore it does not contravene the theory of measuring scales by imposing an interval or ratio scale on structures that are not quantitative. TELER uses numerals not numbers to define codes, and uses permissible statistics to analyse ordinal level data.

Definitions on the codes of the indicators are based on explicit knowledge of the disease and the intervention, and the incorporation of patients’ experiences of the trajectory of change in functional performance resulting from COPD. This ensures that TELER indicators are responsive to changes in functional performance. This documented trade off between responsiveness and reliability is not relevant to ordinal measurement scale (Roach 2006). This is because unlike the interval and ratio scales the size of the unit of measurement is undefined. On interval and ratio level scales the reduction in the size of the unit to increase responsiveness results into reduced reliability. In the ordinal scale responsiveness is increased by the use of sound knowledge in defining the codes, while reliability is ensured by improving documentation, and training of the patients and clinicians in undertaking the measurement (LeRoux 2003).

9.5 Summary

Theoretically the TELER method of measurement appears to fulfil the requirements of an "appropriate" outcome measure of functional performance. Based on the assumptions of TELER it fulfils the following:

1. The identified specifications of an outcome measure of functional performance for people with COPD attending PR.
2. The requirements of the theory of measurement and measuring scales.
3. The quality standards of measurement in clinical setting.

However, TELER "function" indicators for use in people with COPD attending PR, currently does not exist. Therefore, the next three chapters are concerned with the development of these indicators. Whilst the validity, reliability and responsiveness of the indicators should be ensured during the process of development (Kirshner and Guyatt 1985), evidence of the usefulness of the indicators could only be provided by clinical testing of the indicators in clinical setting. The next chapter describes the process of generating the indicators.

Chapter 4: Item selection, reduction and scaling

10 Qualitative exploration of patients' perspective

When developing a new measurement tool, the decision on what should actually be measured is a mutual decision between the clinician and the patient. The clinician has the clinical knowledge to suggest what clinical outcomes could be influenced by a particular intervention. The patient is the most legitimate decision maker on what is problematic and what is important to them (Jones *et al.* 2005).

As acknowledged earlier the measurement of clinical significance should be driven by adequate definition of clinically significant outcomes and the factors influencing them. This would guide the development of a valid outcome measure that adequately reflects the multidimensionality of clinical outcomes. The definition of clinical outcomes should include consultation of patients' perspective on what constitutes a clinically significant outcome and the factors influencing the outcome (Kazdin 1999).

Moreover, during the phase of conceptualisation it was highlighted that due to the progressive nature of COPD, it is important to define the trajectory of change of the patients' clinical outcomes. Clinical knowledge should be incorporated to define the continuum of the process of functional recovery. However, the current knowledge about the disease and the intervention is incomplete. Therefore, it is important to describe the development of functional loss or the recovery of function following PR, by reference to the experience of people living with the disease.

Having identified the trajectory of change in the functional problems, the next step would be to identify and categorise clinically significant changes to generate the codes of the measurement scale. The categorisation and scaling should fulfil the requirements of the theory of measurement and measuring scales (Kazdin 1999).

10.1 Aims of the qualitative study

This qualitative study represents steps two, three, and four of the process of development of an outcome measure of functional performance. Specifically the aims are: identifying clinically significant outcomes and the factors influencing them, item selection and reduction, and item scaling “categorisation and calibration”.

1. Identify the functions “activities and participations” that constitute clinically significant outcomes, and the factors influencing functional performance “facilitators and barriers”.
2. Item selection and reduction: identify a set of functions "activities and participations", important to patients with COPD, which are expected to improve following PR.
3. Categorization: Describe the pattern of the development of functional loss “functional limitations and participation restrictions”. The description should be presented as successive steps between the maximum potential functional limitation and the maximum potential functional performance.

10.2 Objectives of the qualitative exploration

1. Explore the perspectives of people with chronic lung disease on the functional outcomes they want to achieve following pulmonary rehabilitation.
2. Describe the values and weightings people with chronic lung disease attach to certain functional activities of daily living.
3. Describe the dimensions of the experience of people with COPD during the performance of daily life functions.
4. Describe the process of the development of functional loss in people with COPD.

10.3 Research questions

1. What are the functional outcomes people living with COPD want to achieve following pulmonary rehabilitation?
2. What are the functional activities of daily living identified as clinically significant by people with COPD?
3. What are the changes in the performance of daily life functions that result from living with COPD?
4. What are the factors influencing the performance of daily life functions in people with COPD?

10.4 Design of the qualitative exploration

A qualitative study using in depth semi structured interviews, focus group methods, and framework analysis methods.

10.4.1 Philosophical and methodological approach

The “approach” within this thesis

This qualitative study is part of a larger PhD project concerned with the development of a new outcome measure of functional outcomes following PR in people with COPD. Therefore, it is important to highlight how this qualitative study and the knowledge expected to emerge from it relate to other components of the thesis.

First, it is perhaps useful to emphasise two key aspects of the context in which this qualitative study will be used. A primary influential factor is the nature of clinical research, where quantitative methods dominate the practice of scientific enquiry. The second factor is the epistemology of patient safety within clinical research that requires producing research evidence that has been developed using rigorous methods, that is valid and unbiased, and has wider application based on mathematical and statistical inferences (MRC 2006). This suggests that the clinical research paradigm does not lend itself to be fitted in a recognised school of qualitative research.

However, three important realities should be recognised. First the clinical environment is not uniform and entails sophisticated human interaction between health professionals and the patients. Therefore, occasions occurred when quantitative research evidence failed to support clinical decisions or understanding (Higginson and Carr 2001).

Second, the growing epidemic of complex chronic conditions that is influenced by behavioural risk factors demanded a shift in the models of care delivery and the methods of evaluation. This shift requires the involvement of people experiences and perspectives to enhance the knowledge and understanding of clinical conditions (Lloyd and Wait 2005).

Third, the prevailing health care policy views patients as consumers of health and envision integrating health into social care (Department of Health 2006). Therefore, patients are placed at the centre of the process of care that is designed based on patients' needs and demands (Department of Health 2006). This has amplified the need for the adoption of qualitative research methods in the clinical context.

Therefore, during this PhD the researcher has adopted a pragmatic approach that responded to the nature of the problems and research questions. The appropriate methodology for answering such questions was selected. This has resulted in the use of qualitative methods in response to the nature of questions that emerged during the phase of conceptualisation. However the data generated from the qualitative study will be used in the development of a quantitative outcome measure and test in clinical setting using quantitative methods.

The following sections therefore map the key parameters within which this qualitative study will be conducted.

Ontological position

The researcher adheres most closely to what Hammersley (1992) describes as “subtle realism”. It is accepted that although truth exists independently of the individual’s subjective understanding, it is only accessible through respondents’ interpretation. However, it should be emphasised that respondents’ interpretation will be further verified and interpreted by the researcher. In relation to this PhD research it was identified during the phase of conceptualisation that knowledge about the progression of functional loss in COPD is incomplete.

COPD was identified as a heterogeneous disease (Mannino *et al.* 2002). Therefore, this qualitative study seeks to improve current understanding about the progression of functional loss in COPD. It is therefore accepted that diverse perspectives on the experience of functional loss would exist. However, this does not negate the possibility of the existence of an external reality about the pattern of progression that could be captured.

Epistemological position

The epistemological perspective of the researcher reflects the fact that the historical context is largely that of quantitative research. Therefore, the researcher adopts an approach that adapts the concepts of scientific enquiry to qualitative explorations. However, the researcher is also a proponent of a parallel adaptation of quantitative research methods. This is to accommodate the reality of clinical settings, where lack of standardisation and heterogeneous presentation is the standard. This is in line with the current MRC Guideline (MRC 2008) for the evaluation of complex interventions and the growing field of realistic evaluation (Pawson 2003).

A key feature of the researcher perspective is objectivity and neutrality in the collection, interpretation, and presentation of the data. However, the researcher is aware that this could not be fully achieved. Particularly, due to the adoption of subtle realism that entails the co construction of interpretations of the participants and the researcher (Ritchie and Lewis 2003). The research adopts a constructive approach that seeks to synthesise clinical and theoretical knowledge with participants' perspectives. The researcher relies on theoretical and clinical knowledge to interpret participants' accounts. However, when there is lack of knowledge to verify certain accounts, particularly in relation to the experience of functional loss, the interpretations of patients are taken as the primary source of explanation.

Due to the complex nature of the co-construction of knowledge, the researcher recognises the importance of reflexivity in assuring the trustworthiness and credibility of the research findings (Lincoln and Guba 1985). Therefore, the researcher strives to ensure that findings are grounded in the data and not the researcher's previous knowledge. This is further explained in the section on data analysis.

The approach of the researcher embraces aspects of interpretivism. This is reflected by emphasising the importance of understanding the perspectives of patients in the context of COPD and the circumstances of their environment and lives. Therefore, the researcher seeks to develop in depth understanding of the contextual factors influencing people's lives. The researcher also emphasises the importance of the interpretation of findings in the light of clinical and theoretical knowledge, given these are clearly delineated from the views of participants. During the process of interpretation the researcher values the individualised experience, but seeks to identify and synthesise the accounts of a number of participants.

Finally, the qualitative approach used is both inductive and deductive in turn. The researcher identifies emerging themes and patterns derived from the exploration of participants' perspectives. The data is then tested in subsequent data collection and analysis. The data is analysed to develop an increased understanding of patients' perspective on functional loss, functional performance, and the factors influencing it.

However, it should be noted that the qualitative exploration is guided by the theoretical and clinical knowledge that has influenced the decision of the selection of methods. Moreover, the data generated from the qualitative exploration will be synthesised with existing theoretical and clinical knowledge. This new knowledge will be used to validate the definition and the framework for the measurement of functioning developed during the phase of conceptualisation. This will be achieved through a deductive conceptual activity that uses evidence as the genesis of a conclusion (Ritchie and Lewis 2003).

10.4.2 Sampling methods

A sampling method was required that ensured the recruitment of a sample that was small enough in order to ensure in depth exploration of individual's perspective without precluding the generation of original and rich data (Sandelowski 1995). The sample also needed to be large enough to ensure the breadth of people with different perspectives (Bowling 1997). Purposeful sampling was therefore adopted. This method allows for demographic heterogeneity and variation (Sandelowski 1995). It was proposed that the sample would be demographically heterogeneous in terms of gender, and age. People with varying degrees of severity of the disease "mild, moderate, severe" were recruited to achieve variation.

10.4.3 Research participants

10.4.3.1 Participants' recruitment

Participants were recruited through self support groups in the community. These were "Breathe Easy" and "Breezers" in the South Yorkshire area. The study was first introduced at one of the monthly group meetings at a social venue. Participants' information sheet was provided for people expressing interest in taking part in the study (Appendix B.1). Participants expressing interest were given a week to reflect on whether they wished to be interviewed. They were contacted again by the researcher a week after the first meeting. Participants who agreed to take part after the second part were given the opportunity to ask further questions about the study and were asked to sign an informed consent form witnessed by the researcher.

10.4.3.2 Inclusion criteria

People considered candidates for pulmonary rehabilitation as described by The British Thoracic Society Standards of Care Subcommittee on Pulmonary rehabilitation (2001) were recruited. That is “*patients with lung disease whose lifestyle has been adversely affected by chronic breathlessness.*” (British Thoracic Society 2001, P. 829). A self report of diagnosis was accepted for inclusion in the study.

Only people who were able to give informed consent were included. The ability to speak and understand English was a requirement. This is because English is the language that the researcher could communicate in, and no translation was available due to time limitation. Moreover, the issue of language is important in the development of TELER function indicators. The aim of the researcher was to ensure that the description of the codes on the indicators is as close as possible to the language used by participants. This is to facilitate the use of indicators as a patient reported outcome measure. Moreover, the TELER method of measurement requires the selection of the words of the indicators carefully to ensure that they provide singular meaning and reflect the underpinning clinical knowledge.

10.4.4 Ethics issues related to the qualitative exploration

There were a number of ethical issues in interviewing people with COPD. The study was approved the Faculty Research Ethics Committee / Faculty of Health and Wellbeing - Health and Social Care Division -Sheffield Hallam University (Appendix B.2). Further to advice from the supervisory team, and by approaching NHS Research Ethics Committee members at an ethics training day, it was advised that no NHS ethics was required. This is because participants were approached through community support groups not through NHS staff or premises. Moreover, none of the participants included were currently attending PR program.

All participants were given sufficient verbal and written information about the study (Appendix B.1). All participants completed an informed consent form (Appendix B.3). The researcher ensured confidentiality and informed participants about the methods used to ensure confidentiality. This included anonymising transcribed reports and storing all data in a secured cabinet at the university premises and password secured university computer. Participants were informed the anonymous records of data will be shared with the supervisory team and direct quotes will be used in the research reports.

There was a potential that a participant might become distressed when discussing negative experiences related to the disease. Therefore, all participants were assured that they have the right to stop at any point and withdraw their consent for the use of data even after the interview or the focus group without giving a reason.

10.4.5 Methods of data collection

The process of data collection included two stages. The first stage included in depth semi structured interviews and the second stage included a focus group. A topic guide was used to facilitate discussion in the interview and elicit appropriate and relevant responses. The topic guide was developed based on the framework of the measurement of functional performance that was developed during the conceptualisation phase. The topic guide included four main sections, the first was personal history and the experience of diagnosis, the second was performance of daily life activities, the third was the management of activities, and the fourth about the expected outcomes of PR. It was piloted in an initial interview and minor changes were made.

However, following the third interview the wording of questions in the topic guide was changed. This is because it was felt that some words like goals and management were not comprehended adequately by participants. Other words like problematic were found to trigger negative responses and make participants feel uncomfortable; therefore these were avoided or replaced. Participants felt offended when asked about smoking history. This is because of the stigma of the self-inflicted disease. Therefore, this information was not elicited and left to the participant to bring it to discussion if they wanted. The final version of the topic guide is shown in (Appendix B.4)

A different topic guide was used in the focus group (Appendix B.5). Questions focused on eliciting responses related to the specific type of activities influenced by COPD and the steps of the progression of functional limitations.

10.4.5.1 Stage 1: Semi-structured in depth interviews

The aim of the interviews was to generate in depth understanding of the perspectives of people with COPD on functional activities that are affected by the disease. Seven in-depth semi-structured interviews were conducted with people with COPD attending “Breezers”, and “Breathe Easy” self support groups. However, the data from the first interview were not included in the analysis, as this was a pilot to test the interview schedule. The interviews were conducted during November/December 2008.

Participants were offered the option of being interviewed at their own home, at university premises, or at the community venue at which the community support group used to meet. Three participants decided to be interviewed at their homes. This provided a relaxed and comfortable environment for the participant, as they were empowered by being at their own environment. The safety of the researcher was ensured by leaving contact details, and time and venue of the interview with two colleagues at the research centre and a family member. The researcher called on arriving and on leaving the venue to confirm safety. The other three participants were interviewed at the “Breathe Easy” group venue “a local restaurant”. This also provided a quiet and comfortable environment for both the researcher and the participants. The sample characteristics of the participants is presented in Table 5.

Table 5 Sample characteristics of the indepth interviews

| Number | Age | Gender | COPD severity | Marital status | Employment |
|---------------|------------|---------------|----------------------|-----------------------|-------------------|
| 1 | 64 | Female | Severe | Married | Retired |
| 2 | 70 | Male | Moderate | Married | Retired |
| 3 | 74 | Male | Moderate | Married | Retired |
| 4 | 60 | Male | Severe | Married | Retired |
| 5 | 67 | Female | Severe | Married | Retired |
| 6 | 80 | Female | Very severe | Married | Retired |

All interviews were audio-taped and transcribed. During the interview the researcher recorded notes about the environment, and the emotional and general status of the participant. The interviews lasted between 40 and 60 minutes. Issues arising in early interviews provided insight and influenced the discussion at the following interviews.

Ritchie and Lewis (2003) suggested that the use of in-depth interviews is particularly valuable when the nature of data sought has to be related to the personal context of the individual. In-depth semi-structured interviews were used for the exploration of the participants' perspective on significant functional outcomes in the context of their personal experience. It is suggested that the use of the in-depth semi structured interviews followed by the focus group will enhance the understanding of participants' decision about what they set as functional outcomes of pulmonary rehabilitation (Ritchie and Lewis 2003).

The researcher wanted to identify the type of activities affected by the progression of COPD and the factors influencing the performance of daily life activities. Therefore, participants were encouraged to talk about a standard day in their life and the type and nature of challenges to performance they confront in their daily life.

10.4.5.2 Stage 2: Focus groups

One focus group including six people with COPD and two carers was conducted following the interviews. The aim of this focus group was verification and reflection on the findings of the in-depth interviews (Ritchie and Lewis 2003). Participants were invited to discuss the interpretation and the conclusions of the research generated from the in-depth interviews. In addition to verifying the findings from the interviews the focus group was designed to provide a focused insight to reduce the activities generated during the interviews to a core set of significant activities. Another aim was to refine the accounts of the participants in the interviews about the progression of functional loss and generate categories describing the steps of the development of functional loss.

The focus group was conducted in January 2009. The focus group took place at the “Breezers” group social meeting venue. Table 6 shows the sample characteristics of the focus group.

Table 6 Sample characteristics of focus group participants

| Number | Age | Gender | COPD severity | Marital status | Employment |
|--------|---------------|--------|---------------|----------------|------------------------|
| 1 | Carer/ Male | | | | |
| 2 | 73 | Female | Severe | Married | Retired/Cleaner |
| 3 | 74 | Male | Severe | Married | Retired/not reported |
| 4 | 56 | Female | Moderate | Married | Employed /cleaner |
| 5 | 67 | Male | Severe | Widowed | Retired/ Steel worker |
| 6 | 63 | Male | Moderate | Married | Employed/ not reported |
| 7 | 60 | Male | Severe | Married | Retired/Engineer |
| 8 | 77 | Male | Severe | Married | Retired/ steel worker |
| 9 | Carer/ Female | | | | |

Gibbs (1997) suggests that the benefit of the focus groups is 'to gain insights into people's shared understanding of everyday life'. This is directly related to the main aim of this study which is about exploring patients' perspective about the functional outcomes important to them.

Focus groups are useful when there is a power gap between participants and professionals (Gibbs 1997). This was the main drive for doing this study, which has emerged from the idea of empowering people with chronic lung disease to voice their needs and set their own treatment goals. And the development of outcome measures that account for the experience of recovery of the individual patient.

The focus group lasted for approximately 70 minutes. It was facilitated by the researcher. Another PhD/ physiotherapy student from the Health and Social Care Research Centre accompanied the researcher and made field notes about the environment, the discussion, and the interaction amongst participant. The focus group was audio taped and fully transcribed.

The focus groups resulted in 'illuminating the research issue' (Ritchie and Lewis 2003) through group discussions, and interactions among participants. Through talking to each other a range of patients' perspectives were identified. Participants were able to review their thoughts against those of others, reflect on and refine them (Ritchie and Lewis 2003). Moreover, the social context within which the group process occurred addressed the aim of describing the values and weightings participants attach to functional activities of daily living. Thus reducing the set of activities generated from the interviews to those relevant and important to patients.

Functional limitation is a common problem among patients with chronic lung disease. Participants shared this experience, and discussed it in the group setting (Ritchie and Lewis (2003). This has resulted in the categorisation of the process of functional limitations and participation restrictions for selected activities. The group environment minimised the personal influence of the researcher on the perspectives of participants (Ritchie and Lewis 2003).

10.4.6 Methods of data analysis

The adoption of a pragmatic approach with an ontological approach of subtle realism has influenced the selection of data analysis methods. Framework analysis as described by Ritchie and Lewis (2003) was selected. Framework analysis was selected because it firstly allows for the exploration and understanding of patients' perspectives about an external existing reality. Secondly, it accommodates the existing knowledge of the researcher and allows for transparent interpretation of the researcher by the development of a systematic framework for the data analysis.

A thematic framework was used to organise data according to emerging themes. The thematic framework was based on the theoretical underpinnings of COPD and PR identified during the conceptualisation phase and the framework for the measurement of functional performance. The process included five stages:

1. Familiarization. This involved the researcher getting introduced and making sense of the size and diversity of the data. In this qualitative study adequate familiarisation was ensured through the transcription of the records by the main researcher. The researcher listened to the audio tapes, transcribed records and listened again to verify transcription.
2. Identifying thematic framework. This involved coding the data based on a theoretical framework identified from the literature and the identification of emerging themes. Themes relevant to the aims of the study were retained for further indexing.
3. Indexing. An index of themes and subthemes was developed and applied to transcripts. This is presented in (Appendix B.6)
4. Charting. This involved the development of a central chart that allows for across cases comparisons. A separate chart for each theme is created and descriptive accounts are formulated. Only themes related to the performance of functional activities, the factors influencing performance, and management of activities were subjected to further refinement and categorisation.

5. Mapping and interpretation. This involved using the charts to interpret the data and identify patterns and associations among themes. A conceptual framework representing themes related to the performance of functional activities, the factors influencing performance, and management of activities was created.

It is worth mentioning that new themes were added when new data emerged that could not be represented by existing themes. This was performed to ensure adequate coverage of all potential dimensions that might influence the formulation of the categories of the measurement tool. No themes were eliminated unless it became evident that they could be better represented by another existing theme or a new emerging theme. For example “shock” and “event of diagnosis” were removed and data was organised under two subthemes of “diagnosis” which are “social response” and “emotional response”.

Further analysis included identifying elements and dimensions of functional activities and mapping the data to the ICF activity and participation core set for COPD (ICF research branch 2010). After that, patients’ narratives of performing certain activities were arranged into categories describing different levels of functional performance.

One key feature of undertaking qualitative research is the difficulty of the prevention of imposing researcher’s knowledge on data. The clinical background of the researcher and the strong theoretical and clinical knowledge created a risk of over interpretation of participants’ accounts. Although the synthesis of clinical and theoretical knowledge along with patients’ perspective was an important aim, there was a threat of biasing interpretation by the clinical intuition of the researcher.

In order to control for this bias a number of measures were undertaken. Firstly it was decided not to attempt to develop the analysis into abstract conceptualization, establishing typologies, and explanatory accounts. The reasoning is related to the aim of this study which is developing a patient reported outcome measure of functional performance. Therefore, the maintenance of the language and wording used by participants was a priority. Any further analysis could have resulted in the loss of the initial narratives.

Secondly, the researcher maintained reflexivity though all of the stages of the qualitative exploration. This was achieved by providing transparent account about the research activities. A study file was created and all research activities and analysis was discussed with the supervisory team. Moreover, during analysis the researcher maintained vigilant attention to delineate clinical and theoretical interpretation from clinical intuition by continuous reference to the evidence underpinning the interpretations.

Quality and rigour of data interpretation was ensured by using a set of techniques to meet the criteria of “trustworthiness”. This is presented in Table 7.

Table 7 techniques used to meet the criteria of “trustworthiness”

| Criteria | Explanation | Techniques used to meet the criteria |
|------------------------|---|--|
| Credibility | This refers to the “precision” of the result in accurately reflecting the perspectives of the population on the topic of intended investigation | Discussion with supervisory team regarding the interpretation of data. Discussion of emerging themes and interpretations at the support group meetings. |
| Transferability | Generalising from the context of the research study to other contexts | Ongoing verification of interpretation in subsequent interviews. Feedback and summarising techniques during the interview. |
| Dependability | The replicability of research findings | Maintaining a transparent record of research processes and activities. |
| Confirmability | The control for the bias of the researcher | Self-reflection by the researcher. |

Adapted from Tod (2003) with reference to Lincoln and Guba (1985), and Ritchie and Lewis (2003)

10.5 Results of the qualitative study

10.5.1 The context of the qualitative study

In order to identify the context for this qualitative study it is important to start with the sample to verify whether there was adequate variation in the sample. The sample for both the focus group and the interviews provided a good representation of both males and females. The age range of participants was between 56 and 80. The sample included a variety of severities including moderate, severe and very severe as reported by participants. However there was a predominance of “severe COPD” across the sample. Whilst this could have resulted in a bias related to lack of representation of people with mild COPD, this has actually provided a sample with a rich experience about the progression of functional loss. An important point to consider is ethnicity. All of the participants were from a “white” ethnic background; this could have implications on the transferability of results to other ethnic groups.

During the interviews the participants responded positively and engaged in the discussion. However, certain issues have emerged that needed to be addressed, and that possibly had an impact on the nature of the data. One concern was related to the environment of the interview. One lady, who was interviewed at the restaurant, expressed inconvenience regarding the warm room. This has made her uncomfortable and slightly impacted on the focus of the discussion as she talked a lot about the impact of the environment and the weather on the symptoms.

Another important issue was related to smoking. Interviewees became upset when asked about their smoking history. This probably could be related to the stigma of the self-inflicted disease. One participant said that he does not like to talk about it, because people are judgmental and don’t understand why he could not stop, even though it makes him ill. Therefore, the researcher decided not to ask about smoking history unless participants raised it in the discussion.

It is thought that this did not have an impact on the results as smoking history was not directly related to the aims of the study, although it could have been interesting to discuss whether quitting smoking had an impact on functional performance. Participant 3 in the focus group said:

“yeah, but I felt much better when I stopped smoking, and I’m still coughing though.”

Although the researcher was interested in eliciting responses about both negative and positive experiences about the performance of functional activities, the balance of the discussion around these issues was not easily maintained. The researcher was interested in exploring the progression of the functional loss, the current impact of the disease on performance and the current functional potential of participants and how they manage difficult activities. However, participants did provide lengthy and moving accounts about the sense of loss and the profound impact of limited performance on their personal integrity and social life.

Some participants became distressed when they were talking about the functional loss and the limitations to performance they experience on a daily basis. However, due to the background of the researcher as a clinician, this was smoothly addressed and settled. The researcher had to refocus the discussion on the potential and how they manage problems of performance. At this point in the discussion the participants were offered the opportunity to stop the interview, but no participant decided to withdraw. This sometimes resulted in loss in the thread of the discussion. This did not directly affect the data and the interpretations, because most of the time participants returned to continue the story but in a less emotional state.

An important point that was considered during the interviews is that just talking results in increased ventilatory demand and can precipitate breathlessness in people with COPD. Therefore, the participants were given a rest every 10 minutes, and refreshments were available if needed. As this was planned and expected the researcher took the necessary measures to ensure the thread of the discussion was not lost. This included, planning break slots “usually two to three minutes”, keeping a note about the last thing the participant was talking about, and avoiding any distracting discussion during the break.

Next is a presentation of the main finding of the qualitative study.

10.5.2 The findings of the qualitative study

The same thematic framework was used to organise the data of both the individual interviews and the focus groups. However, a different topic guide was used for the focus group. This is because both methods were used to answer the same questions with different levels of detail. The focus group was performed to verify and reflect on the data from the interviews as well as providing more focused discussion about the performance of activities and the specific type of activities that present challenges on daily basis.

The results of this qualitative study are presented in three parts. The first part presents the themes that emerged following the analysis of both interviews and the focus group. The second part presents the validation, using patients' narratives, of the ICF core set for COPD and the framework of the measurement of functional performance that was developed during conceptualisation. The third part presents the development of the first draft of TELER "function" indicators.

10.5.2.1 Part 1: A presentation of the themes that emerged from the qualitative study

Between 11 main themes and 78 subthemes emerged from data. The themes were continuously modified through analysis. A final set was generated after the focus group at the end of the familiarization stage. A thematic chart was developed and data was mapped across all the themes. The chart was continuously modified as new data became available and themes were continuously reviewed following each interview.

The thematic chart was contentiously revisited to ensure that no data relevant to the development of the TELER function indicators were missed. Only the themes which are relevant to developing the categories for TELER function indicators were subject to further analysis. These are themes describing functional performance. Themes that were further analysed included: Functions "activities and participations", management of functions, and pulmonary rehabilitation. A conceptual framework representing the impact of COPD on "functions" and "management of functions" themes and the interaction between them is presented in the Figure 16. Another conceptual framework representing patients' perspectives on the delivery and outcomes of pulmonary rehabilitation is represented in Figure 17.

The reasoning for developing separate conceptual frameworks for functions and for PR is that they serve different purposes in the development of TELER “function” indicators. The themes related to functions contribute to defining the titles of the indicators “goals of the treatment”, and the clinically significant outcomes to be achieved. The PR themes contribute to identifying the nature of the therapeutic input required to induce clinically significant change.

Figure 16 A Conceptual framework representing the impact of COPD on "functions" and "management of functions" themes and the interaction between them

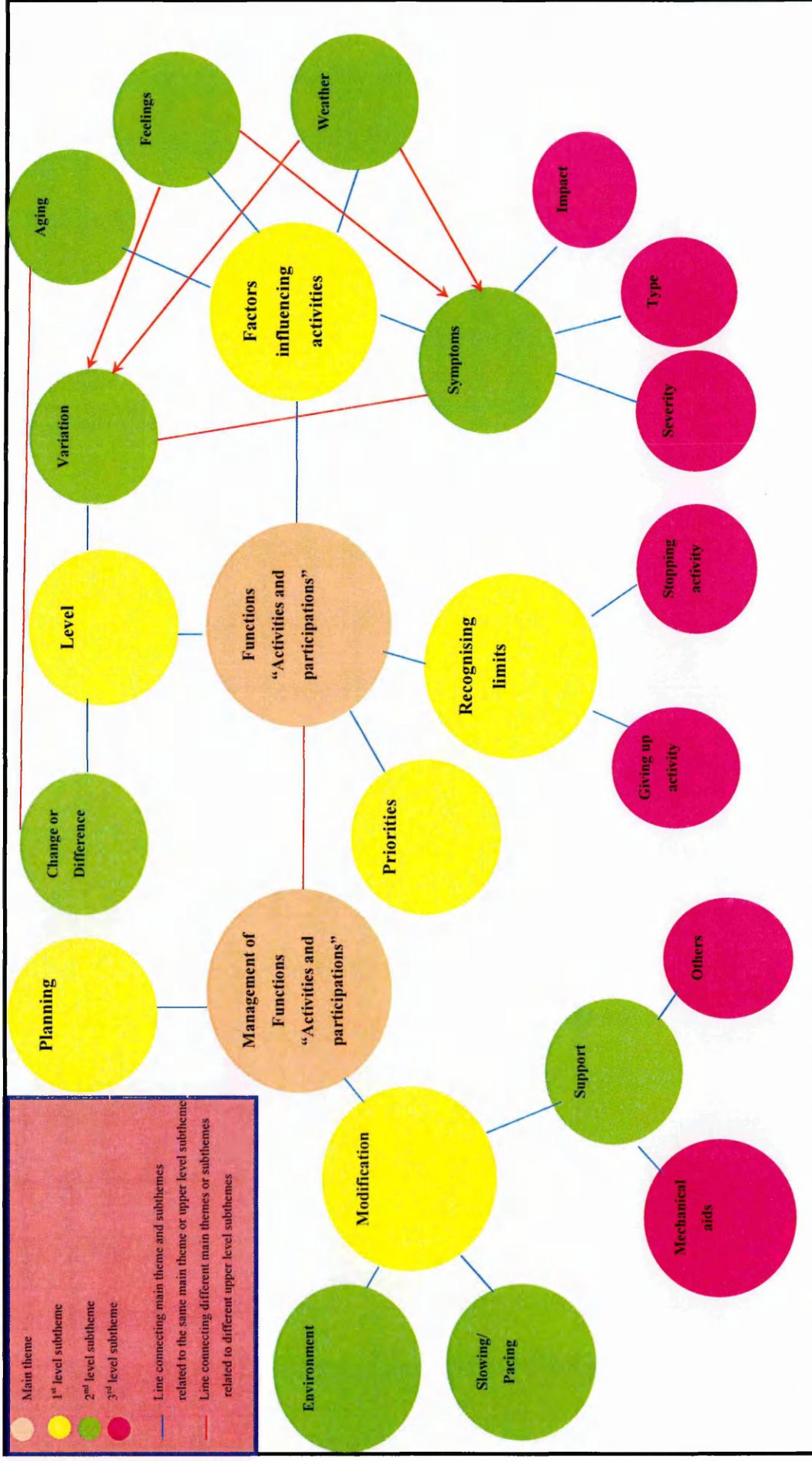
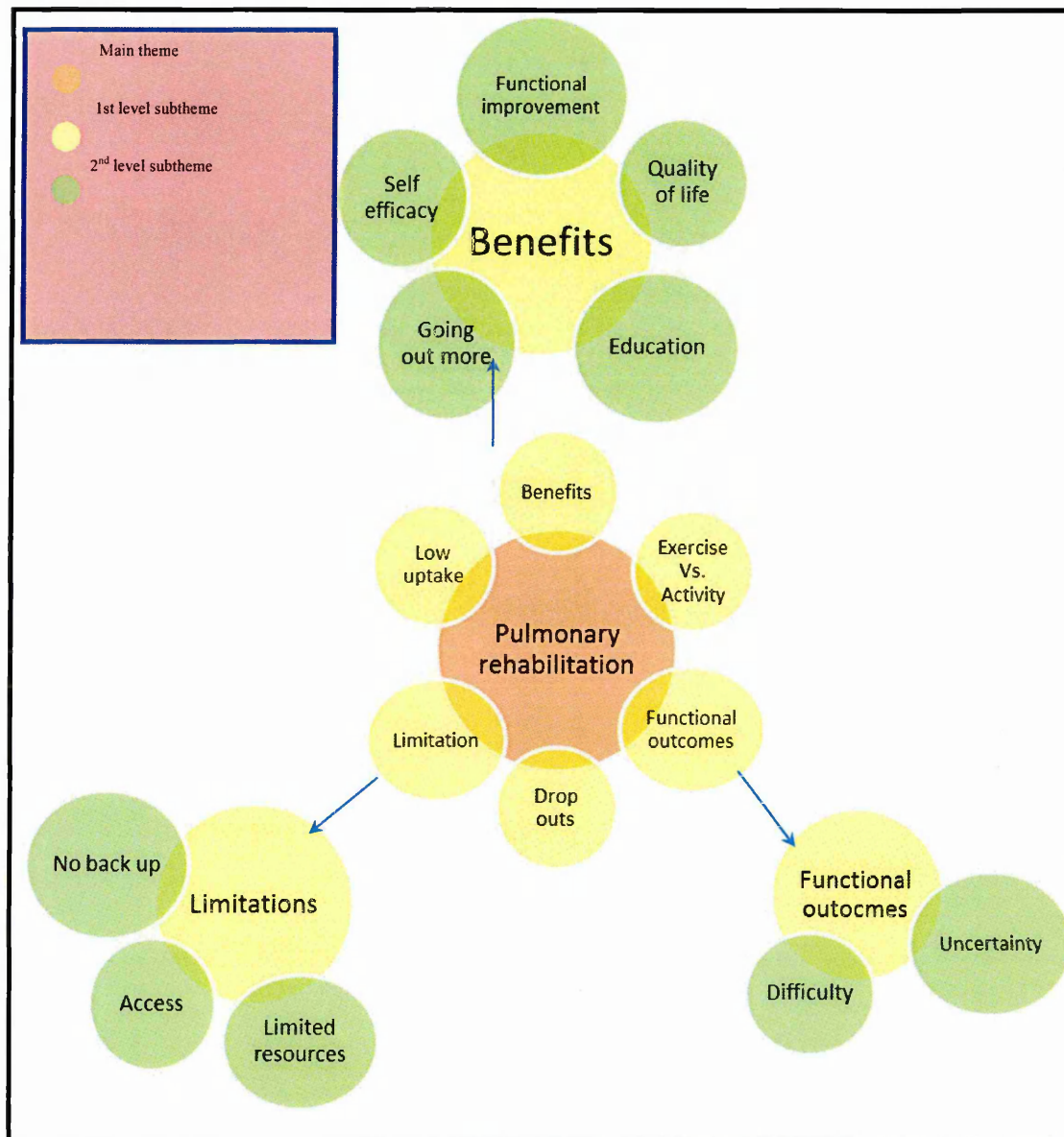


Figure 17 A conceptual framework representing patients' perspectives on the delivery and outcomes of pulmonary rehabilitation



1. Functions “activities and participations”

Interviewees emphasised the impact of COPD on the performance of daily life activities. Participants reported that the presence of COPD affects almost all daily functions. A general perception was that indoor activities were easier to control than outdoor activities and that it required more confidence and control to perform the same activity outdoor.

“like when you're getting ready to go out because you're going out your adrenaline goes up naturally so you have to learn to do it slowly, do it in stages so your adrenalin doesn't get pumping too fast so you don't get breathless.” Participant 5: Individual interview.

The impact of COPD on performance was described in terms of a reduced level of performance as compared to their level of performance before the progression of the disease. The conceptual term used to refer to this reduction in the level of performance is “change”. Patients also compared their current level of performance to other people not affected by COPD. This change was expressed in terms of slower performance, need for support or complete inability to perform certain functions.

“For a year after I were diagnosed I were walking 6 miles a day. but I can't walk for 6 min now I keep walking round house. I couldn't go out on my own now before I was working and things and I could do things by myself but now I can't go out because I can't walk very far. It takes me to do what I used to do like that "clicking with fingers" you know, but it take quite well... three times as long. I can't do gardening now. But I do pot plants in front of the house”. Participant 1: Individual interview.

Participants also described the impact of COPD on functional performance in terms of variation in the level of activity. They experienced variation in the level of activity, across seasons, from day to day and even diurnally. From the perspective of the participants this variation was a result of a number of factors influencing activities. The main factor influencing activity was reported to be symptoms, particularly breathlessness and fatigue.

An important finding was that breathlessness appeared to interfere with their performance, but if the activity is performed for a longer duration or it had more than one component then fatigue starts to interfere with performance as well.

“3: well I now get out of breath when I'm digging in the garden, but I'm still engaging, but after about half an hour it becomes tiring you know.

R: so is it tiring because of weak muscles or because of breathing?

3: both. so fatigue is a problem as well as breathlessness?

3: well after that time yes”. Participant 3: Individual interview.

Coughing was another symptom reported by participants. However, from the perspective of participants coughing has no direct impact on performance. This is because unlike breathlessness coughing is not precipitated by the performance of activities. Coughing was identified as “embarrassing” creating a barrier to participation.

“you lose your confidence, because,,,, you know when you go out amongst people and you start coughing it's a bit embarrassing and so you don't,,,, you start thinking, I'm not going,, you know you are too embarrassed to meet people and what if you start coughing, because sometimes when you start coughing you know you're choking and people just stop and stare sort of thing.” Participant 1: Individual interview.

Other factors that influence the performance of activities and induce variation in the level of performance include weather and feelings. Weather influenced performance indirectly by impacting symptoms.

“The thing that bothers me is the weather, the thing that pulls me in is the weather, it's the wind and rain and cold I really feel the cold and it makes me very breathless”. Participant 4: Individual interview.

Negative feelings made people less active and less engaged in activity, resulting into more sedentary life style.

“To keep trying, and to be active, obviously we are not feeling well you know all the time and this very depressing. I think if you don't keep active mentally and physically as much as you can, it is no good for you at all. You know you've got to keep trying at least.” Participant 6: Individual interview.

Finally, an important issue that emerged from the data is “recognising limits”. Participants identified certain activities that they gave up because of a negative experience of being severely breathless as a result of performing the activity. Some participants reported stopping the activity as a result of symptoms interfering with performance. It was observed that people responded differently to the challenges imposed on performance. People who did not attend PR yet were more likely to give up the activity, while people who attended PR managed the factors influencing performance. This is presented next.

2. Management of activities

One of the most important techniques participants used to manage difficult activities was slowing and pacing.

“you’ve got to walk on your own pace because I’m not going to try and keep up with others so I’m going to walk on my own pace and I can walk all day these things you’ve got to educate yourself to do” Participant 7: Focus group

Other methods of management included using support either from others or by using mechanical aids. They also modify their environment.

“I mean I have a stair lift, I’ve got a stair lift put in, I’ve got a bath seat put in in, at the toilet frame around the toilet, but all these are aids to give me better quality of life, I would have a wet room instead of a bathroom” Participant 4: Individual interview.

Participants also reported planning as a method of conserving energy and avoiding the precipitation of breathlessness.

“To do things on scales now, where I’ve just used to go and do everything. You know like when I go upstairs to put washing away I perhaps plan it to do not go back until I finish all the things I got to do there, and then rest for 5 minutes and then I come back so I just take things in moderation” Participant 1: Individual interview.

3. Pulmonary rehabilitation

Participants expressed uncertainty about describing the improvement of functional activities following PR. They suggested that doing exercises in a standardised environment with all the support and supervision from health professionals is very different to performing daily life activities. However, they thought they had experienced some sort of functional improvement such as doing things for longer, having more control on breathing, and improved self efficacy and confidence.

Improved confidence led to improved participation and more outdoor activities.

“I'm going out more, you know. I have oxygen and I was a bit embarrassed about going out with it but I learnt to live” Participant 1: Individual interview

Another participant described functional improvement resulting from PR by saying:

“It certainly keeping me fit actually, doing that every week and I gradually do more at home every week. It keeps me active my arms, chest, legs and generally my body” Participant 3: Individual interview.

Describing improved breathing control one participant said:

“I recover quicker because I'm breathing now from here (pointing to abdomen) instead of here (pointing to upper chest). It's the diaphragm you've got to build your diaphragm. Most people breathe from the chest, so they've to stop. So you've got to build your diaphragm muscles up. And you can do it a little bit longer” Participant 4: Individual interview

Participant reported that in addition to improved fitness as a result of exercise, other components such as education and psychological support resulted into improved knowledge, confidence and control. These are crucial to induce functional improvement in daily life activity.

“you’ve got to do a rehab which teaches you then self-management, relaxation, confidence, and then you’ve got the ability to do things yourself” Participant 4:Focus group.

Participants referred to the inability to realise the full benefit of PR because of limited resources and difficulty of I accessing to the venue of PR.

10.5.2.2 Part 2: Validation of the ICF core set of activities and the framework for the measurement of functional performance

1. Validation of the framework for the measurement of functional performance

Empirical evidence supporting the framework for the measurement of functional performance was generated during this qualitative study. The framework is based on the ICF model of functioning, disability and health. Patients' narratives on the factors influencing functional performance were all classified as personal or environmental factors (Appendix B.7). Moreover, patients described how symptoms particularly breathlessness and fatigue influenced performance. This is represented on the framework as health condition "disease or disorder".

One of the themes that resulted from the qualitative study was "recognising limits". This theme represents patients' experience of stopping or giving up certain activities. Patients' reported that they had to stop the activity because breathlessness was so severe that they could not control it. This was conceptualised on the framework in terms of functional capacity. Functional capacity was defined as:

"one's maximum potential to perform those activities people do in the normal course of their lives to meet basic needs, fulfil usual roles, and maintain their health and wellbeing. The term refers to potential in any domain, including physical, cognitive, psychological, spiritual, and sociodemographic." (Leidy 1994, P: 198).

One's maximal potential to perform is influenced by the impairments resulting from the disease represented by symptoms. In patients with COPD higher levels of performance results in increased ventilatory demands and precipitates symptoms (Lahaije *et al.* 2010). Symptoms interfere with performance creating limits on the maximal potential for performance. This limit is described in the framework as functional capacity. Participants also described limits to performance imposed by factors other than just capacity. This had occurred when a patient decided to give up the activity as a result of a negative experience of exacerbation during performing certain activities. The multidimensional framework allow for the consideration of personal factors.

2. Validation of the ICF core set for COPD

During analysis the ICF core set of functions “activities and participations” for people with COPD was used to classify patients’ narratives (ICF research branch 2010), this is presented in (Appendix B.8). It was found that there was no need to develop new categories to accommodate the narratives, suggesting adequate representation of the ICF core set of the perspectives of patients in this study.

10.5.2.3 Part 3: the development of the first draft of TELER “function” indicators using patients’ narratives.

1. Item selection and reduction

During the focus group participants were asked to discuss a list of activities generated from previous interviews. The discussion was identified a set of activities that constitute important and challenging activities. Participants thought there is a great variation amongst them in terms of the activities that are important to them. This variation was related to their roles and the support available to them. However, participants placed greater importance on activities related to moving from one place to another such as walking on level, walking up hill, and going upstairs. Another two activities that were identified as important and challenging for all participants were showering and bending.

A set of six Activities were selected by patients during the focus group to be translated into TELER “function” indicators this included:

1. Generic activity indicator.
2. Walking.
3. Walking uphill.
4. Bending forward.
5. Showering.
6. Going upstairs

2. Item scaling “Categorisation”

Categories of functional performance were developed by translating participants’ narratives into functional performance descriptors and arranging them into a hierarchy. These are presented in Appendix B.9.

The categories generated following the qualitative study need to be refined and standardised to meet the requirements of the TELER method of measurement. The next chapter presents the process of calibration and validation of TELER function indicators using consensus methods.

Chapter 5: Item Calibration and validation of TELER “function” indicators

The aims of this chapter are firstly, to refine and standardise the categories developed during the qualitative study to generate TELER codes. Secondly, to calibrate the codes to generate ordinal measurement scales. Thirdly, to validate the definitions of the codes of the indicators from the perspective of patients and experts.

11 Generating TELER codes from performance descriptors

This involved standardising and refining the categories to fulfil the requirements of TELER:

- The codes of the indicators should be unique, that is the language used should provide singular meaning¹⁵. Therefore the words “gave up and could” were replaced by “unable to and able to do”.
- The statements were modified to allow for wider application, this was achieved by using a standardised language that enhances understanding by providing a clarification that preserves the meaning.

¹⁵ The term singular denotes that the statement on the code means one thing, and is not perceived differently by different people.

An example of the process of conversion is provided using the TELER “generic activity” indicator this is show in Table 8

Table 8 TELER “generic activity” indicator

| Performance descriptors | TELER codes |
|--|--|
| I gave up the activity | Unable to do the activity |
| I could still do it but it would get me out of breath | Able to start the activity but cannot complete it |
| I could do the activity but I have to keep stopping for rest | Able to do the activity but has to keep stopping for a rest. |
| I could do the activity without stopping but it takes longer than usual (slow process) | Able to do the activity without stopping but with a slow pace |
| I could do the activity without stopping for a rest in a normal rate but I would start breathing rapidly | Able to do the activity without stopping for rest in an optimal pace, but would start breathing rapidly. |
| I could do the activity without stopping in a normal rate maintaining controlled breathing. | Able to do the activity and maintains controlled breathing |

The statement “I could still do it but it would get me out of breath” became “Able to start the activity but cannot complete it”. This change was performed because the phrase “get me out of breath” implies that the patient was not able to complete the activity but the clinical condition is controlled or the patient was not able to complete the activity and experienced an exacerbation as a result of attempting the activity. There are two levels of performance that should be differentiated. There is a level of performance which is just before a complete loss of function occurs. At this level of performance the patient is still determined to maintain the ability of performing the activity. This is a different level of performance compared to a patient who is completely unable to tackle the activity either for physical or psychological reasons. Participant #1 said described the inability to perform the activity:

“NO I doubt it, it's very,,,,, no I would not attempt it because I've tried it a couple of times and it made me ill. You know because I did try just doing the bottom of it but it didn't work I ended up in hospital”

However participant # 4 described the ability to start the activity but the inability to complete by saying:

“I mean like decorating it’s too frustrating that it took that long, it’s annoying you know and you tend to try and rush it but I won’t rush anything, I just have to plod on, I mean I could only work 3 hours a day, which to me is rubbish, I mean I used to go for 8 hours, but now I could only do 3 hours, and I’ve had it I just have to pack in.”

Another example on modifying the language used is provided using the functional walking indicator. The findings of the qualitative study suggested that the impact of COPD on performance is manifested by slower performance. Therefore, the fourth category on the functional walking indicator was described as “I could walk outside home with a normal pace without stopping for a rest but since I start talking, I get breathless”.

On this category the word “normal” was replaced by the word “optimal”. This is based on the findings of the qualitative study and on clinical and theoretical knowledge. The findings of the qualitative study showed that People with COPD tended to compare themselves to their previous level of functional performance before the progression of the disease, one carer in the focus group said:

“While she were walking up or ride very quickly she turned to walking up and struggling”

Or they compared themselves to other people in the community who do not have functional limitations, patient #2:

“But when I get to the event it's the walking part which has to take me time to do it. When I'm walking I notice that people pass they are 10 times quicker than I, they are miles ahead, which emphasize that I'm slow.”

Based on those findings and on the fact that COPD is a progressive disease, and so precludes recovery of normal pace, it was decided to replace normal pace with optimal pace. Optimal pace is defined as the maximal functional pace achieved by the person given the available functional capacity within a certain context “personal and environmental factors”.

The next step was the calibration and validation of the resulting categories by experts and patients’ focus groups.

12 Expert and patient validation

12.1 Introduction

The aims of this section are to:

1. Validate the construct, the content, and the clinical knowledge underpinning the TELER “function” indicators by experts.
2. Validate the construct, and the content from the perspective of the patients.
3. Test the acceptability of the indicators by patients.
4. Ensure that the outcomes on the indicators are clinically significant outcomes that are potentially influenced by PR, from the perspective of patients and experts.
5. Ensure that the hierarchical stepwise regain of function on the indicators is a valid representation of the recovery of the functions as experienced by patients and experts.

12.2 Validation of TELER function indicators by patients

12.2.1 Methods

The patients’ validation process included a presentation followed by a focus group discussion. The aim of the patients’ focus group was to verify the content and construct validity of the indicators from the perspective of a different group of patients who were not involved in the generation of the indicators. Participants were recruited from a “Breath Easy” group. Participants were already familiar with the study as the researcher had been regularly attending the monthly meeting of the group to present and review the findings of the qualitative study. All participants received a participant information sheet a week before the focus group. The study was approved by the Faculty Research Ethics Committee / Faculty of Health and Wellbeing - Health and Social Care Division -Sheffield Hallam University (Appendix B.2).

12.2.2 Patients' focus group

The group consisted of seven patients and one carer. All participants completed an informed consent form. The presentation included the findings of the qualitative study and the final draft of the indicators. Following the presentation, each participant received a printed copy of the final draft of the indicators, and they were given 10 minutes to read and reflect on them. After that the researcher read each indicator and the participants were asked to:

- Comment on the clarity of the language used
- Express their views on the truthfulness of the description of the codes, as it applies to them by attempting to score themselves on the indicators.
- Comment on the range of functions included and whether there is any important function not included.

The topic guide for this focus group is presented in Appendix B.10

12.3 Validation of TELER function indicators by experts

12.3.1 Methods

A scientific meeting was held for experts that included a presentation followed by focus group discussion. The scientific meeting was held in a room at Sheffield Hallam University. The focus group method was selected because the aim was not to achieve a consensus instead the aim was to create an environment that would facilitate discussion, constructive criticism and improvement of the indicators. Kitzinger (1995) suggested that focus groups provide an invaluable method for critical discussion and providing solutions if the aim of research is to improve products or services. In addition focus group discussions were identified as “ideal” for reviewing the contents of questionnaires or instruments (Bolton and Kitzinger 1994) and (Morgan and O'Brian 1993).

No NHS research ethics approval was required as participants were recruited through clinical interest groups and networks at national conferences, not through NHS services or organisations. However, all participants received an invitation letter and a brief about the study with references on the TELER method two months prior to the meeting in order for them to have time to consider participation (Appendix B.11).

12.3.2 Experts' focus group

A range of expertise was recruited. The group was comprised two TELER experts, two clinical leads on pulmonary rehabilitation programs, one COPD research expert, and two clinical “physiotherapists”. The meeting consisted of two parts. The first part was a series of short presentations each followed by a facilitated discussion. Topics of the presentations included the outcomes of the conceptualisation phase, a description of the TELER method of measurement, and the process of developing TELER function indicators for people with COPD. The second part was a focus group discussion and was facilitated using a questionnaire for the assessment of the validity of the TELER “function” indicators (Appendix B.12).

12.3.3 Findings of the Expert and patients validation of TELER “function” indicators

Although patients and experts focus groups were held at separate occasion the results are reported together because they addressed the same issue. In addition there was agreement on the concepts and issues raised by both groups.

The process of patient and expert validation resulted in a number of changes on the indicators that improved the content and concurrent validity of the indicators, and suggestions to improve the reliability of the indicators.

Content validity

Evidence that the indicators codes provide a valid account of the clinical problems and trace changes in the presentation of the problem should be established (Grocott 2001). Evidence that the indicators have content validity was achieved during the focus groups involving experts and patients validation. During the focus groups the indicators were reviewed to identify:

1. Whether the definitions of the codes represented a valid clinically significant statement of the problem.
2. Whether the codes were able to trace changes in the clinical problem as experienced by the patient or observed by the clinician.

An example is provided using the showering indicator Table 9.

Table 9 The showering indicator

| Showering indicator submitted for review | Showering indicator reviewed |
|---|---|
| 0. Unable to shower | 0. Unable to shower |
| 1. Able to wash head and body in sitting but unable dry self | 1. Able to wash body but unable dry self |
| 2. Able to wash head and body while sitting and dry self | 2. Able to wash body and dry self but feels exhausted |
| 3. Able to wash head and body while standing but unable to dry self | 3. Able to wash body and dry self and does not feel exhausted |
| 4. Able to shower and dry self, but feels exhausted. | 4. Able to wash head and body and dry self, but feels exhausted |
| 5. Able to shower | 5. Able to shower |

The changes that were made can be summarised as follows:

Patients reported that describing the position “sitting or standing” is not relevant and does not affect performance it is a matter of individual preference. Clinicians agreed and added that the ability to stand is a different function that requires another indicator and should not be included with the showering indicator.

Clinicians suggested that washing the head is a difficult function that involves elevation of the arms over the head. This involves a shift in the function of the accessory muscles of respiration to partake in arm elevation. This places increased demand on the already strained main muscle of respiration “the diaphragm” (Velloso *et al.* 2003). Therefore, it was suggested that washing the head should not come early on as an indicator because it requires a larger amount of therapeutic input than washing the body only.

Clinicians found it unreasonable that exhaustion was only mentioned at code 4 and suggested that it is more likely to interfere with the activity at lower levels of performance.

Concurrent validity

TELER “function” indicators are designed to measure changes in functional performance “individualised outcome”. Moreover, changes should be measured at the level of the individual. Therefore, evidence of concurrent validity should prove that TELER “function” indicators conform to the following theoretical assumptions:

1. The measurement of functional performance should be directed by patients' perspective.
2. The measurement of functional performance should be directed by clinical determination of what is achievable.

An example is the “bending to do an activity” indicator. This used to be a dressing indicator describing putting shoes on. Both patients and clinicians suggested that while bending is an important clinical problem that could be improved by the “PR” intervention, patients are more likely to use aids to put shoes on rather than bending to put shoes on. Therefore, it was suggested to change this indicator to a “bending to do an activity” indicator, with a focus on the function “bending”.

Suggestions to improve the reliability of TELER function indicators

It was suggested by the experts' focus group, that the reliability of some indicators to detect clinically significant changes could be improved by adding an indicator of self-efficacy. An example was the walking indicator. Clinicians explained that improvement on the walking indicator from code 1= able to walk freely inside house to code 2 = Able to walk freely outside the house but pace is slow is sometimes due to self efficacy and confidence to leave home rather than physiological capacity and available resources.

The final version of the indicators following patient and expert validation is presented Table 10. The next chapter is "clinical testing" of the indicators in clinical PR setting to test the usefulness of the indicators.

Table 10 The final version of the indicators following patient and expert validation

| | | |
|---|---|--|
| Functional walking 0. Unable to walk freely inside house 1. Able to walk freely inside house only 2. Able to walk freely outside the house but pace is slow 3. Able to walk freely outside the house with an optimal pace, but needs to keep stopping for a rest 4. Able to walk outside the house with an optimal pace, without stopping for a rest but unable to do another function (task) whilst walking (i.e. talking, carrying shopping) 5. Able to achieve functional walking | Slope walking and talking 0. Unable to walk few steps on slope 1. Able to walk a few steps on slope but gets breathless and doesn't continue 2. Able to walk on slope with a slow pace* and needs to keep stopping for a rest 3. Able to walk on slope with an optimal pace but has to keep stopping for a rest 4. Able to walk on slope with an optimal pace without stopping for a rest 5. Able to walk on slope and talk | Going upstairs 0. do not go upstairs 1. go upstairs crawling 2. go upstairs but has to stop for a rest several times 3. go upstairs but it is very slow and has to stop for a rest once 4. go upstairs without stopping for a rest with controlled breathing 5. go upstairs without stopping, with optimal pace and with controlled breathing |
| Showering 0. Unable to shower 1. Able to wash body but unable dry self 2. Able to wash body and dry self but feels exhausted 3. Able to wash body and dry self 4. Able to wash head and body and dry self, but feels exhausted 5. Able to shower | Bending to do an activity 0. Unable to touch table in front. 1. Able to bend forward with back upright and reach forward. 2. Able to bend forward and touch feet distance but unable to maintain. 3. Able to bend forward touch feet and maintain position but unable to do another task. 4. Able to bend forward perform an activity but has to rest before completing the task. 5. Able to bend forward maintain it and complete the task. | Activity (any activity identified by the patient as a problematic activity) 0. Unable to start the activity (gardening) 1. Able to start the activity but cannot complete it. 2. Able to complete the activity but has to keep stopping for a rest. 3. Able to complete the activity without stopping but with a slow pace 4. Able to complete the activity without stopping for rest in an optimal pace, but doesn't control breathing. 5. Able to do the activity and controls breathing. |

Discussion of phase 2: “Development”

The aim of this phase of the phase was to develop TELER function indicators based on the knowledge established during the phase of conceptualisation. The process of development included a number of steps these are:

1. Selection of a method of measurement.
2. Identifying clinically significant outcomes and the factors influencing them.
3. Selection of the item pool and item reduction.
4. Item scaling “categorisation and calibration”.
5. Determination of usefulness, reliability, and validity.

The TELER method of measurement was selected because it fulfilled the specification of an outcome measure of functional performance for use in people with COPD in PR clinical setting.

During the conceptualisation phase it was established that “function” in functional performance is represented by the physical, psychological, social, occupational, and spiritual activities people do to fulfil certain purposes. Therefore, it is important to identify these activities from the perspective of the patients using qualitative methods. Two important points should be highlighted. First is the selection of the activities for inclusion in the measurement tool should be in terms of importance and clinical significance and second is the method of reduction of activities.

Item selection and reduction

Selection of activities for inclusion in the development of TELER function indicators was based on patients' perception of importance rather than difficulty. However, the degree of difficulty and the factors influencing the performance of each activity considered important need to be established in order to enable the categorisation of the levels of performance of the selected function. An example is provided from the CCQ. During the development of the CCQ, the authors attempted to weight items in term of difficulty. However, there was an apparent lack of consensus on the classification of activities as strenuous, moderate or light (Molen *et al* 2003). This highlights the importance of evaluating each single activity separately. The activity to be evaluated should be selected by the patient based on relevance, and importance.

Item reduction in this study was achieved by patients' consensus during focus group. However, it should emphasised that the selection of items is an individualised exercise. Appropriate application of the TELER method requires mutual agreement between the patient and the clinician at the outset of treatment. The therapist should have the clinical knowledge to develop TELER indicators in response to patient's needs. However, for the purposes of this thesis a set of activities representing functions that are important to patients and potentially influenced by PR was created.

Item reduction by statistical models and by experts risk making the resulting measurement tool irrelevant to the individual patient. For example the ranking of the importance of symptoms by experts and clinicians in the CCQ (Molen *et al* 2003) was different to that generated by patients in the qualitative study in this thesis and by other qualitative studies (Williams *et al.* 2007).

An important component of this stage was the qualitative exploration of patients' perspectives on functional activities of daily life. The aim of the qualitative study was to gain an insight into how COPD impacts the performance of daily life functions. This enabled the identifications of the items to be included in the development of TELER function indicators, and to describe the pattern of the development of functional loss.

The categorisation of the process of the development of functional limitation was performed by identifying the factors influencing performance and the process of management of challenging activities as experienced by people living with COPD. In-depth description of the impact of COPD on functional performance and the development of functional limitation was achieved using a structured process of different qualitative techniques to obtain and validate data by patients and experts.

The participants in the qualitative study reported breathlessness as the main symptom interfering with the performance of daily life functions. This is similar to the finding of other qualitative studies (Barnett 2005) and (Christenbery 2005). However, this qualitative study provided an insight into how participants responded to or controlled breathlessness during performance of daily life activities. Participants also reported the impact of fatigue being secondary and not directly influencing performance unless the activity lasted for longer or had more than one component. This is similar to findings of Small and Lamb (1999) who found that patients with COPD cope well with fatigue so that it does not significantly limit performance.

Another important finding of this study that is consistent with the findings of (Christenbery 2005) was the patients' report of managing challenging activities by slowing and pacing. Patients in this qualitative study described different levels of performance based on a number of factors related to both physical and psychological capacity, suggesting the important role of self efficacy and confidence in the performance of daily life activities. This is similar to the findings of (Liedy and Hasse 1999) who reported the impact of COPD on personal integrity and self-efficacy resulting in reduced activity and participation alongside by a more sedentary life style and increased social isolation.

The nature of clinical outcomes experienced by participants following PR implied the treatment needs for this group of patients. Participants in this qualitative study reported the benefits of PR in terms of functional improvement, self-efficacy, quality of life and education resulting into improved control of the symptoms and the disease.

This finding is important because it enables the identification of the type of the therapeutic input required to induce a change and achieve clinically significant outcomes in the performance of activities. While a number of qualitative studies reported similar findings relating to the benefits of PR (Christenbery 2005, Fischer *et al.* 2007, Camp *et al.* 2000), this is the first study that links these benefits to the changes in the performance of daily life functions.

Participants' reported similar concerns to those reported by Fischer *et al.* (2007) regarding the uncertainty and the difficulty of achieving functional improvement following PR, as well as barriers to participation, difficult access and lack of follow up. However, this study has resulted in the development of a measurement tool that has the potential to provide informative clinical data required to address these issues. The usefulness of TELER function indicators in clinical settings is tested in the next phase "clinical testing".

Item calibration and validation

This was a critical stage that included the synthesis of patients' perspective and clinical knowledge of the experts to calibrate and validate TELER function indicators. An initial categorisation was achieved by translating patients' narratives into performance descriptors. Those were further calibrated using expert clinical knowledge and patients' experience through focus groups. This process, along with the consideration of the specifications of the appropriate outcome measure that were identified during the conceptualisation, ensured that the resultant function indicators are valid, reliable and responsive. However, the usefulness of the indicators could not be established without testing them in clinical settings.

Phase 3: Clinical testing

Chapter 6: Determination of the usefulness of TELER “function” indicators

Overview of phase 3 "clinical testing"

The aim of the "clinical testing" was to test the usefulness of the newly developed TELER "function" indicators, in the evaluation of the functional outcomes of pulmonary rehabilitation in people with Chronic Obstructive Pulmonary Disease "COPD". The evaluation complies with the theoretical specifications of the outcome measure and the theoretical principles of measurement in clinical settings, derived during the phase of conceptualisation. The theoretical principles upon which the development of TELER "function" indicators was based is as follow:

- TELER function indicator is an outcome measure of individualised outcomes
- TELER function indicator is designed to be used as a patient reported outcome measure.
- TELER function indicator measures the construct "functional performance".
- TELER function indicator is a clinical measurement instrument that was developed to evaluate the outcome of complex intervention (Pulmonary rehabilitation) in clinical setting¹⁶.
- TELER function indicator is an ordinal scale. The title of the indicator defines a treatment goal that is identified as relevant and important by the patient and the carer. Six codes on the ordinal scale define clinically significant outcomes. These are arranged to represent the hierarchical stepwise regain of function. The definition and the hierarchical arrangement of the clinically significant outcomes were performed by patients, carers and clinical experts.
- TELER function indicator traces changes (improvements or deteriorations) and no changes in functional performance.

These theoretical principles have implications for the methods used to evaluate the usefulness of TELER function indicators in clinical pulmonary rehabilitation settings. This will be explained in further details in the methods section.

¹⁶ Clinical setting refers to the setting within which PR is delivered this could be in the community, a specialist rehabilitation centre or hospital.

Chapter 6: Determination of the usefulness of TELER “function” indicators

13 Usefulness of measurement tools

The usefulness of measurement tools was described in the literature in terms of the feasibility of application and the psychometric properties of the measurement tool. Psychometrics, when applied in accordance with the theory of measurement, provides scientific quantitative evidence on the appropriateness and rigour of the measurement tool to serve its function. However, methods of psychometric analysis are based on testing the measurement tool in a random sample of the population in standardised clinical research settings (De Vet *et al.* 2003). This provides evidence of the usefulness of the measurement tool at the level of the group, in a specific population and a specific context. This does not necessarily reflect the heterogeneous population that the clinician is confronted with in clinical practice.

The TELER function indicators were developed to solve problems of measurement in a clinical PR setting. The critical review of existing outcome measures identified the lack of appropriate measurement tools for use in a clinical setting. Moreover, the review highlighted the inability of existing outcome measures to provide informative data, to achieve full clinimetric analysis when used at the level of individual patient or group of patients in clinical setting, despite their established psychometrics properties. Therefore, evidence of the usefulness of TELER function indicators should be provided in terms of their ability to generate data appropriate for full clinimetric analysis of a clinical phenomenon of interest.

Clinimetrics is a clinically based, patient centred approach to measurement that requires ensuring the appropriateness of the measurement tool for implementation in clinical settings, the quality of the performance of measurement in clinical setting, and the provision of meaningful data that could inform clinical practice (Fette 2006).

One way of ensuring appropriate clinimetric analysis is by linking the outcomes of measurement to clinical notes. The clinical notes should be recorded systematically to provide relevant clinical observations by the clinician and critical clinical incidents as reported by the patient.

During the phase of conceptualisation, it was highlighted that an “appropriate measurement tool” of functional performance for use in clinical PR settings should fulfil the theoretical specifications of the measurement tool and the principles of measurement in clinical setting. The development of TELER “function” indicators was informed by the knowledge that emerged during the phase of conceptualisation. Evidence was established during the phase of development that they fulfil the principles of measurement in clinical setting. A measurement tool that fulfils the principles of the measurement in clinical setting is expected to provide data appropriate for full clinimetric analysis.

The knowledge resulting from clinimetric analysis should enhance the experience of recovery for the patient, facilitate clinical reasoning and decision making for the clinician, and assist the commissioning process for managers and decision makers. Therefore, analysis to demonstrate the clinically informative data generated by the TELER function indicators is performed at different levels to inform the patients, the clinicians, and the managers.

Moreover, the measurement in clinical settings should serve a predefined purpose. Therefore, the usefulness of the measurement tool is determined by providing evidence of its ability to fulfil the purpose of measurement (Sperlinger 2002). Duncan and Velozo (2007) suggested that a main purpose of measurement in PR setting is to track changes in clinical and functional status at the level of the individual patient. Other purposes of measurement in clinical setting include providing evidence of the quality of care delivered to the patient and the efficiency and effectiveness “outcome” of treatment.

TELER function indicators were purposely developed to track changes in functional performance. A measurement tool that is designed to track changes over time, should be responsive to changes in the construct being measured. The ability of the measurement tool to correspond to changes in the construct being measured is defined as responsiveness (Beaton *et al.* 2001). Therefore, evidence of the responsiveness of the measurement tool should be established to demonstrate the usefulness of the measurement tool.

Once responsiveness is established, evidence is needed that data provided by TELER function indicators is appropriate for clinimetric analysis at the level of the individual and at the level of the group. At the level of the individual a qualitative and quantitative analysis of the patient's experience is required to provide evidence of the quality and the outcome of care delivered to the individual patient. Interpretation of the data should be performed using qualitative reasoning with reference to clinical knowledge, the clinical characteristics of the individual patient and the specifications of the clinical setting (Grocott and Campling 2009).

Moreover, Duncan and Velozo (2007) suggested that measurement tools should inform policy and decision making. Thus the usefulness of TELER function indicators should be demonstrated in terms of providing data that could be aggregated and analysed at the level of the group to achieve full clinimetric analysis. This will provide evidence of the quality and outcome of treatment at the level of the group.

The outcomes should be attributed to treatment in order to provide a valid evidence of the effectiveness of care provided (Duncan and Velozo 2007). Therefore, demonstrating the usefulness of TELER indicators requires providing evidence that the data generated could be used to provide evidence of attribution. Attribution requires establishing a cause and effect relationship. When used in a clinical setting, TELER indicators could provide evidence that the observed effect is not random and could be attributed to some cause by establishing statistical significance of treatment effectiveness. However, they do not establish a cause and effect relationship. In order to establish evidence of attribution, TELER indicators should be used in an appropriate research design (LeRoux 2003).

However, this clinical testing study is not concerned with establishing evidence of the effectiveness of PR. The clinical testing presents the methods of calculating statistical significance of the outcome of treatment at the level of the individual patient and the group. This clinical testing is concerned with providing evidence of the appropriateness of the quality and quantity of data generated by TELER function indicators to achieve full clinimetric analysis of a clinical problem in patients with COPD, which is functional performance. This will be achieved by using quantitative and qualitative methods of data analysis.

13.1 Clinical testing study design and data collection

The study was a prospective follow up of people with COPD commencing pulmonary rehabilitation. A baseline measurement on the TELER indicators was performed at the start of the rehabilitation program. TELER measurements were performed twice weekly as the patients attended the rehabilitation session; a final measurement on the TELER indicators was performed at the end of the program. These intervals were chosen to reflect as much changes as possible in patients' functional performance as this construct is known to change continuously in patients with COPD. Also these intervals correspond to the intervals at which a therapeutic input was provided to the patient.

All patients were assessed before and after PR, in accordance with the policy of the pulmonary rehabilitation unit involved. This included a full range of Physiological, psychological and health related quality of life assessment. A list of the instruments used is provided in (Appendix C.1).

13.1.1 Ethics

The study was approved by the Yorkshire and Humber ethics committee (Appendix C.2). Patients who attended a first assessment and booked a rehabilitation session at Breathing Space were sent an invitation letter with information about the study. On their first session patients interested in participation received full information sheet with explanation from the researcher about the study (Appendix C.3). All participants completed an informed consent form (Appendix C.4).

13.1.2 Recruitment and Sample Characteristics

As this is an exploratory study a sample of 10 participants was recruited. People with a diagnosis of COPD attending Pulmonary Rehabilitation program at a specialist rehabilitation centre, at an ex mining area with high prevalence of COPD, were approached by the physiotherapist. To be eligible the patient had to have an established diagnosis of COPD, confirmed by spirometry. Demographic data for the study sample is presented in Table 11.

Of the sample 60% were males and 80% were above 60 (< 50 years 1%, 51-60 years 1 %, 61-70 years 5% and >70 years 3 %). All patients had a spirometry established diagnosis of COPD. of patients 40 % had an established clinical diagnosis of existing co morbidity. All patients were ex-smokers, except one who was still a smoker at admission but quitted during the rehabilitation program.

Table 11 Demographic data for the study sample

| | Diagnosis | Smoking history | Occupation | Co morbidities | Medication | Gender | Age | BMI | FEV1 % pred | FVC% pred | FEV1/FVC |
|----|-----------|-----------------|----------------------------|----------------|---|--------|-----|---------|-------------|-----------|----------|
| AW | COPD | Y | Factory worker | Missing | Salbutamol MDI, Tiotropium, Seretide | M | 65 | Missing | 38 | 39 | 75 |
| CM | COPD | Y | Civil servant | Past PE's, AF | Missing | M | 62 | 27.17 | 73 | 75 | 65 |
| DP | COPD | Y | Dinner lady/Factory worker | Missing | Salbutamol, Tiotropium, Seretide | F | 63 | 23.5 | 64 | 92 | 51 |
| JT | COPD | Y | Cleaner | Missing | Symbicort, Tiotropium, Salbutamol, Atrovent | F | 62 | 27.9 | 61 | 93 | 55 |
| JF | COPD | Y | Textile worker | No morbidities | Salbutamol, Tiotropium, Seretide, Carbocysteine | F | 58 | 19.2 | 63 | 91 | 53 |
| MB | COPD | Y | Unemployed | Anxiety | Formotorol, Salbutamol | M | 48 | 28.72 | 41 | 75 | 45 |

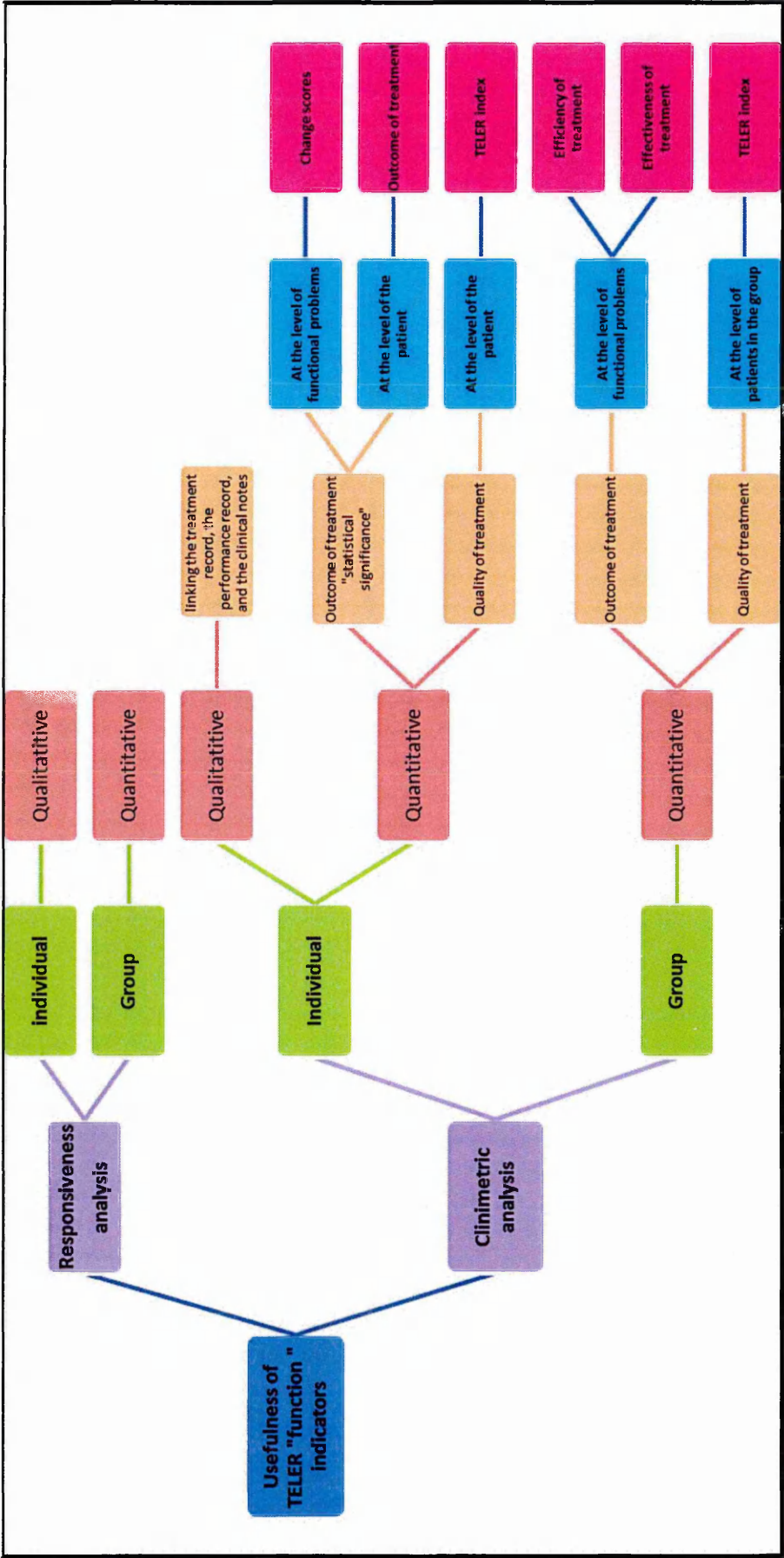
| | Diagnosis | Smoking history | Occupation | Co morbidities | Medication | Gender | Age | BMI | FEV1 % pred | FVC% pred | FEV1/FVC |
|----|-------------------------|-----------------|--------------------|-------------------|--|--------|-----|-------|-------------|-----------|----------|
| MP | COPD | Y | Cleaner | CABG, PVD | Salbutamol, Beclometasone, Carbocysteine | F | 73 | 30.54 | 81 | 124 | 52 |
| MH | COPD | Y | Steel worker | Missing | Carbocisteine, Salbutamol, Symbicort, Tiotropium | M | 75 | 17.1 | 26 | 51 | 38 |
| NS | COPD | Y | Steel worker | Cardiac condition | Missing | M | 65 | 25.86 | 29 | 48 | 48 |
| TB | COPD/ Chronic asthma | Y | Plater engineering | Missing | Salbutamol, Tiotropium, Seretide | M | 70 | 21.61 | 45 | 91 | 38 |

13.2 Analysis of TELER data

TELER software was used to analyse the data. Chi square test (Field 2009) was used to provide statistical evidence for treatment effectiveness and responsiveness of TELER function indicators. Qualitative framework analysis (Ritchie and Lewis 2003) of clinical notes was used to provide qualitative evidence for the qualitative analysis at the level of the patient.

The qualitative analysis involved only charting of responses across a predefined framework, which is the same framework used during the qualitative study in this thesis. This is because the aim of the analysis was to provide an organising framework for the data, to enable creating meaningful links with and explanations of the TELER scores. Figure 18 shows an outline of the different levels and methods of analysis performed.

Figure 18 An outline of the different levels and methods of analysis performed.



13.3 Usefulness of TELER function indicators

13.3.1 Responsiveness

The aim was to evaluate the ability of TELER function indicators to correspond to clinically significant changes in the performance of functional activities, experienced by the patient and observed by the clinician, in the context of a clinical intervention. That is finding out whether TELER indicators could correspond to clinically significant changes in the performance of: generic activity selected by the patient, functional walking, going upstairs, slope walking and talking, and showering. Clinically significant changes are expected to occur due to the introduction of pulmonary rehabilitation. However, during the assessment there needs to be a determination that a clinically significant change has occurred (De Bruin *et al.* 1997). The determination that a clinically significant change has occurred should be based on the clinical knowledge and observation of the clinician as well as patient report of experiencing the occurrence of change.

For the purposes of providing evidence of responsiveness the definition of responsiveness that was developed during the phase of conceptualisation was adopted: responsiveness is the ability of the measurement tool to correspond to change, or no change in the construct being measured, the change should be experienced and recognised by the patient and observed by the clinician. The construct in the context of this study is "functional performance" and is defined in terms of five functional activities of daily living identified as relevant and important by the people with COPD during the qualitative study in this thesis. Change is defined as one unit of clinically significant improvement or deterioration on the TELER "function" indicator (LeRoux 2003). Contextual factors related to changes in functional performance were presented in the phase of conceptualisation within the third section of chapter one. Based on the taxonomy of responsiveness developed by Beaton *et al.* (2001) changes are measured and presented at the level of the individual. The scores contrasted are within person changes.

Scores on TELER “function” indicators are compared to the scores on the CAT “COPD Assessment Test” (Jones *et al.* 2009). The difference between changes recorded on CAT and changes recorded on TELER function indicators were compared using Chi-square test (Field 2009). The change recorded on TELER function indicators should be observed meaningful clinically significant change. However, the changes recorded on CAT are based on the participants’ self scoring. Observed changes and no changes on both tools were recorded.

The reasoning for the selection of CAT is that it is a newly developed outcome measure and has been widely used in clinical trials and data analysed at the level of the group (Dodd *et al.* 2011). The aim was to find out the responsiveness of this outcome measure when used in clinical setting, using data generated at the level of the individual.

A qualitative analysis of the responsiveness of TELER function indicators was performed using the themes on factors influencing the performance of activities generated during the qualitative study. This was performed to account for the role of clinical knowledge and patient experience of change in establishing evidence of responsiveness. The reasoning being that the responsiveness of the measurement tool is dependent on the interaction between the design of the measurement scale and the person recording changes in the construct on the scale (LeRoux 2003).

13.3.2 Clinimetric analysis

13.3.2.1 Analysis of data at the level of the individual

Analysis of data at the level of the individual patient provides evidence that treatment had an effective impact on the patient experience of treatment delivered (Le Roux 2003). Effective outcome is established if the patient and the clinician were able to achieve the goals of treatment. The main goal of PR is the restoration of functional loss within the limits of available capacity, within a specific context “personal and environmental factors”, and the maintenance of the recovered function. Personalised goals of treatment are developed at the beginning of PR. In the current context of the clinical testing study personalised goals were identified in terms of selecting a set of relevant and important functional activities. LeRoux (2003) states:

"Whatever the goal, the analysis is guided by the hypothesis that a change or lack of change seen in a patient or client was produced by the treatment or care received by the patient or client. A correspondence between an observed and expected pattern of change or lack of change suggests that the treatment or care had been effective. Alternatively a lack of correspondence between an observed and expected pattern of change or lack of change suggests that the treatment or care had lacked effectiveness." (Le Roux 2003, PP: 65).

Two types of analysis were performed; quantitative and qualitative. A TELER function indicator is an ordinal scale. However the data for the quantitative analysis consists of counts of clinically significant improvement. This provides an interval level of data; this is explained by the number theory and is presented in the discussion (Le Roux 2003).

- Quantitative analysis

The quantitative analysis is in two distinct parts; statistical significance and the calculation of TELER index. The first part provides evidence of statistical significance by testing the number of improvements and deteriorations recorded on the indicators. A Statistically significant change indicates that an outcome “clinically significant change” has resulted from the intervention and has not occurred by chance (Le Roux 2003).

The second part of the quantitative analysis provides a description of the quality of treatment in terms of six index numbers. These are: the performance index, the maintenance index, the effectiveness index, the change index, the health change index, and the health status index. The TELER software automatically calculates these indices. Formulae for the indices are provided for registered TELER users (Longhand data Limited 2011). Definitions and values of TELER indices are presented in Table 12 (Longhand data Limited 2011).

The quality of the treatment received by a patient is based on the results of an analysis of the data in the Patient Report provided by the TELER Spread sheet. Quality of treatment is defined in terms of the patient outcome and is described as good, satisfactory or poor for each patient. Each level is defined in terms of data provided by the Effectiveness Index, and the Maintenance Index.

The definitions of the quality of treatment used in this study were based on the classification of outcome provided by (Longhand Data Limited 2011). However, the classification of the values of the effectiveness index was changed. This is due to the progressive deterioration of functional performance in people with COPD and the chronic nature of the condition. It was decided, with advice from the steering group¹⁷ meetings at the PR service, to lower the threshold for the definition of “moderate” of the effectiveness index. It should be noticed that those definitions could be tailored to the meet the requirements of various clinical settings:

- An effectiveness index of a value from 0 to 49 is defined as low.
- An effectiveness index of a value from 50 to 79 is defined as moderate.
- An effectiveness index of a value from 80 to 100 is defined as high.

Similar classifications of definitions were used to describe the performance index, health status index and health gain index.

¹⁷ This is the Collaboration for Leadership in Applied Health Research and Care, South Yorkshire (CLAHRC SY) COPD theme steering group meeting. As this PhD project was adopted by CLAHRC SY, the author regularly attended the steering group meetings and provided presentations of results and updates on the progress of the project.

However the steering group at the PR centre suggested adopting the same definitions for maintenance index provided by Long hand data, as it was found relevant to this group of patients.

- A maintenance index of a value from 0 to 30 is defined as unstable clinical condition.
- A maintenance index of a value from 31 to 60 is defined as marginally unstable clinical condition.
- A maintenance index of a value from 61 to 100 is defined as stable clinical condition.

Patient outcome is described as good, satisfactory or poor based on the definitions of the effectiveness and maintenance index.

Good patient outcome

Treatment that had two characteristics:

1. The treatment was of either high or moderate effectiveness.
 - The value of the Effective Index is 80 – 100.
 - The value of the effectiveness index is 50-79.
2. The patient’s clinical condition was stable.
 - The value of the Maintenance Index is 61-100.

Satisfactory patient outcome

Treatment that had two characteristics:

1. The treatment was of either moderate or low effectiveness.
 - The value of the Effective Index is 50 – 79.
 - The value of the effectiveness index is 0-49.
2. The patient clinical condition was marginally unstable.
 - The value of the Maintenance Index is 31 - 60.

Poor patient outcome

Treatment that had two characteristics:

1. The treatment was of either moderate or low effectiveness.
 - The value of the Effective Index is 50 – 79.
 - The value of the Effective Index is 0 –49.
2. The patient clinical condition was unstable.
 - The value of the Maintenance Index is 0 - 30.

- Qualitative analysis

Qualitative analysis provides a description of the duration of treatment, the number of clinical contacts, a tracking of scores, the effectiveness of treatment and patient health status at admission and discharge in terms of performance index and health change index.

Qualitative analysis involves linking the treatment record, the performance record, and the clinical notes. However, as treatment was standardised for all patients during the whole rehabilitation program, no changes were introduced to treatment except for reducing the intensity of training when patients reported that they were feeling unwell. It is worth mentioning that this is a national malpractice of the current delivery of PR. Current delivery of PR is based on protocols that is delivered to the group of patients. However, the design of PR protocols is not consistent and there is no evidence to support a certain protocol. This emphasise the need for tailoring PR interventions to the individualised needs of the patient. This is discussed into further details in the overall discussion of the thesis.

Table 12 Definitions and values of TELER indices

| TELER index | Definition | Value | Meaning |
|---------------------|--|---|---|
| Performance index | Shows current performance as a percentage of optimum performance. It shows the extent of functional loss and the potential for improvement. | Range from 0 to 100. | 0 denotes maximum possible functional loss 100 denotes the maximum possible performance. A value in between denotes a partial performance. |
| Change index | Shows the extent to which the loss of function has changed based on their overall potential to change, while the patient or client was under treatment. | Two parts: Positive indicating improvement and range from 0 to 100. Negative indicating deterioration and range from 0 to -100. | Shows the change in lost function Zero indicates no change When positive shows the percentage decrease in lost function When negative shows the percentage increase in lost function |
| Maintenance index | Shows the variability of a patient's condition Shows net change “the difference between improvement and deterioration” as a percentage of the total change. | Range from 0 to 100. | A value of 0 denotes loss of stability. A value of 100 denotes maximum possible stability. A value less than 100 shows the extent of the variation in patient's condition. |
| Effectiveness index | Shows the extent to which the treatment or care delivered to and accepted by the patient had been effective. Shows improvement as percentage of total change. | Range from 0 to 100. | 0 shows that treatment or care had been completely ineffective in achieving improvement. 100 shows that treatment or care had been completely effective. Values between 0 and 100 show that treatment had been partially effective. |
| Health change index | Shows the standardized overall extent to which the loss of function had changed during treatment or care. | Range from 0 to 100. | Negative values of the health change index denote deterioration beyond the overall deficit on admission. |
| Health status index | Performance Index standardised for number of deficits treated | Range from 0 to 100 | Provides a deficit based standardisation of the purposes of comparison between groups |

13.3.2.2 Analysis at the level of the group

TELER data at the level of the group is analysed quantitatively using statistical significance and TELER index.

"The analysis of collated TELER data is guided by the hypothesis that a change or lack of change, seen in a patient was produced by the treatment the patient had received. The improvements or lack of changes exhibited by a group of patients therefore maybe explained as the collective outcome of the totality of treatment that had been delivered. If instead the group of clients had exhibited deteriorations then the deteriorations are attributable to lack of effectiveness in the treatment" (Le Roux 2003, PP: 75).

The analysis of the collated TELER data is in two parts. The first part is concerned with the outcome of treatment this involves providing evidence of the effectiveness and efficiency of treatment. The second part of the analysis describes the quality of the treatment using the TELER index.

Analysis of the outcome of treatment

The effectiveness analysis provides statistical evidence of the outcome of treatment through the calculation of statistical significance of the improvements that the group had experienced (Le Roux 2003). The efficiency analysis provides evidence of the appropriate allocation of inputs to produce the desired outputs.

Efficiency of care is defined by the Agency for Health Care Research and Quality website as:

"An attribute of performance that is measured by examining the relationship between a specific product of the health care system (also called an output) and the resources used to create that product (also called inputs). A provider in the health care system (e.g., hospital, physician) would be efficient if it was able to maximize output for a given set of inputs or to minimize inputs used to produce a given output."

For the purposes of this analysis this definition is used as a guidance for planning the analysis. Therefore it is required to define the outputs and inputs while identifying the perspectives upon which these definitions are based. As the purpose is to provide evidence of efficiency of the delivery in clinical setting rather than standardised research setting, it was decided to adopt definitions that represent the perspectives of patients, clinicians, and managers.

Following consultation during the steering group meetings¹⁷ at the PR service which included patients’ representatives, clinical and financial managers, physiotherapists, nurses and other PhD students. It was decided that an input of common interest is “time units” and the output of common interest is “clinically significant change”. Table 13 shows the framework that guided the efficiency analysis. This was based on the typology for the evaluation of efficiency provided by the Agency for Health Care research and Quality.

Table 13 The framework that guided the efficiency analysis

| Metric | Perspective | Objective | Output | Input |
|---|---|--------------------------------------|--|-------------------------------------|
| Cost per clinically significant improvement | <ul style="list-style-type: none"> • Consumers of health care. • Clinicians. • Managers. | Identify the optimum duration of PR. | Total number of clinically significant changes in functional performance | Total number of treatment contacts. |

Analysis of the quality of treatment

This analysis is concerned with providing informative evidence about the quality of treatment to the managers and policy makers. The description is provided by the TELER index and is based on the assumption that the clinically significant improvements experienced by the group had been the outcome of its treatment. The description is in four parts which show:

1. The overall extent of the group's functional loss and potential for improvement on admission.
2. The overall extent of the group's change on discharge.
3. The overall extent of the effectiveness with which the group's treatment had been delivered.
4. The success in maintaining the group's overall condition at all times during treatment (Le Roux 2003).

Whether the aim of the analysis is to provide evidence of outcome of treatment (effectiveness and efficiency) or evidence of the quality of treatment, it is worth noting that the group could be analysed at different levels, depending on the definition of the group Table 14.

Table 14 Different levels of group analysis and their definitions (Le Roux 2003).

| Levels of group analysis | Unit of study | Variable under study | Definition of group |
|--|----------------------|-----------------------------|--|
| At the level of the problems presented | Group | Functional problem | An assembly of functional problems. |
| At the level of patients in group | Group | Functional problem | An assembly of patients and a patient is defined as an aggregate of problems |

13.4 Results of clinical testing

All the 10 patients completed the baseline assessment. Below is a table listing the titles of the TELER indicators used and the number of participants who completed each indicator Table 15. Indicators were chosen by the participants according to their relevance and importance to them. Functional walking, slope walking and talking and going upstairs were chosen by all participants.

Table 15 Number of patients completing each of the TELER function indicators

| Indicator Title | Number of patients |
|----------------------------|---------------------------|
| Generic activity indicator | 5 |
| Functional walking | 10 |
| Slope walking and talking | 10 |
| Going upstairs | 10 |
| Showering | 2 |
| Bending to do an activity | 8 |

13.4.1 Results of Responsiveness

13.4.1.1 *Quantitative analysis of responsiveness (Chi-Square test)*

The aim was to assess the differences in the distribution of clinically significant changes and no changes on CAT and TELER "function" indicators. Therefore a definition of clinically significant change is required.

TELER "function" indicators were designed and calibrated to measure clinically significant change. Thus the individual was defined as changed when the change index was not zero at the end of treatment. Clinically significant change is not defined on CAT. For the purposes of this analysis, clinically significant change on CAT was defined as a change of at least one score or more on each scale of the 8 scales on the questionnaire. Thus a change of 8 scores in the total is required to define the patient as changed on CAT. Appendix C.5 shows the probability distribution of both CAT and TELER. A total of eight patients were included in this analysis because CAT data was missing for two patients. Table 16 shows the distribution of change and no change on both TELER and CAT

- The Null hypothesis was that there was no difference between the "distribution of change and no change" recorded on TELER and the "distribution of change and no change" recorded on CAT.
- The alternate hypothesis was that there is a difference between the "distribution of change and no change" recorded on TELER and the "distribution of change and no change" recorded on CAT.
- A significance level of 95% confidence was set before calculation, $P < 0.05$.

Table 17 shows the calculation of the expected values corresponding to the distribution of changed and not changed on both TELER and CAT.

- The expected value for the cell in row 1 at column 1 is (the probability that a subject will have the characteristic “change” on both CAT and TELER by chance) \times (grand total).
- The probability that a subject will have the characteristic “change” on both CAT and TELER by chance is (the probability that a subject will have the characteristic “change” on CAT by chance) and (the probability that a subject will have the characteristic “change” on TELER by chance).
- The probability that a subject will have the characteristic “change” (improvement or deterioration) on CAT by chance is $2 \div 3$.
- The probability that a subject will have the characteristic “change” on TELER by chance is also $2 \div 3$.
- The probability that improvement, deterioration and no change occurs by chance on each scale is $\frac{1}{3}$, $\frac{1}{3}$, and $\frac{1}{3}$ respectively.
- Independence is ensured by collecting the data on TELER and on CAT by two different clinicians.
- When the measurement made on CAT is made independently of the measurement made on TELER, (the probability that a subject will have the characteristic “change” on CAT by chance) and (the probability that a subject will have the characteristic “change” on TELER by chance) is $(2 \div 3) \times (2 \div 3)$. The expected value therefore is $(2 \div 3) \times (2 \div 3) \div 8$.
- On the contingency tables: C denotes changed, and NC denotes not changed.

Table 16 Distribution of changed and not changed on both TELER and CAT

| TELER | CAT | | TOTAL |
|-------|-----|---|-------|
| | C | N | |
| C | 2 | 6 | 8 |
| N | 0 | 0 | 0 |
| TOTAL | 2 | 6 | 8 |

Table 17 Expected values corresponding to the distribution of changed and not changed on both TELER and CAT

| TELER | CAT | | TOTAL |
|-------|--|--|-------|
| | C | N | |
| C | $(\frac{2}{3} \times \frac{2}{3} \times 8) \div 8$ = 3.56 | $(\frac{2}{3} \times \frac{1}{3} \times 8) \div 8$ = 1.78 | 5.34 |
| N | $(\frac{2}{3} \times \frac{1}{3} \times 0) \div 8$ = 1.78 | $(\frac{1}{3} \times \frac{1}{3} \times 0) \div 8$ = 0.89 | 2.67 |
| Total | 5.34 | 2.67 | 8.01 |

Table 18 Chi square calculation

| $(O - E)^2 \div E$ values | | | |
|---------------------------|--------|-----------|-------|
| TELER | CAT | | Total |
| | Change | No change | |
| Change | 0.68 | 10.00 | 10.68 |
| No change | 1.78 | 0.89 | 2.67 |
| Total | 2.46 | 10.89 | 13.35 |

- Degrees of freedom =1
- Tabulated $\chi^2 = 3.84$ at $P = 0.05$ and $df = 1$
- The total of the $(O - E)^2 \div E$ values, namely 13.35, shows statistical significance. The critical chi-square value at the 95% confidence level is 3.841.

Since the calculated $\chi^2 >$ tabulated χ^2 , this is at the 95% confidence level, the null hypothesis is rejected and the alternate hypothesis is accepted. There is a difference between observed and expected changes and no changes recorded on both TELER and CAT. As TELER has enabled the recording of more changes then it is more responsive to changes.

It is worth noting that the CAT “no change” value of 10.00 is a massive outlier in comparison with the other three $(O - E)^2 \div E$ values. This prompts the question “how much of the statistical significance is due to the outlier, and how much is due to a lack of similarity between TELER and CAT?”

To examine the effect of the outlier it is replaced by the corresponding expected value. If the new total does not show statistical significance, then the outlier caused the statistical significance. If the new total does show statistical significance, then the outlier had no effect on the statistical significance.

The expected value corresponding to the outlier in Table 6 is the average of the other three values, namely $(0.68 + 1.78 + 0.89) \div 3 = 1.12$. Now the total of the $(O - E)^2 \div E$ values is $0.68 + 1.12 + 1.78 + 0.89 = 4.47$, which shows statistical significance

and implies that TELER and CAT are not equally responsive. As TELER shows more changes than CAT, TELER is the more responsive to clinically significant changes.

13.4.1.2 Qualitative analysis of responsiveness

Patient MH was selected because he experienced the largest number of clinically significant changes. The TELER form under consideration is shown in (Appendix C.6). The form shows that during the two months starting from 19-August-2010 and ending 14 October-2010, the patient received 12 treatment sessions and one maintenance. This is a total of 13 treatment contacts.

It could be argued that this patient had used all 6 function indicators, so he had more chances to record more clinical changes. However one of the indicators that he used was not changed. On the “Generic activity” driving; the patient reported being on code 0 on assessment and on all occasions after that except on the 10th and 11th session. The reason the patient was reporting inability to drive was due to “symptoms”, particularly coughing, and lack of confidence (Appendix C.7). The indicator “Showering” did not change because the patient was not able to get a bath seat. The only reason he could not shower was because he could not do it while standing and it was very difficult for him to rise from sitting on the floor bath or to squat.

On the 23-August-2010, the second treatment session; the patient was not changed on all indicators except two, the “functional walking” and the “bending to do an activity” indicators. The patient explained the three clinically significant improvements on the “bending to do an activity” indicator as a result of improved confidence and education resulting in improved ability to control breathlessness and being able to perform the activity (Appendix C.7). Other improvements (one clinically significant improvement on the functional walking, slope walking and talking and going upstairs) occurred on the 5th and the 6th sessions, which is mid-way during treatment.

On the 7th treatment session the patient experienced one clinically significant deterioration on the functional walking indicator, the patient explained this by the changing weather, and a feeling that his chest is rough suggesting that he might be having an infection. No formal clinical test was performed to diagnose the presence of infection on that occasion (Appendix C.7). It is not known why scores on slope walking and talking have not changed. One explanation might be that the functional walking indicator was more responsive than other indicator “slope walking and talking”. It could also be that the patient has avoided the slope walking outside due to the fact he was feeling rough. However, when he was asked to perform it on the treadmill it was observed that he is still on code 2. The other indicators represented indoor activities and therefore were not affected by the colder weather.

On the 8th treatment session the patient regained the lost function on the functional walking indicator, however he experienced a clinically significant deterioration on the “going upstairs” indicator. On the 10th session the patient regained the loss of function on the going upstairs indicators and experienced one clinically significant improvement on both of the “Generic activity-Driving” and the “functional walking” indicator.

On the 12th session the patient experienced two clinically significant improvements on the “going upstairs” indicator, but one clinically significant deterioration on the functional walking indicator, the patient attributed this to rough chest and cold weather affecting his walking performance outside home. Again no change on “slope walking” indicator suggests functional walking is being more responsive to changes (Appendix C.7).

Improvement on the going upstairs even when the patient said his chest was feeling rough was explained by the patient by the fact that going upstairs is indoor so the weather has no influence, moreover the patient reported that a rough chest

“breathlessness” does not prevent him from going upstairs, because he could stop for a rest (Appendix C.7).

13.4.2 Results of the analysis at different levels

In what follows the terms “score” and “code” have the following meanings¹⁸:-

Code: The number of clinically significant functions of a particular type a subject is able to perform.

Score: The total number of clinically significant functions of all types a subject is able to perform.

The terms “statistical significance” and “clinical significance” on the TELER “function” indicators have the following meanings¹⁸:

Statistical significance: Shows a change/outcome could not have occurred by chance and has some cause.

Clinical significance: A change/outcome that is not statistically significant could have occurred by chance and is not attributable to some cause. This does not make the change/outcome any less real to the patient or clinician, and when it occurs before treatment the change/outcome will still require treatment. Clinical significance rather than statistical significance therefore is the proper basis for analysing clinical change/outcome.

13.4.2.1 Results of analysis at the level of the individual

- Quantitative analysis

This analysis includes the calculation of statistical significance. It is worth noting that statistical significance at the level of the patient could be shown in two ways:

1. The statistical significance of the change of scores on all indicators used by one patient.

¹⁸ The definitions were provided by Mr A.A. LeRoux , the developer of the TELER method of measurement.

2. The statistical significance of the outcome of treatment “statistical significance of the outcome score on three indicators used by all patients”

1. Statistical significance of the change of scores on all indicators used by one patient.

The numbers of improvements or deteriorations that are statistically and clinically significant on all indicators used by one patient are presented in

Table 19 and Table 20 for patient CM and patient MH respectively. In both Table 19 and Table 20, data above the dashed line represent no change or deterioration, data below the dashed line represent clinically significant changes, and data below the thick line represent clinically and statistically significant changes. The calculation of statistical significance at the level of the individual patient is based on calculating the probability of chance occurrence of improvement, or deterioration or no change. A statistically significant change has a probability of occurrence that is very small to be explained by chance. That is the probability of occurrence is smaller than the arbitrary p value of 0.05 (LeRoux 2003).

Table 19 The significance of a number of improvements/deteriorations on a TELER indicator by code on admission and code on discharge. Patient CM

| Code on discharge | Code on admission | | | | | |
|-------------------|-------------------|---|---|---|---|---|
| | 0 | 1 | 2 | 3 | 4 | 5 |
| 0 | | | | | | |
| 1 | | | | | | |
| 2 | | | | | | |
| 3 | | | | | | |
| 4 | | | 1 | 1 | | |
| 5 | | | 1 | | | 2 |

Table 20 The significance of a number of improvements/deteriorations on a TELER indicator by code on admission and code on discharge. Patient MH

| Code on discharge | Code on admission | | | | | |
|-------------------|-------------------|---|---|---|---|---|
| | 0 | 1 | 2 | 3 | 4 | 5 |
| 0 | 2 | | | | | |
| 1 | | | | | | |
| 2 | 1 | | | | | |
| 3 | | 1 | | | | |
| 4 | | 1 | | | | |
| 5 | | | 1 | | | |

Similar tables of data distribution were developed for all patients (Appendix C.8).
A summary is presented in

Table 21 shows the number of total clinically significant changes and the number of total statistically significant changes at discharge for each patient on all indicators used.

Table 21 Summary of clinically significant versus statically significant changes

| Patient Code. | Number of clinically significant changes | Number of statistically significant changes |
|----------------------|---|--|
| AW | 2 | 0 |
| CM | 6 | 1 |
| DP | 2 | 0 |
| JT | 5 | 0 |
| JF | 8 | 0 |
| MB | 8 | 0 |
| MP | 2 | 0 |
| MH | 10 | 1 |
| NS | 4 | 0 |
| TB | 1 | 0 |

2. Statistical significance of the outcome of treatment

This could be calculated on three indicators used by all patients. Statistical significance analysis of the outcome of treatment provides evidence of effectiveness of treatment delivered and is calculated by the TELER software.

The outcome scores for improvements experienced by each patient on three indicators completed by all patients “functional walking, slope walking and talking, going upstairs” is presented in Table 22. An admission score is the total of the outcome on the three indicators on admission that is the total number of the counts of clinically significant changes experienced on all of the three indicators. An outcome score is the total of the outcome on the three indicators at discharge. The statistical significance of an outcome count of changes is dependent on the admission count of changes on the three indicators. Statistical significance is calculated by the TELER software and in this case only the outcome of patient MH was statistically significant at the end of treatment on the three indicators.

Table 22 Outcome scores on three TELER indicators statistically significant at the 5% one-tailed level

| Patient Code | Admission count of changes | | | | Outcome count of changes |
|---------------------|-----------------------------------|---------------------------------|---------------------------------|--------------|---------------------------------|
| | 1st indicator | 2nd indicator | 3rd indicator | Total | |
| AW | 2 | 2 | 4 | 8 | 10 |
| CM | 2 | 2 | 5 | 9 | 14 |
| DP | 3 | 2 | 4 | 9 | 10 |
| JT | 3 | 2 | 3 | 8 | 12 |
| JF | 3 | 2 | 4 | 9 | 12 |
| MB | 1 | 1 | 2 | 4 | 6 |
| MP | 2 | 1 | 3 | 6 | 8 |
| MH | 1 | 0 | 1 | 2 | 9 |
| NS | 3 | 2 | 4 | 9 | 11 |
| TB | 2 | 2 | 4 | 8 | 8 |

Table 23 shows the clinical and statistical significance of the outcome of treatment on all indicators used by each patient.

| Patient code | Clinically significant improvements | Statistically significant | |
|--------------|-------------------------------------|---------------------------|----|
| | | Yes | No |
| AW | 2 | | √ |
| CM | 6 | | √ |
| DP | 2 | | √ |
| JT | 5 | | √ |
| JF | 8 | | √ |
| MB | 5 | | √ |
| MP | 2 | | √ |
| MH | 10 | | √ |
| NS | 4 | | √ |
| TB | 1 | | √ |

- Qualitative analysis of outcome

Patient MH was selected because he experienced the largest number of clinically significant changes. However, the outcome of treatment was not statistically significant. The TELER form under consideration is shown in (Appendix C.6). The form shows that during the two months starting from 19-August-2010 and ending 14 October-2010, the patient received 12 treatment sessions and one maintenance. This is a total of 13 treatment contacts.

The outcome of treatment on the three indicators “functional walking, slope walking and talking and going upstairs” was statistically significant, this is shown in Table 22. This means there is sufficient evidence that the outcome is not a chance effect and maybe explained by treatment (PR) received.

However, Table 23 shows that the overall outcome of treatment on all indicators was not statistically significant. This means there is insufficient evidence to conclude that the outcome was treatment effect. However, with reference to the clinical notes it could be seen that the patient expressed improvement in some functions and attributed this to benefits gained from PR, specifically improved capacity and control of breathlessness.

Patient’s qualitative report of improved functional performance could be verified by reference to the performance record. In the performance record the performance index shows that on admission the patients' problems were assessed as an 87% loss of function. The performance index on discharge was 47%. The corresponding change index shows a recovery of 38% of the lost function. This was accompanied by an improvement of 8% on the health change index.

The performance record also shows that the value of the effectiveness index has dropped on the 7th treatment session to 88% and dropped further by the end of treatment to 78%. This means that the treatment was not delivered with maximum effectiveness. This was accompanied by increased variability in patient’s status and a reduction in the maintenance index towards the end of the treatment. This instability was explained by the patient as a result of chest infection and increased breathlessness.

The performance record and the therapist's notes therefore show that the patient improved during treatment but was unable to experience the full benefit of physiotherapy. A moderate value of the effectiveness index and a maintenance index showing the patient condition was marginally unstable suggest that the patient outcome was satisfactory.

Tracking score changes on the TELER sheet it was noticed that the showering indicator was not changing because the patient was not able to perform the function without a bath seat. The patient was referred to the OT to arrange for a home visit and prescribe environmental modifications. This shows how this TELER “function” indicator has informed clinical decision making by identifying the specific type of intervention that the patient needs, in this case OT. Also it was shown that the driving indicator was not changing. This was explained by lack of confidence due to fear of loss of control as a result of coughing. However, no specific advice was provided for the patient to address this problem.

13.4.2.2 Results of analysis at the level of the group

Results of quantitative analysis at the level of functional problems presented (Outcome of treatment/Analysis of effectiveness)

An overall number of TELER function indicators tracing on admission and discharge is provided in Table 24.

Table 24 Observed number of indicators tracing improvement, deterioration and no change from admission to discharge

| Indicator code at discharge | Indicator code on admission | | | | | Number of indicators tracing | | | Total |
|-----------------------------|-----------------------------|---|----|---|---|------------------------------|-----------|---------------|-------|
| | 0 | 1 | 2 | 3 | 4 | Improvement | No change | Deterioration | |
| 0 | 2 | | | | | | 2 | | 2 |
| 1 | | 1 | | | | | 1 | | 1 |
| 2 | 1 | 2 | 5 | | | 3 | 5 | | 8 |
| 3 | | 3 | 7 | 4 | | 10 | 4 | | 14 |
| 4 | | 2 | 3 | 3 | 4 | 8 | 4 | | 12 |
| 5 | | | 2 | 1 | 5 | 8 | | | 8 |
| Total | 3 | 8 | 17 | 8 | 9 | 29 | 16 | 0 | 45 |

- Chi square test was used to test for treatment effectiveness.
- Null hypothesis: There were no treatment effects.
- Alternate hypothesis: There were treatment effects (that is, treatment effects that could not have occurred by chance, and are attributable to some cause).
- A significance level of 95% confidence was set before calculation, $P < 0.05$

Table 25 Chi-Square test calculation

| Expected number of indicators at discharge | | | | | | | | | | | Calculated Chi-square | | |
|--|------------|----------|-------|----------|-------|---------|-------|----------|-------|----------|-----------------------|-----------|-----------------------|
| | Start code | | | | | | | | | | Total (E) | Total (O) | (O-E) ² /E |
| | 0 | | 1 | | 2 | | 3 | | 4 | | | | |
| | (b) | | (b) | | (b) | | (b) | | (b) | | | | |
| | 3 | t0 | 8 | t1 | 17 | t2 | 8 | t3 | 9 | t4 | | | |
| Discharge code | p0 | p0 * (b) | p1 | p1 * (b) | p2 | p2* (b) | p3 | p3 * (b) | p4 | p4 * (b) | | (a) | |
| 0 | 0.278 | 0.834 | 0.267 | 2.136 | 0.13 | 2.21 | | | | | 5.18 | 2 | 1.952201 |
| 1 | 0.351 | 1.053 | 0.33 | 2.64 | 0.241 | 4.097 | 0.111 | 0.888 | | | 8.678 | 1 | 6.793234 |
| 2 | 0.225 | 0.675 | 0.221 | 1.768 | 0.259 | 4.403 | 0.222 | 1.776 | | | 8.622 | 8 | 0.044872 |
| 3 | 0.106 | 0.318 | 0.123 | 0.984 | 0.222 | 3.774 | 0.333 | 2.664 | 0.333 | 2.997 | 10.737 | 14 | 0.991634 |
| 4 | 0.034 | 0.102 | 0.047 | 0.376 | 0.111 | 1.887 | 0.222 | 1.776 | 0.333 | 2.997 | 7.138 | 12 | 3.311718 |
| 5 | 0.006 | 0.018 | 0.012 | 0.096 | 0.037 | 0.629 | 0.111 | 0.888 | 0.333 | 2.997 | 4.628 | 8 | 2.456868 |
| Total | 1 | 3 | 1 | 8 | 1 | 17 | 0.999 | 7.992 | 0.999 | 8.991 | 44.983 | 45 | 15.55053 |

- Degrees of freedom (df): This is the number of indicator codes minus 1. Here $df = 6 - 1 = 5$.
- Tabulated $\chi^2 = 11.07$ at $P = 0.05$ and $df = 6$
- The total of the $(O - E)^2 \div E$ values, namely 15.55, shows statistical significance. The critical chi-square value at the 95% confidence level is 11.07.
- Since the calculated $\chi^2 > \text{tabulated } \chi^2$, this is at the 95% confidence level, the null hypothesis is rejected and the alternate hypothesis is accepted.

***Results of quantitative analysis at the level of functional problems presented
(Outcome of treatment/Analysis of efficiency)***

- The total number of clinically significant improvements experienced by the group is 45 (Appendix C.8 - Table 20).
- The total number of treatment contacts received by the group is 128, and the average number of contacts per patient is 12.8 (Appendix C.8 –Table 21).
- The number of contact/Clinically Significant Improvement = $128/45 = 2.84$.
- Cost per contact¹⁹ = 120 Minute.
- Cost per Clinically Significant Improvement = $2.84 * 120 = 341.3$ Minutes.

¹⁹ This is the routine duration of one rehabilitation session at the PR service.

Results of quantitative analysis at the level of patients in the group (Quality of treatment)

The Analysis at the level of the group –the quality of treatment is presented in Appendix C.8.

The quality of treatment delivered to the group is presented in Table 27, this is described in terms of the number of clinically significant improvements at the end of treatment, the improvements as a percentage of total change “effectiveness index”, the stability of patients’ clinical condition “maintenance index” and the excellence of treatment. From admission to the date of discharge, 50% of patients received treatment of satisfactory quality, 20% of patients received treatment of good quality and 30% of patients received treatment with poor quality. It could be seen that patients who received poor quality treatment had a moderate effectiveness index at the end of treatment, but the maintenance index shows that their clinical condition was unstable resulting in the loss of some of the improvements gained. Patient MH has experienced the largest number of clinically significant changes but his maintenance index show that his clinical condition was marginally unstable resulting in a satisfactory but not good quality of treatment at discharge. These findings highlight the importance, but the difficulty of the maintenance of the clinical condition in this group of patients.

These findings could be further examined by calculating the percentage of treatments the maintenance index was =100 and the percentage of contacts the maintenance index was < 100. Table 28 shows that in relation to maintenance of the clinical condition this group could be classified into three subgroups. 10% of patients were easy to maintain, 50% difficult to maintain, and 40% very difficult to maintain. It could be seen that there was only one patient “CM” who was easy to maintain and a concentration of patients in the other two groups.

This could be explained by reference to the clinical characteristics of the patients and the performance index. Patient CM has the highest performance index on admission. By examining the clinical notes, it could be seen that he was the only patient

who did not experience an exacerbation, a chest infection or any other clinical or psychological complications during treatment. This raises two important points.

First is the relevance of the delivery of standardised intervention for the whole group. Second is the importance of critical incidents during the course of treatment and its impact on functional performance. For example patient DP was admitted with a high performance index “70”, but was not able to experience the full benefits of treatment, because she had multiple drop outs due to depression as a result of a family death.

All patients who were admitted with a low performance index were either unstable or marginally unstable on discharge, this presented in Table 29. However, evidence of the association between the performance index on admission on maintenance index on discharge is inconclusive. This is because of the 70% of patients who were admitted with moderate performance index, on discharge 29% were unstable, 42 % were marginally unstable and 29% were stable. This further emphasises the importance of the effects of critical incidents such as exacerbations, chest infections, and clinical and psychological complications on the maintenance of the benefits of PR. Table 26 shows the critical incidents experienced by each patient during treatment extracted from the clinical notes.

Table 26 Critical incidents experienced by each patient during treatment

| Patient code | Critical incident |
|---------------------|--|
| AW | Chest infection |
| CM | Not reported |
| DP | Family death |
| JT | Upper airways infection |
| JF | Not reported |
| MB | Exacerbation of COPD |
| MP | Deep vein thrombosis |
| MH | Upper airways infection |
| NS | Upper airway infection/Stopped smoking gained weight-reduced fitness |

| | |
|-----------|----------------------|
| TB | Exacerbation of COPD |
|-----------|----------------------|

The effectiveness of treatment received by the group in relation to the performance index on admission is shown in Table 30. 20 % of patients were admitted with a low performance index however the effectiveness index on discharge was moderate. 80% of patients were admitted with moderate performance index of those 75% had a moderate effectiveness index on discharge and 25% of those admitted with moderate performance index had a high effectiveness index on discharge.

Further examination of the patients who were discharged with high effectiveness index reveals that one of them had the highest performance index on admission “CM” suggesting an influence of the performance index on admission on the potential for experiencing treatment with high effectiveness. However the other patient had a moderate performance index on admission that is not amongst the highest in the group “JF”. What those two patients had in common is that both of them did not experience a critical incident that might influence functional performance during treatment.

The extent of functional loss on admission and on discharge is presented in Table 31. It could be seen that 30 % of patients were admitted with low performance index, those had low to moderate performance index on discharge. 70% of patients had moderate performance index on admission, those had moderate to high performance

index on discharge. On important finding was that one patient was admitted and discharged with low performance index. However, this patient has experienced the largest number of clinically significant improvements amongst the group. This prompts further examination of the case.

Although this patient had a low performance index on discharge he had actually the largest health change index on discharge. The maintenance index also shows that this patient had a marginally unstable clinical condition on discharge, which is not enough to explain the low performance index on discharge despite the large number of improvements experienced. This patient used six TELER indicators.

Analysis of statistical significance shows that this patient had experience only one statistically significant change on the indicators used, which is a movement from code 2 to code 5 on the bending to do an activity indicator. However, analysis of statistical significance of the outcome of treatment on 3 indicators shows that his outcome was statistically significant. Therefore, an explanation of this case is that this patient had experienced small but multiple improvements on all the indicators.

This suggests that patients admitted with a low performance index might have a small potential to improve due to limited resources, implied by the small functional capacity, available to enable improvement. However, they have the potential to experience multiple clinically significant improvements on a number of functions that is relevant and important to them. This also prompts the importance of not relying on one index in evaluating the quality of treatment as this patient had a low performance index on discharge, but a large number of clinically significant improvements.

Health status index on admission and on discharge is shown in Table 32. The findings suggest that all patients except one had high health status index on admission and discharge. Not surprisingly the one patient who had moderate health status index on admission and on discharge is MH, who had a low performance index on admission and

on discharge and used all the indicators expressing a large number of deficits requiring treatment.

This finding is difficult to interpret given the difficulty of treating this group of patients highlighted in previous findings due to the instability of the clinical condition across the group. One explanation might be that health status index is standardised for the number of deficits treated. The assumption is that the larger the number of deficits treated the worse the clinical condition. This might not be relevant to this group of patients. This is because patients with COPD experience functional limitations with almost all of the functions of daily life²⁰.

In this study when an indicator was not used it was because the patient had given up the activity due to its high difficulty and low relevance, or is completely dependent on a carer for performing the activity. Thus lower number of indicator used might suggest greater disability not otherwise.

Health status index on admission and health change index on discharge is presented in Table 33. It is thought that the fact that all patients except one had high health status index on admission is misleading due to the reasons identified earlier. However, a low health change index could be explained by the high variability of the clinical condition and the difficulty of the maintenance of improvements gained.

The overall extent of the group’s functional loss on admission, the extent of effectiveness with which group treatment had been delivered and the success in the maintenance of the patients’ clinical condition are presented in Table 34. The results show that on admission 30% of patients had low performance index suggesting high functional loss, and 70% of patients had moderate functional performance index suggesting moderate functional loss. Despite the finding that on discharge 80% of patients had moderate effectiveness index and 20% of patients had high effectiveness index. The results show that 70% of patients had experienced low change index, and only 30% had experienced moderate change index. This could be explained by the

²⁰ This is known to the researcher from clinical experience, the findings of the qualitative study, and the ICF core set of activities and participations for COPD which includes a large range of daily life functions (ICF research branch 2010).

difficulty of the maintenance of change in this group of people with 30% of patients having a maintenance index on discharge showing that they were unstable and 60% of patients were marginally unstable.

Table 27 The quality of treatment delivered to the group

| Patient code | Performance index on admission | Clinically significant improvements | Effectiveness index | Maintenance index | | Excellence of treatment |
|--------------|--------------------------------|-------------------------------------|---------------------|-------------------|--|-------------------------|
| | | | | Net improvement | | |
| AW | 60 | 2 | 75 | 50 | | Satisfactory |
| CM | 73 | 6 | 100 | 100 | | Good |
| DP | 70 | 2 | 67 | 33 | | Satisfactory |
| JT | 60 | 5 | 78 | 50 | | Satisfactory |
| JF | 53 | 8 | 82 | 64 | | Good |
| MB | 25 | 5 | 67 | 33 | | Satisfactory |
| MP | 40 | 2 | 56 | 11 | | Poor |
| MH | 13 | 10 | 78 | 56 | | Satisfactory |
| NS | 55 | 4 | 57 | 14 | | Poor |
| TB | 53 | 1 | 52 | 3 | | Poor |

Table 28 The percentage of treatments the maintenance index was =100 and the percentage of contacts the maintenance index was < 100

| Patient Code | Maintenance index (%contacts) | |
|--------------|-------------------------------|------|
| | <100 | =100 |
| AW | 80% | 20% |
| CM | 0 | 100% |
| DP | 100% | 0 |
| JT | 45% | 55% |
| JF | 55% | 45% |
| MB | 82% | 18% |
| MP | 58% | 42% |
| MH | 58% | 42% |
| NS | 99% | 1% |
| TB | 67% | 33% |

Table 29 Performance index on admission versus maintenance index on discharge

| Performance index on admission | Maintenance index on discharge | | | |
|--------------------------------|--------------------------------|---------------------|--------|-------|
| | Unstable | Marginally unstable | Stable | Total |
| Low | 1 | 2 | 0 | 3 |
| Moderate | 2 | 3 | 2 | 7 |
| High | 0 | 0 | 0 | 0 |
| Total | 3 | 5 | 2 | 10 |

Table 30 Performance index on admission versus effectiveness index on discharge

| Performance index on admission | Effectiveness index on discharge | | | |
|--------------------------------|----------------------------------|----------|------|-------|
| | Low | Moderate | High | Total |
| Low | 0 | 2 | 0 | 2 |
| Moderate | 0 | 6 | 2 | 8 |
| High | 0 | 0 | 0 | 0 |
| Total | 0 | 8 | 2 | 10 |

Table 31 Performance index on admission versus performance index on discharge

| Performance index on admission | Performance index on discharge | | | |
|--------------------------------|--------------------------------|----------|------|-------|
| | Low | Moderate | High | Total |
| Low | 1 | 2 | 0 | 3 |
| Moderate | 0 | 4 | 3 | 7 |
| High | 0 | 0 | 0 | 0 |
| Total | 1 | 6 | 3 | 10 |

Table 32 Health status index on admission versus health status index on discharge

| Health status index on admission | Health status index on discharge | | | |
|----------------------------------|----------------------------------|----------|------|-------|
| | Low | Moderate | High | Total |
| Low | 0 | 0 | 0 | 0 |
| Moderate | 0 | 0 | 1 | 1 |
| High | 0 | 0 | 9 | 9 |
| Total | 0 | 0 | 10 | 10 |

Table 33Health status index on admission versus health status index on discharge

| Health status index on admission | Health change index on discharge | | | |
|----------------------------------|----------------------------------|----------|------|-------|
| | Low | Moderate | High | Total |
| Low | 0 | 0 | 0 | 0 |
| Moderate | 1 | 0 | 0 | 1 |
| High | 9 | 0 | 0 | 9 |
| Total | 10 | 0 | 0 | 10 |

Table 34 Performance index on admission, and Change index, effectiveness index and maintenance index on discharge

| Value of index | Performance index on admission | Change index on discharge | Effectiveness index on discharge | Maintenance index on discharge |
|-----------------------|---------------------------------------|----------------------------------|---|---------------------------------------|
| 0-9 | | 1 | | 1 |
| 10-19 | | 1 | | 2 |
| 20-29 | 2 | 3 | | |
| 30-39 | | 1 | | 2 |
| 40-49 | 1 | 1 | | |
| 50-59 | 3 | 1 | 3 | 3 |
| 60-69 | 2 | | 2 | 1 |
| 70-79 | 2 | 2 | 3 | |
| 80-89 | | | 1 | |
| 90-99 | | | | |
| 100 | | | 1 | 1 |
| Total | 10 | 10 | 10 | 10 |

14 Summary of key clinically significant findings of the analysis of TELER data

Summary of the results of responsiveness analysis

- Quantitative analysis of responsiveness using chi-square test shows that there is a statistically significant difference between the distribution of change and no change recorded on TELER and the distribution of change and no change recorded on CAT. As TELER has recorded more clinically significant changes, it is suggested that TELER is more responsive than CAT.
- Qualitative analysis of responsiveness was performed to establish the importance of the ability of the clinician to detect and report clinically significant changes recognised and experienced by the patient. Changes in functional performance were reliably detected by the clinician and attributed to influencing factor experienced by the patient. A number of factors that influenced changes in functional performance were identified. These included contextual factors “personal and environmental” and symptoms “breathlessness”. Improvements were attributed by patients to the beneficial effects of PR and included improved confidence and improved control of breathing. Environmental modifications were prescribed but not implemented. The analysis also identified differences in the change on the indicators between indoor and outdoor activities. With outdoor activities being more affected by influencing factors.

Summary of the results of clinimetric analysis

1. Results of analysis at the level of the individual

- Results of quantitative analysis at the level of the individual showed that all patients experienced clinically significant changes.
- Analysis of statistical significance of changes on all indicators used by one patient showed that only two patients experienced one statistically significant change each.
- Analysis of statistical significance of the outcome on three indicators used by all patients showed that only one patient experienced statistically significant change.
- Qualitative analysis at the level of the individual provided a method for interpreting patient’s outcomes by reference to the treatment record, performance record and clinical notes. Three important issues emerged in the qualitative analysis that should be considered in the interpretation of patient’s outcome and making clinical decisions, these are:
 1. The impact of clinically significant changes achieved on patient’s satisfaction with the treatment delivered.
 2. Identifying health condition “critical incidents” experienced by the patient during treatment that might influence functional performance such as an exacerbation of COPD, chest infection, upper airways inflammation, other clinical complications, and psychological distress.
 3. Identifying contextual factors that might influence functional performance, this includes personal and environmental factors.

2. Results of analysis at the level of the group

- Quantitative analysis of treatment effectiveness at the level of the group showed that by the end of treatment all patients experienced either no change or improvement of the TELER codes on all indicators used.
- There was a statistically significant difference between the distribution of the change “improvement” and no change on all indicators, suggesting that the group received an effective treatment.
- Quantitative analysis of treatment efficiency showed that the cost per one clinically significant contact was 341.3 minutes, which equals an average of approximately 3 clinical contacts.
- Quantitative analysis of the quality of treatment showed that 50% of patients received satisfactory treatment, 20% of patients received good quality treatment and 20% received poor quality treatment.
- The inability of the group to experience the full benefits of treatment was attributed to the difficulty of the maintenance of clinical condition in patients with COPD. The results showed that the variation in the clinical condition of 10% of patients was easy to control, for 50% of patients it was difficult to control, and for 40% of patients it was very difficult to control.
- The findings of this study suggest that it is difficult to predict response to treatment or the patent of recovery based on baseline clinical characteristics, such as performance index on admission. However, the data shows that a possible association might exist between performance index on admission and the performance index on discharge, the extent of effectiveness with which group treatment had been delivered, and the maintenance of clinical condition of the group.
- Patient admitted with low performance index were either unstable or marginally unstable on discharge. Patients admitted with moderate performance index were unstable, marginally unstable, or stable on discharge. Patients who had stable maintenance index on discharge have not experienced any critical incidents during the treatment.
- On discharge all patients had received treatment with moderate to high effectiveness.

- The use of health status index was not informative in this group as patients who used smaller number of indicators had more functional limitations than patients who used larger number of indicators; this contradicts the assumption upon which health status index is calculated²¹. It could be argued that this might be a data collection problem and that when the patients decided not to use an indicator that should be used then the codes of the indicators should be entered as 0 on the data sheet. A caveat here is that if the patient decided that this function is not relevant anymore because it was given up, then including it and scoring it as 0 might overstate functional loss when the results are communicated to the patient.
- Low health change index on discharge in this group could be explained by the difficulty of controlling the variability in the clinical condition in patients with COPD.

²¹ The health status index is based on the assumption that the use of larger number of indicators indicates more functional loss. In this study patients might have used less indicators because they have given up the functions described by some indicators, and therefore they are more functionally limited.

Discussion of Phase 3: Clinical testing

The aim of the clinical testing study was to demonstrate the usefulness of TELER “function” indicators in terms of its responsiveness to clinically significant changes and providing data appropriate for clinimetric analysis when used in clinical PR setting. However, before providing a discussion of the usefulness and of TELER “function” indicators it is important to identify the context of the clinical testing to ensure the validity of the interpretations of the results of the analysis of TELER data.

14.1 Identifying the context of the clinical testing study

Identifying the context of the study requires examining the purpose of measurement in the current study, identifying the nature of the data subjected to analysis and the level of measurement, and identifying the reliability of measurement.

14.1.1 The purpose of measurement in the clinical testing study

The purpose of measurement in this clinical testing was the collection and analysis of data on the improvements in functional performance experienced by patients with COPD participating in PR program. The aim was not to establish the effectiveness of PR, therefore inferences withdrawn from the clinical testing is based on TELER evaluation not attribution.

It is important to recognise the difference between the TELER evaluation and the TELER attribution. In TELER evaluation the clinician has an assumption that the treatment is effective. Therefore, the observed patterns of change or lack of change are compared with expected patterns of change or lack of change. In TELER evaluation a correspondence between the observed and expected pattern of change or lack of change is taken as evidence of effective treatment, and lack or correspondence is taken as lack of change.

In TELER attribution it is required to determine whether an observed pattern of change or lack of change is unlikely to have occurred by chance. An observed pattern of change or lack of change is unlikely to have occurred by chance when it is statistically significant. In TELER attribution the guiding principle is uncertainty about the cause of an observed pattern of change or lack of change. When used in an appropriate research design TELER attribution does identify the cause of the observed pattern of change or lack of change which is unlikely to have occurred by chance.

14.1.2 Identifying the levels of measurement using the TELER indicator

It has been highlighted earlier the clinically significant outcomes are different to clinically significant changes. This implies that the level of measurement of a clinically significant outcome is different to the level of measurement of a clinically significant change. Clinically significant outcomes are represented as the definitions of the codes on the TELER indicator. Each code presents a clinically significant outcome that is defined in reference to theoretical and clinical knowledge and patients' and clinicians' experience. These codes are represented by "numerals" and provide an ordinal level of measurement (LeRoux 2003).

On the other hand clinically significant change is the amount of clinical change that is required to achieve the next clinically significant outcome on the TELER indicator. That is on the TELER indicator there are six clinically significant outcomes. To achieve code 5 on the indicator the patient should experience five clinically significant amounts of change. The fact that this is an ordinal scale the amounts of change between two successive codes on the indicators are not equal. Therefore the amount of clinically significant change required to achieve one clinically significant outcome could not be quantified. However, the number of changes required for achieving a certain clinically significant outcome on the scale could be counted. Counting entities does not require equality. It is similar to counting persons with all the inherent differences between people counted. Counts of clinically significant changes are represented by numbers that could be subjected to operations of algebra (Michle 1983). Lord states:

"The numbers do not know where they came from" (Lord 1953, P: 751).

Therefore, data for the quantitative analysis uses the counts of clinically significant changes and not the numerals representing the codes of the indicator.

14.1.3 Reliability of TELER "function" indicators

Three important theoretical principles should be considered when evaluating the reliability of the TELER "function" indicators. First, functional performance is continuously changing in patients with COPD. Therefore consistency of measurement could not be used as an evidence of reliability. Second, TELER "function" indicators are designed to measure change within the individual patient. This requires high reliability because error cannot be eliminated by averaging. Third, appropriate use of the TELER method requires that the clinician has adequate knowledge, of what constitutes a change and to record the change reliably each time it occurs.

When attempting to establish evidence of the reliability of indices generated qualitatively by patients it should be noticed that these will vary naturally because of their highly individualized nature, resulting in multiple contextual factors influencing the change. Thus assessing reliability using traditional statistics would provide results that are misleading and difficult to interpret (Guyatt *et al.* 1987a).

Reliability of measurement in clinical setting could be increased by reducing measurement error each time the measurement is performed at the level of the individual. This could be achieved by ensuring that the observer "the clinician" has adequate knowledge and skills in identifying and recording "true" change when it has occurred in systematic and consistent manner. One way by which TELER ensures consistency is by defining the codes of the indicators using statement that have singular meaning. That it is it could be interpreted in one way only. Moreover, adequate training on the use and implementation of TELER system is mandatory to ensure reliability.

In the context of this study measurement was jointly performed by the patient and the researcher. The measurement was recorded by the researcher who received extensive training on the TELER method and a one to one support provided by TELER limited.

Having established the context of the clinical testing a discussion of the usefulness of TELER function indicators in terms of its responsiveness and providing data appropriate for clinimetric analysis is presented next.

14.2 A discussion of the usefulness of TELER function indicators in clinical setting

It has been highlighted earlier that the usefulness of TELER function indicator is determined by establishing evidence of responsiveness and appropriateness of data generated for clinimetric analysis.

14.2.1 Responsiveness of the TELER “function” indicators

Evaluation of the responsiveness of the TELER “function” indicators is based on the following theoretical principles:

1. The clinician has the knowledge to recognise a clinically significant change when it has occurred and record it.
2. The categories of the construct “functional performance” are defined so that they are mutually exclusive and exhaustive. That is the definition of the codes on the scale should allow for identifying the clinically significant differences between the codes.

In other words detecting clinically significant changes in functional performance requires a measurement scale that has construct validity and a reporter “patient or clinician” who has the knowledge to recognize and record a change when it has occurred.

Responsiveness of TELER “function” indicators was established using quantitative and qualitative methods. The difference between the distribution of change and no change on both TELER indicators and CAT was calculated using Chi square test. CAT was selected because it is a feasible tool for clinical practice that could be completed by patients and clinicians. The results suggest that there is a clinically significant difference between the distribution of change and no change on both TELER and CAT. The fact that there are more changes reported on TELER suggests that the TELER “function” indicator is more responsive than CAT.

It is worth mentioning that CAT and TELER data were collected by different clinicians. However both were clinicians with similar experience and level of training, and are expected to have comparable levels of knowledge. The difference could be explained by the fact that definitions on CAT lacked precision.

The definition of the codes of the TELER function indicators allow for recording more clinically significant changes than CAT. This is because the codes on the indicators define clinically significant outcomes that are meaningful to the patient and the clinician. Therefore, these changes could be recognised, observed and recorded.

14.2.2 The appropriateness of TELER data for clinimetric analysis

A full clinimetric analysis requires the measurement to accurately record the clinical phenomena experienced by the patient and observed by the clinician. This includes a number of components that constitute the elements of the clinical encounter. These components were collated from a number of papers on clinimetric and the implementation of measurement in clinical setting (Feinstein 1983, Greenfield and Nelson 1992, Higginson and Carr 2001, and Sperlinger 2002):

1. Identifying changes in the clinical problem "functional performance" and the factors influencing it.
2. Identifying the benefits experienced by patients as a result of treatment delivered
3. Identifying problems that prevented the patients from experiencing the full benefits of treatment.
4. Identifying the clinical characteristics of the group and the pattern of recovery.
5. The process of clinical decision making, clinical reasoning and judgment based on evidence grounded in the outcome of measurement at the level of the individual in clinical settings.

Evidence of the appropriateness of data generated by TELER function indicators for clinimetric analysis is provided by identifying how the analysis of the TELER data has informed each one of the components of the clinical encounter.

1. Identifying changes in the clinical problem "functional performance" and the factors influencing it.

It was established that TELER "function" indicators were responsive to changes in functional performance. The definition of the codes on the indicators enabled the recording of change when it has occurred, and was observed by the researcher and recognised by the patient.

The TELER method of measurement enables the identification of changes in functional performance by two main methods. The first method is by providing a trace of scores on the data sheet of TELER software; this provides session by session information on change. The second method is by the calculation of a change index; this provides an estimate of the overall change at the end of treatment.

The measurement of functional performance is performed each time the patient attends the PR session and data is recorded on the data sheet. This provides a longitudinal follow up of changes in functional performance during PR. The meaningfulness of the changes recorded is implied by the definition of the codes of the indicators and has been discussed earlier during development. However, it is the responsibility of the clinician to respond to the recorded changes whether this was an improvement or deterioration. The response of the clinician is in the form of maintaining treatment, altering treatment, or withdrawing treatment. Changes in functional performance occur in the form of improvements or deteriorations.

The clinical relevance of improvements recorded on TELER function indicators

In the context of PR recording the ability to recognise and record an improvement when it has occurred reliably and systematically, provides invaluable clinical information. This includes information regarding the number of sessions required to induce an improvement, the maintenance of improvements, and the maximum potential improvement for a particular patient.

In this clinical testing study all patients experienced improvements during the course of treatment. This was expressed as a positive change index for all patients at the end of treatment. However, all patients only experienced a low to moderate change index on discharge. This suggests that there are other factors than treatment influencing the change experienced by patients. Another explanation might be the lack of specificity of the intervention. This will be further discussed in the overall discussion.

Of the patients 60% started to experience improvements on the 5th treatment session. Other patients experienced earlier improvements after the 1st session. These improvements were on the "showering" and "bending to do an activity" indicators. These early improvements were attributed by patients to environmental modifications, improved breathing control and learning a better technique for performing the activity that resulted into energy conservation during performance. For example patient JF explained the early improvement on the showering indicator from code 2 to code 4, after the 1st session, by having a shower seat, so that she does not have to stand during showering, and sitting in the towel and "drip dry" instead of actively drying herself.

Other improvements occurred later on the 8th, 9th and 12th treatment sessions these included functional walking, slope walking and talking, and going upstairs. These activities are related to moving from one place to another and are associated with high ventilatory demand, and the involvement of the large muscles of the lower limbs resulting into increased oxygen consumption (Palange *et al.* 2000). Therefore, inducing a change in these activities required a combination of improved physiological capacity, self-efficacy and control of breathlessness.

Results of a recent systematic review on the minimum duration of PR required for inducing changes in Health Related Quality of Life and walking tests were reported by the authors to be inconclusive (Beauchamp *et al.* 2009). The authors explained their findings by the heterogeneity of the literature and lack of standardised outcome measures. The findings of this study suggest despite the heterogeneity of the population of people with COPD, TELER "function" indicators enabled the clinician to identify the treatment session when clinical improvements in functional performance started to occur. This provides the information required to make clinical decisions on the optimum length of PR based on the individual's needs, clinical characteristics and response to treatment.

Solanes *et al.* (2009) investigated the minimum duration required to induce a plateau in HRQoL in patient with COPD attending outpatient PR. The authors reported The number of patients achieving stability after 8 weeks, showing continued improvement after 8 weeks, and demonstrating an erratic pattern of change was as follows: for physical function measured on CRQ (56%), (37%) and (7%) patients.

This study shows an explicit example of the difficulty of making clinical decisions based on research studies. In this study the authors identified the inclusion criteria, as an age under 65, no home oxygen use, clinically stable nutritional status, no exacerbation in the last month or changes in medication in the last 4 months. This striving for homogeneity and stability in research samples to reduce bias and improve control, precludes useful inferences from these studies about the individual in the clinical context.

This emphasises the need for a measurement tool that enables clinimetric analysis and inform clinical decision making. The decision about the duration of treatment should be individualised and based on when the specific individual starts to experience improvements, and the nature of therapeutic input required to induce an improvement in functional performance.

Another important point is the need for a paradigmatic shift in research methods. This shift should enable more realistic evaluation for complex interventions such as PR in heterogeneous population such as COPD (MRC 2008) and (Pawson 2003).

The clinical relevance of deteriorations recorded on TELER function indicators

Due to the progressive nature of COPD one of the aims of treatment is the prevention of deteriorations in functional performance. This information is provided by the TELER software in the form of maintenance index.

However, the data shows that this is a difficult aim to achieve in this group. This is due to the progressive nature of the disease and to the multidimensional nature of functional performance. Functional performance is influenced by a number of factors. Changes result from the interaction of factors related to the disease and contextual factors. Therefore linking clinical notes with the trace of score changes is crucial to enable identifying the factors that resulted in the deterioration and target the treatment to alter these factors.

2. Identifying the benefits experienced by patients as a result of treatment delivered

This information is provided by the TELER method in the form of effectiveness index. The effectiveness index shows improvements as a percentage of total change. Despite the instability in the clinical condition the data shows that by the end of treatment all patients had experienced moderate to high effectiveness. The data presented here confirms positive changes reported by patients in the qualitative study in functional performance. It also confirms the beneficial effects of PR on functioning, which was shown in terms of improvements in the walking tests (Dolmage *et al.* 2011) and physiological parameters (Laccasse *et al.* 1996). However TELER function indicators show how these physiological improvements have translated into improved day to day functioning at the level of the individual patient.

3. Identifying problems that prevented the patients from experiencing the full benefits of treatment.

Whilst this is a matter of clinical reasoning and clinical knowledge of the clinician, the TELER method provides the tool that enables the clinician formulate explanations of the clinical problems that precluded or delayed full recovery. In a chronic condition such as COPD this is a question of maintenance. This requires the clinician to identify the point in treatment when he/she lost control over the clinical condition of the patient. More importantly is identifying the factors that resulted in this loss of control.

This information is presented on the TELER form as the maintenance index. Maintenance index is calculated by the TELER software throughout the treatment. The maintenance index provides information on the variability of the patients' clinical condition. While this group of patients experienced large variability in their clinical condition, the important issue is the explanation of this variability. By reference to the clinical notes it was identified that patients started to show instability, a short time before, during, and a short time following a critical incident. This information is very important. This because clinical stability and lack of exacerbation is a standard inclusion criteria in almost all research studies on PR. Clinically variation in the clinical condition was the main factor that precluded experiencing the full benefit of PR.

4. Identifying the clinical characteristics of the group and the pattern of recovery

As this clinical testing study is concerned with the evaluation of functional performance in clinical PR setting, the clinical characteristics of the group is best described in terms of the performance index. The performance index shows current performance as percentage of optimal performance. On admission 30% of patients had a low performance index and 70% of patients had moderate performance index, on discharge 10% of patients had low performance index, 20% of patients had moderate, and 30 % had high performance index.

A caveat here is that it is important to consider other indices when making decisions about the pattern of recovery. During analysis one patient was identified who had a low performance index on admission and on discharge. However this patient has experienced the largest number of clinically significant improvements.

The pattern of recovery was heterogeneous across the group with some patients experiencing small improvements on all indicators and others experiencing large improvements on small number of indicators. The pattern of recovery of the functional loss was partially described by performance index on admission. The other main factor that influenced the trajectory of change of functional performance in this group was the occurrence of a critical incident that had an impact on functional performance. A critical incident could be related directly to COPD such as an exacerbation, or to other clinical condition. The critical incident in this study was also described in terms of psychological disturbance resulting from a social or family incident.

An important point to highlight here is that functional performance is influenced by a number of factors and might change instantaneously as a result of these factors such as the weather. Therefore, in the context of this study was described as a critical incident that resulted in deterioration of functional status that was maintained over two points of clinical contacts. Another way of verifying this is by calculating statistical significance of the movement on the indicators. However, it remains important to consider clinical significance when making clinical decisions.

Existing research studies that attempted to investigate the pattern of recovery following PR stratified patients at baseline based on physiological variables (Antonelli-Inclazi *et al* 2003), (Takigawa 2007a), (Takigawa *et al.* 2007b), and (Trooster *et al.* 2001), functional variables (Berry *et al* 1999), and (Plankeel *et al* 2005), or based on the severity of symptoms (Wedzicha *et al* 1998) (Trooster *et al* 2001). Results were inconclusive and contradicting. This could be explained by the variability of PR protocols used in each study, and variability in the baseline characteristics of participants in different studies.

This study has contributed to the knowledge about the pattern of recovery and response to PR by providing qualitative evidence that functional performance is influenced by a number of factors upon which is physiological capacity and symptoms. Therefore, a direct measure of functional performance is essential to enable the description of the pattern of recovery following PR. However, it should be ascertained that explanations should be contextualised. Moreover, the findings of this study suggest that a general descriptive pattern that could be applied to all individuals within the group is unlikely to occur in the current knowledge about COPD, PR, and the factors influencing functional performance. Particularly that this group of patients show clinical variability in clinical status that is difficult to control.

In this study the pattern of recovery of functional performance reflected an individualised experience of recovery that is influenced by the progression of the disease as well as personal and environmental factors. Therefore, clinical decisions should be individually based and treatment interventions should be tailored to target the needs and the circumstances of the individual patient. The TELER "function" indicators were shown to be a useful clinical tool that enables tracing change scores at the level of the individual and describe the pattern of recovery of the individual patient.

5. The process of clinical decision making, clinical reasoning and judgment based on evidence grounded in the outcome of measurement at the level of the individual in clinical settings.

A crucial feature of the TELER method that facilitates making clinical decisions is the note making system. Linking treatment record, clinical notes, and the performance record enables the clinician to generate explanations of changes experienced by the patient. Moreover, it enables evidence based selection and targeting of interventions to address the needs and experience of recovery of the individual patient.

The knowledge about the functional performance, the factors influencing it, and the changes in the construct in response to PR that emerged during the three phases of this thesis has provided new insights that could guide the process of clinical reasoning in PR setting during the treatment of people with COPD.

Overall discussion

15 Introduction to the overall discussion

This overall discussion will summarise and reflect on the methods and findings of this research. The discussion will be tailored to support the conclusion that a new outcome measure of functional performance for people with COPD that is underpinned by theoretical specifications and is appropriate for implementation in clinical PR setting has been developed following a rigorous research process. In order to achieve this, the overall discussion is presented in two main parts, these are:

1. Identifying the need for the measurement of health outcomes in clinical setting.
2. The contribution of this thesis to the knowledge in the area. This includes:
 - A reflection on the suitability of the methodologies used within this thesis for the development of the outcome measure, and the new knowledge that emerged during different phases. This includes identifying the specifications of a clinical outcome measure, the development of a conceptual framework for the measurement of functioning, and new insights into the experience of functional loss in people with COPD
 - A discussion of the appropriateness of the TELER “function” indicators for measurement in clinical settings
 - A discussion of the new knowledge that has emerged during the clinical testing about the delivery and response to PR.

This is followed by a discussion of the limitations of this research, dissemination of research findings and future research.

16 The need for measurement of health outcomes in clinical settings

This thesis responds to the worldwide drive for developing and evaluating interventions required for tackling the epidemic of non-communicable diseases (WHO 2008). The WHO predicted that chronic conditions will become the leading cause of disability worldwide in (2020), inflicting substantial costs on health care systems (WHO 2008). This comes at a time when the health care systems work under the challenge of making efficiency savings, but maintaining quality, through productivity and innovation (Department of Health 2010a). This challenge could not be met without appropriate outcome measures that provide informative data about the quality and outcome of treatment.

The clinical case studies presented in the clinicians' guide for Meeting the challenge of the QIPP²² agenda, suggested enhanced recovery and facilitated early discharge as two methods of meeting the demands of the prevailing fiscal policy (Department of Health 2010a). This suggests that clinicians treating patients with chronic conditions need appropriate measurement tools and systematic clinical records to enable them to trace changes in the individual patient. Measurement at the level of the individual provide valuable information for making informed, evidence based clinical decisions in response to the documented changes in the patient's clinical condition.

Moreover, appropriate measurement of health outcome in clinical settings enable clinicians to detect deteriorations once they have occurred and act upon them. This will ultimately result in the delivery of specifically targeted interventions that enhance recovery and facilitate discharge.

Despite the financial challenges the WHO warned that if not managed appropriately chronic conditions will strain the economic structures inside and outside the health system. This would result from the increased rates of readmissions, increased severity of cases requiring more expensive interventions including surgeries and intensive care, and increased disability resulting in the increased need for environmental modifications and professional care at home and in the community (WHO 2008).

²²“Quality Innovation Productivity and Prevention”

This suggests that financial savings should be thoughtfully planned to ensure that it does not result into indirect substantial increases in the economic burden. Such planning could not be achieved without outcome measures that provide veracious evidence to managers to make informed decisions about rationing resources.

The above discussion suggests that in order to meet the requirements for measurement in clinical setting, a clinical measurement tool is required. This measurement tool should be able to measure changes in the clinical condition at the level of the individual, detect early changes and provide clinically informative data that enables swift management of the deteriorations to facilitate early discharge. During the phase of conceptualisation it was identified that a measurement tool that is appropriate for measurement in clinical PR setting currently does not exist. This PhD research has filled this gap by developing a new outcome measure, the TELER “function” indicators, which is appropriate for measurement in clinical PR settings.

During the clinical testing phase it was shown that the TELER method of measurement provided the appropriate clinical tool for tracing changes in the clinical condition at the level of the individual. The clinical note making system enabled identifying the underlying causes of change. It is assumed that this will facilitate making evidence based clinical decisions by addressing changes with targeted interventions specific to the needs of the individual, and the nature of the problem presented. Ultimately this will enhance the experience of care of the individual and facilitate early discharge by early detection of deteriorations and taking specific and individualised clinical actions.

Moreover, the TELER method of measurement provided information that could enable early discharge while avoiding too soon readmission. This is achieved by calculating a maintenance index that reflects the stability of the clinical condition. This ensures that the patients are not discharged without being clinically stable. However, due to the progressive nature of COPD, it is expected that patients will experience deterioration in functional performance following discharge. Therefore, patients should be equipped with a patient reported outcome measure that enables them to detect early changes in functional performance and communicate those to health professionals or re

admit themselves to PR. The fact that TELER “function” indicators are grounded into patients’ narratives suggest that they have the potential to be used as a patient reported outcome measure. This is further discussed in the future research section.

17 The contribution of this thesis to the knowledge in the area

During the phase of conceptualisation, improving functioning was identified as the central aim of PR in the management of people with COPD. However, it was found that the construct functioning was poorly defined in the literature, resulting into plethora of measurement tools for the measurement of quality of life, health status and functional status of people with COPD. However, the conceptualisation of the constructs of these outcome measures was imprecise and lacked specificity by measuring more than one thing at the same time. Therefore, this PhD research has improved the knowledge in the area by reviewing the models of functioning, and developing a new framework for the measurement of functioning in people with COPD. This model was based on the theoretical underpinnings of COPD, PR, and models of functioning.

Moreover, during the phase of conceptualisation it was identified that despite the established effectiveness of PR in clinical trials at the level of the population, four main problems remained unresolved.

1. Physiological improvements realised from PR were not translated into improved day to day functioning.
2. Outcome measures used in clinical trials did not fulfil the requirement of the theory of measurement and measuring scales.
3. Outcome measures used in clinical trials were not appropriate for measurement in a clinical setting, and did not provide informative clinical information, when used at the level of the individual.
4. Clinical problems in the delivery of PR service. These clinical problems included the inconsistency in research reports regarding the optimum duration of PR, the appropriate mix of components, the pattern of recovery of functional loss during PR, and the maintenance of the outcomes after PR.

A new outcome measure was developed during this PhD research to fill the current gap in the clinical measurement of the functional outcomes of PR. Functional performance was identified as a clinically significant outcome of PR, and an outcome measure of functional performance for people with COPD that is appropriate for implantation in clinical PR settings, was developed.

Evidence of the appropriateness of the TELER “function” indicators for the measurement of functional performance in clinical PR settings was ensured by adequate “conceptualisation” and thoughtful consideration of the theoretical knowledge. This enabled the selection of the appropriate methods for “development” and “clinical testing”. This has ultimately resulted in an outcome measure that is valid, reliable, and responsive when used in the population and context for which it was developed. This has also resulted in clinical data that is informative for patients, clinicians and managers.

The next section is a reflection on the methodology used within this thesis to develop the new outcome measure.

17.1 A reflection on the suitability of the methodologies used within this thesis for the development of the outcome measure

Whilst a number of documents provided guidance on the development and evaluation of complex intervention (MRC 2008) and (Walach *et al.* 2006), none provided similar guidance on the development of outcome measures for the evaluation of such interventions in clinical setting. This thesis contributes to the development of knowledge in this area by providing an example of a rigorous process for developing an outcome measure of a complex intervention “PR”. This part of the discussion examine the methodologies used pre development, during development and post development and its impact on the quality of the TELER “function” indicators.

17.1.1 Selection of the TELER method of measurement

During the phase of development it was shown how the TELER method fulfilled the theoretical underpinnings identified during the conceptualisation phase. However, certain points should be further discusses.

First is the measurement of individualised outcomes. It should be noticed the TELER method provides a conceptual tool for measurement. However, it is the responsibility of the user, whether this is a clinician or research, to ensure that the definition of the indicators constitute individualised outcomes. This could be achieved by selecting an appropriate method for defining individualised outcomes. However, it remains to be established whether these outcomes could be influenced by the intervention based on the theoretical underpinnings and clinical experience.

Second is the measurement of clinically significant change. It is important to differentiate between “clinically significant outcome”, and “clinically significant change”. Clinically significant outcomes are abstract concepts that should be defined from the perspective of the patient and the potential of the intervention to alter these outcomes. On the other hand “clinically significant change” is the changes experienced by the patient in the “clinically significant outcomes”. This change could be induced or could occur spontaneously over a continuum of recovery.

Current methods of measuring clinically significant change define cut-off point to classify patients into changed or not changed. The selection of the cut-off point is based on establishing a relationship between mean scores and global ratings of change and no change (Kazdin 1999). This method creates two main problems. First it is based on mean scores. This results in the lack of representation of the individual patient. The misclassification of one patient reporting him/her self improved as non-improved and vice versa has already been reported in the literature (Beaton *et al.* 2000).

The second problem is that this method suggests that during treatment there is a potential for one clinically significant change. This is not true, because changes occur over a continuum of recovery. Changes occur in small steps and might require long time to develop. Current methods provide very little information about change that could not inform clinical decision making. A TELER function indicator is an outcome measure of clinically significant change and provides information on whether the patient improved, deteriorated or not changed during treatment. Each of this information prompts different clinical actions.

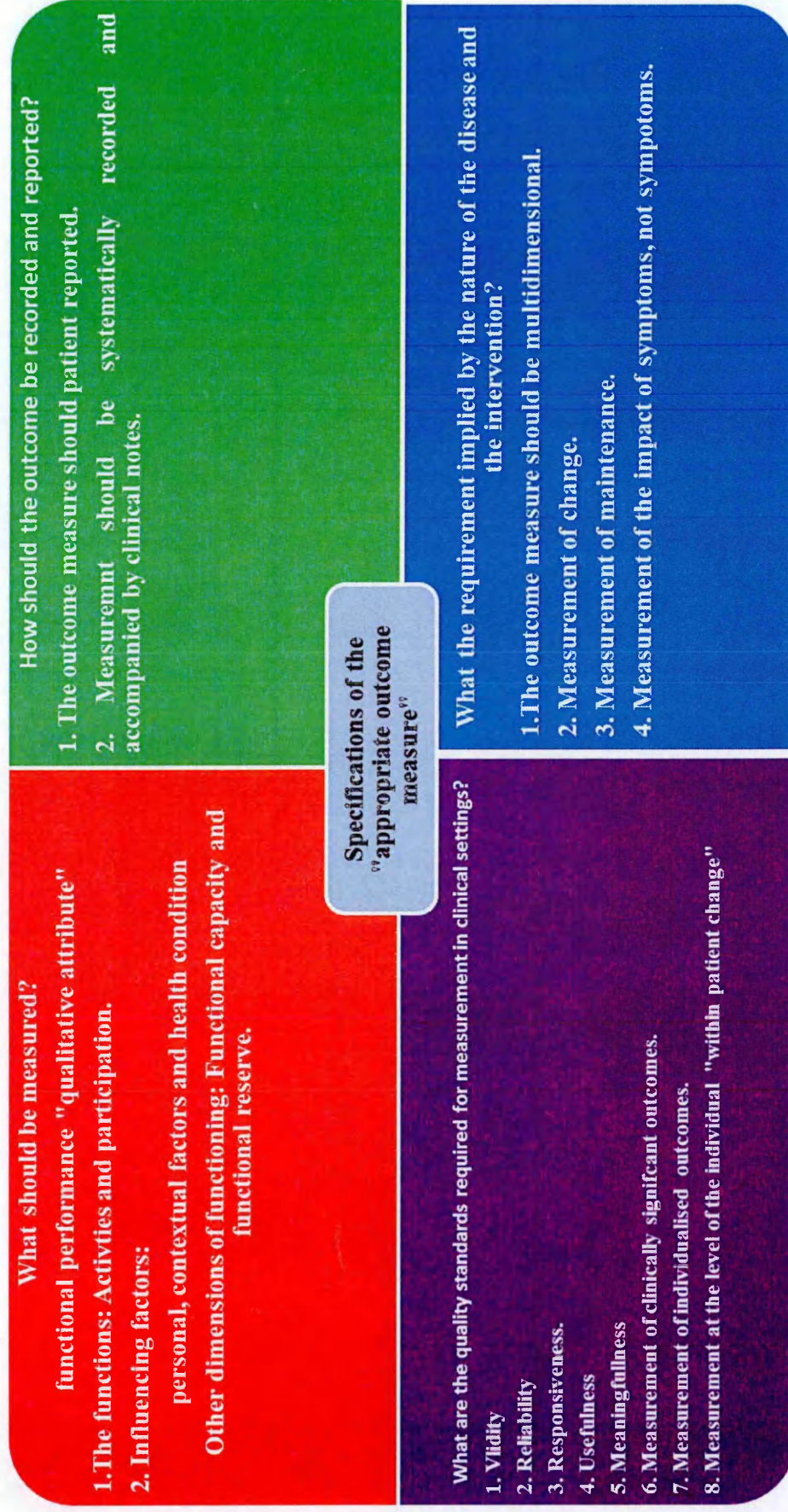
On the TELER method evidence of true clinically significant change is established by the observation of change and recording observed change on the measurement scale. This requires defining the pattern of the occurrence of change, and the ability of the reporter “patient or clinician” to detect change and record it on the scale. Points on the scale should be defined based on empirical evidence or clinical and theoretical knowledge. During the phase of conceptualisation it was found that the knowledge of the natural history of COPD and the pattern of the development of disability is incomplete. Therefore, the trajectory of change in functional performance should be defined from the experience of patients living with the disease. This was achieved during calibration and is discussed next.

17.1.2 Validity of TELER “function” indicators

Evidence of validity is provided by establishing that the outcome measure conforms to the theoretical specifications of the outcome measure established in the phase of conceptualisation, this is shown in Figure 19. During the phase of conceptualization theoretical assumptions about the specifications of the outcome measure were formulated.

Evidence of construct validity is established by identifying what should be measured “functional performance” and how it should be defined in terms that are clinically significant. When the clinical knowledge for defining clinically significant outcome is incomplete or when the aim is the measurement of individualised outcomes, then a synthesis of available clinical knowledge, theoretical knowledge, patients’ experience, and clinicians’ perspective is required (McDowell 2006).

Figure 19 the specifications of the outcome measure generated during "conceptualisation"



17.1.3 Identifying and defining “functional performance”

TELER “function” indicators measure the construct functional performance. A critical literature review of the models of functioning resulted in a framework for the measurement of functioning. The model describes the dimensions of functioning and the factors influencing it. Functional performance was shown to be a dimension of functioning. Domains of functional performance were identified as “activities and participation”. In the framework a number of factors were identified to influence the construct functional performance “health condition or the disease, environmental factors and personal factors”.

Functional performance was defines as *"the physical, psychological, social, occupational, and spiritual activities that people do in the normal course of their lives to meet basic needs, fulfil usual roles and maintain their health and wellbeing."* (Leidy 1994, P: 198).

During the phase of conceptualisation, a number of models describing functioning in people with COPD were identified. However these models provided a framework for the assessment and classification of functional problems. This research has developed the knowledge in this area by developing a multidimensional framework for the measurement of functional outcomes. This was achieved by adequate definition and conceptualisation of the domains of functioning resulting into specific and precise definition of the constructs, identifying the interaction between the constructs, and the influencing contextual and disease related factors.

Whilst this framework was based on critical review and synthesis of the literature on the models of functioning in chronic conditions, its validity was further verified during the qualitative study. The results of the qualitative study showed that “functions-activities and participations” and “factors influencing activities” emerged as two main themes on the thematic chart.

Appendix B.7 shows a classification of patients’ narratives on the theme “factors influencing the performance of activities”. It could be seen how the identified factors from narratives fit in the classification of the factors influencing activities identified in the theoretical framework.

In the qualitative study performance of activities was described in terms in “being able to do” a statement that is very close to that provided by the theoretical definition “activities people do”. An example is provided from the narrative of patient #2, she said describing her current level of functional performance:

*“I’m not **able to do** as much as I did then, I mean two years ago”*

This notion of “ability” implies that other than the factors influencing activities there is some sort of limitation imposed on the ability to perform. This limitation was described by the framework as “functional capacity”. Patients describe the limitation imposed by capacity on performance by saying:

*“I do so much then I have to rest, and then go back to it and do things. But you know I know my own way, that **I can only do so much**, and I can push myself that little bit more. But **I know when I’ve got to stop**. I’ve gone to rehab and **I push my limits as far as I can go** doing the exercises and things like that. And **doing that I know when my limits finish**, you know, so **I know when to stop**”*

This suggests that the construct of functional performance and the factors influencing it was a valid representation of the patients’ experience of performing functional activities, because they are grounded in the narratives of patients. It follows that there is a qualitative evidence of the construct validity of TELER “function” indicators. This evidence is derived from theoretical conceptualisation of the construct and validation by empirical qualitative evidence.

Another theoretical requirement was that the outcome measure should measure individualised outcomes. This requires using a valid method of item selection and reduction that preserve patients’ perspective and needs. During the qualitative study patients described a wide range of activities. The narratives of patients were classified using the activities’ core set of the ICF. The core set was generated using consensus methods involving experts. This suggests that the set of activities generated during the qualitative study is consistent with expert opinion on what constitute a problematic activity for patients’ with COPD. Moreover, it serves to validate the ICF core set of activities and participation for COPD from the perspective of patients.

Theoretically, a valid item reduction method should preserve patients' perspective on what is important. Item reduction methods reported in the literature included statistical methods of reduction (Garrod *et al.* 2000) or expert opinion (Molen *et al.* 2003). The result is a set of items that could not be validated by direct reference to the patient. In this study the final item reduction procedure was performed by patients in the focus group. The set of activities selected was found to be consistent with the activities reported by other qualitative (Williams *et al.* 2007).

However, this evidence shows that TELER "function" indicators actually measure "what should be measured", but not how it should be measured to provide clinically significant definitions of the codes. To provide such evidence the author refers to the process of construction of the indicators.

17.1.4 Defining clinically significant outcomes

This requires using clinical knowledge to define the categories of the construct "functional performance". However, during the phase of conceptualisation it was found that currently the knowledge about the progression of functional limitation in COPD is incomplete. Therefore, the only way to ensure a valid definition of the codes on the indicators is by referring to the experience of functional limitations of patients and the clinical perspectives of experts.

The use of patients' narrative to evaluate outcomes has been reported in the literature. France and Uhlin (2006) reviewed a number of studies that used narratives as an evaluation tool of the treatment in psychosis. They concluded that use of narrative, particularly the change in narratives was a valid and reliable method of evaluating outcomes in this group of people. Paterson and Britten (2000) compared narratives to a standardised questionnaire in the evaluation of the outcomes of medical consultations. They concluded that the standardised questionnaire failed to demonstrate all outcomes important to the patients that were generated from the narratives. This highlights the importance of narratives in providing a valid representation of the attribute that should be measured, particularly when theoretical and clinical knowledge are lacking.

When developing a measurement scale it should be noticed that a measuring scale has two components: the scale, a “reference manual” or “aide-memoire”, and the translating medium, the “mechanism” that converts an attribute into a point on the measuring scale (LeRoux 2003). In COPD clinical and theoretical knowledge about the pattern of progression of disability is incomplete (Barnes and Kleinert 2004). Therefore, the translating medium is a synthesis of the experience of the patient represented by narratives and available clinical knowledge. This ensures fulfilling one of the logical requirements of measurement that is the definition of categories of the construct so that they are mutually exclusive and exhaustive.

A caveat here is that describing the full pattern of the development of functional limitation based on the experience of each patient involves two assumptions. First all patients have experienced the full trajectory of change from maximum functioning to complete loss of function. Second the patient is able to fully remember the stages of functional loss as they developed. Neither logic nor empirical evidence from the qualitative study suggests that either of the two assumptions is true. The first assumption is fallible because none of the patients who participated in the study has experienced complete functional loss in all of the activities. The second assumption invites memory bias.

Therefore, the generation of indicator codes from narratives was guided by a theoretically established knowledge. That is, the level of functional performance varies between patients, and each patient performs at a certain level across the continuum of performance (Eisner 2011). COPD results in physiological impairment. The extent of impairment is described in terms of functional capacity and creates a limit on the functional performance (Liedy 1994). Although the amount of this limitation could not be measured, and actually varies between patients, available knowledge suggests that patients could not function beyond the limits created by physiological and pathological impairment because these are irreversible (Eisner 2011).

Having established that, it follows that patients are similar in that they all have limits on the potential for performance. This was presented on the indicators as optimal performance. Another assumption is that when the disease has severely progressed then capacity becomes very low imposing greater limits on performance. This results in increased difficulty in performing the activity and triggers adverse physiological responses manifested by increased breathlessness. This creates the point when the patient “give up the activity”, that is they are unable to perform the activity anymore.

Having established the upper and the lower boundaries of functional performance, the intermediate categories should be established. These are represented by functional capacity utilization (Leidy 1994). Patients vary in the utilization of functional capacity. While this is influenced to a certain degree by patient’s choice, it is also influenced by the factors influencing activity such as symptoms, personal factors and environmental factors. While these do not constitute the translating medium of the construct being measured, they should be acknowledged as the sources of variation in the level of performance. They explain the varying levels of performance experienced by patients. They also constitute the factors that are potentially modifiable by the intervention “PR”, once maximum physiological gain has been achieved²³. Therefore, patients’ narratives were used as translating medium converting intermediate levels of performance to points on the scale.

Whether the narratives represent all possible patterns of functional performance prompts the question of transferability. It is important to recognise the limitation of any method of establishing knowledge within a certain context when considering the transferability of this knowledge to other contexts (Pawson 2003). However certain measures were implemented to ensure that this has a potential in providing adequate representation. First, saturation was reached before terminating the study. After the fourth interview no new patterns were emerging. However, another two interviews and a focus group were performed after saturation. Second, during clinical testing patients were asked if they felt that they are performing in a different way that is not presented in the codes on the indicators. None of the patients claimed so.

²³ This knowledge was established in chapter4

However, it remains plausible that new patterns may emerge. A possible solution is provided by the flexibility of the TELER method. The TELER method enables the clinician to define codes on the indicators relevant to the needs of their patients, given that they have adequate clinical knowledge about the condition and the intervention (Le Roux 2003). Currently, the codes on the new developed TELER “function” indicators are the only available description of the pattern of functional loss in a population of people with COPD.

17.1.5 Identifying the level of measurement and the mathematical properties of the resulting scale

An isomorphism between the observed structure of the construct being measured and the assigned mathematical structures should be established. TELER “function” indicator is an ordinal scale, therefore it should be shown that categories on the scale are, connected, transitive, and asymmetric. This is shown by using one TELER “function” indicator as an example.

Bending to do an activity

0. Unable to touch table in front.
1. Able to bend forward with *back upright* and reach forward.
2. Able to bend forward and touch feet distance but unable to maintain.
3. Able to bend forward touch feet and maintain position but unable to do another task.
4. Able to bend forward perform an activity but has to rest before completing the task.
5. Able to bend forward maintain it and complete the task.

It was shown earlier that each code on the scales represents a level of performance that was generated from the patients’ narratives. That is each statement is unique because it describes a level of performance that requires a different set of resources and skills “connectivity”. That is moving down the scale the patient requires more resources to enable him/her to perform at a higher level. A patient performing at a higher level has the resources required to perform at the lower levels but not the higher ones. That is higher levels of performance are related to lower levels but not vice versa “Asymmetry”. If the patient has the resources to perform at code 4, then he/she has more resources than a patient performing at code 3, but fewer resources than a patient performing at code 5. It follows that a patient on code 5 has more resources than a patient on all the previous codes “transitivity”. An explanation is provided next.

- On code 0 the patient does not have the physiological capacity, or the flexibility required to bend.
- On code 1 the patient has partial physiological capacity and partial flexibility that enables her/him to bend forward with back straight and adequate upper limb control to reach forward.
- On code 2 the patient has adequate flexibility but not adequate physiological capacity, once this patient bends forward the abdominal contents are pushed upward creating pressure on the diaphragm. This pressure displaces the diaphragm from the position of the maximal mechanical efficiency to less efficient position. If the patient has adequate physiological capacity, he/she will be able to maintain the position and achieve code 3. If not this is code 2.
- On code 3 the patient does not have adequate physiological capacity to do another task that requires more ventilatory reserve.
- On code 4 the patient has more ventilatory reserve that enables him/her to do another task but not complete it.
- On code 5 the patient has adequate physiological capacity and flexibility to achieve the task.

This suggests that there is an isomorphism between the mathematical structure of the ordinal scale and the structure of the phenomenon “bending to do an activity”. Therefore, the indicator fulfils the requirement of the theory of measurement and measuring scale. Finally as required by theory and the TELER method of measurement the arbitrary unit of measurement was defined as “one unit of clinically significant change”.

17.2 A discussion of the appropriateness of the TELER function indicators for measurement in clinical settings

Evidence of the appropriateness of TELER “function” indicators for measurement in clinical settings require examining the feasibility of TELER function indicators in clinical settings, and the usefulness of TELER function indicators in providing informative data.

Feasibility of application has been frequently described in reports on developing outcome measures. It was described in terms of time required to complete measurement, and the resources required to perform and record measurement. During the clinical testing it was found that completion of indicators by patients in the presence of the therapist required on average about 10 minutes. This is very reasonable particularly when compared with other outcome measures like the CRQ which requires 20 minutes.

However, it is important to notice that time required for completion should not only be assessed in terms of length, but also in terms of relevance and importance to the patients. If a certain outcome measure required 10 min to be completed, but provided very limited information, then it is not feasible. Assuming that on average the number of patients attending at the department on a certain day is 40, and then this is a waste of 400 minutes, completing the outcome measure. This should have been better invested in treatment, unless the outcome measure provides information that could support clinical decisions and inform the treatment (Lakeman 2004).

This raises the question of how informative are TELER “function” indicators. This is discussed at the level of the patient, at the level of the clinician and at the level of the group.

17.2.1 The type of information required by the patient

17.2.1.1 Providing feedback about the outcome to the patients

During the qualitative study patients reported that one of the important sources of feedback about their progress is clinical tests. However, they explained that most of the time they could not interpret the results. Moreover, Higginson and Carr (2001) suggested that reporting progress of treatment to the patient is one of the important aims of measurement in clinical settings.

The fact that TELER function indicators are grounded in patients' narratives and reflects their experience of functional performance suggest that scores recorded on the TELER indicators are recognised and interpretable by the patient. Evidence of this was provided during the qualitative analysis of the outcome of treatment at the level of the individual, as the patient was able to identify the factors influencing change and relate different components of the PR program to the type of change in the scores on the indicators.

17.2.1.2 Detect exacerbations

Exacerbation is manifested as an aggravation of the symptoms, and might present as increased fatigue, depression and sleeplessness resulting from a worsening lung condition (Rodriguez-Roisin 2000). During the phase of conceptualisation it was highlighted that emphasis on early detection and treatment of the COPD exacerbation is needed. This requires equipping the patients with tools that enable them to recognize their exacerbation and initiate therapy promptly may, or seeking professional support. This will ultimately reduce complications and decrease the risk of hospitalization.

The clinical hallmark of exacerbation is increased symptoms and altered psychological status; both were identified as factors influencing functional performance. TELER function indicators are tailored, and it was shown during clinical testing that they correspond to factors influencing functional performance. Moreover, TELER function indicators provide a longitudinal trace of scores. This enables the detection of deterioration when it has occurred.

The fact that exacerbation is a worsening of patient's condition beyond day to day variation is addressed by the TELER method in two ways. Firstly, it allows the calculation of statistical significance allowing for the verification of true change from random change. Secondly, one change on TELER indicators is clinically significant; if this change was maintained over a clinically significant period of time then it is a change beyond the normal variation and should prompt clinical action. However, the length of the clinically significant period of time remains to be established.

TELER function indicators enable the detection of deterioration in a clinical parameter "functional performance" that is directly related to exacerbation. However, it is currently the only measurement tool that could quantitatively differentiate between day to day variation and a clinical COPD exacerbation.

17.2.2 The type of information required by the clinician

Clinicians require information that enables them to provide evidence based practice, and making informed clinical decisions. Therefore they require information that enables designing appropriate treatment plan, detecting and responding to changes in the patient's status, and deciding when to discharge the patient.

The TELER function indicators provide a longitudinal follow up of clinically significant outcomes; this enables the clinician to detect the point in time when the patient starts to experience the benefits of the treatment. Moreover, the trace of codes on the TELER data sheet enables the clinician to detect deterioration once it has occurred. The fact that the codes on the TELER function indicator are clinically significant outcomes, and a change from one code to another represent a clinically significant change enables the clinician to make clinical inferences based on changes in patients' scores. Linking the codes on the data sheet with clinical notes enables the clinician to identify the factors that has resulted in the deteriorations or the improvements. This provides the clinical information required to take informed clinical actions.

Currently the TELER method of measurement is the only method in the area of PR that enables the calculation of a quantitative estimation of the variability of the clinical condition at the level of the individual patient “maintenance index”. Given that variation in the clinical condition is a recognised clinical feature of COPD emphasise the significant of using the TELER method in clinical PR settings for patients with COPD. The maintenance index enables the clinician to ensure that the patient is not discharged unless the clinical condition is controlled and stable.

17.2.3 The type of information required by managers

Managers require information that enables them to make informed decisions about the rationing resources. In the current NHS structures there are service providers and commissioners. Service providers are interested in the outcome “effectiveness and efficiency” of treatment, while commissioners are interested in the outcome of treatment “effectiveness and efficiency”.

During the clinical testing study evidence was established that TELER function indicators provide relevant information of interest to service providers. This information includes the clinical characteristics of the group of patients treated, the overall outcome of treatment, the duration of treatment required to establish improvement and maintenance of effect. Moreover qualitative evidence of the quality of treatment based on the performance index and maintenance index was provided.

Moreover, during the clinical testing it was shown the TELER data collected at the level of the individual could be aggregated to provide group data of interest to commissioners. This data was analysed to provide evidence of the effectiveness of treatment in terms of statistical significance. Evidence of the efficiency of treatment was calculated using the time units required to induce one clinically significant change.

17.3 A discussion of the new knowledge that has emerged during the clinical testing about the delivery and response to PR.

Current clinical problems in PR are described in terms of the provision and the outcomes of clinical PR services at the level of the individual and at the level of the group. Issues related to the provision were identified during the phase of “conceptualisation” and include the optimum duration of the program, the components of the program, the pattern of recovery, and the prediction of response to PR.

When discussing the new knowledge that has emerged during the clinical testing two important points should be recognised. Firstly, the findings are based on a prospective follow up of patients over a period of time; therefore causality could not be established unless TELER was implemented within an appropriate research design. Secondly, conclusions withdrawn from the clinical observation are limited by the small sample size. Therefore interpretations are not conclusive but provide guidance for further investigation. The findings also highlight the value of the developed TELER “function” indicators in solving current clinical problems in the provision of PR services.

17.3.1.1 Duration of PR

Current guidance on the optimum duration of PR is based on the average response of patients to PR. Evidence from research studies suggest that the longer the program the greater the benefits gained (ATS/ERS 2004). This presents two main clinical problems, the first is the longer the program the less likely it is that patients adhere to the full length and complete the program. The second problem is the cost implications in longer programmes, this is particularly important when recognising that research evidence that supported the longer duration did not provide evidence of cost effectiveness of the longer programs.

This PhD research has contributed to the knowledge about the optimum length of PR. Firstly, during the qualitative study, patients reported that they find it more beneficial to have shorter intensive programs, but more frequent back up after the end of PR. Secondly, During the clinical testing it was found that most of the patients started to experience improvement on the 5th session, suggesting that 5 session of PR is the minimum number of sessions required to induce a physiological change in capacity.

Moreover, it was found the number of sessions required to induce an improvement is dependent on the type of the activity and the nature of therapeutic input required inducing change. Activities such as showering, bending to do an activity, and generic activity indicator improved quicker because the nature of therapeutic input was to in the form of environmental modification, education, control of symptoms, and self-management techniques. While activities such as going upstairs, slope walking and talking, and functional talking required longer to improve. This is because these activities could not improve without adequate physiological change in capacity. This physiological improvement requires a long time to develop.

The findings of the clinical testing suggest that the decision to discharge the patient should be an individualised decision, and is should be based on the variability of the clinical condition of the patient. Patients should not be discharge until they have achieved the maximum potential improvement that requires an intervention to occur and a stable clinical condition.

17.3.1.2 Components of the PR program

PR is a complex, multidisciplinary intervention. During the phase of conceptualisation it was identified that there is no consensus on the most effective components and the optimal combination of interventions. The findings of the qualitative study and the clinical testing suggest that this should be tailored to meet the need of the individual patient depending on the pattern of recovery experienced by the patient.

During clinical testing it was observed that some patients experienced large improvement on a small number of indicators. This pattern of improvement was attributed to improved physiological capacity experienced by the patient reflected as reduced breathlessness and improved exercise tolerance. This emphasise the importance of the exercise component for this group of patients. However, other patients experienced small number of improvements on a large number of indicators; these patients attributed improvements to improved self efficacy and control of breathlessness. This emphasise the importance of the education and self-management components of the program.

If the performance record of the TELER function indicators was linked to the treatment record and the clinical note making system, then it provides valuable information of the specific components required to induce improvements in functional performance at the level of the individual patient. This will eventually result into improved effectiveness and efficiency of treatment delivered.

These findings suggest that, while delivering a mix of intervention is required to address all the factors influencing performance, the influence of certain factors on performance is more pronounced in one patient than the other. Therefore, PR components should be targeted to address the specific needs of the individual patient and the observed response to treatment. The TELER method of measurement provides the clinically relevant information that enables making informed decisions about selecting appropriate components for the individual patient.

17.3.1.3 Predicting the response to PR

Predicting the outcomes of PR requires identifying baseline characteristics that might determine which patients would benefit more from treatment (Garrod *et al.* 2006)

It is important to recognise that current knowledge suggest that COPD is a heterogeneous disease and is manifested differently by each patient. Attempts to predict the pattern of recovery during PR based on clinical parameters were inconclusive. The clinical testing findings suggest that performance index on admission and the occurrence of a critical incident should be considered jointly when attempting to predict patient's response to treatment. The extent of improvement was limited by the variability of the clinical condition, and the variability was linked to the occurrence of a clinical incident. The findings of the clinical testing suggest a possible association between performance index on admission and, performance index and effectiveness index in discharge.

The performance index on discharge is influenced by the effectiveness of treatment and the stage of the disease. The effectiveness of treatment is influenced by the appropriateness of the treatment delivered and variability in the clinical condition. This suggest while performance index have the potential to predict the response of treatment at the level of the individual when implemented in an appropriate research deign. However, other factors such as the stage of the disease and the variability of the clinical condition should also be considered suggesting that a combination of factors rather than one factor might have greater potential in predicting response to PR.

18 Limitations of the research

18.1 Limitations related to the process of development

The codes on the TELER "function" indicators were developed from the perspective of patients recruited during this research process. However, different groups of patients were recruited for the indepth interviews, the two focus groups and the clinical testing. Therefore, the codes on the indicators were reflective of four different cohorts of patients recruited at different time periods. However, a common limitation amongst the four cohorts of patients is the exclusive white ethnicity. This is particularly important, because there is emerging evidence that the risk for the development and the severity of COPD is different amongst different ethnicity, with black race being associated with greater COPD severity (Eisner *et al.* 2011).

Nevertheless, new TELER indicators should be developed according to the goals of treatment agreed between the individual patient and the clinician. The process presented in this thesis provides guidance for the development of new indicators.

It is important to recognise that TELER indicators generated during this study resulted from the synthesis of clinical and theoretical knowledge, and empirical qualitative evidence. The fact that the indicators were grounded in the narratives of the patients, suggest that response shift should be considered (Eton 2010). While this will not affect the measurement generated from the indicators as the scientific structure of the indicators preclude invalid recording of scores. For a change to be recorded it should be recognised by the patient and observed by the clinician. However it remains plausible that these indicators might become irrelevant to the patients, new indicators should be developed then.

Another limitation is that the indicators were validated from the perspective of clinicians involved in development "five physiotherapists, one occupational therapist and one COPD nurse". Mutli professional team should be involved, as the delivery of PR is multidisciplinary. However, the researcher attended the steering group¹⁷ meetings of the rehabilitation centre and provided a presentation of the research process. This has provided insight from other health professionals.

18.2 Limitations related to clinical testing

An important limitation of the clinical testing study is that sample size was small and not random. However, this sample size was selected because the aim was to evaluate the newly developed TELER “function” indicators within a real clinical context. A number of 10 represent the standard size of the group attending the PR at the site of clinical testing. Moreover, the design of the clinical testing study was a prospective follow up of patients. Therefore, the findings should be interpreted carefully considering the context and the design of the study. However, the sample size and the design provided a realistic insight into the nature and diversity of clinical data. It also showed that if collected and documented systematically using the appropriate measurement tool and method of measurement, clinical measurement could provide informative data to the patients, clinicians and managers.

It should also be noticed that functional performance changes continuously and is affected by many contextual factors. The fact that TELER "function" indicators were developed to account for different factors influencing performance suggests that they might change on day to day basis. However, this change does not prompt clinical action as it is a natural variation. In the clinical testing some patients reported deterioration due to weather or "feeling rough" at that particular point in time.

To overcome this problem during clinical testing a change was not considered as a change that requires clinical action, unless it was maintained over two points of measurement. However, the clinically significant period of time required to differentiate day to day variation from change that requires a change in the treatment delivered remains to be established.

18.3 Limitations related to the TELER method of measurement

This is related to barriers for implementation. Implementation of TELER method in clinical settings requires adequate training of staff and patients on the use of the indicators, to ensure reliability. Moreover, clinicians should be trained on the use of the TELER software, the entry of data and the generation of patients' reports. There are also cost implications related to cost and software licensing.

Another important issue related to the implementation is clinicians' resistance to changes in the routine delivery of care. Moreover, currently clinicians use assessment tool as outcome measure. Clinicians should be educated about the difference between and assessment tool and a measurement tool. This requires increasing the awareness of the clinicians about the importance of appropriate measurement in clinical settings and the impact this has on the effectiveness and quality of care delivery as well as providing appropriate documentation and legal protection.

19 Dissemination and communication of the research findings

The findings of the qualitative study were communicated via oral presentations at a local university conference and a national conference. These are:

Okasheh R., Mawson S., Tod A. (2008). Patient set goals of pulmonary rehabilitation. The Faculty of Health and Wellbeing Research Day "Oral presentation".

Okasheh R., Mawson S., Tod A. (2009). Measurement of functioning following Pulmonary Rehabilitation: What matters to people? The 5th Qualitative Colloquium-East Anglia "Oral presentation".

The development of TELER "function" indicators were presented via a poster presentation at two international conferences (Appendix D.1). These are:

Okasheh R., Mawson S., LeRoux B., Tod A. (2010). Development and validation of a new measurement tool of functional performance for use in pulmonary rehabilitation in people with COPD "Poster presentation". CLAHRC national conference.

Okasheh R., Mawson S., LeRoux B., Tod A. (2010). Development and validation of a new measurement tool of functional performance for use in pulmonary rehabilitation in people with COPD "Poster presentation". COPD7

A journal Publication plan was formulated and submitted to the Health and Social Care Research Centre/ Sheffield Hallam University. This is presented in Appendix D.2.

20 Future research

Future research includes three main streams. The first is related to developing new TELER indicators for PR. The second is related to the implementation of TELER “function” indicators in clinical PR settings and in the clinical education of undergraduate and post graduate clinicians. The third is related to using the newly developed TELER “function” indicators within an appropriate research design to resolve clinical problems in the provision of PR.

20.1 Future development of TELER “function” indicators

During this PhD research qualitative evidence of the validity and reliability of the TELER “function” indicators at the level of the individual was established. The validity and reliability were ensured by adequate conceptualisation and using appropriate methodologies for development. Moreover, the responsiveness of the indicators was tested during the phase of clinical testing and evidence was established qualitatively at the level of the individual, and quantitatively at the level of the group. However, before the introduction of the TELER method as a research tool, the psychometric properties of the TELER indicators at the level of the group should be established considering the principles of the theory of measurement and measuring scales.

During the qualitative study, personal factors were identified amongst the factors influencing functional performance. Moreover, during the clinical testing it was identified that the components of the PR program that influenced improvement differed based on the needs of the individual. While some patients reported improved self efficacy as the cause of improvements, others reported improved physiological capacity as the cause of improvements experienced. New indicators of self efficacy and an appropriate research design that examine the association between functional improvements and physiological improvements are required. This will improve the knowledge and support clinical decisions about which components of the PR to include for the individual patient.

Moreover, facilitated early discharge necessitates that patients are equipped with skills and tools that enable them to monitor their own condition and self manage the changes that might occur to avoid readmission. The use of TELER function indicators as a patient reported outcome measure should be examined. The National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care, South Yorkshire NIHR/CLAHRC SY-COPD theme has funded a post-doctoral study on the usefulness of TELER function indicators as a patient reported outcome measure at home and local community settings.

20.2 The implementation of TELER “function” indicators in clinical PR settings and in the clinical education of undergraduate and post graduate clinicians

During this research it was identified that there was a critical gap in the knowledge of clinicians in the delivery of PR, and particularly physiotherapists about the principles of measurement in clinical setting. Moreover, a limited number of research reports addressed the issue of outcome measurement in clinical PR settings. Therefore, the author is involved in a project that is supported by Longhand data, to implement the TELER method of measurement in the education of undergraduate students at the faculty of the Rehabilitation Science/University of Jordan. Moreover the researcher is currently part a member of the supervisory team of another PhD student undertaking a project on measurement in low back pain.

With support from Longhand data, the newly developed TELER “function” indicators will be implemented in a clinical PR program at the University of Jordan Hospital. However, in order to do this a preliminary project that includes the translation and the cultural adaptation of the indicators will be performed supported by the Higher Research Department/University of Jordan.

20.3 Using the newly developed TELER “function” indicators to resolve clinical problems in the provision of PR.

It is worth mentioning that the new scientific domain of realistic evaluation and the evaluation of complex interventions provides opportunities for new methods of clinical research. This will include the standard randomized trials and observational cohort studies as well as other observational methods such as case control studies, and cross sectional surveys (MRC 2008). The TELER method of measurement will bring to these observational methods the appropriate tool for the measurement of outcomes.

A number of the clinical problems in PR require further investigation, using a realistic evaluation approach (Pawson 2003) and (MRC 2008). This includes the optimum duration of the program, the appropriate mix of components, and the prediction of the response to PR, improving concordance, and the maintenance of benefits of PR following discharge. While currently no funding is secured for these projects, a number of potential national and international funders have been located and will be contacted in due course. This includes the European Respiratory Society “ERS Fellowship in memory of Walther Guerrero Ciquer” which supports scientists from low-medium income countries, the Medical Research Council “The methodology research program”, and the United States Agency for International Development “USAID”/Jordan.

21 Conclusion

This research program has succeeded in its aim of developing a new outcome measure of functional performance for people with COPD that is appropriate for implementation in clinical PR settings. It has developed an outcome measure that is feasible and useful in clinical PR settings. The process used rigorous, iterative and novel approach that included predevelopment phase “conceptualisation”, Development, and post development “clinical testing”.

The outcome was the development of a set of specifications of an appropriate outcome measure for implementation in clinical settings; this could guide the selection of measurement tools for clinical practice. A new framework for the measurement of functioning that could guide the development of new outcome measures for different domains of functioning based on clinical needs. And a new outcome measure of functional performance that is the currently the only one in the area that is underpinned by adequate conceptualisation, provides clinically informative data through full clinimetric analysis. The new tool has the potential for being used as a patient reported outcome measure to provide follow up post discharge, and to resolve current problem in PR

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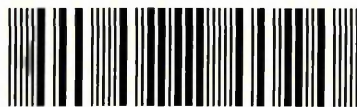
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REFERENCE

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- Appendix B: Phase 2 “Development”.
- Appendix C: Phase 3 “Clinical testing”.
- Appendix D: Overall discussion.

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Appendix A: Phase 1 “Conceptualisation”

- Appendix A.1: Physiological response to exercises

Appendix A.1: Physiological response to exercises

| Physiological response | Effect | Evidence | Expected impact on exercise performance |
|--|--|------------------------------|---|
| Increased fat free mass and reduced fat mass. | Improved body composition and body mass index. | Bernard <i>et al.</i> (1999) | Improved muscle strength. |
| Conversion from fast low oxidative fatigable fibre type (type II) to a slow high oxidative fatigue resistant fibre type (type I) | Reduced afferent chemoreflex (reduction in breathing stimulus) resulting in reduced dynamic hyperinflation. improved efficiency of peripheral muscles | Whittom <i>et al.</i> (1998) | Reduced perception of dyspnoea. |

Table 1 Physiological response to exercises

| | | | |
|---|---|--|--|
| Increased mitochondrial numbers and increased activity of mitochondrial enzymes such as citrate synthase and 3 hydroxyacyl-CoA dehydrogenase. | Improved aerobic capacity of peripheral muscles and delayed onset of lactic acidosis production | Jolley and Moxham (2009) | Delayed onset of fatigue. |
| Increased capillary contacts in proportion to increase in fibre cross sectional area. | Facilitate oxygen delivery and extraction | Mador <i>et al</i> (2001) | Improved exercise tolerance. |
| Reduced lactic acidemia at iso work rate, compensation for decline in intracellular pH and PCr/Pi. Faster PCr recovery. | Reduced decline in muscle pH and PCr/Pi, resulting in preservation of glycogen stores. | Casaburi <i>et al.</i> (1991), Sala <i>et al.</i> (1999) | Delayed onset of fatigue. Improved exercise tolerance. |

Appendix B: Phase 2 “Development”

- Appendix B.1: Participant information sheet- Qualitative study
- Appendix B.2: Ethics approval
- Appendix B.3: Consent form- Qualitative study
- Appendix B.4: Topic guide – individual interviews
- Appendix B.5: Topic guide-Focus group.
- Appendix B.6: Index of themes and subthemes
- Appendix B.7: Validation of the framework for the measurement of functional performance
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- Appendix B.9: Development of the categories of TELER “function” indicators using patients narratives
- Appendix B.10: Topic guide for focus group –validation by patients.
- Appendix B.11: Scientific meeting-Invitation letter.
- Appendix B.12: A questionnaire for the assessment of the validity of the TELER “function” indicators.

Appendix B.1: Participant information sheet- Qualitative study



Sheffield Hallam University

Faculty of Health and Wellbeing

PARTICIPANT INFORMATION SHEET

Patient set goals of pulmonary rehabilitation: Perspectives on functional and physical activities of daily living

You are invited to participate in a study to explore your views about the activities of daily living you consider important and wish to set as treatment goals for pulmonary rehabilitation.

“Why I have been asked to take part in this study?”

We have designed a study to give people the chance to voice their needs and tailor the treatment goals to meet the demands of their everyday life.

“How long will the study last?”

The whole study will last about one month. You will be involved for an hour on one or two occasions.

“What will it involve?”

If you agree to participate in this study you will be asked to join a group gathering held at the place where self support groups for patients with chronic lung disease usually meet. The researcher will talk to the group and ask them about activities of daily living they wish to set as treatment goals for pulmonary rehabilitation. You have also the option of attending an individual interview.

“Where the study will be done?”

The study will be carried out in the community where self support groups usually meet. If you opt for attending the individual interview you would agree with the interviewer on the place of the interview. This could be a meeting room at the university, community centre, or your own home.

“How often will I have to come?”

One or two times.

“What If I don’t wish to take part?”

It is completely up to you. There is no problem.

“What if I change my mind during the study?”

You are free to withdraw from the study at any time.

“What will happen to the information from the study?”

All information will be kept entirely confidential. The data will be destroyed at the end of the study. No individual will be identifiable in the report. You will be informed of the results of the study if you wish.

“What if I have further questions?”

If you have any questions, please contact:

Rasha Okasheh

PhD physiotherapy student

Sheffield Hallam University

Faculty of health and wellbeing

Collegiate Hall

Room A214

S10 2BP

E-mail: R.O.Okasheh@shu.ac.uk tel.: 0114 225 2458

Appendix B.2: Ethics approval-Qualitative study

**Faculty of Health and Wellbeing Research Ethics Committee
Health & Social Care Research Ethics Review Group
Report Form**

Title: Patient set goals of pulmonary rehabilitation:
perspectives on functional activities of daily living.

Principal Investigator: Rasha Okasheh

Recommendation:

Acceptable:

| |
|---|
| ✓ |
|---|

Not acceptable, see comments:

| |
|--|
| |
|--|

Acceptable, but see comments:

| |
|--|
| |
|--|

Comments:

Please see review sheet for comments.

Signature : Peter Almark Date: 2/5/08

Peter Almark,
Chair
HSC Research Ethics Review Group

Please remember that an up-to-date project file must be maintained for the duration of the project and afterwards. The project file might be inspected at any time.

Note: Approval applies until the anticipated date of completion unless there are changes to the procedures, in which case another application should be made.

Comments from the Ethics Committee have been addressed.

Signature of Tutor / Director of Studies / Supervisor :

Susan Mawson Date: 2/5/08

Name of Tutor / Director of Studies / Supervisor : Prof. Sue Mawson

Appendix B.3: Consent form- Qualitative study



Sheffield Hallam University

Faculty of Health and Wellbeing (Health and Social Care Research Center)

CONSENT FORM

Patient set goals of pulmonary rehabilitation: Perspectives on functional and physical activities of daily living

Please give your consent to participating in the study by answering the following questions (please tick the boxes)

Have you read the information sheet about this study? Yes ☐ No ☐

Have you been able to ask questions about this study? Yes ☐ No ☐

Have you received answers to all your questions? Yes ☐ No ☐

Have you received enough information about this study? Yes ☐ No ☐

Which investigator have you spoken to about this study?

Are you involved in any other studies? Yes ☐ No ☐

- If you are, how many?

Do you understand that you are free to withdraw from this study?

- At any time? Yes ☐ No ☐
- Without giving a reason for withdrawing? Yes ☐ No ☐

Do you agree to take part in this study? Yes ☐ No ☐

Your signature will clarify that you have had adequate opportunity to discuss the study with the investigator and have voluntarily decided to take part in this study.

Please keep your copy of this form and the information sheet together.

Signature of participant.....Date.....

Name (Block letters):.....

Signature of investigator:.....

Appendix B.4: Topic guide – individual interviews

Opening:

(Establish rapport) Hello, my name is Rasha I'm a PhD student at Sheffield Hallam University. We've met before and I'm here today further to our last telephone chat. I'm really pleased that you are interested in taking part in this study.

(Consent) To start with could you please take 10 min to read the participant's information sheet and sign the consent form? The interview will be recorded, however no names will be mentioned in the reports and the tapes will be destroyed at the end of the study. Only the researcher and the supervisory team will have access to the data.

(Introduction) The interview will last for about 45 minutes; it is divided into three sections. The first section is about the physical activities you do everyday. Then we'll move to the second section where we'll chat about how you manage difficulties while undertaking the activities. Finally we'll talk about your goals and expectations from a pulmonary rehabilitation program.

(Motivation) I hope to use this information to develop a measurement tool for functioning following pulmonary rehabilitation. Your contribution is valuable as we are hoping that this tool will focus on the individual and reflects your needs.

Before we start I'm here today to conduct the interview. I don't have access to your medical records, so could you please start by telling a bit about your lung condition, when did it start? What was the diagnosis, how do you feel now, is it stable, improving or worsening....etc?

Functional performance

What are the activities you need and want to do in your daily life, but can't because of illness?

How important are these activities to you?

Why are these activities important?

prompts:

Responsibilities

Role in the family, work...etc.

How difficult is it to perform them?

Prompts:

How much effort do you put into this and when would you give up.

Distress

Duration

Is there anything that you do that would help you do the activity?

Prompts:

Skills

Devices (assistive physical aids)

Strategies

Self management

That was great (name) we are moving now to the second section where we'll chat about self management issues

Do you undertake any particular steps (or do anything) to control your symptoms?

I would like you to think about a time when you tried to do (the named activity) and were successful?

How did that feel?

Now, I would like you to think about a time when failed to do the (activity)?

How did that feel?

Are there times when you feel down and unable to do or complete?

How do you overcome these downs?

Goal setting

The last section is about your expectations from pulmonary rehabilitation...

If you were starting a pulmonary rehabilitation program and you have been asked to identify a number of activities or functions that you would like to achieve from attending pulmonary rehabilitation what would these goals be?

Please try to be specific about your functions or activities.

What do you think you need to do to achieve that function or activity?

Prompts:

Any particular steps

Use of services

Assistance from others

What do you need to learn in order to perform the function or activity?

Prompts:

Control symptoms.

Control feelings

Learn how to be committed.

Learn how to control anxiety and depression.

Increase efficacy.

How difficult would it be to achieve the function or activity?

Do you believe you would be able to achieve them?

How long do you think you need to be able to perform function or activity?

What are the physical or practical outcomes that you expect from being able to perform the function or activity?

How committed are you to your goals? (How hard are you prepared to work)

Prompts:

Effort

Time

Perseverance.

What are the difficulties do you expect to face?

Prompts:

Symptoms or something related to illness.

Access.

Quality of service

Lack of support.

Lack of adequate feedback.

Would anything help you to overcome these difficulties?

Prompts:

Support from others

Persistence to achieve goals.

Learning new strategies.

How do you expect to find out about how well you are doing?

Is there any specific sort of feedback you will find helpful?

Prompts:

Feedback from family member or health professional

Closing

(Maintain Rapport) I appreciate the time you took for this interview. Is there anything else you would like to tell me?

(Action to be taken) I should have all the information I need. Would it be alright to call you at home if I have any more questions? Thanks again.

Appendix B.5: Topic guide-Focus group.

Doctoral Research Program

Development of a measurement tool of functioning in people with Chronic Obstructive Pulmonary Disease (COPD)

Phase 1: qualitative study "Patient set goals of pulmonary rehabilitation: Perspectives on functional activities of daily living"

This study is part of a doctoral research project that aims to find the best way of measuring the outcomes of pulmonary rehabilitation. we have done 11 individual interviews so far and the aim of this focus group, is to give the opportunity as a group to tell us more about the functions and activities of daily life that are important to you so that we could use those as a bases for the measurement of improvement following rehabilitation, and to give us the opportunities as researchers to clarify some of the new interesting finding that resulted from the individual interviews.

Stage 2: Focus group

To start with I would like to hear from you about the time when you were first diagnosed with COPD.

Prompts:

When was that?

Who confirmed the diagnosis?

What health problems or symptoms did you have (breathing problems) before diagnosis?

How has your life change since then?

In terms of activity.

In terms of role.

Is there any activity that you find particularly problematic now you have COPD?

Prompts:

Putting shoes on/off

Hovering/ dusting

Bathing

Walking to market

Carrying shopping basket

Why do you find this activity difficult?

What do you do to manage the difficulty?

How important are these activities to you?

Prompts:

How do you feel when you can't do them, or face difficulties doing them?

Could anybody else do it for you or help you doing it? (How does that feel?)

How does your level of activity vary throughout the day/year/seasons?

Prompt:

Is there a time of day/year/season when it's more difficult to be active?

When is this?

Why?

Could you think about an activity that you started to do but stopped before completing it?

Prompts:

What was the activity?

Why did you stop?

When did you stop? (After how long)

What was the consequence of stopping? e.g. did you do something else? How did it make you feel?

What did you do to manage the problem?

I would like to hear from a bit about the environment at home, if you were to change something in your home to give you a better quality of life what would that be?

Do you think there is a link between being physically active and being mentally active?

The ones who have done pulmonary rehabilitation before, how did it help?

Prompts:

What has improved?

Think about an activity that you couldn't do before rehabilitation but managed after it, or an activity that has become less problematic.

A lot of people talked about being more confident after pulmonary rehabilitation how was that?

If you were about to start a new rehabilitation program, what would your goals be?

Prompts:

What would you like to be able to do?

What would you like to improve?

How did the education during rehabilitation affect your perception of the disease?

Appendix B.6: Index of themes and subthemes

Diagnosis

Response or impact

Delay

Having the diagnosis

Emotional response

Social response

Characteristics of the disease

Chest infection

Exacerbation

Medication

Time of use

Use of oxygen

Quitting smoking

Feelings

Triggers to quit

Timing

Activity

Level

Change or difference

Variation

Goals

Factors influencing activity

Aging

Weather

Symptoms

Type

Severity

Impact

Feelings

Recognizing limits

Stopping activity

Giving up activity

Priorities

Management of activities

Planning

Modification

Environment

Slowing/pacing

Support

From others

Using mechanical aids

Finding alternatives

Reduced physical effort

Reduced risk of infection

Pulmonary rehabilitation

Exercise vs. Activity

Benefits

Functional improvement

Quality of life

Education

Going out more

Self efficacy

Goals

Uncertainty

Difficulty

Limitation

No backup

Limited resources

Access

Drop outs

Low uptake

Perceptions of the disease

Causes

Consequences

No treatment/ no cure

Living with it

Progression

Management

Having control

Being in control

Being an expert

Keeping o top of it

Psychological impact

Keeping active

Social interaction/isolation

People attitudes

Stigma of the disease

Sources of feedback

Self

Partner

Health professionals

Tests and investigations

Reduced use of NHS

Other people

Employment

Occupation

Employment status

Appendix B.7: Validation of the framework for the measurement of functional performance

Table 2 Validation of the measurement of functioning framework

| Activity | Factors influencing the activity | | | | | |
|----------------|----------------------------------|---|------------------------------|---|---|---|
| | Symptoms | Narratives | Personal factors | Narratives | Environmental factors | Narratives |
| Going upstairs | Breathlessness | I couldn't walk upstairs, there is 2 flights of stairs at the station to get to the rest room, and I had to stop halfway, I had to stop on every landing, and I'm very breathless | Fear of aggravating symptoms | I can't even hang washing up you know because this,, after that I've done this for a couple of times, and I started fighting for my breath | Going outside | going into town then obviously it takes me an awful amount of time to walk around town and I plan my route I go same route every time and because it's the easiest route |
| Walking | Breathlessness | and I find it difficult to breathe, walking in town | Aging | But I get tired more because I'm getting older I think. I'm 74 now rather than out of breath. I think my organs are wearing out. | weather | winter is worse than summer because of the nature of the disease winter time is the worst time in the year so everything is doubly slower in the winter, |
| Walking uphill | Breathlessness | Walking I could walk 3 miles along the beach and that's no problem, but since I start going uphill, then I get out of breath. If I walk up to the top of that lane (about half a mile) I'll get breathless before getting there | Stigma of the disease | I'm going out more, you know. I have oxygen and I was a bit embarrassed about going out with it but I learnt to live with that now through seeing other people at rehab, rehab is a good thing. | Improved performance in group settings/ support from others | if it was just me doing it it wouldn't have worked because there was 16 of us and I was determined to meet them. I tend to push myself, he's done that in a minute I'm going to do that, so eventually we were like that it was a competition between us. |

| | | | | | | |
|-------------------------------|---------------------------|--|--------------------------------------|---|--|--|
| showering | Breathlessness | you know like bathing you know when you've got washed you can't breathe | Positive perception of self efficacy | and that's a big achievement that ,,,and to know you can do it yourself you but you've got to just sit there and again it takes me time sometimes it took me 2 hours but that's an achievement because I've got to have my bath | | |
| Bending to do an activity | Breathlessness | the illness in my lungs and I bend down so everything pushes up, so everything on my lungs, so that in itself makes putting socks and shoes on really really difficult | Frustration | I find very frustrating it's one of the things that I really hate about my illness, just not being able to put shoes and socks on. | | |
| Generic activity (Gardenin g) | Breathlessness Fatigue | I get out of breath when I'm digging in the garden after about half an hour I get breathless and I stop. "Is it tiring because of weak muscles or because of breathing? Both. So fatigue is a problem as well? after that time yes | negative perception of self efficacy | I mean I could only work 3 hours a day, which to me is rubbish, I mean I used to go for 8 hours, but now I could only do 3 hours, | | |

Appendix B.8: Validation of the ICF core set for COPD

Table 3 Validation of the ICF core set of activities

| ICF Code | | ICF Category Title | Theme | Narratives |
|-----------|-----------|----------------------------|--|---|
| 2nd Level | 3rd Level | Carrying out daily routine | Management of activities /problematic activities | <p>5: I have to say first I don't let it stop me unless I'm really laid up I don't let my disease stop me from doing anything it hinders me but it doesn't stop me. when I get up in the morning, obviously the first thing that I do is to go to the bathroom so everything I do I do in slow motion, I do it at my own pace and I do it slowly, once I've been to the bathroom I go down stairs and I take my medication, I'm used to have a drink and my medication, and everything is really slow because I have to do it slow because I can't do it quickly, because when I start to get quicker I get more breathless. So then usually what I do is I go back upstairs this could be probably after about an hour, because I could go straight back upstairs because I wouldn't be able to do it.</p> <p>1: Sometimes I get the wife to assist me when I'm struggling but, I do try myself, sometimes she has to help me sometimes I can't get out of the bath, possible she has to help me in that aspect, not always but sometimes.</p> |
| d230 | | | | |

| ICF Code | ICF Category Title | Theme | Narratives |
|----------|---|---|--|
| d240 | Handling stress and other psychological demands | Psychological impact/keeping active | Everything I do I mean it's hard to explain to people who are breathing properly and healthy it gets you down sometimes; it's depressing you that you can't do things that you used to do. I've always done everything myself and now, it's not depressing I think depressing doesn't describe it, it's frustrating. I mean like the job that I've just finished decorating it's too frustrating that it took that long, it's annoying you know and you tend to try and rush it but I won't rush anything, I won't get anybody in to do it, so I just have to plod on, I mean I could only work 3 hours a day, which to me is rubbish, I mean I used to go for 8 hours, but now I could only do 3 hours, and I've had it I just have to pack in. So it took me a long time to do it. |
| d330 | Speaking | Management of activities/problematic activities | And talking it's difficult, you may not see it but it's difficult to talk. |
| d410 | Changing basic body position | Management of activities/problematic activities | You know just standing up and sitting down that's a killer that's enough exercise to me, even though I do it a lot it's still a killer. |
| d430 | Lifting and carrying objects | Management of activities/problematic activities | well it's very difficult it you know carrying if I have to carry something that seems to cause lots of problem, breathing wise, I'll be breathless, you know weight even if I just pick something up without moving so that's the sort of things that really bother me. |

| ICF Code | ICF Category Title | Theme | Narratives |
|----------|---|---|--|
| d450 | Walking | Management of activities/ problematic activities | It's the walking part which has to take me time to do it. When I'm walking I notice that people pass they are 10 times quicker than I, they are miles ahead, which emphasize that I'm slow. |
| d455 | Moving around | Management of activities/ planning | To do things on scales now, where I've just used to go and do everything, you know like when I go upstairs to put washing away I perhaps go back cause I've got exercise back upstairs, so perhaps I go on this 5 minutes and then I come and rest so I just take things in moderation |
| d460 | Moving around in different locations | Management of activities/ Modification/slowing and pacing | if I'm going into town then obviously it takes me an awful amount of time to walk around town and I plan my route I go same route every time and because it's the easiest route and because it's from the car to the shops back to the car, it's a circle I do a circle, I always try to do a circle so that I start at the car in then to do in between what I have to do and I finish at the car I might be in town 4 hours to get 3 things, but I'm still going out |
| d465 | Moving around using equipment | Management of activities/ modification/support/mechanical aids | When I go out because I can't walk so far anyway so I have a mobility scooter, but it gets me about and you know and when I go out I don't to come back. |

| ICF Code | ICF Category Title | Theme | Narratives |
|----------|--------------------------------------|---|--|
| d470 | Using transportation | Management of activities/ problematic activities | but if I thought about getting into a bus, and to rely on the bus to get somewhere, just the physical effort for getting to the bus stop would knock me off. Let alone setting in the public transport; don't take me wrong I'm not against it but all people with all the germs on it especially in the winter time. You know so I think probably if I couldn't drive my car, I think that would be my biggest thing, my biggest worry. |
| d475 | Driving | | |
| d4750 | Driving human-powered transportation | Management of activities/ problematic activities | I'm lucky I drive, but just getting in the car is tiring, and well I don't drive now because just of that cough, it wouldn't let me I mean I can't concentrate. |
| d510 | Washing oneself | Management of activities/ problematic activities | there are many things that make you very tired now, that you used to take for granted like showering it's not so much showering I mean showering drains me strength, but it's drying, when I finish I'm really drained and I'm upstairs for another hour to sort of recovering |
| d540 | Dressing | Management of activities/ problematic activities | I usually have about half an hour to get around form actually getting dressed, because getting dressed is very difficult it's very slow progress and as I say I know I'm referring to this time of the year but unfortunately it's layer on layer, more layers on to warm me up when I go out especially when it is winter time |

| ICF Code | ICF Category Title | Theme | Narratives |
|----------|-----------------------------------|--|---|
| d570 | Looking after one's health | Pulmonary rehabilitation/benefits/education | Now if I wake up in the morning and I feel a bit rough for some reason I've got medications that I put myself onto it. This is what they call self management I've got all the medications I need, so it's the same medications the hospital would give me anyway. So I have it at home, I don't need them to tell me I'm poorly, I know myself I'm poorly, so I'm the expert of the disease now. |
| d620 | Acquisition of goods and services | Management of activities/problematic activities | Things like shopping and going out socializing and things you know cause I couldn't go out on my own now before I was working and things and I could do things by myself but now I can't go out because I can't walk very far |
| d640 | Doing housework | Management of activities/problematic activities | Now ironing is very very hard, it is for me because I use a steam iron, and if my chest is bad like it is at the moment the steam that gets of the iron, you'd think it would be good for you but it's actually not, it makes me cough so I can end up taking hours to do the ironing |
| d650 | Caring for household objects | Management of activities/recognizing limits/giving up activities | Well I generally stopped now. I had to do DIY but I don't do now |

| ICF Code | ICF Category Title | Theme | Narratives |
|----------|---|---|--|
| d660 | Assisting others | Management of activities/ support/from others | I do the washing up, drying, and the housework with the wife because she has arthritis we both sort of do it jointly together |
| d770 | Intimate relationships | | |
| d845 | Acquiring, keeping and terminating a job | Employment/employment status | I was first diagnosed with this illness, because I was still working and everything then, but because of illness I had to retire early |
| d850 | Remunerative employment | Management of activities/ recognizing limits/giving up activities | you know you are not working you've got empty time |

| ICF Code | ICF Category Title | Theme | Narratives |
|----------|--------------------|--|--|
| d910 | Community life | Psychological impact/social interaction- isolation/people attitude | <p>I get in my car in, I get in car and go away to Doncaster, because I can walk on my own pace, people know me can't see me, because I've been reported for the security for taking my dog for a walk, the reason why I say what I have said that yesterday Sunday morning I went to lakeside at Doncaster, nice and sunny, cup of coffee, toilets the reason is there is lots of space into Doncaster lakeside centre, Frenchgate centre, walk around there. I know I can do it I know people think I shouldn't be doing it, it's a mental thing because I think if someone sees me walking down the street or around a reservoir they're going to report me again and these are the things, these are the difficulties that we have, people's impression of us and people's impression of the disease, and the illness that we have, I don't think it has so much to do with rehabilitation, it's the impression outside that causes the problem.</p> |

| ICF Code | ICF Category Title | Theme | Narratives |
|----------|------------------------|-------|---|
| d920 | Recreation and leisure | | <p>you lose your confidence, because,,,,, you know when you go out amongst people and you start coughing it's a bit embarrassing and so you don't,,,,, you start thinking, I'm not going,, you know you are too embarrassed to meet people and what if you start coughing, because sometimes when you start coughing you know you're choking and people just stop and stare sort of thing but know I got used to it and well I know how to control myself really you know. I've started going to little, shows, because we used to go to theatre a lot but obviously I couldn't go because I start coughing so usually I go to little shows and you know they've all accepted me now so things like that that's</p> |

Appendix B.9: Development of the categories of TELER “function” indicators using patients narratives

Table 4 Generic activity indicator

| Theme | Narrative | Performance descriptor |
|---|---|--|
| Management of activities/recognizing limits/giving up | <i>There might be one or two things that I just can't do.</i> <i>Well I generally stopped now. I had to do DIY but I don't do now</i> | I gave up the activity |
| Management of activities/recognizing limits/stopping activity | <i>well I now get out of breath when I'm digging in the garden, but I'm still engaging, but I've had to stop because I can't breathe</i> | I could still do it but it would get me out of breath |
| Factors influencing activity performance/Symptoms | <i>After about half an hour I get breathless and then I stop. Oh dear...well I never actually panted for breath, I do tend to breathe more quickly, when I get breathless. "So it isn't often I get breathless as such.</i> <i>After about half an hour I get breathless and then I stop. And then I perhaps carry on and do another half an hour. So it's never happened that you have to stop activity? Completely no, I work for half an hour then have an hour rest then do another half an hour. Yes and this when I sit down, and relax and then I start my breathing techniques and then that helps</i> | I could do the activity but I have to keep stopping for rest |
| Management of activities/Slowing /pacing | <i>everything I do I do in slow motion, I do it at my own pace and I do it slowly, and everything is really slow because I have to do it slow because I can't do it quickly, because when I start to get quicker I get more breathless. But whatever I do I take my own time</i> | I could do the activity without stopping but it takes longer than usual (slow process) |
| Factors influencing activity/impact | <i>I enjoy that. Walking, which they've got me doing at rehab, mmm I like to walk, but I don't like to walk in their pace, they drive you. Eventually I'm running which is probably good because this does get me out of breath that gets me out of breath after about 5 minutes.</i> | I could do the activity without stopping for a rest in a normal rate but I would start breathing rapidly |
| | | I could do the activity without stopping in a normal rate maintaining controlled breathing. |

Table 5 Bending to do an activity

| Theme | Narrative | Performance descriptors |
|---|---|--|
| Management of activities/recognizing limits/giving up | <i>I don't bend down, I can't bend it's very difficult to bend up and down very difficult</i> | I could not bend forward |
| Management of activities/modification/support/mechanical aids | <i>I put my foot higher up, I put it on something rather than me bend down to it, I put my foot on something that's higher up, so I'm not bending down as far, so I'm not bending right over I'm bringing the foot to me</i> | I could bend forward but could not reach my feet |
| Management of activities/recognizing limits/stopping activity Factors influencing activity performance/Symptoms/impact | <i>To bend down very difficult, as I said earlier bending pushes everything up onto your lungs, so your lungs being small capacity anyway, then you've made them even smaller, when bend over because everything pushes up onto them, so there is more pressure on them</i> | I could bend reach my feet but I could not keep it to put shoes |
| Factors influencing activity performance/Symptoms/impact | <i>the actual bending down to put on something on your feet is because the illness in my lungs and I bend down so everything pushes up, so everything on my lungs, so that in itself makes putting socks and shoes on really really difficult</i> | I could bend forward, and maintain it |
| Factors influencing activity/symptoms/impact Management of activities/modification/slowing-pacing | <i>sometimes I can't bend to fasten my shoes, I mean I have to get back</i> | I could bend forward, maintain it, and start doing another activity while bending (putting on shoes, hovering) but this would get me out of breath, so that I need to get back for a rest before completing the activity |
| Performance of activity/level/variation | <i>sometimes I put shoes on and never think about it</i> | I could bend forward, maintain it and fully complete another activity without resting |

Table 6 Functional walking

| Theme | Narratives | Performance descriptors |
|--|---|--|
| Management of activities / modification/ support/ mechanical aids | <i>I can't walk far my breathing and osteoarthritis I use a walker</i> | I could not walk I'll get breathless after standing and taking few steps |
| Management of activities/modification/ slowing-pacing | <i>like when you're getting ready to go out because you're going out your adrenaline goes up naturally so you have to learn to do it slowly, do it in stages so your adrenalin doesn't get pumping too fast so you don't get breathless.</i> <i>I find it difficult to breathe, walking in town, people don't notice</i> | I could walk inside or around home but not any further |
| Management of activities/modification/ slowing-pacing. Factors influencing activity performance/ Symptoms / impact | <i>But whatever I do I take my own time, even walking, when anybody is walking with me they have to walk at my pace, I can't walk at their pace, their pace is far too fast for me.</i> | I could walk outside home but my pace is far slower than other people |
| Management of activities/modification/ slowing-pacing | <i>I feel breathless after going to a walk, but I recover quicker because I'm breathing now from here (pointing to abdomen) instead of here (pointing to upper chest). It's the diaphragm you've got to build your diaphragm. Most people breathe from the chest, so they've to stop. So you've got to build your diaphragm muscles up. And you can do it a little bit longer</i> | I could walk outside home with a normal pace but I have to keep stopping for a rest |
| Factors influencing activity/ symptoms/impact | <i>I mean he and I will go for a walk, and set off marching, if he starts talking His lung just ceases up and he can't walk very fast</i> | I could walk outside home with a normal pace without stopping for a rest but since I start talking, I get breathless |
| Factors influencing activity/ symptoms/impact | <i>Well, walking I could walk 3 miles along the beach and that's no problem</i> | Walking outside is not a problem |

Table 7 walking uphill

| Themes | Narratives | Performance descriptors |
|--|--|---|
| Management of activities/recognizing limits/giving up | <i>I've done this for a couple of times, and I started fighting for my breath</i> | Unable to walk uphill |
| Factors influencing activity/symptoms/impact | <i>If I walk up to the top of that lane (about half a mile) I'll get breathless before getting there</i> | Able to walk a few steps uphill but gets breathless and stops |
| Management of activities/modification/ slowing-pacing. Factors influencing activity performance/ Symptoms / impact | <i>when I'm walking uphill I get out of breath, and I have to rest</i> | Able to walk uphill with a slow pace* and needs to keep stopping for a rest |
| Management of activities/modification/ slowing-pacing Factors influencing activity/symptoms/impact | <i>and we actually lived on a little hill, but a very steep hill and while she were walking up or ride very quickly she turned to walking up and struggling she keeps stopping</i> | Able to walk uphill with a normal pace but has to keep stopping for a rest |
| Performance of activity/variation | <i>If it is warm and nice then I could take it at my own pace</i> | Able to walk uphill with a normal pace without stopping for a rest |
| | | Able to do hill walking and talking |

Table 8 Going upstairs

| Themes | Narratives | Performance descriptors |
|--|--|--|
| Management of activities/recognizing limits/giving up | <i>I wouldn't go downstairs, because everything was upstairs I was frightened to go downstairs so I got a stair lift put in so I could move up and down stairs</i> | Unable to go upstairs |
| Management of activities/recognizing limits/stopping | <i>I stop after 2 I can't' carry on</i> | Able to take a few steps distance upstairs but gets breathless and stops |
| Management of activities/ modification/ slowing-pacing. Factors influencing activity performance/ Symptoms / impact | <i>I start moving about upstairs and I feel as I didn't have the nebuliser, something is not alright here I sit down a bit and see if it eases off.</i> | Able to walk upstairs distance but stops after a few steps (2 or 3) |
| Management of activities/modification/ slowing-pacing Factors influencing activity/ symptoms/impact | <i>walk upstairs and that take me some doing I'm really exhausted by the time I get to the top I can't do it all at once I do it in threes</i> | Able to walk upstairs with a normal pace speed but has to keep stopping for a rest |
| Pulmonary rehabilitation/ benefits/ functional improvement | <i>It's sort of doubling; I mean it's taking me half the time to go upstairs</i> | Able to walk stairs with a normal pace without stopping for a rest |
| Factors influencing activity/ symptoms/impact | <i>Going upstairs, that's no problem at all. I'm not that bad yet.</i> | Able to walk stairs with a normal pace without stopping for a rest and do another function |

Table 9 Showering

| Theme | Narratives | Descriptors of performance |
|---|--|---|
| Management of activities / modification/ support/ others | <i>I get the wife to assist me when I'm struggling, she has to help me</i> | Unable to shower independently |
| Factors influencing activity/ symptoms/impact | <i>showering problem I think one of the problems is everything that is a lot of arm movement, especially over the head like washing the hair</i> | Able to wash head and body in sitting but unable to get dried |
| Management of activities/modification/ slowing-pacing. Management of activities / modification/ support/ mechanical aids | <i>I get in I get in the shower and I've got a seat in there I get in the shower I shower off and then I have to sit down in the towel to drip dry</i> | Able to wash my head and body while sitting but unable to get dried |
| Management of activities/modification/ slowing-pacing | <i>You've had your shower but it's really a hard work trying to get dried with a bath sheet, so I dry my top and then use a small towel to dry my feet</i> | Able to wash my head and body while standing and get dried |
| Factors influencing activity/ symptoms/impact | <i>I mean showering drains me strength, but it's drying, when I finish I'm really drained and I'm upstairs for another hour to sort of recovering</i> | Able to shower but feels exhausted |
| | | Able to shower |

Appendix B.10: Topic guide for focus group –validation by patients.

Focus group (Validation by patients): Perspectives of people with COPD on TELER function indicators for use in pulmonary rehabilitation for people with COPD

This focus group is planned at two stages the first stage is a discussion of the outcome and the second stage is a discussion of the order of improvement.

Stage1: The following treatment outcomes would be presented on a flipchart:

Participants are asked to read the outcomes, and a brief description of each outcome is provided.

Able to do the activity (any activity selected by the patient) and maintains controlled breathing.

Able to achieve functional walking

Able to do hill walking and talking

Able to put shoes on

Able to do walk up stairs and talk

Able to shower

Q1: Do those outcomes matter to you?

Prompts:

Is it important to be able to do these activities?

If you were not able to do them, how would that affect your daily life?

Q2: Is that what you expect to achieve following pulmonary rehabilitation?

Prompts:

Do you see these outcomes as something that could be improved by pulmonary rehabilitation?

Q3: Are there any outcomes that matters that are not listed?

Prompts:

Is there anything missing?

Any other important activities that we did not cover?

Q4: Considering these outcomes do you think you could go any further?

Prompts:

Is that the maximum possible improvement?

Do you think you could push your limits any further?

Stage 2: TELER function indicators are presented on a flipchart, one indicator at a time:

Participants are asked to read the indicators

Q1: if your condition is improving, do you see it improving in that order?

Prompts:

What would be an improvement from which you are at now?

If you look at the steps of improvement is there any missing step that you have experienced?

Appendix B.11: Scientific meeting-Invitation letter.

Scientific Meeting: Development And Validation Of TELER Functional Indicators For Use In Pulmonary Rehabilitation For People With Chronic Obstructive Pulmonary Disease.

Consensus meeting (Activity #1): Questionnaire For The Assessment Of The Validity Of TELER Functional Indicators For Use In Pulmonary Rehabilitation For People With COPD

Rasha Okasheh

this questionnaire consists of 6 pages (one work sheet for each TELER Function Indicator)

You have got 5 minutes for completing each evaluation sheet.

Answer the questions by ticking the appropriate box.

If you Selected (No) or (Don't know) for any of the questions, please flip the paper and answer the questions provided on the back of the sheet.

| TELER indicator #1 | Assessment of validity | Yes | No | Don't know |
|--|--|-----|----|------------|
| <p>Activity (any activity identified by the patient as a problematic activity)</p> <p>0. Unable to do the activity (gardening)</p> <p>1. Able to start the activity but cannot complete it.</p> <p>2. Able to do the activity but has to keep stopping for a rest.</p> <p>3. Able to do the activity without stopping but with a <i>slow pace</i> speed</p> <p>4. Able to do the activity without stopping for rest in an <i>optimal pace</i>*speed, but would start breathing rapidly.</p> <p>5. Able to do the activity and maintains controlled breathing.</p> <p><i>*People with COPD who were interviewed in the preliminary work tended to compare themselves to their previous functional status before the diagnosis or to other people in the community who are not disabled by COPD. Based on this knowledge optimal pace is defined as the maximal functional pace achieved by the person with available functional capacity within a certain environment.</i></p> | <p>Dose This TELER function indicator have face validity?</p> <p>Are there any codes that do not denote a clinically significant outcome, that is, an outcome that can be justified by reference to clinical or other relevant knowledge?</p> <p>Are there any codes that do not have one clinical meaning?</p> <p>Are there any codes that do not denote a clinically significant change between two successive codes, that is, a change that can be explained by reference to clinical or other relevant knowledge?</p> <p>Are there any codes that do not denote an improvement or lack of deterioration between two successive codes that requires a clinically significant amount of therapeutic input?</p> | | | |

If you have answered no or don't know for any of the above question, please answer the following questions.

It is important that you write down all your ideas and thoughts as these ideas would form the bases for the next rounds of the validation process:

Why have you answered no\ don't know?

How would you change the code to satisfy what is required by the question?

| TELER indicator #2 | Assessment of validity | Yes | No | Don't know |
|--|--|-----|----|------------|
| <p>Functional walking</p> <ol style="list-style-type: none"> 0. Unable to walk 1. Able to walk in and around the house 2. Able to walk outside the house but pace is slow 3. Able to walk outside the house with an optimal pace*, but needs to keep stopping for a rest 4. Able to walk outside the house with an optimal pace*, without stopping for a rest but unable to do another function (task) whilst walking (i.e. talking, carrying shopping) 5. Able to achieve functional walking <p><i>*People with COPD who were interviewed in the preliminary work tended to compare themselves to their previous functional status before the diagnosis or to other people in the community who are not disabled by COPD. Based on this knowledge optimal pace is defined as the maximal functional pace achieved by the person with available functional capacity within a certain environment.</i></p> | Dose This TELER function indicator have face validity? | | | |
| | Are there any codes that do not denote a clinically significant outcome, that is, an outcome that can be justified by reference to clinical or other relevant knowledge? | | | |
| | Are there any codes that do not have one clinical meaning? | | | |
| | Are there any codes that do not denote a clinically significant change between two successive codes, that is, a change that can be explained by reference to clinical or other relevant knowledge? | | | |
| | Are there any codes that do not denote an improvement or lack of deterioration between two successive codes that requires a clinically significant amount of therapeutic input? | | | |

If you have answered no or don't know for any of the above question, please answer the following questions.

It is important that you write down all your ideas and thoughts as these ideas would form the bases for the next rounds of the validation process:

Why have you answered no\ don't know?

How would you change the code to satisfy what is required by the question?

| TELER indicator #3 | Assessment of validity | Yes | No | Don't know |
|---|--|-----|----|------------|
| <p>Hill walking and talking</p> <p>0. Unable to walk uphill</p> <p>1. Able to walk a few steps uphill but gets breathless and stops</p> <p>2. Able to walk uphill with a slow pace and needs to keep stopping for a rest</p> <p>3. Able to walk uphill with an optimal pace* but has to keep stopping for a rest</p> <p>4. Able to walk uphill with an optimal pace without stopping for a rest</p> <p>5. Able to do hill walking and talking</p> <p><small>*People with COPD who were interviewed in the preliminary work tended to compare themselves to their previous functional status before the diagnosis or to other people in the community who are not disabled by COPD. Based on this knowledge optimal pace is defined as the maximal functional pace achieved by the person with available functional capacity within a certain environment.</small></p> | <p>Dose This TELER function indicator have face validity?</p> <p>Are there any codes that do not denote a clinically significant outcome, that is, an outcome that can be justified by reference to clinical or other relevant knowledge?</p> <p>Are there any codes that do not have one clinical meaning?</p> <p>Are there any codes that do not denote a clinically significant change between two successive codes, that is, a change that can be explained by reference to clinical or other relevant knowledge?</p> <p>Are there any codes that do not denote an improvement or lack of deterioration between two successive codes that requires a clinically significant amount of therapeutic input?</p> | | | |

If you have answered no or don't know for any of the above question, please answer the following questions.

It is important that you write down all your ideas and thoughts as these ideas would form the bases for the next rounds of the validation process:

Why have you answered no\ don't know?

How would you change the code to satisfy what is required by the question?

| TELER indicator #4 | Assessment of validity | Yes | No | Don't know |
|---|--|-----|----|------------|
| Dressing (putting shoes on) 0. Unable to put shoes on 1. Able to bend forward with <i>back straight</i> and <i>touch a table</i> in front 2. Able to bend forward and <i>touch feet distance</i> but <i>unable to maintain time</i> it 3. Able to bend forward touch feet and maintain position 4. Able to bend forward put on shoes but has to rest before completing the task. 5. Able to put shoes on | Dose This TELER function indicator have face validity? | | | |
| | Are there any codes that do not denote a clinically significant outcome, that is, an outcome that can be justified by reference to clinical or other relevant knowledge? | | | |
| | Are there any codes that do not have one clinical meaning? | | | |
| | Are there any codes that do not denote a clinically significant change between two successive codes, that is, a change that can be explained by reference to clinical or other relevant knowledge? | | | |
| | Are there any codes that do not denote an improvement or lack of deterioration between two successive codes that requires a clinically significant amount of therapeutic input? | | | |

If you have answered no or don't know for any of the above question, please answer the following questions.

It is important that you write down all your ideas and thoughts as these ideas would form the bases for the next rounds of the validation process:

Why have you answered no\ don't know?

How would you change the code to satisfy what is required by the question?

| TELER indicator #5 | Assessment of validity | Yes | No | Don't know |
|---|--|-----|----|------------|
| <p>Going upstairs</p> <p>0. Unable to go upstairs</p> <p>1. Able to take a <i>few steps distance</i> upstairs but gets breathless and <i>stops</i></p> <p>2. Able to walk upstairs but it is very <i>slow</i> and has to keep <i>stopping</i> for a rest</p> <p>3. Able to walk upstairs with a <i>optimal pace* speed</i> but has to keep stopping for a <i>rest</i></p> <p>4. Able to walk stairs with a <i>optimal pace* without stopping</i> for a rest</p> <p>5. Able to do walk up stairs and talk</p> <p><small>*People with COPD who were interviewed in the preliminary work tended to compare themselves to their previous functional status before the diagnosis or to other people in the community who are not disabled by COPD. Based on this knowledge optimal pace is defined as the maximal functional pace achieved by the person with available functional capacity within a certain environment.</small></p> | <p>Dose This TELER function indicator have face validity?</p> <p>Are there any codes that do not denote a clinically significant outcome, that is, an outcome that can be justified by reference to clinical or other relevant knowledge?</p> <p>Are there any codes that do not have one clinical meaning?</p> <p>Are there any codes that do not denote a clinically significant change between two successive codes, that is, a change that can be explained by reference to clinical or other relevant knowledge?</p> <p>Are there any codes that do not denote an improvement or lack of deterioration between two successive codes that requires a clinically significant amount of therapeutic input?</p> | | | |

If you have answered no or don't know for any of the above question, please answer the following questions.

It is important that you write down all your ideas and thoughts as these ideas would form the bases for the next rounds of the validation process:

Why have you answered no\ don't know?

How would you change the code to satisfy what is required by the question?

| TELER indicator #6 | Assessment of validity | Yes | No | Don't know |
|--|--|-----|----|------------|
| Showering 0. Unable to shower 1. Able to wash head and body in sitting but unable dry self 2. Able to wash my head and body while sitting and dry self 3. Able to wash my head and body while standing but unable to dry self 4. Able to shower and dry self, but feels exhausted 5. Able to shower | Dose This TELER function indicator have face validity? | | | |
| | Are there any codes that do not denote a clinically significant outcome, that is, an outcome that can be justified by reference to clinical or other relevant knowledge? | | | |
| | Are there any codes that do not have one clinical meaning? | | | |
| | Are there any codes that do not denote a clinically significant change between two successive codes, that is, a change that can be explained by reference to clinical or other relevant knowledge? | | | |
| | Are there any codes that do not denote an improvement or lack of deterioration between two successive codes that requires a clinically significant amount of therapeutic input? | | | |

It is important that you write down all your ideas and thoughts as these ideas would form the bases for the next rounds of the validation process:

Why have you answered no\ don't know?

How would you change the code to satisfy what is required by the question?

Invitation to a scientific meeting:

Pulmonary Rehabilitation performance indicators for COPD

We have the pleasure of inviting you to participate in a scientific meeting on the *"Development and validation of TELER functional performance indicators for use in Pulmonary Rehabilitation for people with Chronic Obstructive Pulmonary Disease"*.

The meeting will take place on the 2nd of March 2010 at Sheffield Hallam University, Sheffield.

Aim of the meeting

The objective of the scientific meeting is to obtain expert validation of a newly developed measurement tool that measures functional activities following pulmonary rehabilitation. We are inviting academics and clinicians to participate from local and national organizations. Participants will be experts in measurement, respiratory physiotherapy, pulmonary rehabilitation, or the TELER method of measurement.

Meeting plan

We are aiming to make the day interesting and useful to you as well as informative to us.

The day will consist of three parts.

1. A presentation of the protocol by which the TELER function indicators were developed.
2. An introduction to the TELER method of measurement.
3. A structured discussion to generate consensus on the TELER function indicators. These indicators will then be tested in clinical practice at Rotherham Breathing Space.

If you would like to participate in this meeting we would be grateful if you could respond as soon as possible to Rasha (R.O.Okasheh@shu.ac.uk). Her full contact details are bellow.

We look forward to hearing from you soon.

Yours sincerely,

Rasha Okasheh

PhD student/Health and Wellbeing

Health and Social Care Research Centre

Sheffield Hallam University

Collegiate Hall/ 31 Collegiate Crescent

R.O.Okasheh@shu.ac.uk

Tel: 0114 225 5898

Professor Sue Mawson

Director NIHR CLAHRC for South Yorkshire.

Susan.mawson@sth.nhs.uk

Professor of Rehabilitation

Centre for Health and Social Care

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+44 (0)114-2255675

+44 (0)114-2255377

Appendix B.12: A questionnaire for the assessment of the validity of the TELER “function” indicators.

Appendix C: Phase 3 “Clinical testing”

- Appendix C.1: A list of the instruments used for routine clinical assessment.
- Appendix C.2: Ethics approval-Clinical testing
- Appendix C.3: Participant information sheet-Clinical testing.
- Appendix C.4: Consent form-Clinical testing.
- Appendix C.5: The probability distribution of both CAT and TELER.
- Appendix C.6: The TELER form / Patient MH.
- Appendix C.7: Qualitative analysis of factors influencing activity/Patient MH.
- Appendix C.8: Analysis tables and graphs – Clinical testing.

Appendix C.1: A list of the instruments used for routine clinical assessment.

Table 10 Pre and post PR data on routine assessment tools

| | ISWT (meters) | | CAT | | CRQ DYS | | CRQ FAT | | CRQ Emotion | | CRQ Mastry | | HAD Anxiety | | HAD Depression | | MRC | |
|----|------------------|------|-----|------|---------|------|---------|------|-------------|------|------------|------|-------------|------|----------------|------|-----|------|
| | Pre | Post | Pre | Post | Pre | Post | Pre | Post | Pre | Post | Pre | Post | Pre | Post | Pre | Post | Pre | Post |
| 1 | 120 | 200 | 21 | 25 | 2.40 | 2.00 | 1.75 | 1.75 | 4.51 | 4.51 | 4.50 | 6.00 | 3 | 4 | 5 | 6 | 4 | 4 |
| 2 | 520 | 590 | 13 | | 3.00 | | 4.00 | | 5.43 | | 6.50 | | 0 | | 4 | | 3 | 3 |
| 3 | 190 | 330 | 24 | 15 | 3.20 | 3.20 | 4.75 | 6.00 | 4.14 | 5.43 | 6.25 | 7.00 | 5 | 2 | 3 | 1 | 3 | |
| 4 | 270 | 330 | 20 | 15 | 3.60 | 4.60 | 4.25 | 5.25 | 4.43 | 5.57 | 4.75 | 5.50 | 10 | 6 | 8 | 5 | 3 | 3 |
| 5 | 260 | 360 | 25 | 24 | 2.40 | 3.60 | 2.75 | 4.50 | 2.86 | 4.29 | 3.25 | 4.50 | 13 | 8 | 10 | 9 | 3 | 3 |
| 6 | 70 | 120 | 40 | 39 | 1.20 | 1.20 | 1.50 | 2.25 | 1.14 | 1.00 | 1.00 | 2.00 | 21 | 21 | 16 | 21 | 4 | 4 |
| 7 | 260 | 230 | 23 | 6 | 2.00 | 1.00 | 2.75 | 4.00 | 3.57 | 5.00 | 2.25 | 4.00 | 9 | 8 | 7 | 6 | 4 | 4 |
| 8 | 70 | | 28 | | 3.60 | | 4.00 | | 5.71 | | 4.25 | | 5.00 | | 13 | | 4 | |
| 9 | 210 | 250 | 25 | 23 | 4.00 | 1.80 | 1.75 | 2.50 | 5.29 | 4.86 | 6.75 | 6.75 | 3 | 5 | 7 | 8 | 4 | 4 |
| 10 | 210 | 250 | 27 | 31 | 2.20 | 1.80 | 2.75 | 3.75 | 2.71 | 2.86 | 2.75 | 3.25 | 7 | 10 | 7 | 10 | 5 | 5 |

Appendix C.2: Ethics approval-Clinical testing

12.0710
Mrs Ohasheh
Apartment 14
Lindley Hieghts
2 Lindley Place
Sheffield
S5 6UX

RFT Ref: - 00250 *Please quote this number on all correspondence*
REC Ref No :10/H1310/37

Dear Mrs Okasheh

Re: Usefulness of TELEH in evaluating pulmonary rehabilitation

The Research and Development department has completed the governance appraisal for the above study.

Documents reviewed

| Document | Version | Date |
|-----------------------|---------|---------------|
| Rec application | | 12 May 2010 |
| Protocol | 2.5 | 15 June 2010 |
| Investigator CV | | 12 April 2010 |
| Consent form | | 15 June 2010 |
| Information sheet | | 15 June 2010 |
| Self management diary | | 12 May 2010 |

On behalf of the Research & Development Lead, Jo Abbott, I am writing to confirm that your research proposal has been approved on the understanding and provision that you will adhere to the following conditions:-

That the research should:

- Be conducted in accordance with ICH GCP guidelines and that you and your team are familiar with issues of informed consent within research having completed the 'Good Clinical Practice' training within the last 2 years
- Comply with the requirements of the Research Governance Framework for Health and Social Care (2nd DH 2005)
- Comply with regulatory requirements and legislation relating to: clinical Trials, Data Protection, Health & Safety, Trust Caldicott Guidelines and the use of Human Tissue for research purposes

You must also:

- Request written approval for any change to the approved protocol/study documents that you or the Chief Investigator wish to implement
- Ensure that all study personnel, not employed by NHS Rotherham hold either a letter an honorary contract with the Trust or a letter of access issued by the Trust, before they have access to any facilities, patients, staff, their data, tissue or organs
- You complete and return the standard progress report form on a six monthly basis from the date on this letter. This form should also be used to notify the R&D department when your research is

completed. At the point of completion, please submit your findings, any publication or presentations of your findings.

- For monitoring purposes, you should maintain an up to date site file with all relevant information. This may be used for audit purposes in the future. Research documentation should be retained for fifteen years after the study has been completed.
- If you decide to terminate this research prematurely, you send a report to this office within 28 days indicating the reason for the early termination.
- You advise this office of any unusual or unexpected results that raise questions about the safety of the research. Also, any adverse events experienced during the course of research projects must be registered with the Trust Risk manager according to local policy.

The project must be started within 1 year of the date on this letter.

If you have any further queries do not hesitate to contact the Research office.

Yours sincerely



Angela Ross
Research Coordinator

Enc Monitoring/Progress Report Form
 Site file contents list

Rotherham Research Alliance
Research & Development, DLE91, D Level, PGME corridor

*Leads in Research & Development Miss D Patel & Jo Abbott
Research Coordinator Dr Angela Ross Direct Line 01709 307739/4177 Email angela.ross@rothgen.nhs.uk
In partnership with NHS Rotherham and Rotherham Community Health Services*



Appendix C.3: Participant information sheet-Clinical testing.



PARTICIPANT INFORMATION SHEET

Testing the usefulness and responsiveness of TELER function indicators during Pulmonary Rehabilitation “PR” in people with Chronic Obstructive Pulmonary Disease “COPD”

You are invited to participate in a research study to test a new tool for tracing improvement in functions and activities during Pulmonary Rehabilitation. Before you decide to take part in the study please take time to read the following information. If you have any questions or you want more information do not hesitate to contact me on the address provided at the end of this information sheet.

Thank you for reading this.

“What is the title of the study?”

Testing the usefulness and responsiveness of TELER function indicators during Pulmonary Rehabilitation (PR) in people with Chronic Obstructive Pulmonary Disease (COPD)

“What is the purpose of the study?”

During my PhD I have developed a new way of measuring the benefits a person may gain from attending pulmonary rehabilitation. This measures how you perform daily life activities. The measure has been developed to be used by patients themselves to help them record changes in their ability to do these activities giving them more knowledge and more control about their progression during pulmonary rehabilitation. To test this measure I would like to give it to a group of people with COPD and ask them to score themselves using a diary within their own home, and compare their scoring with the ones collected at Breathing space by the Physiotherapist.

“Why I have been asked to take part in this study?”

You have been invited to participate in the study because you were diagnosed with COPD and referred to pulmonary rehabilitation.

“Do I have to take part?”

It is up to you whether or not to take part. If you decide to take part you will be given this information sheet to keep, and you will be asked to sign a consent form. If you decide to take part you are still free to withdraw from the study at any time and without giving any reason. If you decide not to take part in the study or if you withdraw later, this will not affect the standard of care you receive from any health or social care service.

“What will happen if I want to take part?”

You will be given a consent form to sign, and the process will be explained again in details.

“How long will the study last?”

The whole study will last about 6 months. You will be asked to score yourself each week during the 6 weeks rehabilitation program.

“What will it involve?”

If you agree to participate in this study you will be asked to complete the routine assessment that is usually done with patients attending pulmonary rehabilitation. Also you will be asked to select 3 activities from a set of daily life activities and rate your performance of these activities using the new measure. After this you will be given a diary of these activities and score each activity 3 times weekly until the end of your rehabilitation program.

“Where the study will be done?”

The study will be carried out in Breathing space when you attend for your pulmonary rehabilitation session

“Will taking part cost me?”

No.

“What If I don’t wish to take part?”

It is completely up to you. There is no problem if you decide not to take part in the study and this will not affect the standard of care you receive from any health or social care services.

“What if I change my mind during the study?”

You are free to withdraw from the study at any time without giving any reason.

“What will happen to the information from the study?”

All information will be kept entirely confidential. No individual will be identifiable in the report. You will be informed of the results of the study if you wish.

“Will my taking part in the study be kept confidential?”

Yes, all the information collected about you during the study will be kept strictly confidential. You will be identified by a code number rather a name, your name will not be disclosed.

“What if there is a problem?”

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you are harmed by taking part in the study, there are no special compensation arrangements. If you wish to complain, or have any concerns about any aspect of the way you have been approached during this study, the normal National Health Service Complaints mechanisms should be available to you. You can contact Mrs. Angela Green for details or if you have internet access you can make a complaint directly using the following links:

http://www.direct.gov.uk/en/Dio11/DoItOnline/DG_4018299

<http://www.nhs.uk/service directories/pages/hospital.aspx?id=rhng&v=4>

"Who has reviewed this study?"

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your interests. This study has been reviewed by South Yorkshire Ethics Committee.

"Further information/independent advice"

The Patient advice and liaison service is available

Monday to Friday 8.30 am to

5.00pm and can be contacted

In the following ways:

By calling in to the Patient

Services Department,

Level D of the main hospital

By calling direct on 01709 307646

By calling the free phone number 0800 9531303

E-mailing: pals@rothgen.nhs.uk

Writing to:

Patient advice and liaison services

Level D

Rotherham General Hospital

Moorgate Road

Rotherham

S60 2UD

“What if I have further questions?”

If you have any questions now or later, please contact me at the address below:

Rasha Okasheh

PhD physiotherapy student

Sheffield Hallam University

Faculty of health and wellbeing

Collegiate Hall

Room A214

S10 2BP

E-mail: r.o.okasheh@shu.ac.uk

Appendix C.4: Consent form-Clinical testing.

CONSENT FORM

**Testing the usefulness and responsiveness of TELER function indicators during
Pulmonary Rehabilitation (PR) in people with Chronic Obstructive Pulmonary Disease
(COPD)**

Please give your consent to participating in the study by answering the following questions (please tick the boxes)

Have you read the information sheet about this study? Yes ☐ No ☐

Have you been able to ask questions about this study? Yes ☐ No ☐

Have you received answers to all your questions? Yes ☐ No ☐

Have you received enough information about this study? Yes ☐ No ☐

Are you involved in any other studies? Yes ☐ No ☐

- If you are, how many?

Do you understand that you are free to withdraw from this study?

▪ At any time? Yes ☐ No ☐

▪ Without giving a reason for withdrawing? Yes ☐ No ☐

I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

Yes ☐ No ☐

I understand that the information will be kept on paper and computer database and that access will be restricted to the researchers. Yes ☐ No ☐

I agree to take part in this study? Yes ☐ No ☐

Your signature will clarify that you have had adequate opportunity to discuss the study with the researcher and have voluntarily decided to take part in this study.

Please keep your copy of this form and the information sheet together.

Name of participant

Date

Signature

.....

.....

.....

Name of researcher

Date

Signature

.....

Appendix C.5: The probability distribution of both CAT and TELER.

Add picture to library

Slide Show

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| <div>Add picture to library</div> <div>Slide Show</div> | | Contact: | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | | | |
| <div>Check warnings?</div> <div>See comment page</div> <div>Treatments:</div> <div>Assessment</div> <div>Information giving</div> | | Date: | 19-Aug-10 | 23-Aug-10 | 26-Aug-10 | 2-Sep-10 | 6-Sep-10 | 9-Sep-10 | 13-Sep-10 | 17-Sep-10 | 20-Sep-10 | 23-Sep-10 | 27-Sep-10 | 30-Sep-10 | 14-Oct-10 | | | |
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| <div>Show indicator details</div> | | Status: | | | | | | | | | | | | | | | | |
| Indicators: | | Expected: | | | | | | | | | | | | | | | | |
| Standard number of indicators: | | 25 | | | | | | | | | | | | | | | | |
| Add Indicator? Enter expected outcome: | | | | | | | | | | | | | | | | | | |
| Drop Indicator? Enter expected outcome: | | | | | | | | | | | | | | | | | | |
| activity (driving) | | 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | | | |
| Functional walking | | 5 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 2 | 2 | 3 | 3 | 2 | 3 | | | |
| lope walking and talking | | 5 | 0 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | | | |
| ending to do an activity | | 5 | 2 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | | | |
| going upstairs | | 5 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 1 | 1 | 2 | 2 | 4 | 4 | | | |
| howering | | 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | |
| total number of missing codes | | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| estimated total for missing codes | | | | | | | | | | | | | | | | | | |
| xpected outcome score | | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | | | |
| otal score for visit | | | 4 | 8 | 8 | 8 | 8 | 10 | 10 | 10 | 10 | 13 | 13 | 13 | 14 | | | |
| ase score | | | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | | | |
| umber of active indicators | | | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | | | |
| performance Index | | | 13 | 27 | 27 | 27 | 33 | 37 | 33 | 33 | 33 | 43 | 43 | 43 | 47 | | | |
| hange Index | | | 0 | 15 | 15 | 15 | 23 | 27 | 23 | 23 | 23 | 35 | 35 | 35 | 38 | | | |
| aintenance Index | | | 0 | 100 | 100 | 100 | 100 | 100 | 75 | 60 | 60 | 69 | 69 | 53 | 56 | | | |

| Probability distribution | | | | |
|--------------------------|--------------------|-------------|------------------------|----------------------|
| Total | Number of profiles | Prob(Total) | Cumulative Prob(Total) | TELER indicator code |
| 0 | 1 | 5.96586E-07 | 5.96586E-07 | 5 |
| 1 | 8 | 4.77269E-06 | 5.36927E-06 | |
| 2 | 36 | 2.14771E-05 | 2.68464E-05 | |
| 3 | 120 | 7.15903E-05 | 9.84367E-05 | |
| (4) | 330 | 0.000196873 | 0.000295310 | |
| 5 | 792 | 0.000472496 | 0.000767806 | |
| 6 | 1,780 | 0.001061923 | 0.001829730 | |
| 7 | 3,368 | 0.002009302 | 0.003839032 | |
| 8 | 6,147 | 0.003667215 | 0.007506246 | |
| 9 | 10,480 | 0.006252222 | 0.013758469 | |
| 10 | 16,808 | 0.010027419 | 0.023785888 | |
| 11 | 25,488 | 0.015205786 | 0.038991674 | 4 |
| 12 | 36,688 | 0.021887551 | 0.060879225 | |
| (13) | 50,288 | 0.030001122 | 0.090880346 | |
| 14 | 65,808 | 0.039260138 | 0.130140484 | |
| 15 | 82,384 | 0.049149149 | 0.179289633 | |
| 16 | 98,813 | 0.058950462 | 0.238240095 | 3 |
| 17 | 112,008 | 0.066822415 | 0.305062510 | |
| 18 | 125,588 | 0.074924055 | 0.379986565 | |
| 19 | 133,288 | 0.079517768 | 0.459504332 | |
| (20) | 135,758 | 0.080991335 | 0.459504332 | |
| 21 | 133,288 | 0.079517768 | 0.459504332 | |
| 22 | 125,588 | 0.074924055 | 0.379986565 | |
| 23 | 112,008 | 0.066822415 | 0.305062510 | |
| 24 | 98,813 | 0.058950462 | 0.238240095 | |
| 25 | 82,384 | 0.049149149 | 0.179289633 | 2 |
| 26 | 65,808 | 0.039260138 | 0.130140484 | |
| 27 | 50,288 | 0.030001122 | 0.090880346 | |
| 28 | 36,688 | 0.021887551 | 0.060879225 | |
| 29 | 25,488 | 0.015205786 | 0.038991674 | |
| 30 | 16,808 | 0.010027419 | 0.023785888 | 1 |
| 31 | 10,480 | 0.006252222 | 0.013758469 | |
| 32 | 6,147 | 0.003667215 | 0.007506246 | |
| 33 | 3,368 | 0.002009302 | 0.003839032 | |
| 34 | 1,780 | 0.001061923 | 0.001829730 | |
| 35 | 792 | 0.000472496 | 0.000767806 | |
| 36 | 330 | 0.000196873 | 0.000295310 | |
| 37 | 120 | 7.15903E-05 | 9.84367E-05 | |
| 38 | 36 | 2.14771E-05 | 2.68464E-05 | |
| 39 | 8 | 4.77269E-06 | 5.36927E-06 | |
| 40 | 1 | 5.96586E-07 | 5.96586E-07 | |
| Total | 1,676,204 | 1.000000000 | | |

Probability that a score on each of the eight symptoms is marked at random:

- $(1 \div 6)^8 = 5.95374E-07$; alternatively
- $1 \div 1,676,204 = 5.96586E-07$
 - Error = +0.002036 or +0.2036%; alternatively
 - Rounding error in $(1 \div 6)^8 = -0.2033\%$

Appendix C.6: The TELER form / Patient MH.

Appendix C.7: Qualitative analysis of factors influencing activity/Patient MH.

Table 11 qualitative analysis of patient's response on TELER "function" indicators

| TELER "function" indicator | Factors influencing activity | Reasons provided for being on score 2 on the first assessment | Reasons provided for changed score |
|----------------------------|--|--|--|
| Bending to do an activity | Aging | Wife: he is quite old, old and weak if he bends he might get dizzy or... I don't know it is safer if I do it for him. | |
| | Symptoms Impact Severity Type | patient: if I'm feeling well and not coughing then I might be able to control my breath, as they told us control your breath don't hold it but control it. | |
| | recognizing limits | Carer: I don't know it is safer if I do it for him. patient: well yeah maybe I could do it | |
| | confidence | | (23-Aug-2010) I think I know how to control my breathing now, beside it was just that I haven't do it before, I've tried it and I could do it. |

| | | | | |
|--------------------|---------------------|--|--|--|
| | Education | | | I think I know how to control my breathing now |
| Driving | Symptoms | | It is my cough, well I do not cough all the time but if started then I can't...It's horrible it does not stop and I'm scared I might lose control, and you know it driving it could be very dangerous if you can't control it. | (23-Sep-2010) Well I'm feeling better my cough is easier, so I think I might be able to tackle it not sure I could do it all way though. |
| | Impact | | | |
| | Severity | | | |
| | Type | | | |
| Functional walking | Confidence | | I'm scared I might lose control | (30-Sep-2010) it's meaningless if I couldn't do it all the way them why bother, |
| | Support from others | | | (30-Sep-2010) my wife could do it anyway, so I do not have to. |
| | Symptoms: | | | (13-sep-2010) my chest is feeling rough |
| | Impact | | | |
| | Weather | | | (13-sep-2010)The weather is changing, it is getting colder, and windy I can't do with the wind it makes me ill. |

| | | | |
|----------------|---------------------|--|---|
| Going upstairs | Symptoms: Impact | | <p>(17-sep-2010)Well, I don't think it my chest I think I'm feeling weak a bit it feels like a big job going all the way up.</p> <p>(30-sep-2010) I feel stronger my muscles are strong now and I could do it all the way upstairs of course I need to stop but this does not putt me off doing it, I do it . I hold on the rail but I do it. Being breathless does not stop form going upstairs it is when I feel weak that I could not do it if I'm too tired to go up I stay down or don't leave my room in the morinig I stay up there.</p> |
| Going upstairs | Weather | | <p>(30-sep-2010)Going upstairs has nothing to do with the weather it's not windy inside (Laughing).</p> |

Appendix C.8: Analysis tables and graphs – Clinical testing.

- Analysis at the level of the patient- the significance of a number of improvements/deteriorations on a TELER indicator by code on admission and code on discharge: Table 12 to 19.
- Analysis at the level of the group – the outcome of care /efficiency of care: Table 20-22.
- Analysis at the level of the group –the quality of care: Table 23- 30.

Table 12 Patient AW

| Code on discharge | Code on admission | | | | |
|-------------------|-------------------|---|---|---|---|
| | 0 | 1 | 2 | 3 | 4 |
| 0 | | | | | |
| 1 | | | | | |
| 2 | | | | | |
| 3 | | | 2 | | |
| 4 | | | | | 2 |
| 5 | | | | | |

Table 13 Patient DP

| Code on discharge | Code on admission | | | | |
|-------------------|-------------------|---|---|---|---|
| | 0 | 1 | 2 | 3 | 4 |
| 0 | | | | | |
| 1 | | | | | |
| 2 | | | 1 | | |
| 3 | | | 1 | 1 | |
| 4 | | | | | |
| 5 | | | | | 1 |

Table 14 Patient JT

| Code on discharge | Code on admission | | | | |
|-------------------|-------------------|---|---|---|---|
| | 0 | 1 | 2 | 3 | 4 |
| 0 | | | | | |
| 1 | | | | | |
| 2 | | | | | |
| 3 | | | 1 | | |
| 4 | | | | 1 | |
| 5 | | | | 1 | 1 |

Table 15 Patient JF

| Code on discharge | Code on admission | | | | |
|-------------------|-------------------|---|---|---|---|
| | 0 | 1 | 2 | 3 | 4 |
| 0 | | | | | |
| 1 | | | | | |
| 2 | | | | | |
| 3 | | 1 | 1 | | |
| 4 | | | 1 | 1 | |
| 5 | | | | | 2 |

Table 16 Patient MB

| Code on discharge | Code on admission | | | | |
|-------------------|-------------------|---|---|---|---|
| | 0 | 1 | 2 | 3 | 4 |
| 0 | | | | | |
| 1 | | 1 | | | |
| 2 | | | 1 | | |
| 3 | | 1 | | | |
| 4 | | 1 | | | |
| 5 | | | | | |

Table 17 Patient MP

| Code on discharge | Code on admission | | | | |
|-------------------|-------------------|---|---|---|---|
| | 0 | 1 | 2 | 3 | 4 |
| 0 | | | | | |
| 1 | | | | | |
| 2 | | 1 | 1 | | |
| 3 | | | 1 | 1 | |
| 4 | | | | | |
| 5 | | | | | |

Table 18 Patient NS

| Code on discharge | Code on admission | | | | |
|-------------------|-------------------|---|---|---|---|
| | 0 | 1 | 2 | 3 | 4 |
| 0 | | | | | |
| 1 | | | | | |
| 2 | | | | | |
| 3 | | | | 1 | 1 |
| 4 | | | | 1 | |
| 5 | | | | | 1 |

Table 19 Patient TB

| Code on discharge | Code on admission | | | | |
|-------------------|-------------------|---|---|---|---|
| | 0 | 1 | 2 | 3 | 4 |
| 0 | | | | | |
| 1 | | | | | |
| 2 | | 1 | 2 | | |
| 3 | | | | 1 | |
| 4 | | | | | 2 |
| 5 | | | | | |

Table 20 Number of patients by the number of clinically significant improvements at the end of treatment

| Clinically significant improvements (x) | Tally | Number of patients (f) | Total number of improvements (x.f) |
|---|-------|------------------------|------------------------------------|
| 0 | | | |
| 1 | | 1 | 1 |
| 2 | | 3 | 6 |
| 3 | | | |
| 4 | | 1 | 4 |
| 5 | | 2 | 10 |
| 6 | | 1 | 6 |
| 7 | | | |
| 8 | | 1 | 8 |
| 9 | | | |
| 10 | | 1 | 10 |
| Total | | 10 | 45 |

Table 21 Number of patients by the number of treatment

| Treatment contacts | Patients | | Total contacts (x.f) |
|--|-------------------|------------|----------------------|
| | Tally | Number (f) | |
| 1 to 5 | | | |
| 6 to 10 | 8 | 1 | 8 |
| 11 to 15 | 12,12,12,13,13,13 | 7 | 87 |
| 16 to 20 | 16, 17 | 2 | 33 |
| Total | | 10(n) | 128(N) |
| Average number of treatment contacts per patient: $N \div n =$ | | | 12.8 |

of treatment contact at the end of

Table 22 Quality of treatment by number of contacts

| Quality of treatment | Tally number of contacts | Average number of contacts |
|----------------------|--------------------------|----------------------------|
| Good | 12 12 | 12 |
| Satisfactory | 16 8 12 12 13 | 12.2 |
| Poor | 13 17 13 | 14.3 |
| Total | 128 | |

Table 23 number of patients by effectiveness index on

| Effectiveness index on discharge | Tally | Number of patients |
|----------------------------------|----------|--------------------|
| Low | 0 to 9 | |
| | 10 to 19 | |
| | 20 to 29 | |
| | 30 to 39 | |
| | 40 to 49 | |
| Moderate | 50 to 59 | 3 |
| | 60 to 69 | 2 |
| | 70 to 79 | 3 |
| High | 80 to 89 | 1 |
| | 90 to 99 | 1 |
| | 100 | 100 |
| Total | | 10 |

discharge

Table 24 Number of patients by maintenance index on

| Maintenance index on discharge | | Tally | Number of patients |
|--------------------------------|-----------|-------|--------------------|
| Unstable | 1 to 10 | | 1 |
| | 11 to 20 | | 2 |
| | 21 to 30 | | |
| Marginally unstable | 31 to 40 | | 2 |
| | 41 to 50 | | 2 |
| | 51 to 60 | | 1 |
| Stable | 61 to 70 | | 1 |
| | 71 to 80 | | |
| | 81 to 90 | | |
| | 91 to 100 | | 1 |
| | Total | | 10 |

discharge

Table 25 Number of patient by health change

| Health change index on discharge | Tally | Number of patients |
|-------------------------------------|----------|--------------------|
| Low | 0 to 9 | 10 |
| | 10 to 19 | |
| | 20 to 29 | |
| | 30 to 39 | |
| | 40 to 49 | |
| Moderate | 50 to 59 | |
| | 60 to 69 | |
| | 70 to 79 | |
| High | 80 to 89 | |
| | 90 to 99 | |
| | 100 | |
| Total | | 10 |

index on discharge

Table 26 Performance index on admission versus maintenance index on discharge

| Performance index on admission | Maintenance index on discharge | | | | | | | | | | | | | |
|--------------------------------|--------------------------------|----|----------|----|----------|----|----------|----|----------|----|----------|----|----------|----|
| | 1 to 10 | | 11 to 20 | | 21 to 30 | | 31 to 40 | | 41 to 50 | | 51 to 60 | | 61 to 70 | |
| | Tally | No | Tally | No | Tally | No | Tally | No | Tally | No | Tally | No | Tally | No |
| 0 to 9 | | | | | | | | | | | | | | |
| 10 to 19 | | | | | | | | | | | | | | |
| 20 to 29 | | | | | | | 1 | 1 | | | 1 | 1 | | |
| 30 to 39 | | | | | | | | | | | | | | |
| 40 to 49 | 1 | 1 | | | | | | | | | | | | |
| 50 to 59 | 1 | 1 | 1 | 1 | | | | | | | 1 | 1 | | |
| 60 to 69 | | | | | | | | 11 | 2 | | | | | |
| 70 to 79 | | | | | | | 1 | 1 | | | | | 1 | 1 |
| 80 to 89 | | | | | | | | | | | | | | |
| 90 to 99 | | | | | | | | | | | | | | |
| 100 | | | | | | | | | | | | | | |
| Total | | 2 | | 1 | | | | 2 | 2 | | 1 | 1 | | 1 |
| | | | | | | | | | | | | | | 10 |

| Performance index on | Effectiveness index on discharge |
|----------------------|----------------------------------|
|----------------------|----------------------------------|

Table 27 Performance index on admission versus effectiveness index on discharge

| | 0 to 9 | | 10 to 19 | | 29 to 29 | | 30 to 39 | | 40 to 49 | | 50 to 59 | | 60 to 69 | | 70 to 79 | | 80 to 89 | | 90 to 91 | | 100 | | Total |
|-------------|--------|----|----------|----|----------|----|----------|----|----------|----|----------|----|----------|----|----------|----|----------|----|----------|----|-------|----|-------|
| | Tally | No | Tally | No | Tally | No | Tally | No | Tally | No | Tally | No | Tally | No | Tally | No | Tally | No | Tally | No | Tally | No | |
| 0 to 9 | | | | | | | | | | | | | | | | | | | | | | | |
| Performance | | | | | | | | | | | | | | | | | | | | | | | |
| 10 to 19 | | | | | | | | | | | | | | | | | | | | | | | |
| 20 to 29 | | | | | | | | | | | | | | | | | | | | | | | |
| 30 to 39 | | | | | | | | | | | | | | | | | | | | | | | |
| 40 to 49 | | | | | | | | | | | | | | | | | | | | | | | |
| 50 to 59 | | | | | | | | | | | | | | | | | | | | | | | |
| 60 to 69 | | | | | | | | | | | | | | | | | | | | | | | |
| 70 to 79 | | | | | | | | | | | | | | | | | | | | | | | |
| 80 to 89 | | | | | | | | | | | | | | | | | | | | | | | |
| 90 to 99 | | | | | | | | | | | | | | | | | | | | | | | |
| 100 | | | | | | | | | | | | | | | | | | | | | | | |
| Total | | | | | | | | | | | | | | | | | | | | | | | |

Table 28 Performance index on admission versus performance index on discharge

| index on admission | 0 to 9 | | 10 to 19 | | 29 to 29 | | 30 to 39 | | 40 to 49 | | 50 to 59 | | 60 to 69 | | 70 to 79 | | 80 to 89 | | 90 to 91 | | 100 | | Total |
|--------------------|--------|----|----------|----|----------|----|----------|----|----------|----|----------|----|----------|----|----------|----|----------|----|----------|----|-------|----|-------|
| | Tally | No | Tally | No | Tally | No | Tally | No | Tally | No | Tally | No | Tally | No | Tally | No | Tally | No | Tally | No | Tally | No | |
| Health status | | | | | | | | | | | | | | | | | | | | | | | |
| 0 to 9 | | | | | | | | | | | | | | | | | | | | | | | |
| 10 to 19 | | | | | | | | | | | | | | | | | | | | | | | |
| 20 to 29 | | | | | | | | | 1 | 1 | | 1 | | | | | | | | | | | 2 |
| 30 to 39 | | | | | | | | | | | | | | | | | | | | | | | |
| 40 to 49 | | | | | | | | | | | 1 | 1 | | | | | | | | | | | 1 |
| 50 to 59 | | | | | | | | | | | 1 | 1 | | | 11 | 2 | 1 | 1 | | | | | 4 |
| 60 to 69 | | | | | | | | | | | | | | | | | 1 | 1 | | | | | 1 |
| 70 to 79 | | | | | | | | | | | | | 1 | 1 | | | | | 1 | 1 | | | 2 |
| 80 to 89 | | | | | | | | | | | | | | | | | | | | | | | |
| 90 to 99 | | | | | | | | | | | | | | | | | | | | | | | |
| 100 | | | | | | | | | | | | | | | | | | | | | | | |
| Total | | | | | | | | | 1 | | 3 | 1 | | 1 | 2 | 2 | 2 | | 1 | | | | 10 |

Table 29 Health status index on admission versus health status index on discharge

| index on admission | 0 to 9 | | 10 to 19 | | 20 to 29 | | 30 to 39 | | 40 to 49 | | 50 to 59 | | 60 to 69 | | 70 to 79 | | 80 to 89 | | 90 to 99 | | 100 | | Total |
|--------------------|--------|----|----------|----|----------|----|----------|----|----------|----|----------|----|----------|----|----------|----|----------|----|----------|----|-------|----|-------|
| | Tally | No | Tally | No | Tally | No | Tally | No | Tally | No | Tally | No | Tally | No | Tally | No | Tally | No | Tally | No | Tally | No | |
| 0 to 9 | | | | | | | | | | | | | | | | | | | | | | | |
| 10 to 19 | | | | | | | | | | | | | | | | | | | | | | | |
| 20 to 29 | | | | | | | | | | | | | | | | | | | | | | | |
| 30 to 39 | | | | | | | | | | | | | | | | | | | | | | | |
| 40 to 49 | | | | | | | | | | | | | | | | | | | | | | | |
| 50 to 59 | | | | | | | | | | | | | | | | | | | | | | | |
| 60 to 69 | | | | | | | | | | | | | | | | | | | | | | | |
| 70 to 79 | | | | | | | | | | | | | | | | | I | 1 | | | | | 1 |
| 80 to 89 | | | | | | | | | | | | | | | | | | | III | 3 | | | 3 |
| 90 to 99 | | | | | | | | | | | | | | | | | | | IIIIII | 6 | | | 6 |
| 100 | | | | | | | | | | | | | | | | | | | | | | | |
| Total | | | | | | | | | | | | | | | | | 1 | | 9 | | | | 10 |

Table 30 Health status index on admission versus health change index on discharge

| Health status index on admission | Health change index on discharge | | | | | | | | | | | | | |
|----------------------------------|----------------------------------|----|----------|----|----------|----|----------|----|----------|----|----------|----|----------|----|
| | 0 to 9 | | 10 to 19 | | 20 to 29 | | 30 to 39 | | 40 to 49 | | 50 to 59 | | 60 to 69 | |
| | Tally | No | Tally | No | Tally | No | Tally | No | Tally | No | Tally | No | Tally | No |
| 0 to 9 | | | | | | | | | | | | | | |
| 10 to 19 | | | | | | | | | | | | | | |
| 20 to 29 | | | | | | | | | | | | | | |
| 30 to 39 | | | | | | | | | | | | | | |
| 40 to 49 | | | | | | | | | | | | | | |
| 50 to 59 | | | | | | | | | | | | | | |
| 60 to 69 | | | | | | | | | | | | | | |
| 70 to 79 | I | 1 | | | | | | | | | | | | 1 |
| 80 to 89 | III | 3 | | | | | | | | | | | | 3 |
| 90 to 99 | IIIIII | 6 | | | | | | | | | | | | 6 |
| 100 | | | | | | | | | | | | | | |
| Total | | 10 | | | | | | | | | | | | 10 |

Appendix D: Overall discussion

- Appendix D.1: Poster presentation.
- Appendix D.2: Journal publication plan.

Appendix D.2: Journal publication plan

| Title | Authors | Journal | Proposed submission date |
|--|--|---|--------------------------|
| Measurement of functional outcomes in clinical PR settings: A critical review of the literature | Rasha Okasheh, Sue Mawson | Informa Health care: Journal of Chronic Obstructive Pulmonary Disease | August 2011 |
| A literature review "measurement of functioning in people with COPD: A review of existing outcome measures". | Rasha Okasheh, Sue Mawson | Informa Health care: Journal of Chronic Obstructive Pulmonary Disease | September 2011 |
| Development and validation of TELER "function" indicators 1: A qualitative study "patient set goals of pulmonary rehabilitation: perspectives on functional activities of daily living". | R. Okasheh, Angela Tod, Sue Mawson | Journal of Cardiopulmonary Rehabilitation and Prevention | October 2011 |
| Development and validation of TELER function indicators 2: Service Users and Expert validation of TELER function indicators | Rasha Okasheh, Sue Mawson, Angela Tod. | Journal of Cardiopulmonary Rehabilitation and Prevention | November 2011 |
| Development and validation of TELER function indicators 3: Testing the usefulness of TELER in a PR clinical setting. | Rasha Okasheh, Sue Mawson, Angela Tod | Journal of Cardiopulmonary Rehabilitation and Prevention | November 2011 |