THE ASSESSMENT OF OUTCOME FOR MUSCULOSKELETAL SHOULDER PAIN:

A MIXED METHODS STUDY

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ABSTRACT

Evidence that patients are able to provide valid and reliable judgements about changes in their health status underpins the use of patient reported outcome measures (PROMs), which assess different aspects of physical, emotional and social functioning. However the extent to which existing validated shoulder region-specific PROMs reflect patients' perspectives is not known.

This mixed methods study set out to determine which PROMs should be used in the self-assessment of musculoskeletal shoulder pain, from the patient's perspective, using the International Classification of Functioning, Disability and Health (ICF) as a reference tool. Firstly a phenomenological approach was used to gain patients' perspectives on which outcomes should be assessed. Secondly, to facilitate comparison of the content of PROMs and the views of patients, the outcomes assessed in twelve PROMs were collated and linked to relevant categories of the ICF. Thirdly the unifying language of the ICF was used to compare the outcomes patients identified as important and PROMs.

Patients articulated personally relevant outcomes which they may use to judge treatment success. Patients expected to be symptom free, regain their former level of upper limb use, resume their usual activities, regain a sense of emotional well being resume their former family relationships and social interactions and independently manage their own shoulder condition.

The Disabilities of the Arm, Shoulder and Hand (DASH) reflected all outcomes patients considered important. Of the remainder five PROMs included three-quarters, four one half and two one quarter of important outcomes for patients.

Information that PROMs satisfactorily reflect patients' perspectives is important for researchers in the selection of relevant outcome measures for the assessment of musculoskeletal shoulder pain in clinical trials. This may in turn facilitate the pooling of data in future meta-analyses. Gaining the patient's perspective therefore may enable patients to participate in evaluating and improving the quality of their own future healthcare.

PRESENTATIONS

Norfolk & Norwich University Hospital, Bicentenary Trust: Allied Health Professions Research Prize, Norwich, February 2010

“Key outcomes for shoulder pain, from the patient's perspective”

British Elbow and Shoulder Surgeons Annual Scientific Conference: Best Presentation Prize, Oxford, March 2010

“An ICF-based comparison of the outcomes which patients consider important and the content of patient reported measures”

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“Key outcomes for shoulder pain, from the patient's perspective”

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“Key outcomes for shoulder pain, from the patient’s perspective”

“ICF-based comparison of the content of shoulder region-specific patient reported outcome measures”

“Key outcomes for shoulder pain: an ICF-based comparison of important outcomes for patients and the content of patient reported measures”

Chartered Society of Physiotherapy Annual Congress: Poster Presentations, Liverpool, October 2010

“Key outcomes for shoulder pain, from the patient’s perspective”

“Key outcomes for shoulder pain: an ICF-based comparison of important outcomes for patients and the content of patient reported measures”

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"If I have seen a little further it is by standing on the shoulders of giants"

- Isaac Newton, letter to Robert Hooke (5th February 1676)

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LIST OF ABBREVIATIONS

A&PL	Activities and participation limitation
BPS	Biopsychosocial
CI	Confidence interval
CTS	Carpal tunnel syndrome
DNA	Data not available
EBP	Evidence based practice
ES	Effect size
IBF	Impairment body function
IC	Internal consistency
ICC	Intraclass correlation coefficient
ICF	International Classification of Functioning, Disability and Health
GIR	Guyatt Index Responsiveness
HRQOL	Health-related quality of life
MCID	Minimal clinically important difference
MDC	Minimal detectable change
MED	Medical
MH	Mental health
MSK	Musculoskeletal
MSP	Musculoskeletal shoulder pain
NMSK	Neuromusculoskeletal
NRS	Numerical Rating Scale
OA	Osteoarthritis
PP	Patient's perspective; patients' perspectives
PROM	Patient reported outcome measure
PSI	Patient-specific index
RCT	Randomised controlled trial
SEM	Standard error of measurement
SD	Standard deviation
SRM	Standardised response mean
VAS	Visual analogue scale
WHO	World Health Organization

Definition construct: A construct is an abstract concept which cannot be measured directly; however it may be inferred by measuring an observable behaviour or event (Portney & Watkins 2009)

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CHAPTER ONE

INTRODUCTION

1.0 Introduction

The purpose of this chapter is to present a brief overview of the research. Firstly it will explore the evidence which currently underpins the assessment of outcome for musculoskeletal shoulder pain (MSP) to identify the research problem. Secondly it will detail the purpose of the research and define the questions which this mixed methods study set out to address. Finally it will outline how the thesis has been structured.

1.1 Morbidity of musculoskeletal shoulder pain

MSP is a common condition which has been estimated at 7% in the general population and 26% in the elderly (Chard et al. 1991; Linsell et al. 2006). Musculoskeletal (MSK) shoulder conditions are often refractory in nature and evidence suggests they are a significant cause of morbidity and disability (Chard et al. 1991; van der Windt et al. 1995; Kuijpers et al. 2006; Largacha et al. 2006; Linsell et al. 2006). This places a considerable burden on both the individual, society and the healthcare system (Bongers 2001; Bevan et al. 2009). Referral rates, for specialist opinion, are estimated between 10 and 41% during the first year following presentation and 28% at end of the third year of follow up (van der Windt et al. 1996; Solomon et al. 2001). This suggests that not all MSK shoulder conditions resolve satisfactorily with treatment (Linsell et al. 2006).

1.2 Implementation of evidence based practice for MSP

Despite extensive research the evidence on the effectiveness of common interventions for MSP is inconclusive (Green, Buchbinder & Hetrick 2003). One reason put forward is the lack of agreement on which measures should be used in the assessment of outcome for MSP (Green, Buchbinder & Hetrick 2003; Grimmer et al. 2004). This has impeded the pooling of data in systematic reviews of clinical trials which is integral to the provision of evidence-based healthcare (Green, Buchbinder & Hetrick 2003; Grimmer et al. 2004).

1.3 Importance of gaining the patient’s perspective

MSP may lead to a person’s inability to perform a wide range of different activities of daily living, work or recreation (Bongers 2001; Mitchell et al. 2005). Clinically based measures of impairment may therefore not capture all aspects of the impact of MSP on an individual (Roddey et al. 2005). Evidence suggests that patients themselves are able to provide valid and reliable judgements about changes in their functioning and health or benefits of treatment (Fitzpatrick et al. 1998; Haywood 2006). It is also suggested that gaining the views of patients on their experiences, beliefs, expectations and perceptions may improve their response to (Testa & Simonson 1996; Mancuso et al. 2002) and satisfaction with (Solomon 2001) an intervention. Therefore, when evaluating the success of an intervention for MSP it is important to include the patient's perspective.

1.4 Patient reported outcome measures for MSP

Recognition of the need to incorporate the patient's perspective into the assessment of health outcomes led to the development and validation of a large number of patient reported outcome measures (PROMs) (Fitzpatrick et al. 1998; Appleby & Devlin 2004). However, very few studies asked patients for their views on which outcomes are important to them (Terwee et al. 2007). Therefore the extent to which PROMs currently reflect important outcomes, from the patient’s perspective, is not known. However evidence suggests that it should be possible to identify one or a combination of more than one PROM, which if not a perfect match would adequately reflect the outcomes patients consider important.

PROMs use a biopsychosocial (BPS) approach to capture data on different aspects of physical, emotional and social functioning related to a MSK shoulder condition (Terwee et al. 2007). However PROMs were developed in a myriad of ways, with differing number of items contained in a variety of scales or subscales with a variety of different response options. Lack of evidence, on the extent to which validated shoulder region-specific PROMs currently reflect the same outcomes therefore presents clinicians and clinical researchers with dilemmas in their selection of one or a combination of more than one relevant PROM, which captures the intended content. Evidence suggests however it should be possible to identify a model of health and disability which may be used as a reference tool to compare the content of PROMs to address this issue.

1.5 The ICF model of disability and health

The unifying language and conceptual framework of the International Classification of Functioning, Disability and Health (ICF) (WHO 2001), which also uses a BPS approach, may be used to categories and compare the outcomes assessed in PROMs to facilitate choice between individual measures (Cieza et al. 2005). It should then be possible to use the unifying language of the ICF to compare the content of existing shoulder region-specific PROMs with the outcomes which patients with MSP identified as important to determine how adequately existing validated shoulder region-specific PROMs currently reflect patients’ perspectives. This is a key issue to investigate.

1.6 The purpose of the research

The purpose of this research project was to conduct three independent, but inter-related, consecutive studies, using a mixed methods approach, firstly to gain patients' perspectives on what outcomes should be assessed for MSP, secondly to determine what outcomes are currently assessed by validated shoulder region-specific PROMs and thirdly to determine the extent to which the outcomes that patients with MSP consider important are reflected in existing measures.

Clinicians and clinical researchers may use this information in their selection of one or a combination of more than one PROM, which are relevant and meaningful to patients, and which captures the intended content. They may then evaluate its other measurement properties to enable them to select the most suitable PROM for their different purposes (Terwee et al. 2007).

1.6.1 The overarching research question

The overarching research question posed in this study was ‘which patient reported measures should be used in the assessment of outcome for musculoskeletal shoulder pain, from the patient’s perspective’?

1.6.2 The component research questions

It was proposed that a range of questions needed to be answered to address different components of the research question, each requiring a different type of qualitative or quantitative data:

i) Which outcomes of intervention for MSP are important, from the patients' perspective?

ii) To what extent do the outcomes assessed in validated shoulder region-specific PROMs reflect the same ICF categories?

iii) To what extent are the ICF-based outcomes patients consider important reflected in the content of validated shoulder region-specific PROMs?

1.7 The structure of the thesis

Chapter two will explore the scientific evidence which underpins the use of PROMs in the management of MSP. It will provide a clear rationale, grounded in scientific evidence, for the development of the overarching research question and for those of each of the three independent, but inter-related, component studies conducted within this research.

Chapter three will then briefly outline the studies, each designed to answer a different component of the overarching research question. It will present the argument that a mixed methods approach, when used to compare the views of patients and the outcomes currently assessed in patient reported measures, provides a more complete analysis than if either qualitative or quantitative approaches were used alone.

Each of the studies will then be reported in individual, successive chapters, using appendices where appropriate for ease of reading.

Chapter four will report a phenomenological study which explored the lived experience of MSP, to identify which outcomes of intervention are considered important, from the patient's perspective.

Chapter five will describe the methods used to collate the outcomes currently assessed in validated shoulder region-specific patient reported measures, using the International Classification of Functioning, Disability and Health (ICF) as a reference tool (World Health Organization 2001). This information will be used to facilitate a comparison of the content of existing patient reported measures and the views of patients, in a subsequent study.

Chapter six will describe how the unifying language of the ICF was used to compare the outcomes that patients identified as important with the content of validated shoulder region-specific patient reported measures, to determine how adequately PROMs currently reflect patients' perspectives.

Chapter seven will firstly determine the extent to which the purpose of the research was fulfilled. It will discuss to what extent findings have moved knowledge on the assessment of outcome for MSP forwards and discuss how consistent existing evidence is with this new knowledge. It will then discuss how the findings may resonate with clinicians and clinical researchers in their selection of relevant outcomes for their different purposes in future practice and research studies. Finally it will present a short critique of the research and make recommendations for future research, grounded in the new knowledge.

Finally the conclusion will briefly summarise the main research findings and detail which psychometrically robust PROMs should be used in future clinical practice and research studies for the assessment of outcome for MSP, from the patient's perspective.

CHAPTER TWO

THE IMPORTANCE OF PATIENT REPORTED OUTCOME MEASURES IN THE EVIDENCE BASED MANAGEMENT OF MUSCULOSKELETAL SHOULDER PAIN

2.0 Introduction

The purpose of this chapter is firstly to explore the scientific evidence which underpins the use of PROMs, in the management of MSP. It will then provide a clear rationale for the development of the overarching research question and for those of each of the three independent, but inter-related, component studies to determine which PROMs should be used in the assessment of outcome for MSP, from the patient's perspective.

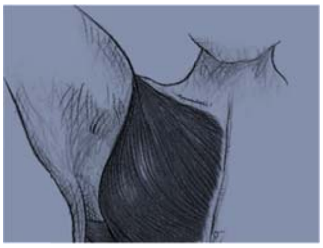


Image 2-1 (LHS)**:** Impact of shoulder pain (http://www.flickr.com/photos/anikat)
Image 2-2 (Centre)**:** Functional anatomy of the shoulder (adapted from Myers 2001)
Image 2-3 (RHS)**:** Shoulder X-ray (http://www.primalpictures.com)

2.1 Function of the shoulder

The function of the shoulder is subservient to that of the upper limb, which is to grasp and manipulate objects, play a role in communication, provide a major sensory input, support the body weight and act as a weapon and a means of transmitting force (Trew & Everett 2005). The shoulder consists of the bones, joints, muscles, tendon and ligaments of the shoulder and shoulder girdle which function in a precise, co-ordinated and timely manner to accommodate the demands of the upper limb (Peat 1986; Trew & Everett 2005).

Biomechanical considerations include balancing mobility and stability requirements. Inter-relationships between joints are critical in providing a full, functional range of movement whilst the soft tissue components maintain joint relationships, withstand forces applied to joint surfaces and stabilise the unsupported limb (Peat 1986; Donatelli 2004).

The shoulder has an extensive range of movement which is essential if the hands are to have access to all areas of the body and surrounding space during reaching and overhead activities. The position of the shoulder blade ensures the shoulder muscles are working in their stronger, middle range when the hands are performing their intricate, gross and skilled functions in the visual work space (Peat 1986; Norkin & Levangie 2005; Trew & Everett 2005). Feeding is an important function of the upper limb; internal rotation of the shoulder facilitates this activity and ensures that getting the hand to the mouth requires minimal muscle activity. As there is a limited need to have the hands behind the body, other than for a small number of toileting and dressing activities, it appears to be of little consequence that these movements utilise the end of joint and muscle range.

This arrangement works well under normal circumstances but the shoulder is susceptible to problems arising from the conflicting mobility-stability requirements of such a wide range of different functions (Donatelli 2004). Its integrity may be further compromised by overuse, injury or the ageing process (MacDermid et al. 2006); failure of normal functional movement may in turn lead to MSP (Peat 1986).

2.2 Musculoskeletal shoulder pain

MSP may be defined as pain of an inflammatory or mechanical nature, arising from pathological changes within one or more of the joints or soft tissue components of the shoulder complex (Peat 1986). Pain may lead to impairment in shoulder function, including stiffness and weakness, and impact on an individual's ability to perform daily activities, including eating, dressing and personal hygiene, work and recreation (Bongers 2001; Hayes et al. 2001; 2002; Mitchell et al. 2005).

2.3 Prevalence of musculoskeletal shoulder pain

The overall prevalence of MSP in the adult, UK population is estimated at 7% (Linsell et al. 2006), rising to 21-26% in those aged 70 years or over (Chard et al.

1991; Linsell et al. 2006). The overall prevalence rate of adults consulting their GP with MSP is 2.36% and this rate also increases with age, to 3.9% in those aged 80 years or over (Linsell et al. 2006). MSP is therefore a significant problem, particularly in the elderly.

2.4 Morbidity of musculoskeletal shoulder pain

MSP is often refractory in nature (Kuijpers et al. 2006; Largacha et al. 2006). In up to 50% of cases pain and disability may persist at 12 to 18 months (Chard et al. 1991; van der Windt et al. 1995) and of these nearly 30% will have pain at three years (Linsell et al. 2006). This suggests MSP is a significant cause of morbidity and disability.

2.5 Societal cost of musculoskeletal shoulder pain

Whilst there are no figures for MSP itself, an estimated 375,000 people in the UK are affected by non-specific work-related upper limb disorders (Bevan et al. 2009). Musculoskeletal (MSK) disorders as a whole, which affect over one million people in the UK, have a significant impact on people’s ability to work. In 2005–2006 MSK disorders were responsible for 9.5 million lost working days, the cost of which has been calculated at over £7billion a year (Bevan et al. 2009). MSK disorders, including MSP, therefore place a considerable burden on both the individual, society and the healthcare system (Bongers 2001).

2.6 Referral rates for specialist opinion

Referral rates by GPs for specialist opinion are estimated at 18% during the first three months following presentation (Linsell et al 2006). Referral rates to an Orthopaedic surgeon or Rheumatologist range between 10 and 41% during the first year following presentation, and 28% by the end of the third year of follow up (van der Windt et al. 1996; Solomon et al. 2001). This suggests that not all MSK shoulder conditions resolve satisfactorily with treatment.

2.7 Management of musculoskeletal shoulder pain

This section aims firstly to present existing evidence on the challenges of implementing evidence based practice, including those associated with conducting randomised controlled trials RCTs and to provide the justification for exploring one of the key issues i.e. that of the assessment of outcome for MSP, in this research project. Secondly this section will detail recent changes in the NHS healthcare agenda, including the priority for measuring health outcomes and provide patient-centred healthcare, to provide a rationale as to why the assessment of outcomes, especially from the patient's perspective, is important.

2.7.1 Implementation of evidence based practice

The management of MSP is a complex issue which presents challenges for clinicians and clinical researchers wishing to implement evidence based practice (EBP) (Grimmer et al. 2004). EBP may be defined as is the integration of the best research evidence with clinical expertise and patient values to inform decisions regarding clinical practice (Sackett et al. 2000). However there are significant barriers to the successful interpretation and implementation of research evidence within the clinical setting (Grimmer et al. 2004).

In the hierarchy of evidence randomised controlled trials RCTs and their meta-analyses are considered to provide the best evidence of the effectiveness of interventions (Jadad 1998; Sackett et al. 2000; Grimmer et al. 2004). Although research is extensive, the evidence on common interventions for MSP is inconclusive (Green, Buchbinder & Hetrick 2003). Whilst this suggests the need for further RCTs, their capacity to provide high quality clinically applicable evidence has been challenged (Grimmer et al. 2004). One reason put forwards is the number of methodological limitations in existing RCTs (Green, Buchbinder & Hetrick 2003). These include inadequate allocation concealment (which helps prevent selection bias), inadequate blinding of patients, clinicians or assessors (which helps prevent ascertainment bias) and small sample sizes all of which may, by systematically under or over-estimating the effect of the intervention under investigation, be key factors which limit the generalisability of research findings to clinical practice (Jadad 1998). Other issues which may reduce the external validity of research findings and therefore should be addressed when planning an RCT include the clinical relevance of the interventions investigated, the definition of the clinical diagnostic criteria and the clinical relevance of the outcome measures to all stakeholders and across all subgroups of patients with the same condition.

It is suggested therefore that it may be premature to conduct further experimental studies without first conducting lower order studies within the hierarchy of evidence that specifically explore measurement and design issues (Sackett et al. 2000; Grimmer et al. 2004). It is also proposed that the research agenda needs to address these challenges, including understanding patients' perspectives using qualitative research (Grimmer et al. 2004; Jones et al. 2006), if it is to produce better quality and more clinically relevant evidence.

Existing evidence suggests that RCTs, investigating the effectiveness of different interventions for MSP, use different types and numbers of outcome measures (Green, Buchbinder & Hetrick 2003). As there also appears to be no agreement amongst clinicians and clinical researchers, on which are the most relevant outcome measures to use in the assessment of MSP this research project will investigate this key issue.

Evidence on the criteria which clinicians and clinical researchers may use to measure treatment success in RCTs may in turn facilitate the pooling of data in future meta-analyses (Green, Buchbinder & Hetrick 2003; Grimmer et al. 2004). Whilst it is acknowledged that other problems in designing good quality RCTs would still exist, this research has the potential to make an important contribution towards the implementation of EBP for MSP in the future.

2.7.2 Changes in healthcare policy

In the 21st century a new NHS healthcare agenda has emerged to meet the challenges of providing a high quality patient-centred service, in an increasingly financially challenging environment (Department of Health 2000; 2009; Portney & Watkins 2009). All relevant stakeholders including NHS policy makers and partner organisations, commissioners, service providers, service users and the public need to know more about the relative costs, safety and clinical effectiveness of all procedures used for diagnosis, treatment and prevention (Department of Health 2008; Portney & Watkins 2009). The requirement for service providers not only to measure clinical outcomes but also the patient experience and patients' views on treatment success to validate the quality of healthcare has therefore informed the clinical research agenda (Appleby &

Devlin 2005; Darzi 2008; Portney & Watkins 2009). The measurement of health outcomes to provide evidence of treatment success, from the patient's perspective, is therefore an important issue to investigate.

2.7.3 Measurement of health outcomes

Outcomes research is the study of the end results of health services that takes patients' experiences, preferences, and values into account (Clancy & Eisenberg 1998). Outcomes were traditionally measured in terms of morbidity and mortality without consideration of how the patient was affected by a health condition (Portney & Watkins 2009). Since 1948, when the World Health Organisation defined health as 'a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity', the outcomes agenda has been expanded to look beyond the focus on pathologies or impairments to measure improvement in health outcomes. The use of patient-based measures of functioning and disability, health-related quality of life (HRQOL) and health preferences may provide evidence which influences future healthcare policy, informs the management of patient care on a case-by-case basis or evaluate the end point in effectiveness trials (Portney & Watkins 2009).

The development and validation of such patient-based measures, for use on all stages of the clinical pathway from prevention and well-being through to specialist disease management and rehabilitation, therefore has become very important in the current healthcare climate (Department of Health 2009). Patients may use functional outcomes to assess the success of an intervention and patient-based measures provide a mechanism for understanding how functional outcomes relate to different healthcare interventions (Portney & Watkins 2009). Evidence suggests that a standardised assessment of patient outcomes in effectiveness trials would facilitate the future provision of high quality EBP (Green, Buchbinder & Hetrick 2003).

2.7.4 Provision of patient-centred healthcare

Patient-centred care may be defined as 'care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions' (Institute of Medicine 2001). In today's NHS patient-centred care means putting the patient and their experience at the heart of quality improvement (Appleby & Devlin 2004). The use of PROMs as a standard of practice therefore represents a fundamental shift towards patient-centred care (Wright 2000). Involving patients, as service users, in practice and research therefore enables them to make an important contribution towards evaluating and improving the quality of their own future healthcare (Haywood 2006).

Evidence suggests that patients are able to provide valid and reliable judgements about changes in their functioning and health (Fitzpatrick et al. 1998). It has also been proposed that when evaluating the success of any intervention gaining the views of patients on their experiences, beliefs, expectations and perceptions may improve their response to (Testa & Simonson 1996; Mancuso et al. 2002) and satisfaction with (Solomon et al. 1999) an intervention. However it is not known to what extent the views of patients are currently reflected in the validated shoulder region-specific PROMs commonly used in clinical practice and research. This is a therefore an important issue to investigate.

2.8 Outcome measures

An outcome may be defined as a change in the health status of a patient and outcomes research is based on the principle that any change, as a result of an intervention, can be measured (Clancy & Eisenberg 1998). Outcome measures provide quantifiable measures of treatment effect; measures therefore should be valid, reliable and sensitive to detect changes in an individual’s health status over time and between treatment groups. Measures should also be relevant across all subgroups of patients with the same condition and to all relevant important stakeholders. The latter includes clinicians needing to identify effective treatments and patients either wishing to make informed choices about different treatments or rate the severity of their symptoms and their ability to perform daily activities, work and recreation (Clancy & Eisenberg 1998).

This section will describe the different types of outcome measures currently used in clinical practice and research studies to measure treatment success. It will then provide the rationale for the use of patient-based measures and the criteria which may be used, by clinicians and clinical researchers, when selecting which validated shoulder region-specific PROMs to use for their specific application, patient population and setting (Fitzpatrick et al. 1998). Finally, it will consider the issue of patient involvement in the development of PROMS.

2.8.1 Types of outcome measures

Clinicians and clinical researchers use a wide range of different outcomes including technical, clinical and patient-based measures (Cieza et al. 2005). Technical measures include laboratory tests or radiological examinations, clinically-based measures include tests of physical and cognitive impairment and patient-based measures include the self-assessment of functioning and disability and HRQOL and health preferences (Clancy & Eisenberg 1998; Cieza et al. 2005).

Traditionally the measurement of outcomes focussed on changes in pathophysiology and impairments (Grimmer et al. 2004; Michener & Snyder 2008). Shoulder pathology may be assessed using X-ray or ultrasound examination whilst impairments of shoulder function may be assessed using clinically-based measures of physical performance. Examples of the latter include the use of a hand held goniometer to measure shoulder movement or a dynamometer to measure muscle strength (Hayes et al. 2001; 2002). However it cannot be assumed that there is a direct relationship between the measurement of impairment and limitations of activity and participation (Grimmer et al. 2004) i.e. restriction in shoulder movement may not impact on an individual's activities of daily living (ADL), work or recreation.

Patients also appear to be able to discriminate between their physical impairment and health-related functional limitations on personally relevant outcomes (Roddey et al. 2005). This would suggest that measures of impairment may fail to capture the impact of a shoulder condition on an individual's health-related physical, emotional and social functioning and not only are poor indicators of outcome but also have little meaning for patients in judging treatment success (Bot et al. 2004; Roddey et al. 2005; Michener & Snyder 2008).

Evidence demonstrates that patients are able to provide reliable and valid judgements about changes in their own functioning and health and that gaining the views of patients on their experiences, beliefs, expectations and perceptions may improve their response to and satisfaction with an intervention (Testa & Simonson 1996; Fitzpatrick et al. 1998; Solomon et al. 1999; Mancuso et al. 2002; Haywood 2006). This would suggest that the only way to comprehensively capture the impact of a shoulder condition on an individual's ability to perform activities of daily living, work and recreation is to incorporate the patient's perspective into the assessment of health outcomes (Fitzpatrick et al. 1998; Appleby & Devlin 2004).

This has led to the development of a large number of different types of patient-based measures which assess functional health status and level of disability, from the patient's perspective (Michener & Snyder 2008). Such measures more adequately capture different aspects of health-related physical, emotional and social functioning than measures of impairment (Bot et al. 2004; Roddey et al. 2005). PROMs therefore may be a better indicator of clinical outcome and more relevant and meaningful for patients in judging treatment success (Roddey et al. 2005; Michener & Snyder 2008).

However, the many patient-based measures which have been developed appear to assess different aspects of health-related functioning, as a result of a MSK shoulder condition. This presents clinicians and clinical researchers with dilemmas when selecting one or a combination of more than one relevant and meaningful PROM, which captures the intended content.

2.8.2 Patient reported outcome measures

PROMs aim to capture data on an individual's view of their own health status to provide an objective measure of a subjective construct such as health-related functioning and disability (Haywood 2006). A construct is an abstract concept which cannot be observed directly. It therefore can only be represented by inference, by measuring an observable behaviour or event (Portney & Watkins 2009).

PROMs usually take the form of questionnaires made up of a fixed number of items or questions (Wright 2000). Patients are asked to rate different aspects of their health status, over a given timeframe, using ordinal numerical scales. For each item the graded response options e.g. no difficulty, severe difficulty, moderate difficulty, minor difficulty or unable to do, are contained within a measurement scale. Ideally each construct should be measured on a separate scale. Individual scores are combined to produce a summary score which may be said to represent the impact of a health condition on that person. Once assigned a numerical value constructs can be manipulated as variables and their relationships examined (Portney & Watkins 2009). Any change in health status, as a result of an intervention, can therefore be measured.

A large number and wide range of different PROMs have been developed and validated to capture data on an individual's level of health-related functioning or disability due to a MSK shoulder condition. Evidence suggests shoulder questionnaires assess a wide range of different constructs which may be contained in a variety of different scales and subscales (Bot et al. 2004). A typical example is the Shoulder Pain and Disability Index (Roach et al. 1991). Thirteen items are contained in two scales purporting to measure the constructs of pain and disability; responses are rated using an eleven point numerical rating scale. Scores are combined to give a summary score between 0 and 100, where a higher score is said to represent greater pain and disability.

It is suggested however that the wide range of different PROMs available present clinicians and clinical researchers with dilemmas when selecting relevant outcome measures for their different purposes. The next section details the importance of involving patients, as service users, in the development of PROMS, the different purposes for which PROMs were developed and the different types of PROMs which may be appropriate for the research questions being addressed.

2.8.3 Patient involvement in the development of PROMs

Patient acceptability refers to the ability or willingness of patients to complete a questionnaire (Fitzpatrick et al. 1998). If patients find completing PROMs a burden missing values or incomplete responses may compromise the quality of the data (Fitzpatrick et al. 1998; Streiner & Norman 2003). Whilst increasing the number of complete datasets may facilitate pooling of data in meta-analyses it cannot be assumed that findings are meaningful to patients. Therefore quantitative methods may not be the best way to assess patient acceptability.

Involving patients, as service users and potential research participants, at all stages of the generation and final selection of the items in proms, to ensure that outcomes are relevant and meaningful, from the patient's perspective would in turn increase their acceptability (Terwee et al. 2007). This may in turn increase response rates.

Another important consideration is the readability and comprehension of a measure (Bot et al. 2004). Completion rates may be influenced by the first language of the patient e.g. tap and faucet, trousers and pants. Other problems may be due to poor sentence construction, ambiguous terminology or the use of jargon (Terwee et al. 2007). Patient involvement will identify items perceived to be ambiguous, irrelevant or where response options are limited or inappropriate (Bot et al. 2004). Feedback may be used to ensure items are well constructed and written in unambiguous language which may overcome another barrier to completion.

Involving patients, as service users, in the development of PROMs therefore not only has the potential to increase the quality of the data but also to ensure the findings are clinically meaningful (Fitzpatrick et al. 1998; Haywood, 2007).

2.8.4 Specific applications of PROMs

PROMs have been developed and validated for a wide range of different purposes (Fitzpatrick et al. 1998; Portney & Watkins 2009). Measures may be used to:

i) Assess the cost-effectiveness of healthcare interventions; such discriminative measures need to be sufficiently reliable to differentiate between subjects or groups at the endpoint in effectiveness trials and sufficiently responsive to justify smaller sample sizes in effectiveness trials.

ii) Assist healthcare professionals in caring for individual patients; such evaluative measures need to be sufficiently reliable to differentiate clinically important change from measurement error and sufficiently responsive to capture meaningful and important change over time.

iii) Assess the health needs of populations to inform healthcare policy; measures used to predict outcome or prognosis may include surveys which assess different aspects of health status.

iv) Measure health outcomes and health improvement; such measures may be used to provide external evidence of healthcare performance or to validate the quality of healthcare against benchmarks informed by evidence-based standards of care (Haywood 2006).

2.8.5 Types of PROMs

Four types of patient-based measures, which differ in both content and intended purpose, are presented in this section. The different types, with an example of each, are presented in Table 2-1.

Table 2-1: The different types, with examples, of patient-based measures (adapted from Fitzpatrick et al. 1998)

Type of measure	**Example**
Generic measures	SF-36 HRQOL questionnaire (Ware & Sherbourne 1992)
Region-specific measures	Shoulder Pain and Disability Index (Roach et al. 1991)
Disease-specific measures	Disease-specific HRQOL measurement tool for osteoarthritis of the shoulder: the WOOS (Lo, Griffin & Kirkley 2001)
Patient-specific indices	Measure Yourself Medical Outcome Profile (Paterson 1996)

Generic measures such as the SF-36 (Ware & Sherbourne 1992), which measures health-related quality of life (HRQOL) from an individual and societal perspective, capture a wide range of different aspects of health status (Fitzpatrick et al. 1998). Whilst generic measures may be relevant to a wide range of patients with different health conditions, one disadvantage is that, having fewer relevant items for any more specific purpose, they may be less sensitive to changes in health status as a result of an intervention. It may be argued therefore that disease-specific measures, which may be more sensitive to changes in health status should be used in patient subgroups e.g. with different types of shoulder pathology (Gabel et al. 2007).

However PROMs such as the disease-specific quality of life measurement tool for osteoarthritis (OA) of the shoulder (Lo, Griffin & Kirkley 2001), as judged by the relevance and comprehensiveness of items, may not include all outcomes patients with a shoulder condition consider important. Their limited application across a variety of different clinical and research settings may not satisfy the need to standardise the assessment of outcome, across all subgroups of patients with MSP, as a standard of practice (Gabel et al. 2006; Silva Drummond et al. 2007).

It is therefore suggested that identification of one or a combination of more than one region-specific PROMs e.g. the Shoulder Pain & Disability Index (Roach et al. 1991), where impairments and limitations are not contingent on aetiology, type of pathology or stage of the disease process, having a wider application across a variety of different clinical and research settings (Gabel et al. 2007) should be used to more comprehensively assess all relevant outcomes which are meaningful to patients. Should any outcome which patients consider important not be reflected in existing PROMs then it may be appropriate to include a patient-specific index (PSI) in which patients are asked to identify any personally relevant important outcomes which they may use to measure treatment success (Fitzpatrick et al. 1998; Wright 2000). Some existing validated PROMs e.g. the Shoulder Rating Questionnaire (L'Insalata 1997) include an item asking patients to identify and rank personally relevant important outcomes; patients are then asked to rate their functional status on a five point categorical scale.

The Measure Yourself Medical Outcome Profile (Paterson 1996) is a questionnaire which asks patients to identify and rate personally relevant impairment and activity limitations on a seven point numerical rating scale.

However the MYMOP has not been validated in generic populations of patients with MSP, which limits its application.

Having identified one or a combination of more than one relevant PROM, clinicians and clinical researchers may evaluate its measurement properties to enable them to select the most suitable patient reported measure, for their different purposes (Terwee et al. 2007).

2.9 Measurement properties of PROMs

Once it has been established that a PROM is fit for a specific application and is suitable for the patient population, intervention and research setting in which it is to be used, further assessment regarding its measurement properties may be made (Fitzpatrick et al. 1998; Bot et al. 2004). Both qualitative and quantitative methods may be used to assess the quality of PROMs (Streiner & Norman 2003; Bot et al. 2004; Terwee et al. 2007). Measurement properties of validity, reliability, responsiveness and interpretability are described and the criteria, against which each may be rated, are defined.

2.9.1 Validity

Validity is an assessment of the extent to which an instrument measures what it purports to measure (Fitzgerald et al. 1998). Content validity is one of the most important properties of a patient-based measure (Terwee et al. 2007). It involves making a qualitative assessment of how well the outcome of interest is comprehensively sampled by the items in the measure, in relation to its intended purpose (Fitzpatrick et al. 1998). A more quantitative method of assessing validity is also necessary; construct validity examines the relationship of constructs underpinning a measure to those assessed in similar instruments (Fitzpatrick et al. 1998).

2.9.1.1 Content validity

PROMs should contain items that comprehensively sample the outcomes which patients with shoulder conditions perceive to be important (Terwee et al. 2007). This section will therefore examine the intended application of the PROM, the outcomes purported to be measured and the extent to which individuals with

MSP were involved in the generation of the item pool and the final selection of the items included in the questionnaire. Patient acceptability has previously been considered in relation to the practical burden of administering PROMs, however in this study it will be considered within the context of patient involvement of the development of PROMs.

i) Intended application of PROMs

Shoulder region-specific PROMs may be developed for discriminative or evaluative purposes, in a variety of different groups or subgroups of patients who may receive a variety of different interventions. Different research contexts may include the manner in which the questionnaire was administered e.g. at home or waiting area, self-completed or through interview with outcomes being measured over different timeframes. As relevant measurement properties may differ between populations and settings it is important that an adequate description is given to facilitate the choice of the most suitable questionnaire for a specific application.

i) Outcomes purported to be assessed by PROMs

Relevant outcomes may be defined in terms of functioning, health-related quality of life and health preferences (Cieza et al. 2005). PROMs included in this study contained items purporting to measure functions of the shoulder or different aspects of health-related physical, psychological or social functioning related to a MSK shoulder condition.

ii) Item generation and final selection

Methods of generating an item pool may include a search of the scientific literature, examination of the content of existing PROMs, a retrospective review of patient records, by conducting focus groups or individual patient interviews or by seeking expert opinion (Terwee et al. 2007). Items in the PROMs should reflect the outcomes which are clinically relevant and meaningful to patients, as service users and potential research subjects.

Only those with an experience of a health condition can determine the relevance and meaningfulness of any item in a questionnaire. A question on shoulder stiffness may be valid for use in the measurement of the impact of OA on function but the same question may not be valid in measuring the effect of a drug therapy. It may be argued that a PROM developed to measure dysfunction in the upper extremity e.g. the DASH (Hudak, Amadio & Bombardier 1996) or ULFI (Gabel et al. 2006), contain items on hand function which may not be valid in patients with a shoulder condition. As the shoulder is designed to enable the hand to perform gross and skilled functions (Peat 1986) a patient with MSP may find items on 'reaching to put an object on a shelf' and 'doing up buttons' equally valid.

However evidence suggests that whilst some researchers incorporated patients' views when developing the item pool, ultimately they generated the items themselves (Terwee et al. 2007). Therefore it cannot be assumed that PROMs currently reflect all important outcomes from the patient's perspective.

2.9.1.2 Construct validity

An abstract construct may be used to infer a measurement in a relevant or correlated behaviour or event, where it is not possible to measure an outcome directly (Portney & Watkins 2009). Construct validity is assessed by examining relationships between a construct and other PROMs, which are underpinned by the same theoretical framework (Fitzpatrick et al. 1998). Construct validity should be established by testing predefined hypotheses, on the direction and magnitude of expected correlations between the constructs being measured (Terwee et al. 2007). There are no agreed standards on how high correlations should be; however if correlations are low the questionnaire may not be valid. A common approach to construct validation is factor analysis (Portney & Watkins 2009).

Most instruments, which assess outcomes from the patient's point of view, are multidimensional i.e. they assess different aspects of a health condition. It is recommended that different constructs should be assessed using separate scales or subscales (Terwee et al. 2007). Factor analysis may be used to analyse items in a scale or subscale to determine the extent to which they measure a single underlying construct. This information is important in understanding which outcomes underpin the assessment of MSP in individual PROMs.

2.9.2 Reliability

Reliability is an important property of an instrument as it is essential to establish that any changes in a patient's health status are due to an intervention and not to measurement error (Fitzpatrick et al. 1998). Reliability assesses the extent to which a measurement is consistent and free from random error; it may be considered the amount of score that is signal rather than noise (Fitzpatrick et al. 1998; Portney & Watkins 2009).

Small measurement error is required for evaluative purposes in which one wants to distinguish clinically important changes from measurement error. Reliability is also important for discriminative purposes; it concerns the degree to which patients can be discriminated from each other, despite measurement error. An unreliable measure may underestimate the size of the effect, which has implications for the calculation of the sample size in effectiveness trials. Three aspects of reliability, test-retest reliability, standard error of measurement and internal consistency, will be examined in this section.

2.9.2.1 Test-retest reliability

A reliable instrument will obtain the same results with repeated administrations of the test in stable patients. Test–retest reliability involves the administration of a PROM on two occasions separated by a suitable time period. A test–retest period of between two days and two weeks has been recommended for most conditions (Streiner and Norman, 2003); a shorter period may be associated with patient recall of answers, thus over-estimating reliability, whilst too long a period may be associated with actual change in health status.

Test-retest reliability is estimated using an intraclass correlation coefficient (ICC). Values range from -1 to +1, with 0 indicating random correlation between scores. However reliability is not a fixed property but is dependent on the intended application; whilst estimates above 0.70 are acceptable for group comparisons it is suggested that for the clinical assessment of individual patients reliability should exceed 0.9 (Fitzpatrick et al. 1998; Portney & Watkins 2009).

2.9.2.2 Standard error of measurement

An estimate of the variability in a set of repeated scores is termed the standard error of measurement (SEM), the more reliable the measure the smaller the SEM (Portney & Watkins 2009). If the SEM is known it is possible to calculate the smallest amount of change in a score, above measurement error, that would reflect a true change in health status. This amount of change is termed the minimal detectable change (MDC). The relationship between the SEM and MDC in the definition of that amount of change which patients perceive to be beneficial is examined further in the next section.

2.9.2.3 Internal consistency

PROMs commonly measure a single underlying construct using a number of items, as it is suggested that several related observations will produce a more reliable estimate than a single one (Fitzpatrick et al. 1998). For this to be true individual items in a questionnaire should measure different aspects of the same construct rather than different constructs (Streiner & Norman 2003). Whilst individual items on the same scale should relate to one another each should contribute some unique information as well.

Internal consistency is a measure of the extent to which items in a questionnaire scale or subscale are correlated i.e. the extent to which they measure the same construct (Fitzpatrick et al. 1998; Terwee et al. 2007). Measured using Cronbach's alpha, values range between zero and one, where one represents perfect correlation between items. Streiner & Norman (2003) suggest that an alpha value between 0.7 and 0.9 is acceptable, as it would ensure items reflect the complexity and diversity of a construct. A value above 0.9 would suggest that one or more items, which may ask the same question in slightly different ways, are redundant (Terwee et al. 2007). It is suggested that discarding such items would improve the internal consistency of the scale (Portney & Watkins 2009).

2.9.3 Responsiveness

Responsiveness is the ability of a measure to detect important change over time in the construct being measured (Bot et al. 2004). Any PROM should be able to distinguish important change from that due to measurement error. The minimal detectable change (MDC) is defined as the smallest amount of change which would be statistically significant.

All estimates of responsiveness are based on change scores i.e. the difference between baseline and endpoint assessment scores. Responsiveness may then be calculated using a variety of indices, a higher value indicating greater responsiveness. The effect size statistic (ES) is calculated by dividing the mean change score divided by the standard deviation of baseline scores and the standardised response mean (SRM) is calculated by dividing the mean change score by the standard deviation of the change scores. High variability in the baseline scores or change scores will result in a smaller ES or SRM respectively.

Effect sizes can be translated into benchmarks for assessing the relative size of change (Cohen 1977; Kazis, Anderson & Meenan 1989). Cohen's criteria in which an ES or SRM of 0.2 is considered small, 0.5 medium and 0.8 or more large, permits comparisons between measures. However as responsiveness is not an inherent property of an instrument but related to a specific application, the interpretation of responsiveness is a subjective one (Fitzpatrick et al. 1998).

2.9.4 Interpretability

A statistically significant difference may not reflect a clinically important difference. Therefore the interpretability of a measure is defined as the degree to which one can assign qualitative meaning to quantitative scores (Portney & Watkins 2009). The smallest amount of change which patients perceive to be beneficial and which would mandate a change in the patient's management is termed the minimally clinically important difference (MCID) (Jaeschke, Singer & Guyatt 1989).

The MCID may be calculated by anchoring change scores to an external criterion such as the patient's global rating of overall change scale, where response categories may range from 'improved' to 'worse', with zero indicating no change. Williams, Holleman & Simnel (1995) calculated that a change of 10 points or more in the SPADI, with a potential range 0-100, would be clinically significant in outpatients with pain and disability due to shoulder pathology.

Information on the relationship of the MCID to the standardised error of measurement (SEM) and minimal detectable change (MDC), in that group of patients who experienced important change, is summarised in Figure 2-1.

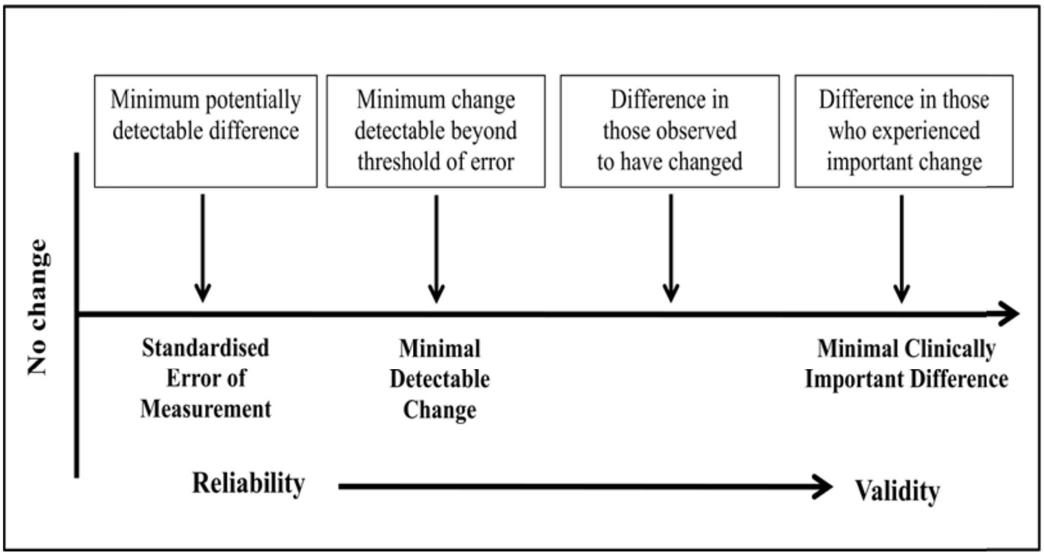


Figure 2-1: The relationship of the MCID to the SEM and MDC, in that group of patients who experience important change (adapted Portney & Watkins 2009)

The MCID is important as it may be used to judge the magnitude of benefit from different treatments, justify the sample size in effectiveness trials or assist in determining the proportion of patients who may benefit from a given treatment (Plancher & Lipnick 2009).

Caution should be used when interpreting these estimates as PROMs may not measure all levels of health-related functioning with equal precision (Bot et al. 2004). Further deterioration in patients with poor health-related function or improvement in those who are functioning well may not be captured by a measure. Termed a floor or ceiling effect, should more than 15% of patients achieve either the lowest or highest possible scores then the true effect of an intervention may not be detected (Portney & Watkins 2009).

To enable meaningful comparisons interpretation of the MCID should be made with reference to the patient group or subgroup, intervention and research context (Portney & Watkins 2009).

Criteria have been defined to guide clinicians and clinical researchers in their selection of relevant PROMs, for their different purposes (Bot et al. 2004;

Terwee et al. 2007). Based on the measurement properties of existing PROMs there is no substantial evidence to recommend one patient-based measure over the others. Comparisons of measurement properties are subjective and should be made with reference to the patient group or subgroup, intervention and research context in which the PROM will be used. This will enable meaningful comparisons to be made across similar clinical populations (Portney & Watkins 2009). Any gaps in existing knowledge, on the criteria which should be used to judge the measurement properties of PROMs, should be evaluated in future research studies.

2.10 Assessment of outcome for shoulder pain

This section will provide evidence to underpin the use of patient-based measures within the context of the assessment of outcome for MSP.

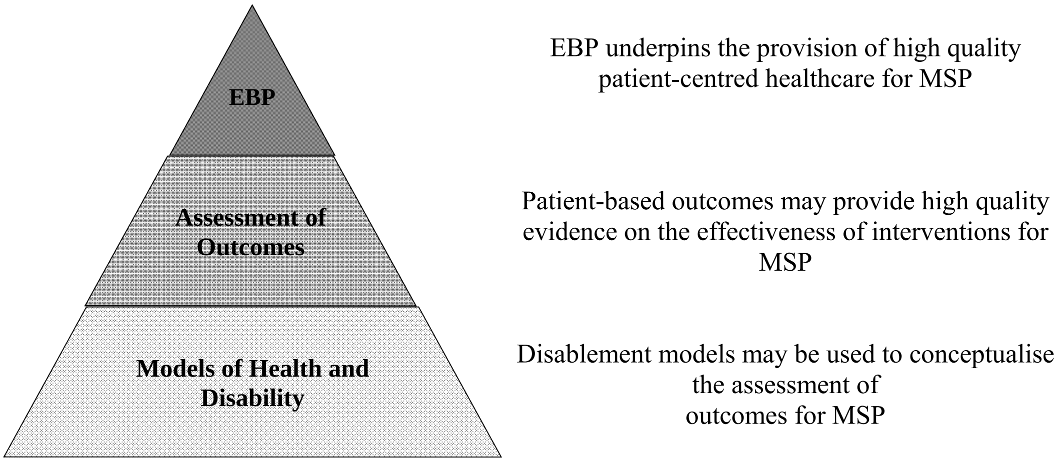


Figure 2-2: Conceptualisation of the key issues underpinning the provision of patient-centred evidence based healthcare for MSP (adapted Snyder et al. 2008)

It will demonstrate how models of health and disability may be used to conceptualise the patient-based assessment of outcome for MSP to provide evidence on the effectiveness of interventions, which may in turn facilitate the provision of high quality patient-centred evidence based healthcare (Michener & Snyder 2008; Snyder et al. 2008; Portney & Watkins 2009). The inter-relationship between the key issues involved in the assessment of outcome for MSP is represented in Figure 2-2.

2.10.1 Models of health and disability

A variety of conceptual models have been proposed to understand and explain functioning, disability and health (Jette 2006). Historically the biomedical model focussed on a linear relationship between pathology and resulting impairments. Within this model health is viewed as absence of disease and the primary outcomes of interest are the traditional endpoints of morbidity or mortality (Portney & Watkins 2000). However evidence suggests MSP may impact on an individual's ability to perform a wide range of different activities of daily living, work and recreation (Linsell et al. 2006; Terwee et al. 2007); the biomedical model therefore may be an inadequate way of conceptualising health outcomes.

The disablement model, originally conceptualised by Nagi (1965), expanded the biomedical model to more adequately conceptualise the consequence of active pathology related to an injury, condition or disease (Michener & Snyder 2008). It used a biopsychosocial approach to demonstrate the theoretical inter-relationships between pathology, impairments and limitations in activities of daily living and performance of activities within socially defined roles (Portney & Watkins 2009). A more recent and expanded model is the International Classification of Functioning, Disability and Health (ICF) (World Health Organization 2001). The ICF was used in this research because, rather than focussing on the negative impact of a health condition, it uses an internationally agreed unifying language to conceptualise how people may live with a health condition. Unlike earlier models, this is irrespective of the aetiology, type of pathology or stage of disease process and from both an individual and societal perspective (Portney & Watkins 2009). The ICF therefore may facilitate conceptualisation of health-related functioning and disability, across different subgroups of patients with a condition, such as MSP.

2.10.2 The ICF classification

The ICF belongs to a family of international classifications, developed by the World Health Organization (WHO 2001) to create a scientific basis for understanding and studying health and health-related outcomes. Its purpose was to improve communication between all relevant stakeholders, including policy makers and partner organisations, commissioners, service providers, service users and the public. The ICF purports to encompass the complete spectrum of the human experience of functioning and disability and the complete spectrum of environmental factors which contextualise that experience (Cieza & Stucki 2008). It's unifying language and conceptual framework facilitates the categorisation and comparison of data on health-related functioning and disability.

2.10.2.1 Organisation of the ICF classification

The hierarchical framework of the ICF systematically organises health-related information in two parts i) functioning and disability and ii) contextual factors.

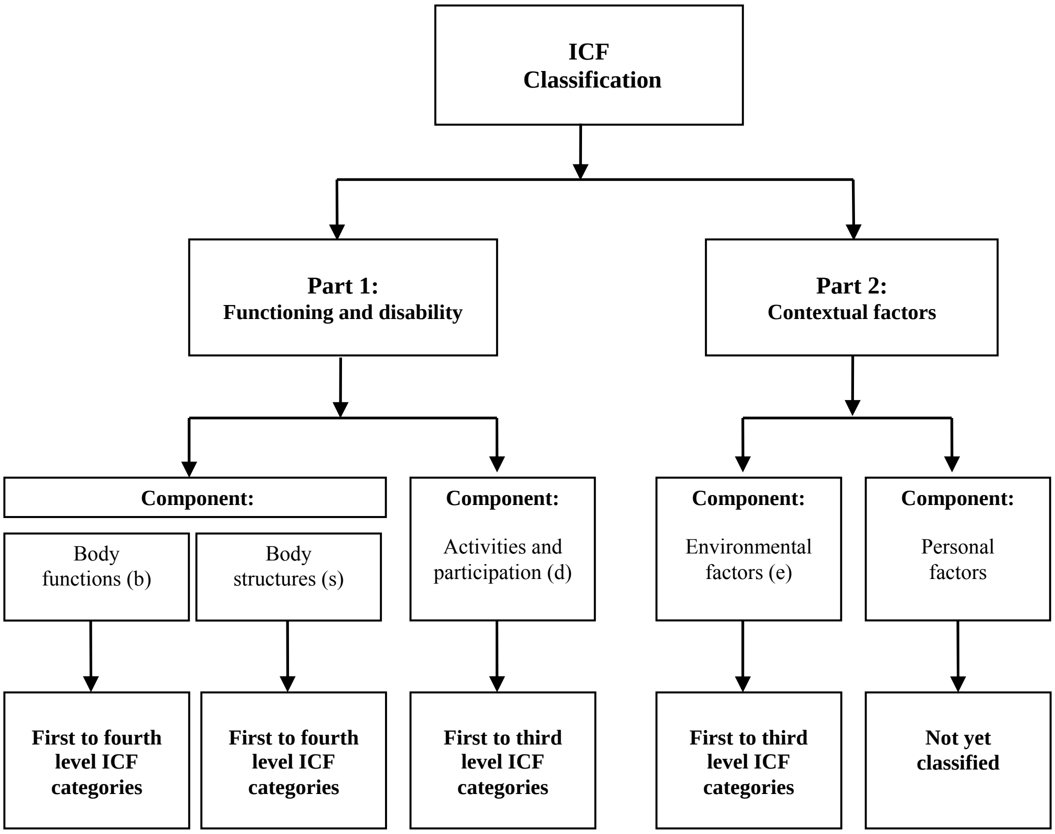
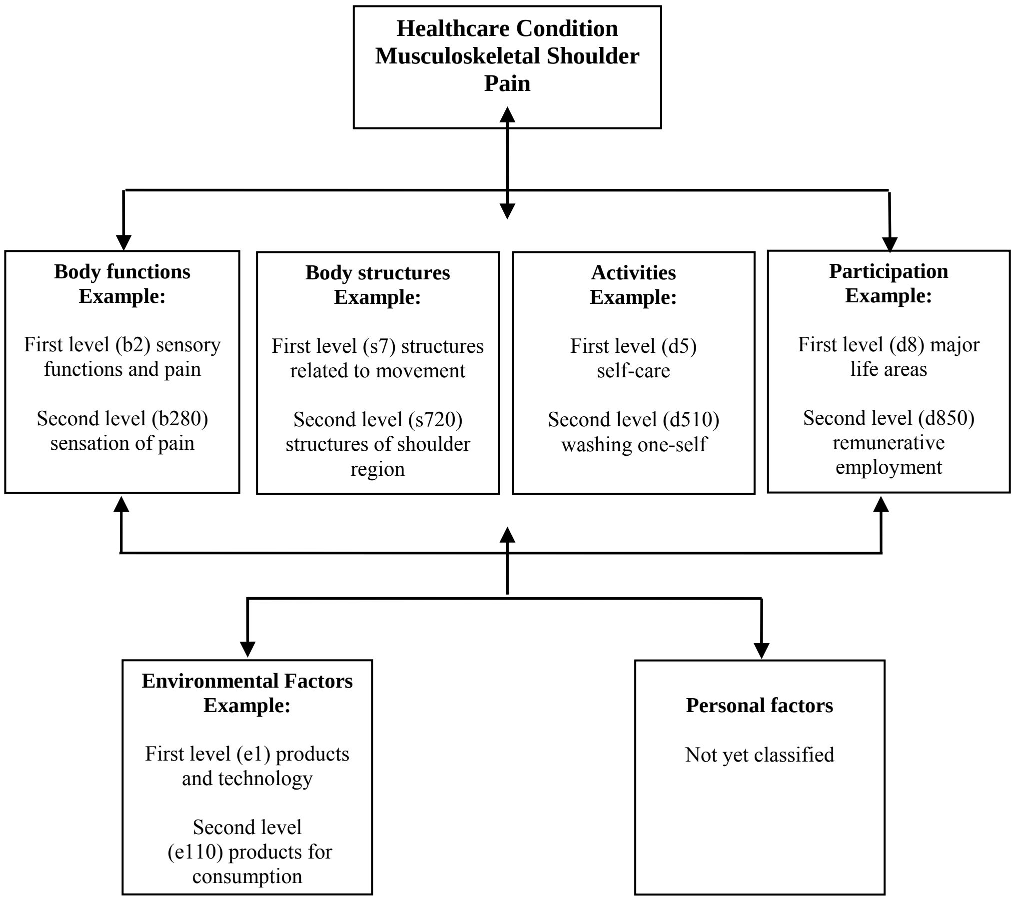


Figure 2-3: The hierarchical organisation of the ICF demonstrating the relationship between the different ICF components, body functions and structures and activities and participation and contextual factors, and illustrating the different levels of ICF categories (adapted Cieza & Stucki 2008)

Each part has two components which are independent of each other. The first component comprises two classifications, one for physiological and psychological body functions and one for body structures. The second component, activities and participation, covers the complete range of functioning from both an individual and a societal perspective. Factors which contextualise the experience of a health condition comprise environmental factors and personal factors.

ICF categories are the building blocks of the classification (Stucki et al. 2008). The different ICF chapters, the broadest categories, are made up of a practical, meaningful set of related physiological functions, anatomical structures, actions, tasks or areas of life. Categories are arranged in a stem-branch-leaf scheme with up to four levels. The more specific lower level categories share the same attributes as the less specific higher level category.



Adapted: http://www.who.int/classifications/icf/

Figure 2-4: An example of the interactions of ICF components when related to a MSK shoulder condition

The hierarchical organisational framework of the ICF, demonstrating the relationship of the individual components and contextual factors, and illustrating the different levels of ICF categories is presented in Figure 2-3. An example of the interactions between the ICF components, related to a MSK shoulder condition is then presented in Figure 2-4.

2.10.2.2 Linking health-related information to the ICF

Rules have been established to identify and link the meaningful concepts contained in health-related information to the most relevant and precise ICF categories in a systematic and rigorous manner (Cieza et al. 2005). However, Xiong & Hartley (2008) suggest that challenges may be encountered when using the ICF as a research tool; one reason put forward is that the linking rules may be open to different interpretation. Evidence does suggest that measures put into place to check the level of agreement between two raters independently linking data to the ICF may not only demonstrate the reliability and consistency of the application of the linking rules but also enhance the quality of the data (Silva Drummond et al. 2007). The result of applying the linking rules is a list of ICF categories which may be said to equate in content to the original health-related information with a second list reflecting any meaningful concepts not currently covered by the ICF classification (Cieza et al. 2005).

2.10.2.3 Application of the ICF

There is no gold standard agreement on the methods which should be used to measure health outcomes or health improvement (Appleby & Devlin 2005). The key justification for the innovative use of the ICF in this research is that it is the only existing model of health and disability which, in common with existing evidence on the impact of MSP on individuals and the outcomes currently assessed in shoulder region-specific PROMs, adopts a biopsychosocial view of health-related functioning and disability.

The ICF with its unifying language and conceptual framework may therefore be used to compare the outcomes patients consider important and the content of validated shoulder region-specific PROMs, to identify which individual measures most adequately reflect the patient's perspective.

2.11 Definition of the gap in existing knowledge

Evidence suggests that gaining the views of patients on their experiences, beliefs, expectations and perceptions may improve their response to an intervention (Testa & Simonson 1996; Mancuso et al. 2002). Therefore, when evaluating the success of an intervention for MSP it is important to include the patient's perspective. However, very few studies have asked patients with MSP, as users of research, for their views on which outcomes are important to them (Terwee et al. 2007). Eliciting patients' experiences of MSP, to determine which personally relevant and important outcomes should be included in the assessment of MSP, is therefore a very important issue.

Patients are able to provide reliable and valid judgements about changes in their functioning and health status (Fitzpatrick 1998; Haywood 2006). This evidence has led to the development and psychometric evaluation of a large number of validated shoulder region-specific PROMS. However there appears to be little agreement, amongst clinicians and clinical researchers, on which are the most relevant and meaningful outcome measures to use with patients with MSP. Outcome measures should also be valid, reliable and sufficiently sensitive to both detect changes in an individual's health status over time and between individuals or groups. It is therefore important firstly to compare the content of individual PROMS and secondly to rate the measurement properties of PROMs, to facilitate the evidence based selection of PROMS, for both discriminative and evaluative purposes. In turn, it is also important to determine the extent to which the patient's perspective is currently reflected in validated shoulder region-specific PROMs, commonly used in clinical practice and research studies.

Existing evidence illustrates how the unifying language and conceptual framework of the ICF (WHO 2001), has been used to link the outcomes assessed in PROMS, to facilitate comparison of the content of individual measures (Reference). No such work has been undertaken to compare the outcomes assessed in the patient reported measures used to capture the impact of a MSK shoulder condition, on shoulder function and an individual's ability to perform activities of daily living, work and recreation. In addition there is no evidence that different methodologies have been explored to integrate patients' subjective experiences and views of MSP with the content of shoulder region-specific PROMS. It is very important to investigate this key issue to determine how adequately existing validated shoulder region-specific PROMS currently reflect the patient's perspective.

Gaps in existing knowledge have identified an under-researched clinical and conceptual area, which should be investigated to inform clinicians and clinical researchers which relevant and meaningful outcome measures should be used for MSP, from the patient's perspective.

2.12 Premise of the thesis

MSP may impact on an individual's shoulder function or ability to perform a wide range of different activities of daily living, work and recreation; PROMs capture data on different aspects of physical, emotional and social functioning. By design PROMs use a biopsychosocial approach, some more so than others depending on the included content. The unifying language and conceptual framework of the ICF, which also uses a biopsychosocial approach, may therefore be used to identify and collate the outcomes in PROMs to enable meaningful comparisons of the content of measures to be made.

However the extent to which existing validated shoulder region-specific PROMs reflect the patients' perspectives is not known. Evidence suggests that as patients with MSP were involved in the development of some PROMs it should be possible to identify one or a combination of more than one measure which if not a perfect match would adequately reflect the outcomes patients consider important. The unifying language of the ICF may be used to compare important outcomes for patient and the outcomes assessed in validated shoulder region-specific PROMs to determine how adequately PROMs currently reflect patients' perspectives.

Clinicians and clinical researchers, who wish to include patients' perspectives, would be able to use this information in their selection of one or a combination of more than one PROM which covers the intended content.

Theoretically it should then be possible to gain an expert consensus on a core set of validated PROMs which should be adopted as a standard of practice assessment of outcome for MSP. This would fulfil the need to standardise the assessment of outcomes, across all subgroups of patients with MSP, in future clinical practice and research studies.

2.13 Purpose of the research

The purpose of this research project was to conduct three independent but inter-related studies, within a mixed methods design, firstly to gain patients' perspectives on what outcomes should be assessed for MSP, secondly to determine what outcomes are currently assessed by validated shoulder region-specific PROMs and thirdly to determine the extent to which the outcomes that patients with MSP consider important are reflected in existing measures.

It is proposed that clinicians and clinical researchers should use this information in the selection of the most relevant PROMs which covers the intended content.

It is further proposed that findings would also provide the evidence for a well-defined research project to gain an expert consensus on a ‘core set’ of psychometrically robust PROMs, which are relevant and meaningful to patients, and which should be adopted as a standard of practice for the assessment of outcome for MSP in future clinical practice and research studies.

This may in turn facilitate the pooling of data in future meta-analyses, which is integral to the provision of patient-centred evidence based practice. This research therefore has the potential to enable patients with a MSK shoulder condition to make an important contribution towards evaluating and improving the quality of their own future healthcare.

The findings from this thesis will also increase existing knowledge on how the ICF classification, which is under development, may be used to conceptualise the assessment of outcome, from the patient's perspective, for MSP.

2.14 Research questions

2.14.1 Overarching research question

The overarching research question posed in this research is ‘which patient reported measures should be used in the assessment of outcome for musculoskeletal shoulder pain, from the patient’s perspective’?

2.14.2 Component research questions

The research questions posed in each of the three component studies are:

i) Which outcomes of intervention for musculoskeletal shoulder pain are important, from the patients' perspective?
ii) To what extent do the outcomes assessed in validated shoulder region-specific patient reported measures reflect the same ICF categories?
iii) To what extent are the ICF-based outcomes patients consider important reflected in the content of validated shoulder region-specific patient reported measures?

2.15 Aims of the research

The aims of this research are:

i) to capture in-depth, rich interview data from patients reflecting a typical range of characteristics and with relevant experiences of MSP

ii) to identify which outcomes of intervention are considered important, from the patient's perspective

iii) to identify validated shoulder region-specific PROMs which meet the eligibility criteria

iv) to synthesise existing evidence on the measurement properties of PROMs, using clearly defined criteria

v) to collate the items contained in PROMs

vi) to identify the outcomes currently assessed in PROMs, by linking the meaningful concepts in items to the most relevant and precise categories of the ICF classification, using established rules

vii) to compare the ICF-based outcomes assessed in individual PROMs

viii) to link the outcomes patients identified as important to the most relevant and precise categories of the ICF classification, using established rules

ix) to compare the ICF-based patient outcomes and the content of PROMs to determine the extent to which measures currently reflect patients' perspectives

x) to identify any outcomes patients considered important not currently assessed in PROMs

The purpose of this chapter was to synthesise existing evidence to provide a clear rationale, grounded in scientific evidence, for the development of the overarching research question and those for each of the three independent, but inter-related, component studies conducted using a mixed methods approach, to determine which PROMs should be used in the assessment of outcome for MSP, from the patient's perspective. The next chapter will briefly describe each of the component studies and justify the use of a mixed methods approach, in which quantitative and qualitative data derived from different research methodologies was collected, analysed and integrated, to answer the overarching research question.

CHAPTER THREE

THE USE OF A MIXED METHODS APPROACH TO FACILITATE COMPARISON OF THE VIEWS OF PATIENTS AND THE OUTCOMES CURRENTLY ASSESSED IN PATIENT REPORTED MEASURES

3.0 Introduction

Having identified the research problem, this chapter will firstly detail the different type of data and possible research approaches, which may be used to answer the component research questions. For ease of reading each of the three inter-related, but independent, studies will then be detailed. It will then outline the different philosophical assumptions which underpin interpretive and positivist approaches to research. Finally it will address the key issues associated with designing and conducting an exploratory, sequential mixed methods study, which was used in this research, to enable the overarching research question to be answered.

3.1 Methodological framework

The overarching research question addressed in this research was 'which patient reported measures should be used in the assessment of outcome for MSP, from the patient's perspective'? It was proposed that a range of questions needed to be answered to address the different components of the research question and that each question would require a different type of qualitative or quantitative data.

A single dataset was not considered sufficient to answer the overarching research question. Patient-centred data were needed to gain different subjective perspectives, a systematic review was needed to identify validated shoulder region-specific PROMS, and a method needed to be identified to integrate the two types of data, in a rigorous and systematic manner, to enable the overarching research question to be answered.

It would have been possible to conduct three independent, qualitative or quantitative studies, to answer the overarching question. However, it was felt that by conducting three independent, but inter-related, consecutive studies, in which each qualitative or quantitative dataset contributes equally to answering the overarching research question, would provide a more complete analysis of this complex clinical issue, than if qualitative or quantitative approaches had been used alone (Creswell 2003; Tashakkori & Creswell 2007). Therefore, after exploring the alternative, in this research a mixed methods approach was used to collect, analyse and integrate data, on the views of patients and the content of PROMS, to provide a more comprehensive understanding of the outcome measures which should be used for the assessment of outcome for MSP, from the patient's perspective. The three studies are summarised in the order in which they were conducted.

3.1.1 First component study

A phenomenological approach was used to explore experiences of MSP and identify important outcomes of intervention, from the patient's perspective. Purposive maximum variation sampling was used to capture a breadth of relevant experiences. In-depth, individual interviews were conducted with fifteen patients awaiting treatment for MSP. Transcribed interview data were analysed using a four stage analytical framework. Emerging themes, which may be said to represent the outcomes of intervention for MSP which patients consider important, were identified.

3.1.2 Second component study

The first purpose of this study was to identify the outcomes currently assessed in validated shoulder region-specific PROMs, using the ICF as a reference tool, to facilitate comparison of the views of patients and the content of existing measures. Outcomes assessed in twelve PROMs were collated and linked to the relevant categories of the ICF, to determine the extent to which PROMs reflected the same content. The second purpose was to synthesise existing evidence on the measurement properties of PROMs to enable clinicians and clinical researchers to select relevant and meaningful measures, for their different purposes.

3.1.3 Third component study

The unifying language of the ICF was used to synthesise the findings of the two preceding studies. The outcomes patients with MSP identified as important and the outcomes assessed in validated shoulder region-specific PROMs were compared, to determine which psychometrically robust PROMs most adequately reflect patients' perspectives.

3.2 Assumptions underpinning mixed methods research

Each researcher has a philosophical worldview, or a set of beliefs about the nature of reality and how new knowledge is acquired, which influences how studies are designed and conducted (Tashakkori & Teddlie 2003).

Table 3-1: Philosophical stances underpinning interpretivism and positivism (adapted from Creswell 2007)

Interpretivism	**Worldview element**	**Positivism**
Multiple subjective realities No universal truth	**Ontology** The nature of reality	Single reality One objective truth
Closeness Investigators visit participants to collect data	**Epistemology** The relationship between the investigator and participant	Distance and impartiality Investigators assess outcome measures/ administer surveys
Value laden Investigator actively talks about their personal stance and interpretations Reports bias	**Axiology** The role of values	Value free Unbiased Steps taken to remove bias
Inductive Investigators starts with participants' views and builds 'up' to categories, themes and theories Context specific	**Logic** The type of reasoning	Deductive Researchers test a theory a priori Determines effect sizes Works top 'down' Generalisable

This mixed methods study embraced both interpretive (qualitative) and positivist (quantitative) approaches to research, whilst respecting the different philosophical frameworks from which they were derived, to answer the overarching research question Interpretive and positivist approaches have common elements, but the researcher takes a different stance on each element (Creswell & Plano Clark 2007). The different stances underpinning qualitative and quantitative approaches are summarised in Table 3-1.

Qualitative researchers tend to see the world as a social construction in which there are multiple subjective realities. They believe that people are an important part of social reality and that their experiences and behaviours are worthy of investigation (Lincoln & Guba 1985). Theory is developed inductively within an interpretive conceptual framework concerned with understanding the meaning of a lived experience. Whilst it is accepted there may be multiple constructed realities, the researcher actively fosters a relationship with individuals as it is believed it is possible to achieve some level of understanding of that person's lived experience (Lincoln & Guba 1985; Mason 2000). Qualitative data is entirely grounded in the individual and is context specific. Qualitative approaches include phenomenology, which assumes that human experience is the fundamental source of knowledge, narrative research which seeks to tell a story about a person's life, grounded theory research, which seeks to generate a theory to explain a phenomenon, a constructionist approach, which explores how participants' social interactions with others shapes their understanding of a phenomenon and ethnographic research, which seeks to describe the behaviour of a cultural group (Creswell 2007).

Conversely quantitative researchers believe that the world can be understood by a systematic objectivity and that it is possible to represent peoples' experiences and behaviours in an objective manner, without any bias on the part of the researcher (Creswell & Plano Clark 2007). At the heart of this positivist philosophy is the concept of deduction; it seeks to establish universal laws, find causes or relationships. Quantitative research can produce knowledge, through empirical observations and measurement, which has an objective reality and can be captured and translated into testable hypotheses, usually in the form of statistical or other numerical analyses. Methods associated with a quantitative approach include the randomised controlled trial in which the researcher maintains an objective view and has no involvement with research participants; such an approach can assist in guarding against bias.

One fundamental component of the overarching research question was to identify important outcomes of intervention for MSP, from the patient's perspective. The only way to gain the views of patients, which is not about a single objective truth, is through qualitative inquiry which may represent multiple subjective perspectives. Because what people say is reflective of what they are thinking words are important and therefore worthy of data collection. This epistemological stance is consistent with a qualitative approach (Portney & Watkins 2009).

Another fundamental component of the overarching research question was to determine the extent to which the outcomes, assessed in existing validated shoulder region-specific PROMs, reflect the same ICF-based categories. The only way that this may be measured is through quantitative inquiry. The type of data which is integral to answering this question is precisely defined numerical data, collected in an unbiased manner and from which there is no variance. Similarly this type of objective data is integral in determining the extent to which the outcomes currently assessed in individual PROMs reflect the patient's perspective. This stance is consistent with a positivist approach (Portney & Watkins 2009).

Different approaches also require different sampling strategies depending on how the data from the sample are used.

Qualitative research aims to collect rich, in-depth data from a small number of participants, with sufficient breadth of relevant experiences of the phenomenon being investigated, using a purposive sampling strategy. Because of the limited number of participants studied results are context specific rather than being generalisable to a wider population.

Quantitative researchers first select their study population, define it carefully and finally choose a sample which is representative. Methods are used so each person has an equal chance of being selected (Bowling 2007). Generally sample sizes need to be sufficient for bias to be minimised and the study to reach statistical power (Streiner & Norman 2003). This increases the confidence with which the results may be generalised to the wider population.

3.3 Key issues associated with mixed methods research

This section will explore the key issues associated with designing and conducting a mixed methods study, including the integration of qualitative and quantitative data, the measures used to enhance the quality of qualitative and quantitative data and the strengths and limitations of mixed methods research.

3.3.1 Integration of qualitative and quantitative data

Qualitative and quantitative data may be collected, analysed and integrated in a series of studies to provide a more complete analysis of a complex clinical issue (Creswell 2003; Tashakkori & Creswell 2007).

For the purpose of this research it was necessary to identify a method of comparing the qualitative patient-based interview data and the content of PROMs, in a rigorous and systematic manner. It would have been possible for the researcher to compare each item in the questionnaires with the qualitative themes and to make an arbitrary decision as to whether two concepts related to the same content. However as this method may be open to different interpretation it was felt that this was not the most robust strategy.

MSP may impact on shoulder function or an individual's ability to perform a wide range of different activities of daily living, work and recreation. PROMs capture data on different aspects of physical, psychological or social function related to a MSK shoulder condition therefore by design PROMs adopt a biopsychosocial (BPS) approach. Therefore the ICF, which also adopts a BPS approach, was used as a reference tool to facilitate comparison of qualitative and quantitative datasets to identify which PROMs most adequately reflect the patient's perspective. Existing evidence demonstrates the rigour of using the ICF firstly because of established linking rules and secondly the ability to check the level of agreement between two raters independently mapping data to the ICF classification. It may be argued that use of the ICF may result in loss of some of the richness of the patient-based data. However reference was made to the verbatim interview transcripts where necessary to contextualise the patient's experience to resolve dilemmas when applying the linking rules.

3.3.2 Measures used to enhance the quality of data

Rigour is not assessed in the same way in qualitative and quantitative research (Bowling 2004). Whilst in quantitative research the researcher takes steps to guard against bias, in qualitative research the researcher makes explicit their personal stance to set aside any pre-suppositions to demonstrate to the reader that the interpretation was a reasonable one to make.

The rigour of quantitative research is evaluated against the criteria of validity and reliability (Krefting 1991; Whalley Hammell 2000), however in qualitative research the concept of trustworthiness is used to support the argument that the research findings are 'worth paying attention to' (Lincoln & Guba 1985).

In this qualitative study credibility (rather than validity), dependability (rather than reliability), confirmability (rather than objectivity) and transferability (rather than external validity or generalisability) were used to demonstrate the rigour of research findings (Lincoln & Guba 1985).

Measures were put in place to ensure that the researcher's interpretation of the patients' experiences was credible and accurate. Dependability was addressed by making the data analysis process transparent and providing sufficient information to allow other researchers to arrive at comparable conclusions. To confirm that the findings were derived from the data itself research documents were provided as part of the audit trail and sufficient information was provided to allow others to judge if the findings might be transferable to a similar research setting.

Validity is concerned with accuracy, correctness and truth. In quantitative research, it involves elimination of all possible sources of bias within the analysis. The researcher applied the established linking rules when mapping the patient-based interview data and the outcomes assessed in PROMs to relevant ICF categories.

Reliability, in quantitative terms, is concerned with the use of standardised measures and the extent to which they produce consistent results. Research collaborators independently linked a random sample of items in self-assessment questionnaires to the ICF classification and results were compared. The percentage level of agreement was calculated. It was argued that if a 90% level of agreement was reached in the sample of PROMs, then the same acceptable level of inter-rater agreement would be achieved across all PROMs (Miles & Huberman 1994).

3.3.3 Strengths and limitations of mixed methods research

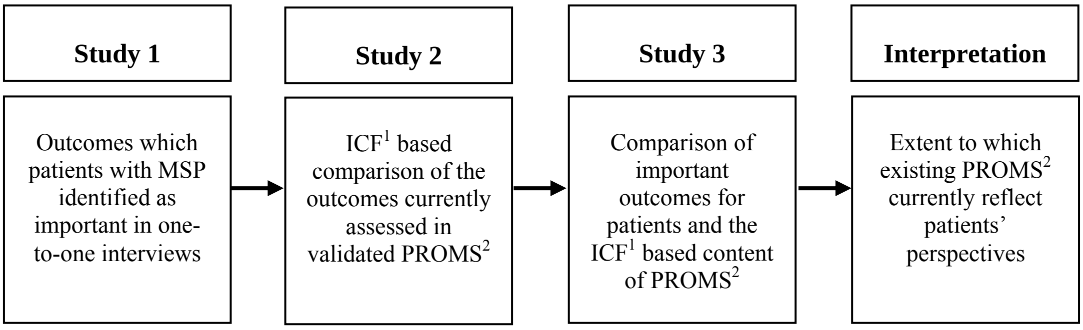
Mixed methods research is said to provide strengths and offset the weaknesses of quantitative and qualitative approaches used alone (Creswell & Plano Clark 2007). Quantitative research is said to be weak in that the voices of participants are not heard directly and the context in which people talk is not fully explored. The personal biases and interpretations of quantitative researchers are seldom discussed. Conversely qualitative research may be seen as deficient because of the bias created by the personal interpretations made by the researcher and the difficulty in generalising findings to a large group because of the limited number of participants studied.

The value of using qualitative and quantitative approaches to answer different components of the overarching research question within a mixed methods study is to gain a more comprehensive understanding of the assessment of outcome for MSP, from the patient's perspective. The same outcome would not be achieved by either qualitative or quantitative approaches used alone.

3.4 Exploratory sequential mixed methods study design

The exploratory sequential mixed methods design recognises that quantitative research has very little meaning without qualitative underpinning (Creswell 2007). Three independent but inter-related component studies were conducted in consecutive stages, with each qualitative or quantitative data set contributing equally to answering the overarching research question.

An interpretive approach was used to gain multiple subjective perspectives on what outcomes should be included in the assessment of MSP before a positivist approach was used in two successive studies to determine, with a systematic objectivity, how adequately the outcomes which patients considered important were reflected in the content of validated shoulder region-specific PROMs. Although inter-related each study were designed to stand alone, data being collected, analysed, interpreted and reported independently of one another. The temporal relationship between component studies is represented in Figure 3-1.



[1] International Classification of Functioning, Disability and Health @ http://www.who.int/classifications/icf
[2] Shoulder region-specific patient reported outcome measures

Figure 3-1: Temporal relationship between component studies

3.4.1 Temporal relationship between component studies

The quantitative results of Study 3 would have very little meaning, in the context of this research, without the initial qualitative exploration based on the views of patients, so Study 1 must precede Study 3. As Study 3 involved the synthesis of the results of both Studies 1 and 2 it had to be conducted last. It would have been feasible to conduct Studies 1 and 2 concurrently. However, it was important that an inductive reasoning process was applied when analysing the qualitative data on the patient experience and not to use the ICF conceptual framework, as in Studies 2 and 3, to quantify the data. Therefore a decision was made to conduct Study 1 before Study 2.

3.5 Feasibility of conducting a mixed methods research

The exploratory sequential design mixed methods study, where only one type of data was collected, analysed and interpreted at a time, makes the research straightforward to describe, implement and report.

There is an argument however that a mixed methods study takes longer to conduct. However in order to answer the overall research question where the results of the preceding qualitative study informs a subsequent quantitative study it is projected that the time taken to conduct three separate studies would be the same as carrying out those three studies within an exploratory sequential design mixed methods study.

It was anticipated that there would not be any additional costs associated with carrying out a mixed methods research project when compared to those associated with conducting three individual research studies.

Conclusion

The purpose of this chapter was to provide a rationale for a mixed methods approach, in which qualitative patient-centred data, reflecting different perspectives, and quantitative data, on the content of validated shoulder region-specific PROMS, was integrated using the ICF as a reference tool, within three inter-related, but independent, sequential studies. It has been argued that identifying the PROMS, which should be used in the assessment of outcome for MSP from the patient's perspective, can only be achieved if quantitative research methods are underpinned by a qualitative exploration. This has provided the justification for the use of an exploratory sequential mixed methods approach, as this outcome could not be achieved by either qualitative or quantitative approaches used alone. Each of the studies will be reported in individual, successive chapters, using appendices where appropriate for ease of reading.

CHAPTER FOUR

A QUALITATIVE EXPLORATION OF IMPORTANT OUTCOMES FOR MUSCULOSKELETAL SHOULDER PAIN, FROM THE PATIENT'S PERSPECTIVE

4.0 Introduction

Existing evidence suggests that patients are able to provide valid and reliable judgements about changes in their functioning and health status (Fitzpatrick 1998; Haywood 2006). It has also been proposed that gaining the views of patients on their experiences, beliefs, expectations and perceptions may improve their response to (Testa & Simonson 1996; Mancuso et al. 2002) and satisfaction with (Solomon et al. 1999) an intervention. Therefore, when evaluating the success of an intervention for MSP it is important to include the patient's perspective. However despite the existence of many self-assessment questionnaires very few studies have asked patients with MSP for their views on which outcomes are important to them (Terwee et al. 2007). This study set out to investigate this key issue using a phenomenological methodology, which captures peoples' lived experiences.

4.1 Research question

The research question posed in this study is 'which outcomes of intervention for musculoskeletal shoulder pain are important, from the patient's perspective'?

4.2 Purpose of the study

The purpose of this phenomenological study was to explore patients' lived experiences of MSP to identify which outcomes of intervention are considered important, from the patient's perspective. These outcomes should be included in the patient reported measures used in clinical practice and research studies. However it is not known how adequately the important outcomes from the patient's perspective are currently reflected in shoulder region-specific patient reported measures (PROMs). Therefore further work is needed to compare the results of this study with the content of existing PROMs.

This information will assist clinicians and clinical researchers in the selection of the most relevant and meaningful PROMs for their different purposes. Such evidence, on the extent to which the views of patients are currently reflected in PROMs, may also be used to gain a widely agreed expert consensus on a core set of psychometrically robust measures which should be adopted as a standard of practice, in future clinical practice and research studies. This may in turn facilitate the pooling of data in future meta-analyses, which is integral to the provision of patient-centred evidence based practice.

This qualitative research therefore has the potential to enable patients with MSP to make an important contribution towards evaluating and improving the quality of their own future healthcare.

4.3 Methodological framework

The purpose of this section, after exploring alternative methodological approaches, is to provide the rationale for the use of descriptive phenomenology to answer the research question. It describes the methods of investigation including the study design, the sample, recruitment, ethics, how the quality of data was enhanced and the analytical strategy chosen. It then presents the research findings, including the researcher's reflections on the process of research and the research findings. A preliminary discussion will be presented at the end for completeness.

4.3.1 Ontological perspective

The ontological perspective adopted in this research is a belief that people are an important part of social reality and that their lived experiences are worthy of investigation (Mason 2002). It makes the assumption that the true breadth and depth of peoples' thoughts and feelings about any phenomenon can only be elicited by asking them for their views (Mason 2002). It also assumes that there is no universal truth value, as an infinite number of interpretations may be made about that person's perceptions, in that setting, on that day. Whilst accepting that there may be multiple constructed realities it is assumed that some level of understanding about how people interpret and make sense of their experiences of MSP can be achieved by talking to them (Lincoln & Guba 1985). This is consistent with phenomenology which premises that there are essential essences in all experiences.

4.3.2 Epistemological stance

This ontological perspective, which seeks to gain an understanding of the views of people, is consistent with the epistemological belief that what people say is reflective of what they are thinking. Therefore words are important and worthy of data collection. This epistemological stance is more consistent with a qualitative, or interpretive, research methodology, than a quantitative approach which seeks to measure a causal or correlational relationship between numerical variables (Grbich 2007; Kvale & Brinkmann 2008). It would therefore be reasonable to talk and listen to people to acquire this type of knowledge. Sources from which relevant data might be generated are individuals or groups of people with relevant experiences of MSP.

The use of a telephone questionnaire was discarded as it was felt unlikely that it would generate a full and fair representation of peoples' perceptions of their MSK shoulder condition. Also, as it is individual experiences that are of interest, a focus group was not felt to be suitable as dominant members of the group may inhibit others from relating their experiences. This justified the use of face to face, in-depth individual interviews, in which knowledge may be constructed through conversation by the social interaction of the researcher and the participant, as a method of data generation (Grbich 2007; Kvale & Brinkmann 2008).

4.3.3 Qualitative research methodology

This epistemological stance is consistent with descriptive phenomenology (Mason 2002). A number of qualitative approaches may use in-depth interviews for a variety of other purposes, including narrative research, which seeks to tell a story about a person's life, grounded theory research, which seeks to generate a theory to explain a phenomenon, a constructionist approach, which explores how participants’ social interactions with others shapes their understanding of a phenomenon and ethnographic research, which seeks to describe the behaviour of a cultural group (Creswell 2007). The purpose of this study was to gain an in-depth understanding of the lived experience of a phenomenon (Patton 2002). Therefore, rather than one of the alternative approaches, descriptive phenomenology was used to generate the type of data which would enable the research question to be answered.

Phenomenology, which assumes that human experience is the fundamental source of knowledge, was founded as a philosophy by Edmund Husserl (1859-1938) and further developed by Martin Heidegger (1889-1976) (Kvale & Brinkmann 2008). Very few studies have investigated peoples' experiences of the phenomenon of MSP to identify the outcomes of intervention which they perceive to be important (Terwee et al. 2007). Rather than use an interpretive phenomenological approach, in which the researcher reconstructs peoples' experiences, this study uses a descriptive phenomenological approach which focuses on presenting experiences, from the person's own perspective (Creswell 2007). With this approach the researcher's role, together with any pre-suppositions they may have about the phenomenon being investigated, is made explicit through phenomenological epoché. Setting aside as far as possible their own taken for granted experiences of MSP enables the researcher to take a fresh perspective towards the experiences of others (Creswell 2007).

A phenomenological approach focuses on how people perceive and transform their lived experiences of a phenomenon through their senses into their conscious awareness (Patton 2002). People try to make sense of their experiences by describing their thoughts and feelings; each person having a unique set of experiences. A phenomenological approach assumes a commonality in those experiences and seeks to reduce the individual subjective perspectives, through interpretation, to a composite description of the shared experiences; anyone with the same lived experience may recognise this description as their own (Sandelowski 1986). It is assumed that using this approach in this study that research findings may resonate with anyone with a MSK shoulder condition.

4.4 Aims of the study

The first aim of this study was to capture in-depth, rich interview data from patients, reflecting a typical range of characteristics and with a breadth of relevant experiences of MSP. The second aim was to identify which outcomes of intervention are considered important, from the patient's perspective.

4.5 Study design

4.5.1 Patient selection

The study sought to recruit individuals, aged 18 years or over, with a wide range of experiences of MSP. Criteria against which patients were screened regarding their eligibility for inclusion in the study are summarised in Table 4-1.

Table 4-1: Criteria against which patients were screened regarding their eligibility for inclusion in the study	
Inclusion criteria	
1	Outpatients, aged 18 years or over
2	Diagnosed with MSP of any duration, aetiology or pathology
3	Awaiting treatment for MSP
4	Attending for a consultation in the Orthopaedic, Physiotherapy or Rheumatology departments
Exclusion criteria	
1	Cognitive impairment, communication difficulty or lack of comprehension of written or spoken English
2	Shoulder immobilised due to a recent fracture, shoulder dislocation or post-operative protocol
3	Specialised shoulder function e.g. elite sportsman or wheelchair user
4	Medical condition which may refer pain to the shoulder region e.g. gall bladder or cardiac disease
5	Recent surgery for a carcinoma of the shoulder region e.g. mastectomy or neck dissection
6	Neurological condition which may affect shoulder function e.g. Multiple Sclerosis, Stroke or Parkinson's disease
7	Systemic rheumatological condition which may affect the shoulder e.g. Rheumatoid Arthritis
8	Muscle impairment of the shoulder e.g. Dystonia or Fibromyalgia

Any patient, attending an initial consultation in the Orthopaedic, Physiotherapy or Rheumatology departments, diagnosed with a musculoskeletal (MSK) shoulder condition of any aetiology or pathology was screened regarding their eligibility. Inclusion of patients awaiting treatment for MSP pre-supposed they would have certain preferences and expectations about what would constitute a successful outcome.

The following groups of patients, not able to relate a sufficient breadth of experiences of MSP, were excluded:

i) Patients not able to give their informed written consent

ii) Patients with limited or atypical experiences of MSP

iii) Patients who may not be able to distinguish their experiences of MSP from that of a co-existing medical condition

4.5.2 Recruitment to the study

4.5.2.1 Sampling strategy

Purposive sampling was used in this study. Qualitative research typically focuses on relatively small samples, selected purposively when seeking to gain an in-depth understanding of a phenomenon (Patton 2002). A maximum variation sample was selected on the basis that a wide range of patients would be able to relate a sufficient breadth of experiences of MSP to enable the research question to be answered. Any common experiences which emerge are said to take on added importance precisely because they emerge out of great variation (Patton 2002).

Patients returning their written consent were purposively selected by the researcher, on the limited sociodemographic data available. This ensured that men and women of differing ages were invited for interview. Other sociodemographic characteristics of interest were elicited during interview; these were handedness and the affected shoulder(s), occupational status and usual sports and hobbies, the nature of the shoulder condition, causative factors, duration of symptoms and any co-existing conditions which might influence patients' experiences of MSP. Sociodemographic data helps the researcher locate each participant in relation to the others taking part in the study (Patton

2002). It serves to demonstrate that the characteristics of interest which may be said to typify MSP are reflected in the resultant study sample.

The key justification for the number of patients was that the sample should maximise the scope and range of knowledge generated (Mason 2002). Very few studies have asked patients with MSP for their views on the outcomes which they consider important to use as a guide (Terwee et al. 2007). The only conclusion that may be drawn is that unlike quantitative methods the sample is small. Based on the results of a scoping exercise conducted by the researcher within the Physiotherapy, Orthopaedic and Rheumatology outpatient services it was proposed to recruit fifteen patients. It was felt that this number would be sufficient to gain a breadth of different perspectives and few enough not to lose the depth of the individual experiences to enable comparisons to be made within and across individual accounts (Patton 2002). It was also thought to be feasible within the time and resources available to the researcher (Patton 2002; Kvale & Brinkmann 2008).

However it was acknowledged that this number, although typical of interview studies (Kvale & Brinkmann 2008), should be flexible. Emerging evidence, during preliminary analysis of the later interviews, that the sample reflected all sociodemographic characteristics of interest and that no new codes were developed would indicate that fifteen patients ensured reasonable coverage of the phenomenon (Patton 2002). It would therefore seem reasonable to stop recruiting at that point.

Probability sampling used in quantitative research typically depends on larger samples, selected randomly, to be able to generalise with confidence any statistically significant findings from the sample to the population that it represents. Purposive sampling typically generates in-depth rich interview data from a small sample which seeks to balance the breadth and depth of experiences (Patton 2002). Therefore findings from qualitative research do not claim to be representative. However the sample will be described in sufficient detail and the research methods and findings in sufficient depth to enable another researcher to replicate as closely as possible the procedures of this study. This would enable another researcher to judge if the research findings are transferrable to similar participants in a similar research setting (Lincoln & Guba 1985).

4.5.2.2 Sampling timeframe

It was planned to conduct the interviews over seven months. As the period after an interview is a critical to the rigour and validity of the qualitative inquiry (Patton 2002), it was anticipated that this would enable the researcher time to reflect between interviews to ensure the quality of the data. It was proposed the researcher would make notes on initial impressions and reflect on what went well and what could have been done better. It was also anticipated that if it were necessary to change any interview questions this could also be accommodated within the proposed timeframe.

4.5.3 Patient recruitment

Patients were recruited through the outpatient service of a district teaching hospital, which accepts referrals from GPs, Clinical Assessment Treatment and Support (CATS) services and Consultants. Research collaborators within three key services Rheumatology, Orthopaedics and Physiotherapy, who manage a wide range of patients with MSP as part of their normal caseload, made the initial approach to all eligible patients about participating in the study. The clinicians were asked to briefly describe the aims of the research and to give any interested patients an information sheet and consent form (Appendix 1), together with a stamped envelope addressed to the researcher, for them to take away. In the absence of independent research collaborators this was to make it less likely that patients felt coerced into taking part because of concerns of prejudicing their treatment. Patients were also given one week to return their written consent to allow them time to seek any additional information necessary to ensure participation was fully informed and voluntary.

The management of MSP may involve patients receiving a number of different treatments, by a variety of different healthcare professionals. Whilst it would have been possible to have interviewed patients more than once in a longitudinal study, it was pre-supposed that experiences of treatment, including interactions with clinicians involved in their ongoing care, might cause them to modify their expectations. Patients were therefore interviewed once, at the outset of their current treatment, to capture data on the important outcomes, from their perspective.

Consenting patients were contacted by the researcher to make a mutually convenient appointment for the interview. To facilitate the establishment of trust and rapport patients were offered a choice of venue for their interview either at the hospital or, should they prefer, at their home or workplace. Interviews were audio recorded.

4.6 Data collection

4.6.1 The role of the researcher

The quality of the information obtained during an interview is largely dependent on the interviewer (Patton 2002). In this section therefore the researcher will explore her roles both an insider i.e. as a healthcare professional with experience of clinical history taking from patients with MSP and as an outsider who may have pre-suppositions about the issues that may arise. The purpose is to demonstrate that there has not been any undue influence when gaining the patient's perspective, on the part of the researcher (Krefting 1991; Patton 2002).

i) The researcher's role as an insider

The researcher was aware of the need to establish rapport with the patients and to appear non judgemental (Lincoln & Guba 1985). In order to appear more neutral and to show that she was not present in her professional capacity, but as a researcher, she did not wear her uniform.

As an insider the researcher, an experienced clinician who understands something about shoulder conditions and the patient experience, was aware of some of the issues that were likely to arise; this informed the type of questions asked. However, an insider also has pre-suppositions so the questions themselves were developed so as far as possible they were very neutral, not leading and did not predetermine the issues. The researcher asked one of the service users i.e. a patient with shoulder pain, to scrutinise the questions regarding their appropriateness and readability. This helped participants give a true account of their experience. During the interview the researcher said very little that would reveal her stance and intervened only to clarify a point or to encourage the patient to explore an aspect further.

The researcher ensured that the interview was not seen as a therapeutic encounter by making it explicit that she was not involved in any aspect of treatment of their shoulder condition. However should participants raise any concern she had an Arthritis Research Campaign booklet entitled ‘The Painful Shoulder’, which is widely available to members of the public, to hand to satisfy the need for information.

ii) The researcher’s role as an outsider

The researcher was an outsider for two reasons. Firstly she was looking at the issue from a professional perspective not as a patient. The second was that even if she had some personal experience of MSP her experience would be different to that of the patient. To ensure that any bias on the part of the researcher should not unduly influence any stage of the research process (Krefting 1991) she kept a reflexive diary which together with peer review served to demonstrate that there had been no undue influence on the data collection.

4.7 Qualitative interviews

As previously indicated qualitative interviews capture data through conversation, by the social interaction of the researcher and the participant (Grbich 2007; Kvale & Brinkmann 2008). The interviews were conducted as an informal conversation, with a limited number of open-ended questions and probes, to allow the patients to express their own views freely (Mason 2002). As a wide range of patients were recruited, each with different experiences, they were all asked the same questions to ensure the same ground was covered with everyone. The probes allowed the researcher to respond to any issues raised or clarify anything which had not been fully understood. Four issues drawn from the scientific literature were explored. Patients were asked about:

i) the range and severity of symptoms

ii) the impact of symptoms on their everyday lives

iii) strategies which they used to manage their shoulder condition

iv) their expectations of the outcome of intervention

Patients were also given an opportunity to explore any other issues not already covered. Key interview questions are summarised in Table 4-2.

Table 4-2: Interview questions

1	How would you describe your shoulder pain?
2	How do you find your shoulder pain affects your ability to carry out everyday activities?
3	How do you cope with having shoulder pain on a day to day basis?
4	Is there anything else that you think affects your ability to cope with the everyday problems of having shoulder pain?
5	How does having shoulder pain make you feel? Have you noticed any changes in yourself?
6	What do you hope will be the result of having treatment?
7	If you had to choose just one of those things to get better which one would it be?
8	Is there is anything else that you feel should happen as a result of your treatment?

4.7.1 The interview guide

The interview guide (Appendix 2) provided a framework to facilitate the exploration of patients' lived experiences. It was produced in sufficient detail to demonstrate that each patient was able to tell their own story, in their own words, without undue influence by the researcher. This increases the confirmability, or objectivity, of the data (Lincoln & Guba 1985).

4.8 Ethical considerations

Qualitative interviews are socially constructed interactions and there is a need to build trust between the researcher and the interviewee (Kvale & Brinkmann 2008). To achieve this four ethical principles, respect for autonomy, beneficence, non-maleficence and justice, were addressed in the design of the study (Mason 2002; Patton 2002).

4.8.1 Respect for autonomy

Autonomy recognises the right of the individual to self determination. Participants were advised that all information they provided would be kept securely and confidentially in accordance with the Data Protection Act (1998). Access to the data was restricted to the researcher and her academic supervisors. Participants were assigned an alphanumeric code prior to the interviews being transcribed and all proper nouns were deleted from the written transcripts so they could not be identified from the information they had provided. Participants were given a pseudonym so their identity could not be discerned from the direct quotes used either in the study report or any publications that may arise as a result of the research; this further enhanced their autonomy.

In the absence of independent research collaborators clinicians, who manage a wide range of patients with MSP as part of their normal caseload, made the initial approach to all eligible patients about participating in the study. Patients were given an information sheet and consent form, together with a stamped envelope addressed to the researcher, for them to take away. Patients were also given one week to return their written consent to allow them time to seek any additional information necessary to make their decision about participating, either way. This was to make it less likely that patients felt coerced into taking part for fear of prejudicing their treatment.

Patients had control over what information they shared with the researcher. They could choose whether or not to answer any questions or stop the interview at any time. It was also made explicit that they could withdraw from the study, should they wish to do so, without having to give a reason and that their treatment would not be prejudiced by their decision. To facilitate the establishment of trust and rapport patients were offered a choice of venue for their interview either at the hospital or, should they prefer, at their home or workplace.

4.8.2 Respect for beneficence and non-maleficence

This means doing good and not doing harm as a result of participation in research. Qualitative interviews are conducted for the purpose of gathering data and are not intended to change people (Patton 2002). There were no perceived benefits of this research to patients and the interview was not intended to be a therapeutic encounter. However, simply by talking about their experiences of MSP may have made them feel better.

The realistic chance of someone being upset by their participation was felt to be minimal as the subject of MSP is not considered to be a sensitive one. It was not anticipated that the nature of the questions would distress, worry or annoy them. In the unlikely event that patients became anxious or emotional the researcher, who has experience of dealing with similar situations in her professional practice, would have been able to offer support in the short term and if appropriate advise that they make an appointment with their GP.

4.8.3 Respect for justice

Respect for justice requires all people to be treated fairly. Although it was recognised that the impact of MSP is as relevant for all patients seeking treatment, any eligible patient who was not capable of giving their informed written consent to participate was excluded from the study.

4.8.4 Value of the conducting the research

One final consideration when carrying out research is that of its scientific worth. Participants were inconvenienced, both when attending the hospital and returning the interview transcript in the post. However these disadvantages, when weighed against the advantage of gaining new knowledge on the outcomes perceived to be important to patients would suggest that this research is worthwhile. Whilst this evidence will not benefit the participants directly has the potential to enable patients with MSP to make an important contribution towards evaluating and improving the quality of their own future healthcare.

Having addressed ethical considerations the research protocol was approved by the local Research Ethics Committee prior to commencement of the study (reference 07/Q010/58). Written informed consent was obtained from all participants according to the Declaration of Helsinki guidelines (World Medical Association 2008).

4.9 Data management

4.9.1 Transcription of the interview recordings

Data were collected from individual interviews with fifteen participants awaiting treatment for MSP. Interview recordings were anonymised and fully transcribed by someone not involved in the research process. The written transcripts were then checked against the recordings by the researcher who made any corrections and inserted any words the transcriber could not decipher, to increase the accuracy of the data.

4.9.2 Member checking of the interview transcripts

One of the methods which may be used to increase the credibility of the data would be to return preliminary research findings to participants asking them to verify the data and their interpretation (Lincoln & Guba 1985). Having had the opportunity to reflect further on their experiences critical feedback from participants may be incorporated into the research findings.

However in this study the researcher was keen to use her skills as a healthcare professional to interpret the patients' experiences at one critical point in the patient's care pathway. Patients were interviewed once before experiences of treatment, including interactions with clinicians involved in their ongoing care might cause them to modify their expectations. Member checking involved asking patients to confirm that the transcript was an accurate account of the conversation as they were remembered it, but not to make any amendments which may offer a different perspective.

4.10 Data storage

Patients' personal details were kept in a locked filing cabinet. All documents produced as a result of the research were anonymised and kept securely, in a second filing cabinet. Audio recordings were deleted once the interview transcripts had been certified as accurate. Interview transcripts were stored electronically using the NVivo8 Computerised Assisted Qualitative Data Analysis Software programme (http://www.qsrinternational.com).

4.11 Data analysis

Data analysis was informed by a phenomenological approach. Each person has a unique set of experiences of MSP and a phenomenological approach assumes a commonality in those experiences. The purpose of data analysis was to reduce the individual subjective perspectives, through interpretation, to a composite description of the shared experiences of MSP for everyone (Patton 2002; Creswell 2007). The aim of data analysis was to represent the multiple subjective perspectives of the participants as adequately as possible so the findings may resonate with all people with MSP who recognise the construction of that experience as their own (Sandelowski 1986; Krefting 1991; Patton 2002).

4.12 Trustworthiness of the data

Trustworthiness is used in a qualitative study to support the argument that the research findings are ‘worth paying attention to’ (Lincoln & Guba, 1985). It has been suggested that the rigour of qualitative research is too frequently evaluated against the criteria of validity and reliability, more appropriate to quantitative research (Krefting 1991; Whalley Hammell 2000). In this study qualitative alternatives i.e. credibility (rather than validity), dependability (rather than reliability), confirmability (rather than objectivity) and transferability (rather than external validity or generalisability) were used to demonstrate the rigour of research findings (Lincoln & Guba 1985); methods used to ensure the trustworthiness, or rigour, of the research findings are summarised in Table 4-3.

4.12.1 Credibility

Validity is concerned with accuracy, correctness and truth. In quantitative research, it involves elimination of all possible sources of bias within the analysis. Methods to establish the truth value or credibility of qualitative research are essential to ensure that the multiple subjective perspectives of the participants’ experiences are accurately represented (Lincoln & Guba 1985; Krefting 1991).

Table 4-3: Methods used to ensure the trustworthiness of the research findings (adapted from Krefting 1991, Whalley Hammell 2002)

Credibility Do the findings ring true?	Data provided were rich and meaningful Member checking accuracy of interview transcripts Peer review with academic supervisors to ensure there were no inconsistencies within the analytical process
Dependability Has the process of the study been conducted carefully?	Research question clearly stated Justification for the study design provided Independent coding of a random selection of interview transcripts Categories derived from the data itself Provision of sufficient information to allow another researcher to repeat the study and arrive at comparable conclusions, given a similar context
Confirmability Do the conclusions stem from the data?	Research documents provided as part of the audit trail Interview guide provided to demonstrate how each interview was conducted (Appendix 2) Critical evaluation of the role of the researcher through peer review, research diary and phenomenological epoché Use of illustrative quotes
Transferability Do the findings fit other contexts?	Sociodemographic characteristics sample fully described Sufficient information provided to allow others to judge if findings might be transferable to another research setting Wider implications of findings discussed

A purposive sampling strategy was used to ensure that the sample reflected a breadth of different experiences of MSP to increase the likelihood that rich, meaningful narrative data were generated.

At interview the researcher was aware of the need to establish a rapport with the participants and to appear non-judgemental; it is more likely that the accounts were based on participants' first hand personal experiences of MSP rather than what they think is the preferred social response (Krefting 1991; Paulhus 1991).

The purpose of peer review was to explore the researcher's biases and to ensure there were no unexplained inconsistencies between the data and their interpretation. The researcher conducted a ‘dummy’ patient interview which was observed before beginning the study, to make explicit any pre-suppositions that might influence the credibility of the data generated. Participants were asked to check the accuracy of interview transcripts.

4.12.2 Dependability

Reliability, in quantitative terms, is concerned with the use of standardised measures and the extent to which they produce consistent results. The qualitative alternative, dependability was addressed in this study by making the data analysis process transparent and demonstrating that the research was thorough, careful, and honest.

Research collaborators, not involved in the data collection, independently coded a random sample of interview transcripts to verify the researcher's data analysis methods. At peer review the coding scheme was revised and refined to offset any bias on the part of the researcher. The final coding scheme, which most accurately reflected the breadth of the participants' lived experiences of MSP, was then applied consistently across all interview transcripts. This addressed any tendency to impose structure on the data, to ensure that categories were developed, using an inductive reasoning process, from the data itself.

Another strategy for establishing the dependability of the research was to provide the methods of data collection, analysis and interpretation, in sufficient detail so another researcher could repeat the study and arrive at comparable conclusions, given a similar research context.

4.12.3 Confirmability

Qualitative research assumes that each researcher brings a unique perspective to a study. Confirmability is a measure of how well the research's findings are supported by the data collected (Lincoln & Guba 1985). It refers to the degree to which the findings could be confirmed by others. The main method for establishing confirmability is through audit. Provision of all research documents, including the researcher's academic supervisory records and reflexive diary would enable another researcher to audit the data collection and analysis procedures to ensure the researcher's interpretation is a reasonable one to make.

4.12.4 Transferability

In quantitative research statistically significant findings may confidently be generalised to the population which the sample represents. Qualitative research findings are context specific. Transferability refers to the degree to which the results of qualitative research can be transferred to other contexts or settings. It is the responsibility of the researcher to provide sufficient information to enable another researcher to determine if the findings may be transferrable. This includes a full description of the sociodemographic characteristics of the sample and the research context, including the philosophical assumptions that underpinned the research.

4.13 Phenomenological approach to data analysis

4.13.1 Phenomenological epoché

Qualitative researchers acknowledge that research is value laden and biases are present (Creswell 2007). Phenomenological epoché is a technique where the researcher first reflects on their experiences of the phenomenon under investigation, from both a personal and professional stance (Grbich 2007). This enables them to set aside, as much as possible, their 'taken for granted' experiences to take a fresh perspective, on the experiences of the research participants, when carrying out analysis of the interview transcripts. The researcher may be able to recognise something not thought relevant and would have discounted or had not expected and might therefore have missed. This increases the credibility of the interpretation (Whalley Hammell 2002; Creswell 2007).

i) Personal stance

Whilst I have not experienced shoulder pain I have had knee surgery, which impacted on my ability to do everyday activities. I thought this might tell me something about how patients with a MSK shoulder condition would feel and what they wanted from treatment. Like some patients my pain came on suddenly as a result of an incident although having had a ligament problem for a number of years I realised that I had subconsciously adapted my lifestyle to avoid pain and the possibility of my leg giving way. This made me very wary of performing the simplest of activities such as coming down stairs.

After my operation I quickly adapted to my new situation which I suspect would not be the same for all patients with MSP. Whilst I took some decisions for myself e.g. when to progress to walking with one crutch or tackle stairs one step at a time I also relied on my family and friends to help me judge progress. However I did not always act on their advice as I suspected they were a little protective of me e.g. when to drive for the first time. I think patients may also modify their expectations during the course of their treatment regarding their ability to perform everyday activities and return to work. Measuring the success of treatment may be dependent on so many other things e.g. I was able to get out and about and socialise and was not dependent on my family to assist me with personal care, so my interpersonal relationships were not affected. Others may find pain and disability has more of an impact on their life and need more psychosocial support. I think they would find like me that physiotherapy, with its problem solving approach, would help them regain their confidence. In the short term my priority was to be able to rely on my knee although I realised that a full recovery might take some time.

Therefore whilst I may have some experience of a MSK condition and I may be able to achieve some level of understanding of the experience of MSP, as an 'outsider' I know my experience will always be different to that of the patient. Setting aside my pre-suppositions will help me take a fresh perspective when analysing the interview transcripts.

ii) Professional stance

As an experienced clinician, who manages patients with MSP as part of her professional role, I thought would have some insight into the patient's experience of a MSK shoulder condition and their expectations of the outcome of treatment. The management of MSP is complex; patients present with a variety of symptoms, of differing duration and from a variety of causes. Whilst the nature of the patient's symptoms may help identify the possible shoulder pathology it is important to gain an insight into the impact of MSP on the individual to guide the clinical examination. Experience has taught me to pick up on non verbal cues such as facial grimaces and lack of willingness to use the affected limb as an indication to carry out a limited physical examination and concentrate on a few functionally based activities that can be carried out at home. Alternatively the patient who happily takes off their top overhead when undressing and has no hesitation in weight-bearing through the affected limb may require a more searching physical examination.

That having been said patients have a lot in common; they all want to be pain free and to get back to some sort of normality which commonly means being able to sleep on their affected side at night. One of the first questions patients ask is “when can I drive”. This may reflect a physical limitation such as not being able to change gear or turn the steering wheel but commonly not being able to drive means different things to different people. It may mean loss of independent living, social isolation or a barrier to returning to work which may have financial implications. As most shoulder conditions are self limiting I am largely able to help patients manage their own condition which may mean not only regaining their former level of physical function but also restoring their confidence, lessening their anxiety and for some not being dependent on medication.

Sometimes the outcome of treatment is influenced by other factors e.g. a co-existing medical condition such as diabetes, previous poor response to treatment because of “wear and tear” in the shoulder. I am always prepared to be proved wrong but I try to help all patients optimise their functional recovery and be self-responsible. I may have to counsel some patients against unrealistic expectations e.g. the plasterer expecting his shoulder to cope with long periods working overhead or the patient with shoulder instability expecting to return to contact sports which may not be advisable. On the whole patients are happy to take professional advice e.g. regarding a phased return to work or use of a trolley when shopping. Treatment aims are reviewed at regular intervals. When patients report that they are happy to manage their condition themselves, even if it may take some time for their overall expectations of treatment to be met, they are discharged from treatment.

Writing this down has enabled me to see just how much influence on a patient's experiences and expectations a healthcare practitioner has. This is why it is important for me to set aside any pre-suppositions I may have to keep me analytically honest and ensure that my interpretation of the data is a reasonable one to make (Miles & Huberman 1994).

4.13.2 Thematic content analysis

Qualitative interviews generate a large amount of in-depth, rich narrative data (Miles & Huberman 1994). Thematic content analysis was used to impose order and structure on the data in a systematic, rigorous and transparent manner (Mason 2002; Grbich 2007). Data were analysed using a four-stage analytical framework; the steps taken are summarised in Table 4-4.

Each transcript was read in its entirety several times to get a sense of the interview as a whole. Data were then reduced into natural meaning units by re-reading the transcript line by line to highlight any words, phrases or paragraphs thought to be significant. Meaning units were assigned a descriptive code to make it easier to identify and retrieve them during later stages of data analysis (Miles & Huberman 1994; Mason 2002). Some coding was descriptive e.g. 'ache (ACH)' and 'insecure (INS)'. Some data were treated interpretively e.g. "I toss and turn a lot in the night" and "I wake with pain in the shoulder" were both perceived to relate to 'sleep disturbance (SD)'. The development of the codes from the data is an iterative process which was refined and revised as more transcripts were analysed. Where codes were synonymous e.g. 'protective (PRO)' and 'guarded (GRD)' they were combined so some codes became redundant. Some units of meaning were re-coded. One example was 'regain household chores (RHC)' which was not, on reflection, in the context of the interview about housework or gardening activity limitations but about the participant's perceived loss of role within the family so was re-coded as 'loss of role (LOR)'.

Table 4-4: Steps used in thematic content analysis (adapted from Miles & Huberman 1994, Braun & Clarke 2006 & Creswell 2002)

1	Data was reduced into natural meaning units by identifying any significant words, phrases or paragraphs thought to be significant.
2	Natural meaning units which related to a single meaning were assigned a descriptive code for the purpose of identifying and retrieving them during later stages of analysis.
3	Codes which appear to relate to the same content were clustered into categories which were assigned a meaningful descriptor.
4	Categories were further reduced, with reference to the research question, into broad overarching themes.

The researcher met with her academic supervisor to compare the results of independently coding a sample of interview transcripts to both validate the data reduction methods and agree a common vision (Miles & Huberman 1994). This ensured that there were no unexplained inconsistencies between the data and its interpretation. Although the essential meaning of the codes was found to be similar, revisions were made where units of meaning had been treated inappropriately e.g. ‘joined a gym’ became (JG) rather than being coded to ‘self-responsibility (SR)’, which later became a category. The final coding scheme, detailed in Appendix 3, which most intuitively reflected the breadth and depth of the participants' lived experiences of MSP, was then applied across all interview transcripts. The frequency with which each code is mentioned was counted and represented in tabular form.

Where the codes appeared to relate to the same content they were clustered together into broader categories which were assigned a meaningful descriptor. One example is ‘difficulty getting off to sleep (DOS)’, ‘sleep disturbance (SD)’ and ‘sleep affected side (SAS)’ which are all members of the Sleep (category). Membership of each category is mutually exclusive.

Twenty-six new category files, which contained all the extracted coded material, were created to enable the researcher to get a sense of the datasets as a whole.

The categories were further reduced, with reference to the research question, into broader overarching themes; the seven emergent themes are summarised:

- **Range of symptoms**
- **Impact on upper limb use**
- **Impact on personal care, daily activities, work and recreation**
- **Impact on personal relationships**
- **Emotional impact of musculoskeletal shoulder pain**
- **Strategies for coping with musculoskeletal shoulder pain**
- **Expectations of the outcome of intervention**

Once again some themes were descriptive e.g. 'Range of symptoms' and some were interpretive e.g. 'Coping strategies'. The overarching themes, derived from the data, may be said to reflect the important outcomes of treatment for MSP, from the patient's perspective. The themes provided a conceptual framework which facilitated the comparison and contrast of data within individual perspectives and across individual accounts (Patton 2002).

4.14 Research findings

Firstly the sample will be described on the socio-demographic characteristics of interest. Then the results of the primary interpretation, which will be presented using the participants' own words supported by explanatory text, theme by theme, describes the shared experiences as constructed by the participants. Next the secondary interpretation, which reduces the individual perspectives to a composite description of the shared experience of MSP for everyone (Creswell 2007), is presented. Finally the outcomes of intervention, which are likely to be important for most people with MSP, are listed.

4.14.1 Sociodemographic characteristics of the sample

The socio-demographic characteristics of the sample are detailed in Table 4-5.

Table 4-5: Socio-demographic characteristics of the study sample

Subject*	**Gender**	**Age** (yrs)	**Affected shoulder**	**Occupation**
Alan	M	59	R	Machine operator
Barry	M	51	R	Unemployed
Chris	M	26	R	Office worker
Daisy	F	51	R	Nurse
Eric	M	55	B (R>L)	Unemployed
Frank	M	43	R	Manager
Gaye	F	46	L	Voluntary worker
Hilda	F	63	R	Retired
Iris	F	44	R	School Cleaner
Jo	F	28	R	Nanny
Kate	F	53	L	Office worker
Les	M	34	R	Farm labourer
Marie	F	49	R	Window cleaner
Neil	M	69	B (R>L)	Retired
Owen	M	50	B (L>R)	N/A

Key: M=male; F=female; L=left; R=right; B=Bilateral; N/A=not applicable
*Pseudonyms have been used to ensure anonymity

Of the twenty five information packs issued, seventeen patients returned a completed consent form. Fifteen were selected for inclusion in the study, based on the socio-demographic characteristics of interest; eight were men and 7 women, reflecting a wide age range (26-69 years). All were right handed. Twelve had pain in their dominant shoulder and 3 bilateral symptoms. Twelve patients were affected by work-related issues. One participant chose to be interviewed at home whilst the remainder preferred to attend the hospital.

Patients presented with symptoms between five weeks and 2 years duration. Seven had episodic shoulder pain (4-30 years duration). Of these six had experience of previous treatment including medication, physiotherapy and exercises, acupuncture, injections, shoulder surgery or a period of immobilisation. Eight reported first time shoulder pain, six as the result of an accident and two of gradual onset, none of whom had experience of treatment for MSP.

Ten patients had a co-existing MSK condition, two being of a familial predisposition. Two had a co-existing medical condition and four a co-existing mental health condition. Information on the history of participant's presenting symptoms, including previous exposure to different treatments, is summarised in Figure 4-1.

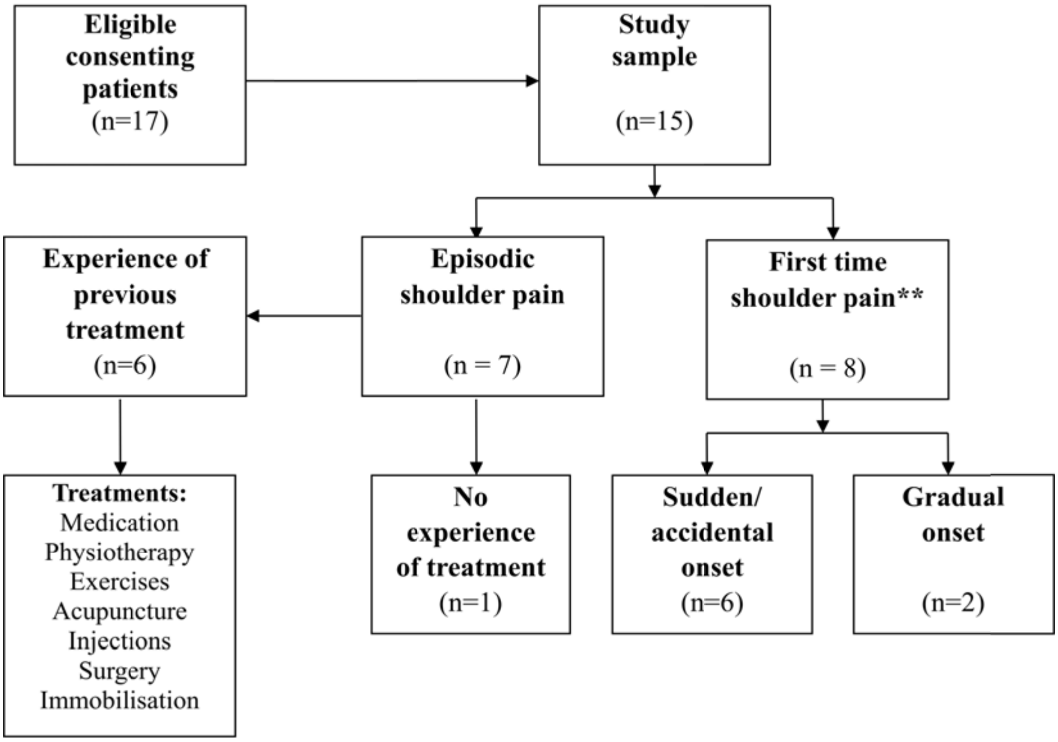


Figure 4-1: Summary of participant's presenting symptoms, including previous experience of different treatments

Socio-demographic data helps the researcher locate each participant in relation to the others taking part in the study (Patton 2002). Findings have demonstrated that the sample reflects the broad range of different sociodemographic characteristics of interest which typify MSP (Chard et al. 1991; Bongers 2001; Linsell et al. 2006). Recruitment of fifteen patients with different types of MSP, symptoms of differing duration and from a variety of causes would suggest that the phenomenon of MSP has been adequately sampled to enable meaningful comparisons to be made within and across individual accounts (Patton 2002).

4.14.2 Primary research findings

Primary research findings will be presented using illustrative quotes, followed by a brief analytical commentary, on the issues the selected data extract may raise for clinical recognition in practice. Illustrative quotes are used to demonstrate that the interpretation of the data is in the participants' own words, rather than those of the researcher (Whalley Hammell 2002; Grbich 2007). The quotes used will represent a range of different perspectives, not just the typical or most extreme view or that of the most articulate people (Whalley Hammell 2002). The use of illustrative quotes adds transparency and confirmability to the interpretation of the data, so another researcher may judge if they support the interpretation, and are representative, of the emergent themes.

The number of participants commenting on any given issue will be included, to demonstrate the relationship of the quotes selected to the main qualitative dataset (Mason 2002). Frequency counts are also used in this study to justify the selection of illustrative quotes, in the interpretation of the data (Miles & Huberman 1994). This is consistent with a descriptive phenomenological approach which assumes a commonality in the individual subjective perspectives (Patton 2002). The frequency, with which each code is mentioned, has been calculated and is represented, in tabular form in Appendix 4.

Research findings will be presented theme by theme; where appropriate the interview question has been included to contextualise the quote used. Any idiom of speech, repetitive speech or conversation, which is not relevant in the illustrative quote, has been edited as (...) for ease of reading.

Range of symptoms

Participants were asked to describe their shoulder problem and prompted, where necessary, to describe the type of symptoms experienced, where they were felt and when they were most noticeable.

Pain was a problem for everyone. People described pain in a variety of different terms, reflecting its severity, diurnal pattern, latency or recovery time. Of these eleven described an ache, nine a discomfort or hurt and five soreness. Thirteen people experienced secondary pain, often referred into the upper limb. Of these six associated secondary pain with a co-existing MSK condition. Eight people experienced sensory disturbance, including pins and needles or numbness, in their shoulder or upper limb.

> *“It's just like having permanent toothache, it would last for hours (Eric: line 175)”*
>
> *“by the end of the day that can be quite uncomfortable (Daisy: lines 223-225)”*
>
> *(Do you have any other feelings in your shoulder?) “Yeh the elbow ... I have a lot of (elbow) pain (Barry: lines 137-139)”*
>
> *“My arm was dead in quite a big area (what do you mean by that?). There was no feeling in it ... to the touch (Iris: lines 141-145)”*

Everyone’s experience of shoulder pain may differ. Closer questioning, when taking a clinical history, may elicit the different type, severity and behaviour of pain sensations, including changes in sensibility, which may assist in making a differential diagnosis. It may also highlight other factors e.g. referred pain, which may be a poorer prognostic indicator.

Everyone experienced sleep disturbance and commonly described problems related to positioning in bed. Of these two had problems getting off to sleep, eleven reported being woken by pain, thirteen experienced problems when lying on their affected side and two people reported difficulties turning over in bed. Six people perceived their symptoms to be aggravated by tiredness.

> *“The sleep has been difficult because you move automatically in sleep and sometimes I’d move and be in terrible pain and wake up again (Owen: lines 381-384)”*
>
> *“I found if I was sleeping on my right shoulder I would actually wake up at night, it would feel uncomfortable and I’d have to move (Jo: lines 84-86)”*
>
> *“I suppose pain makes you tired doesn’t it and I have been tired, the pain seem to make things a lot worse you know (Daisy: line 248)”*

Commonly patients experience sleep disturbance, which may be related to lying on their affected side. Lack of sleep may in turn lead to tiredness, which may affect pain tolerance.

Movement-related disorders:

Everyone reported problems with a wide range of movement disorders, related to voluntary and involuntary shoulder functions. Everyone reported shoulder stiffness and five described shoulder instability. Nine people reported problems related to muscle functions, either as a loss of strength, including a lack of grip, or as increased muscle tension, often when immobilised in a sling. Six people reported the loss of their automatic protective reactions, three when their shoulder was immobilised. Ten people reported problems when weight-bearing through the affected limb.

> *"I just have no movement in me arm at all. I can sort of get it half way up in front of me and half way to the side of me ... but I can't raise me arm above me head (Les: lines 216-219)"*
>
> *"... certain ways that I put my shoulder ... it would feel unsafe ... it felt unstable (Jo: lines 88-89)"*
>
> *"There's not as much strength when I grip as … as there had been (Frank: line 104)"*
>
> *"... it didn't relax in the same way even after I took the sling off my shoulder didn't relax (Jo: lines 154-155)"*

Patients commonly experience different types of movement dysfunction, which may present as shoulder stiffness, related to loss of joint mobility or muscle tension, lack of strength, which may be reported as a lack of grip or loss of involuntary functions, which may be perceived as instability. As a result patients may have different expectations of treatment.

One-handedness was perceived to be a problem for seven people. Of these, three described an imbalance in the muscles of the upper body and four reported difficulty in manoeuvring their arm.

> *"... my whole body is sort of out of sync because I can't use one arm (Gaye: lines 104-105)"*
>
> *"I've been wrestling with being unbalanced (...) because one shoulder is more powerful than the other (Eric: lines 454-455)"*

Patients, in this study, perceived one-handedness to be a separate symptom to other movement-related functions, which may relate to the complex neuromusculoskeletal mechanisms, moderated by higher centres, involved. One-handedness therefore may be a poorer prognostic indicator.

Impact on upper limb use

Participants were asked how their shoulder problem affected their ability to carry out everyday activities. They were asked to think of a typical day from morning to evening to help identify the range of activities affected.

Everyone reported problems with lifting and carrying, whether in the hands, in the arms or on the affected shoulder. Thirteen people identified problems with a wide range of purposeful hand and arm use, of these eight described problems with overhead use, seven with reaching activities and five with a lack of manual dexterity. Seven people described problems with pushing and pulling activities and five people with twisting and turning activities.

> *"Normally I'd get in and out of the car with coats and bags and everything (Marie: line 155)"*
>
> *"I look after my grandchild he's just a toddler and I haven't been able to lift him up (Daisy: lines 153-154)"*
>
> *"I've got a pull switch just above my head which switches the light on ... I cannot do that (Neil: lines 253-255)"*
>
> *"Mouse control on the computer ... it's quite a fine control ... you don't realise it but you don't have that same accuracy (Frank: lines 400-404)"*
>
> *"I mean I've been building the shed for a few months... sawing wood, anything like that (Alan: lines 290-292)"*

MSP commonly impacts on a wide range of different purposeful hand and upper limb activities, which patients, in this study, appeared to differentiate from movement-related disorders. Expectations on the outcome of treatment may reflect this.

Impact on daily activities, work and recreation

Everyone reported problems with their personal care; seven talked about difficulties with washing and bathing, fourteen with dressing activities and four with caring for their hair or teeth. Only one person described problems with toileting.

> *I can't put deodorant on ... it never occurred to me to worry about personal care (Gaye: lines 481-483)"*
>
> *"It's the thing of getting clothes on and off it's not the easiest ... I have to put my bra on back to front (Daisy: lines 162-163)"*
>
> *"... even going to the toilet and things like that ... you know you can't clean yourself properly (Barry: lines 210-213)"*

Thirteen people reported difficulties undertaking a wide range of different activities of daily living. Ten described problems with household chores and three with shopping.

> *"I'm very careful that I only do a certain amount of ironing and hoovering as we've got a heavy vacuum cleaner (Daisy: lines 147-148)"*
>
> *"Shopping was more difficult, food shopping, that sort of thing not being able to drive or carry the stuff back (Frank: lines 185-186)"*

Eleven people reported problems with mobility; six with walking and running, three with stairs and six with cycling, driving or using public transport.

> *"You're aware of other people around you, normally you naturally sort of just navigate yourself around without even thinking ... but with the sling on I was quite aware (Frank: lines 475- 477)"*
>
> *"I went round with my brother to a wildlife park and was walking a lot ... you don't realise you're swinging your arm a lot more (Barry: lines 193-194)"*
>
> *"If you were riding the bike and you were in a certain position your shoulders would ache, its being in that same position, especially early in the morning. (Alan: lines 118-119)"*

Most patients have problems performing their usual daily activities, sometimes at a very basic level e.g. with their personal care, in which case they may not be able to articulate their expectations of treatment, as everything is a problem. Treatment goals may be adjusted at each attendance until the patient is able to gain a perspective on their overall level of recovery.

Twelve people were affected by work related issues. Of these three experienced problems at work because of pain and five had changed their working practices.

Eight people had had time off work and of these, two were planning a return to work and three were seeking alternative employment.

> *"… no I don't believe I have lost time (off work) but that is sort of constant pain (Alan: line 80)"*
>
> *"Although I didn't have any time off work, because of what I did, I was able to moderate everything … I took no unnecessary chances (Jo: lines 72-80)"*
>
> *"I am going to start doing a couple of evenings light duties on office cleaning" (Marie: line 101)"*
>
> *"Because of the fall and the injury to my shoulder they medically dismissed me and now I'm on incapacity benefit and looking for work (Barry: lines 42-47)"*

Work-related issues are often very important to patients, not only because of having to cope with the physical demands, but also because of the psychosocial implications of not being able to perform their usual duties. As the implications of not being able to work may be profound, for some people it may be a priority outcome.

Twelve people described difficulties participating in a broad range of recreational activities, reflecting heavier hand and arm use, including DIY and gardening. Eight people reported difficulties participating in different sports, typically fishing, sailing or climbing.

> *"Not being able to go out and get in my garden ... my garden has gone to pot (Daisy: line 172)"*
>
> *"I know that if I go fishing there's going to be a certain amount of pain, but there again that's a trade off as I want to fish (Neil: lines 430-432)"*
>
> *"You are at a greatly higher risk of the shoulder popping out so that's why I chose to stop climbing (Jo: lines 70-72)"*

Patients who participate in leisure pursuits, which reflect heavier hand and arm use, may be very self-aware of the inherent risks involved in such activities, which may cause them to lower their expectations regarding the outcome of treatment.

Emotional impact of musculoskeletal shoulder pain

Participants were asked how having a shoulder problem made them feel. They were asked if they had noticed any change in themselves or their ability to interact or socialise.

Everyone experienced a wide range of different emotions, as a result of having a shoulder condition, including feeling upset, protective, frightened or wary, worried, frustrated or depressed. Eleven also described feeling pleased or positive or confident, often because they hoped for the best from their treatment.

> *"I'm frightened I'm going to suddenly get that sharp pain (Iris: line 166)"*
>
> *"Getting onto the boat I found I was very wary ... I was scared to do that (Hilda: lines 320-322)"*
>
> *"Even now in the bath I feel a bit anxious because you can feel a bit trapped (Gaye: lines 214-216)"*
>
> *"I don't trust my shoulder to lift a box … let alone do anything else (Chris: lines 95-96)"*
>
> *"I've been pretty optimistic that that's going to be okay (Les: line 447)"*

Patients with MSP experienced a range of different emotions, which they may accept as natural consequence of having a health-related problem. They may therefore expect to regain a sense of emotional well-being as a result of having their condition addressed.

Impact on personal relationships

Ten people reported difficulties with personal relationships, nine describing problems denoting a change of role within the family. Five people experienced difficulties with social interactions, including non-verbal communication.

> *"It did put pressure on my wife. It has now actually ... having to bring me here (Owen: lines 302-303)"*
>
> *"It has been a big upheaval and I'm lucky that I've got some good friends to take me out nights (Les: lines 331-332)"*

For some people MSP may have a significant impact on their role, as a partner or parent, or may impact of their ability to socialise. Patients may hope to become self-responsible and regain their former role, setting treatment goals may involve family members.

Strategies for coping with a MSK shoulder condition

Participants were asked how they coped with having a shoulder problem on a day to day basis and how they got round any difficulties.

Fourteen people described using a wide range of lifestyle adaptations and coping strategies. Seven explained how they tested out their shoulder when performing an unfamiliar or unpredictable activity.

> *"I carried plates with two hands because I didn't want the dinner to go on the floor (Hilda: 410-412)"*
>
> *"A typical impossibility is cleaning the bath ... I end up with the equivalent of a mop well that's what my life is at the moment ... adapting (Eric: lines 365-368)"*
>
> *"If I put my coat on I have to put the left in first because if I put the right one in first I then can't manoeuvre this one round, to get the next arm in (Owen: lines 319-320)"*

Twelve people needed physical assistance often from family members, of these seven used the support of a sling or pillows and four used gadgets or machines.

> *"I used to have to ask my wife to help me eat ... she cut it all up for me (Barry: line 296)"*
>
> *"When I was lying in bed if I wanted to move my arm I had to use the other arm and move it ... you know help it out (Daisy: lines 155-156)"*

Seven consulted a healthcare professional either because of more pain or disability or for advice about planning a return to work. These quotes are typical:

> *"It (the pain) got just a bit annoying you know and so I went I went to the doctor (Alan: lines 18-19)"*
>
> *"I've seen the company doctor and they've basically put me back but only on restricted duties ... I've got an overtime ban (Les: lines 140-142)"*

Thirteen people described the strategies they used to avoid provoking shoulder pain.

> *"I don't use my arm overhead ... you've got to be very careful so I just stand on a pair of steps (Kate: lines 405-400)"*
>
> *"Sleeping was actually quite uncomfortable ... I slept on the couch quite a bit (Frank: lines 154-155)"*

Eleven people described a number of ways, often based on retrospective assessment or professional opinion, that they measured changes in their condition.

> *"I couldn't get my hand above my head at all ... but I can do that now (Gaye: line 272)"*

For many patients gaining a perspective on their expectations of treatment involves a number of subconscious strategies. They may test out their shoulder and gauge the response, before repeating the provocative activity. They may devise ways of adapting how they perform regular activities, which involves an element of learning. They may assess the need for any assistance, including physical or psychological support, which may enable them to achieve the desired result. Finally they may avoid provocative activities all together. Improvement may be measured using a retrospective assessment to help them plan future actions. In this manner patients are able to moderate their overall expectations of treatment, which may change over time.

Expectations of the outcome of intervention

Participants were asked about their expectations of treatment, they were asked what they hoped the outcome would be, how much overall improvement they expected and if they could prioritise the most important outcome.

Everyone expected relief of their symptoms, which may include being free from pain, to sleep undisturbed or to have unrestricted shoulder movement. For seven it was important that they were able to resume their usual activities, including household chores and transportation. Three people hoped that their job prospects would improve. For three people it was very important that they regain their role within the family as a partner or parent and for two, that they end their social isolation. Fourteen people were able to prioritise which outcomes were most important.

> *"I suppose it would really be pain, yes because you don't like to keep pushing through the pain barrier (Marie: lines 286-287)"*
>
> *"All I want is to arrive at a point where I can get a job somewhere along the line (Eric: lines 298-299)"*
>
> *"For me personally an important one was to be able to interact and do the normal sort of things with my daughter (Frank: lines 472-473)"*
>
> *"I want to go out and socialise ... I was always an out person I've never been like it before. (Barry: lines 405-407)"*
>
> *"The reach first of all ... that's a priority and then the lack of strength, I mean the pain is ignorable. (Hilda: line 396)"*
>
> *"I would give pain and restriction an equal priority (Owen: line 166)"*

Patients are able to articulate personally relevant and important outcomes. For many there is a tacit understanding that relief of symptoms will enable them to regain their former activities, personal relationships and social interactions.

Whilst seven people hoped for a full recovery, six people believed that the outcome of treatment may be uncertain. Eleven people believed that any recovery would take time and three thought that different symptoms may change at different rates:

> *"Cure it I hope that's what that will do ... cure it (Iris: line 302)"*
>
> *"I'm hoping it's going to be one of those things that will fade away eventually (Marie: lines 264-265)"*
>
> *"I think I'd expect the stiffness to disappear first and then the guarding the more confidence I get in it (Chris: lines 242-246)"*

On the whole patients are realistic about their chances of gaining a full recovery. The aim of many therapeutic programmes is to put self-help strategies in place, to temporise the situation, which may or may not meet patients' expectations, in the longer term.

Having exhausted their own resources people sought professional advice for information to help them manage their condition. For six people self-responsibility included avoiding the use of prescribed medication or the need to consult healthcare professionals, in the longer term.

> *“I think that it is important knowing how to manage a problem like shoulder pain ... knowing a bit about it and understanding helps (Kate: lines 182-183)”*
>
> *“I don’t expect to be absolutely pain free but pain free enough not to have to take a pill (Daisy: lines 333-336)”*

Patients seeking professional help for a well established condition may not be looking or treatment but to learn physical strategies to help them become self-managing, including not having to rely on taking medication.

4.14.3 Secondary interpretation of research findings

A descriptive phenomenological approach assumes a commonality in the everyday lived experiences for all individuals (Patton 2002). The secondary interpretation reduces the individual perspectives to a composite description of the shared experiences, in this case of MSP, for everyone (Braun & Clarke 2006).

Firstly the symptoms which most people are likely to experience are described. Secondly the impact that pain is likely to have and the strategies which people commonly use to manage their shoulder condition are detailed. Next the expectations which most people may have about their overall level and rate of recovery are described and finally the outcomes which are likely to be important for most people with MSP are listed.

Symptoms

Typically people experience shoulder pain but they may also describe an ache, discomfort, hurt or soreness to reflect the severity or nature of their symptoms. People may have secondary pain symptoms in their neck or affected arm. Some people are likely to have a sensory disturbance in the upper limb and may experience numbness or pins and needles.

Everyone may experience sleep disturbance. People are likely to have problems getting off to sleep and may be woken by pain at night. They commonly have problems sleeping on their affected shoulder or turning over in bed. Pain and a lack of sleep may make people feel tired which in turn is likely to make their pain worse and/ or affect their work.

Everyone is likely to have problems with shoulder and arm movements. Pain can result in shoulder stiffness and weakness and the loss of manoeuvrability of the upper limb. Pain is also likely to result in the loss of automatic protective reactions, which for some is likely to make the shoulder joint feel unstable. Most people are likely to experience problems associated with being one-handed or imbalanced and commonly experience a lack of manual dexterity.

Impact of symptoms

Pain is likely to impact on a number of different aspects of peoples' lives. Pain, shoulder stiffness and weakness commonly result in problems with lifting and carrying things, with reaching activities and with using the arms overhead. More severely affected individuals are likely to have problems when carrying in their hands and experience difficulties when manipulating small objects such as opening a jar. However, more active individuals are likely to have problems with heavier activities such as turning a steering wheel or when carrying in their arms and opening a door simultaneously.

Typically everyone experiences difficulties with personal care. Bathing and dressing are most likely to be affected. Most people are likely to have problems with washing and drying parts of their body and caring for their hair. Most people are likely to be anxious about bathing; typically they describe problems getting in and out of the bath. Some are more likely to be frightened of hurting themselves whilst others are unlikely to trust their affected arm to be able to take their weight. People commonly have problems manoeuvring their arm into a sleeve, getting a garment off over their head or putting a sock on one-handed.

Most people are likely to experience difficulties performing everyday household chores. Tasks such as washing, cleaning and hovering are commonly affected. A few people affected by work issues are likely to have to change their working practices or take time off work, in the short term. Although it is uncommon, for a few people the impact of both acute and chronic pain means they will either lose or have to change their job. People are likely to experience difficulties participating in their usual hobbies and leisure activities. Gardening, swimming, fishing, sailing and going to the gym are amongst the activities which are commonly affected.

Pain is very likely to have an impact on peoples' emotions. Pain may make some people feel anxious, whilst others may feel depressed or tearful and weepy. Some people are likely to be wary and cautious for fear of provoking pain. For a few people tiredness may make them more irritable and bad tempered. Most people are likely to be fearful of their shoulder letting them down, should they move without thinking. A few may feel clumsy and awkward as a result of being one-handed.

The impact of MSP on family relationships and social interactions is likely to be very important for some. They may worry about the loss of their role as a partner or parent and the burden that this is likely to place on their family. Not being able to carry a child is likely to affect family relationships. Some people are likely to be protective of their shoulder fearing that any social contact with others, such as being jostled in public or having to respond to a handshake, will result in more pain. They may become socially isolated as a result.

Management of symptoms

Most people are likely to be able to do quite a lot to manage their symptoms themselves. It is likely however that people with acute and chronic pain do different things to manage their pain.

Most people are likely to find both prescribed and over the counter medication to be effective to some degree. Whilst people are likely to take medication regularly for acute pain, especially to help with sleep disturbance, most are unlikely to view it as a long term solution for chronic pain. To avoid any side effects people with chronic pain often use alternative therapies, such as dietary supplements or arnica oil.

Commonly people with acute pain are protective of their shoulder as they are likely to equate pain with harm. Whist a few people with acute pain avoid going to bed by sleeping in a chair, most are likely to use pillows to position and support their arm when resting to prevent any unplanned movements, such as turning onto their affected side in their sleep. Most people are likely to instinctively massage and move their arm regularly to make their shoulder feel better. It is likely therefore that some people given a sling will discard it because it makes their symptoms worse. Commonly most people with chronic symptoms perform, as pain permits, regular stretching and strengthening exercises often as part of a home exercise programme they have been given. Most people with acute pain are likely to use their arm only below shoulder height and may compensate for a weak grip by using both hands to prevent accidents.

When carrying out personal care some people may avoid taking a bath, rather than ask for assistance, because of a perceived loss of dignity. Most people with acute pain are likely to adapt their dressing habits by wearing oversized clothes and favouring button down the front shirts.

Most people are likely to use gadgets and long handled tools to avoid over reaching or overextending themselves, when carrying out lighter household chores such as cleaning the bath. Commonly heavier tasks such as hoovering of mowing the lawn are either performed one-handed or avoided altogether because of an inability to manoeuvre the machine.

Those people wanting to avoid having time off work or who are planning a return to work after an absence are likely to perform lighter duties or work shorter hours, in the short term. A few people may plan to change to a different, less physically demanding type of work, in the future.

Most people expect that, before resuming their usual activities, work or favoured hobby or leisure activity, they will have to test out the shoulder to avoid provoking pain. People are likely to measure changes in their condition using a variety of strategies. Unplanned symptoms are likely to be perceived to be a warning of imminent harm and are usually allowed to settle before proceeding with any task. Delayed onset pain and stiffness may also signal the need to use pacing techniques or change working practices.

People are likely to cope with the emotional issues associated with MSP in a variety of ways. Most people with an acute condition are likely to be confident that their healthcare condition will resolve in time. Some people with chronic symptoms may remain positive about their overall recovery by comparing their experience with that of others, who they perceive to be worse off.

Most people are likely to recognise that their family and friends will be protective to some extent, in the short term, and accept some assistance with their everyday activities. Some people however may avoid making any social gestures, by using a sling when out of doors or by not travelling unaccompanied, to make them feel more secure. To some extent this support is likely to allow them to test out their abilities when resuming activities such as taking a bath, shopping or driving independently which may increase their confidence.

Commonly people expect to manage their own shoulder condition; self responsibility is likely to take a number of forms. Some may exercise or attend a gym or pool to help prevent a recurrence. Others want to avoid consulting healthcare professionals or taking prescribed medication in the long term.

Expectations of outcome

People may expect to be free from pain, to get a good night's sleep and regain their accustomed position in bed. Most people are likely to expect any sensory disturbance to resolve with time. People are likely to expect to be able to move their arm with confidence and to regain its automatic protective function. Pain relief and unrestricted movement are likely to be identified by most people as priority outcomes although, as some symptoms predate others, they are unlikely to expect them to resolve at the same rate.

People are likely to expect freedom from pain and increased strength to enable them to regain their former level of upper limb use, including lifting and carrying activities. Reaching activities and overhead use are likely to be identified as priority outcomes.

People are likely to expect to resume their usual everyday activities. People may expect that freedom from pain will improve their participation in work and job prospects, in the long term. Commonly most people expect to resume their usual hobbies and leisure activities.

Most people think that emotional issues are a natural consequence of having pain and may expect freedom from pain to enable them to regain a sense of emotional well being. People are likely to hope to regain their role as a partner or parent and resume their former personal relationships. Some people hope to become more confident in their non verbal communication skills and social interactions, to enable them to end their social isolation.

People with acute symptoms are hopeful of making a full recovery. However people with chronic shoulder pain may be less certain of the overall outcome and are therefore less likely to expect a cure. People with an age related MSK shoulder condition or a co-existing medical condition are likely to expect their symptoms to take longer to resolve and may temper their expectations accordingly.

4.14.4 Important outcomes

Outcomes which are likely to be important for most people with MSP may be summarised; these patients may expect to:

- **be symptom free**
- **regain their former level of upper limb use**
- **resume their usual activities**
- **regain a sense of emotional well-being**
- **resume their former family relationships and social interactions**
- **independently manage their own shoulder condition**

Findings show that pain is a very important feature of MSK shoulder conditions. It impacts on a number of different aspects of peoples' everyday lives. People manage their MSK shoulder condition using a number of differing coping strategies. They perceive that freedom from pain will enable them to resume their usual activities and return to some sort of normality. These findings show that people are able to identify important outcomes which they want to be addressed and with which they may judge the success of any intervention. People are also able to articulate the overall level and rate of recovery they expect. Anyone with MSP may recognise their experiences from this description as their own (Sandelowski 1986).

4.15 Reflexivity and reflection

This reflexive account will enable other researchers to determine how adequately I have represented the multiple subjective perspectives of the patients' experiences to enable them to judge if the research findings are transferrable to similar research settings (Lincoln & Guba 1985; Krefting 1991).

Gaining insight into the contributions of a researcher to the production of knowledge requires a reflexive objectivity (Kvale & Brinkmann 2009). In this study I exposed any personal or professional pre-suppositions I may have had about MSP by keeping a research diary and through regular formal and informal peer review to keep me analytically honest (Miles & Huberman 1994). In this section I will reflect on the decisions I made in the research process to enable me to gain a new perspective on the data collection and analysis methods. This will enable me to be better able to justify those things that worked well and reflect on those things that may have benefitted from being done differently.

4.15.1 Patient recruitment

Patient recruitment went well, despite some early concerns on the part of the research collaborators who needed reassurance that unlike quantitative research the purpose of the eligibility criteria was to recruit a broad cross section of patients with MSP. The resultant maximum variation sample reflected a wide range of characteristics which typify MSP, which justified the purposive recruitment strategy. It was proposed that fifteen patients would be sufficient to adequately sample the phenomenon of MSP; however it was also acknowledged that this number, although typical of interview studies, should be flexible. In the event I found evidence during my preliminary analysis that the sample reflected all the socio-demographic characteristics of interest and that no new codes were emerging, therefore I felt it reasonable to stop recruiting at that point. This meant that despite some early slippage it proved feasible to recruit sufficient patients within the four month timeframe of the research programme.

Only one patient chose to be interviewed at home. This suggested that, for the majority, attending the hospital was not perceived to be a barrier to effective communication.

4.15.2 Qualitative interviews

Patients were interviewed once, whilst awaiting treatment for MSP. This presupposed they would have certain preferences and expectations about what would constitute a successful outcome, which would not be modified by any experiences of treatment including interactions with clinicians involved in their ongoing care. This enabled me to use my skills as a healthcare professional to interpret patients' experiences, at one point in the patient's care pathway.

There were some concerns amongst my supervisors that the relatively short data collection period would not allow me time between interviews for reflection. The argument was that a longer interval would have allowed me time to make and test any changes to the interview questions thought necessary. In the event the questions and probes worked very well. On preliminary analysis the questions produced the type of data which would allow the research question to be answered. Therefore I didn't consider any changes were necessary after the earlier interviews. I felt this justified my decision to conduct the interviews within such a short timeframe.

Although I was used to taking clinical histories I was a novice researcher. I carried out a dummy interview prior to the commencement of the study, with my academic supervisor observing, to enable me to test out the interview questions. These appeared to work well. It was helpful to realise that I would be able to elicit the socio-demographic information during the interview itself to help it flow more like a conversation.

I was nervous to start with and recognised that I may have asked leading questions or cut short some responses in my eagerness to adhere to the interview guide. However during later interviews I became a better listener and picked up nuances which I may have missed earlier. Whilst still following the interview guide I became more flexible in my approach which enabled me to explore the depth of patients' thoughts and feelings more completely. No new data emerged as a result of the last open question “Is there anything else that you feel should happen as a result of your treatment?” which pre-supposed that all aspects of the phenomenon had been adequately covered.

When reflecting on the interviews I was surprised how lacking in self-consciousness the patients were when relating their experiences. As MSP is not considered to be a sensitive subject, I didn’t anticipate anyone being upset as a result of talking about their experiences. However, neither did I anticipate how open participants would be about relating their experiences; there was no sense that they felt they had to give socially desirable responses to my questions. No patient saw it as a therapeutic encounter which had initially concerned me as I was very keen to develop my qualitative interview skills. I felt therefore that the measures I had put into place to build up trust and rapport and to appear non-judgemental were justified, as I was able to capture in-depth rich interview data.

4.15.3 Data analysis

Initially I did not understand the practical implications of exposing my pre-suppositions of personal and professional experiences of MSP, through phenomenological epoché. However through peer review I came to understand how to apply a fresh perspective when reading through the interview transcripts and carrying out the data analysis. Even so I felt when reading the early interview transcripts my professional knowledge was tending to impede my objectivity. However I was able to identify through formal peer review when I needed to take a step back and look at things afresh to ensure I didn’t impose my views when interpreting the patients’ experiences.

Initially I found handling such a large volume of narrative data very daunting. As a result I wanted to impose a structure on the data, using the conceptual framework of the International Classification of Functioning Disease and Health, very early on in the data analysis process. Through peer review I was able to regain my objectivity and ensure that the final coding scheme was derived intuitively, from the data itself.

My development as a researcher became apparent when developing the final codes, categories and themes as I was able to demonstrate at peer review that I was more open to alternative interpretations. Having bracketed my presuppositions I became aware of how some of my taken for granted experiences were mirrored in the research findings, whilst others were not perceived to be important to patients. I felt this demonstrated an analytical honesty which justified my approach to the analysis and interpretation of the data (Miles & Huberman 1994).

This reflexive account will enable other researchers to determine how adequately I have represented the multiple subjective perspectives of the patients' experiences to enable them to judge if the research findings are transferrable to similar research settings (Lincoln & Guba 1985; Krefting 1991).

4.16 Discussion

The purpose of this study was to explore the lived experience of patients, reflecting a typical range of characteristics and with relevant experiences of MSP, to identify which outcomes of intervention are considered important, from the patient's perspective.

4.16.1 Methodological considerations

The purpose of this study was to gain an in-depth understanding of the lived experience of MSP. This justified the use of a descriptive phenomenological approach, rather than a constructionist approach, which explores how participants’ social interactions with others shapes their understanding of a phenomenon, to generate the type of data, to enable the research question to be answered.

Research collaborators approached twenty five eligible patients regarding participation to increase voluntariness of consent. Of the seventeen patients who consented, fifteen were purposively selected on the characteristics of gender and age, on the basis that a wide range of patients would be able to relate a sufficient breadth of experiences of MSP, to enable the research question to be answered (Patton 2002).

Content analysis based on a framework was adopted to reduce researcher subjectivity and provide a systematic way of exploring the data. Having exposed any pre-suppositions through phenomenological epoché, the researcher was able to use her expert clinical reasoning skills to interpret how the qualitative themes related to clinical practice.

Notwithstanding, as a novice researcher things might have been done differently e.g. scheduling a longer time between interviews, to make any changes to the interview questions thought necessary, or probing a little more some of the issues raised during interview, measures were put into place to enhance the quality of the data, which if not perfect, seems credible and plausible. Therefore the purpose of the study, which was to explore experiences of MSP to identify what outcomes are important to patients, was fulfilled, which justified the study design and the use of descriptive phenomenology to enable the research question to be answered.

4.16.2 Significance of the findings

This study has ascertained the impact of MSP on an individual's shoulder function and ability to perform a wide range of different activities of daily living, work and recreation. Patients articulated personally relevant and important outcomes, which they may use to judge treatment success. They may expect to be symptom free, regain their former level of upper limb use, resume their usual activities, regain a sense of emotional well-being, resume their former family relationships and social interactions and independently manage their own healthcare condition.

As an expert clinician, the researcher has been able to utilise her well developed clinical reasoning skills to demonstrate the extent to which qualitative research findings may be mirrored in clinical practice (Jones, Edwards & Gifford 2002; May et al. 2008). Findings may therefore resonate with clinicians and clinical researchers wishing to include the patient's perspective in the measures used in the assessment of outcome for MSP, in future clinical practice and research studies.

4.16.3 Transferability of the findings

Participants in this study reflected the broad range of different sociodemographic characteristics of interest which typify MSP (Chard et al. 1991; Bongers 2001;

Linsell et al. 2006); research findings may resonate with anyone with a MSK shoulder condition. There is no reason therefore to suggest that the findings should not be transferable to similar patients in similar research contexts.

4.16.4 Relationship of findings to trends in the literature

The impact of MSP on an individual's shoulder function and ability to perform a wide range of different activities of daily living, work and recreation is consistent with that in other studies (Bongers 2001; Mitchell et al. 2005).

Whilst the content of some shoulder region-specific PROMs was generated with patients' input, most were developed by experts (Terwee et al. 2007); where the views of patients, on the outcomes which should be used for the assessment of MSP, have been elicited, insufficient detail was provided to appraise the quality of the evidence.

No study to date has explored in depth patients' experiences of a MSK shoulder condition, using a phenomenological approach. However, as the shoulder is primarily concerned with accommodating the demands of the upper limb (Peat 1986; Trew & Everett 2005), the impact of a MSK shoulder condition may be similar to that of MSK hand and wrist conditions e.g. wrist disorders (Bialocerkowski 2002), Carpal tunnel syndrome (CTS) (Jerosch-Herold, Mason & Chojnowski 2008), OA hand (Stamm et al. 2008) and Dupuytren's disease (Pratt & Byrne 2009).

All patients with a MSK shoulder condition experienced pain and sleep disturbance, in common with those with CTS and wrist conditions (Pratt & Byrne 2009; Jerosch-Herold, Mason & Chojnowski 2008). MSP commonly impacts on different aspects of mobility, personal care, domestic life, work and recreation, which was similar for patients with MSK hand and wrist conditions. Patients also reported emotional issues as a result of MSP in common with patients with Dupuytren's disease and OA hand (Stamm et al. 2008; Pratt & Byrne 2009). Problems with communication, socialising and interpersonal relationships typify the experiences of patients with MSP and MSK hand and wrist conditions.

One-handedness was perceived to be a problem for patients with MSP, which patients described as feeling “out of sync” or “unbalanced” in that one shoulder was more powerful than the other. Patients with wrist disorders had similar issues with “anything which required the co-ordinated use of both hands” (Bialocerkowski 2002).

Findings that MSP may impact on an individual’s shoulder function and ability to perform a wide range of activities of daily living, work and recreation is consistent with existing knowledge in MSK hand and wrist disorders.

Patients with MSP were not only able to articulate important outcomes but were also able to prioritise their expectations of treatment. That patients with MSP may expect to be symptom free and have their physical, emotional and social needs addressed is similar patients with CTS, who often expect to be symptom free and to resume their usual daily activities (Jerosch-Herold, Mason & Chojnowski 2008).

Conclusion

This phenomenological study identified important outcomes, which patients may use to judge the success of an intervention for MSP. Patients articulated personally relevant and important outcomes; they may expect to be symptom free, regain their former level of upper limb use, resume their usual activities, regain a sense of emotional well being resume their former family relationships and social interactions and independently manage their own healthcare condition. These outcomes should be assessed in the patient reported measures, used in future clinical practice and research studies.

However the extent to which existing PROMs reflect the patient’s perspective is not known. Further work is needed therefore to compare the results of this study with the content of existing PROMs. This provides the justification for the second study, designed to identify and compare the outcomes currently assessed in existing, validated shoulder region-specific patient reported measures, which is reported in the next chapter.

CHAPTER FIVE

AN ICF-BASED COMPARISON OF THE OUTCOMES ASSESSED IN VALIDATED SHOULDER REGION-SPECIFIC PATIENT REPORTED MEASURES

5.0 Introduction

Traditionally clinicians and clinical researchers used a wide variety of different outcome measures (Cieza et al. 2005), including clinically-based measures of physical performance. Evidence suggests however that clinically-based measures may not capture all aspects of the impact of MSP on an individual's ability to perform activities of daily living, work and recreation (Terwee et al. 2007). Evidence also suggests that patients can distinguish between their physical impairment and the impact of a shoulder condition on their health status on personally relevant outcomes (Roddey et al. 2005). This led to the development and empirical validation of a large number and wide range of diverse PROMs, which purport to capture data on different aspects of physical, emotional and social functioning, from a MSK shoulder condition (Terwee et al. 2007). PROMs therefore by design use a biopsychosocial (BPS) approach, some more than others depending on the included content. The ICF classification, which also uses a BPS approach, has been used in some MSK upper limb conditions, to compare the content of patient-based measures (Jerosch-Herold, Leite & Song 2006; Stamm et al 2006). However, no study to date has compared the content of validated shoulder region-specific PROMs, using the ICF as a reference tool, to assist clinicians and clinical researchers in their selection of relevant and meaningful outcome measures. This study set out to investigate this key issue.

5.1 Research question

The research question posed in this study was ‘to what extent do the outcomes assessed in validated shoulder region-specific patient reported measures reflect the same ICF categories’?

5.2 Purpose of the study

The primary purpose of this study was to identify and compare the outcomes currently assessed in validated shoulder region-specific PROMs, using the ICF as a reference tool, firstly to determine how comprehensively PROMs capture data on different aspects of physical, emotional and social functioning, due to MSP and secondly to facilitate comparison of the views of patients and the content of existing patient-based measures, in a subsequent study. This is to determine how adequately existing PROMs currently reflect patients' perspectives. Such findings may be used by clinicians and clinical researchers, wishing to include patients' perspectives, in their selection of one or a combination of more than one PROM which covers the intended content.

A second purpose of this study was to synthesise existing evidence on the measurement properties of selected PROMs. Clinicians and clinical researchers, who wish to capture meaningful and important change either on a case-by-case basis in clinical practice or to measure differences between subjects at the endpoint of a clinical trial, may use this information to identify PROMs, which are sufficiently psychometrically robust to be able to differentiate between different patient groups and different interventions, across a variety of different clinical and research settings.

5.3 Methodological framework

The purpose of this section is to provide the rationale for the use of a quantitative approach to answer the research question. The stance adopted in this research is that the world can be understood by a systematic objectivity and that it is possible to represent peoples' experiences and behaviours in an objective manner, without any bias on the part of the researcher (Creswell & Plano Clark 2007). This is consistent with the belief that data on health-related functioning and disability may be captured by measuring an observable behaviour or event (Haywood 2006; Portney & Watkins 2009). In turn this seems more consistent with a quantitative approach, which seeks to measure a relationship between numerical variables, than a qualitative approach in which the researcher explores peoples' views and experiences, to gain an understanding of a phenomenon.

Sources from which relevant data might be generated are validated shoulder region-specific PROMS, which usually take the form of questionnaires, made up of a fixed number of items or questions. Patients are asked to rate different aspects of their health status, over a given timeframe, using ordinal numerical scales. Individual scores are combined to produce a summary score, which may be said to represent the impact of a health condition on that person's health-related functioning and disability. The type of data therefore, which is integral to answering the research question, is precisely defined numerical data, collected in an unbiased manner, and from which there is no variance (Portney & Watkins 2000).

Firstly it was necessary to conduct a search of the scientific literature, in a systematic and rigorous manner, to identify validated shoulder region-specific PROMs of potential interest. It was then necessary to identify the best method not only to compare the outcomes currently assessed in PROMs but also, within the context of the thesis, a method had to be identified which would facilitate comparison of the content of PROMS with the outcomes patients identified as important, in the preceding study. Finally it was necessary to identify relevant criteria to rate the validity, reliability, responsiveness and interpretability of PROMs, to assist clinicians and clinical researchers in their evidence based selection of relevant measures, for their different purposes.

It would have been possible to identify the meaningful concepts in each item and use a qualitative coding approach, as in the preceding study, which would include putting measures in place to enhance the trustworthiness of the data. However, as indicated above, PROMs purport to capture data on different aspects of physical, emotional and social functioning, which suggests they adopt a biopsychosocial (BPS) approach to conceptualise the impact of a health condition. This in turn presupposes that a model of health and disability, which also adopts a BPS approach, may be used to conceptualise the outcomes assessed in PROMs and facilitate comparison of the views of patients and content of PROMs.

The primary outcomes of interest in the biomedical model of disability, which focuses on the linear relationship between pathology and impairment, are morbidity or mortality (Portney & Watkins 2000). This model is therefore not suitable to conceptualise health outcomes, for MSP. The disablement model (Nagi 1965) expanded the biomedical model to more adequately conceptualise the consequence of active pathology. It was the first model to adopt a BPS approach to demonstrate the theoretical inter-relationships between pathology, impairments and limitations in activities of daily living and performance of activities, within socially defined roles (Portney & Watkins 2009). The most recent and expanded model of functioning and disability, which also adopts a BPS approach, is the ICF (WHO 2001). Existing evidence that the ICF has been used, in other MSK conditions of the upper limb, to conceptualise the outcomes in patient-based measures (Jerosch-Herold, Leite and Song 2006; Stamm et al. 2006), justified its use in this study. Meaningful concepts identified in each item of PROMs may be coded and categorised within the ICF framework and the frequency with which concepts are reflected in PROMS may be counted.

Another reason for using the ICF is that rules have been established to link health-related information to the most relevant and precise ICF categories, in a systematic and rigorous manner (Cieza et al. 2005). Existing evidence also demonstrates the reliability and consistency of the application of the linking rules (Stamm et al. 2006; Silva Drummond et al. 2007). This further justifies the use of the ICF not only to compare the outcomes assessed in PROMs, in this study, but also to compare the content of PROMS with the outcomes patients identified as important, in a subsequent study.

5.4 Aims of the study

The aims of this study were:

i) to identify validated shoulder region-specific PROMs which met the eligibility criteria

ii) to synthesise existing evidence on the measurement properties of PROMs, using clearly defined criteria

iii) to collate the items contained in PROMs

iv) to identify the outcomes currently assessed in PROMs, by linking the meaningful concepts in items to the most relevant and precise categories of the ICF classification, using established rules

v) to compare the ICF-based outcomes assessed in individual PROMs

5.5 Methods of investigation

This section describes the methods of investigation, including the search strategies used to identify PROMS of potential interest, the criteria used to identify eligible PROMS, the criteria used to rate the measurement properties of selected PROMS and methods used to enhance the quality of the data.

5.5.1 Primary literature search

This section describes the rigorous and transparent methods used to identify validated shoulder-region specific PROMs for inclusion in the study. A structured literature search was performed. The electronic databases Medline® (1966-February Week 2 2009), AMED (1985-February 2009), CINAHL® (1982-February Week 3 2009), EMBase (1980-2009 Week 07) and PsycINFO (1966-2009) were searched from their inception to February 2009. The MeSH terms and text words used to identify potentially relevant citations were shoulder pain, disability evaluation, questionnaire, psychometric or clinimetric, validity; reliability and responsiveness or sensitivity. A hand search of citations was performed to identify descriptive, evaluative and psychometric primary research studies; systematic reviews and case reports being excluded. Abstracts of articles written as a full report and published in English in a peer reviewed journal were examined further to identify studies reporting the development or empirical validation of shoulder region-specific PROMs. The names of potentially eligible PROMs were used as terms for a further search of all electronic databases.

To cross check the sensitivity of the electronic search strategy and to identify any additional relevant studies, a hand search of the reference lists of retrieved articles was performed. In addition a hand search of the following key journals was performed to identify any studies which may have been indexed incorrectly: Annals of the Rheumatic Diseases, Journal of Bone and Joint Surgery (Br and

Am), Journal Orthopaedic Sports Physical Therapy, Journal of Rheumatology and Journal of Shoulder and Elbow Surgery.

5.5.2 Secondary literature search

A similar search strategy was used to identify secondary research studies, published up to February 2009 which were designed firstly to identify high quality primary research studies reporting the development and empirical validation of PROMs and secondly to systematically appraise and compare the measurement properties of validated shoulder region-specific PROMs, using clearly defined criteria. This information was used to synthesise existing evidence on the measurement properties of eligible PROMs in this study. Six measurement properties i.e. internal consistency, test-retest reliability, standard error of measurement, responsiveness, minimal detectable change and interpretability will be rated, minimum = 0, maximum = 6, to facilitate comparisons between PROMS. Findings may be used by clinicians and clinical researchers in their evidence based selection of the most appropriate PROMs to use, for their different purposes, in future clinical practice and research studies. Findings may also be used to identify gaps in existing knowledge on the criteria which should be used to judge the measurement properties of PROMs.

5.5.3 Inclusion and exclusion criteria

Region-specific PROMs, containing items on the self-assessment of impairment or physical, psychological or social functioning in musculoskeletal shoulder conditions, were eligible for inclusion in this study. Potentially eligible PROMs were cross-checked against the criteria, summarised in Table 5-1, regarding their suitability for inclusion in the study.

PROMs were excluded if clinically-based measures of impairment or physical function were combined with patient reported items. Shoulder disease-specific PROMs, developed to assess instability, rotator cuff disease or OA, were excluded on the grounds they may not reflect all outcomes, important to all patients (Gabel et al. 2006). PROMs developed for the assessment of specialised shoulder function in the athlete, wheelchair user or specific occupational subgroups such as keyboard operators, were excluded for the same reason.

PROMs developed for the assessment of shoulder pain from a wide range of other pathological conditions, which may affect shoulder function, were excluded on the grounds that patients may not be able to differentiate their MSK shoulder pain from that of other causes. PROMs developed for the assessment of outcome following surgery for carcinoma of the shoulder or neck region were excluded for the same reason.

Table 5-1: Criteria against which PROMs were checked regarding their eligibility for inclusion in the study

Inclusion criteria
Primary research articles on the development or empirical validation of shoulder region-specific patient report measures
PROMs including items on the self-assessment of shoulder functions or physical, psychological or social functioning related to a MSK shoulder condition.
Written as a full report, published in English in peer reviewed journals, irrespective of the date of publication
Exclusion criteria
Any item asking patients to rate the overall change or level of satisfaction in their health status would not be subjected to further analysis
Any measure sampling a single construct e.g. pain
Combined patient reported and clinically-based measures of impairment or physical function
Shoulder disease specific measures e.g. instability, rotator cuff disease or arthritis
Measures developed for the assessment of specialised shoulder function e.g. elite swimmer or professional cricketer or where the patient is a wheelchair user
Specific occupational subgroups e.g. keyboard operators
Shoulder pain from other pathological causes: Carcinoma of the shoulder region e.g. surgery for Ca breast or neck region Neurological conditions e.g. Multiple Sclerosis, Parkinson's disease or Stroke Systemic rheumatological conditions e.g. Rheumatoid Arthritis Muscle impairment of the shoulder e.g. Dystonia or Fibromyalgia

5.6 Collation of items contained in PROMs

This section describes the methods used to collate the items contained in PROMs in preparation for further data analysis. The scales of each PROM were deconstructed and items on the self-assessment of impairment or physical, psychological or social functioning in musculoskeletal shoulder conditions were identified. Where terminology was ambiguous items were interpreted with relation either to the instructions to patients or the range of possible response options. However the time interval to which the item referred e.g. 'during the last week' was not included in this process. Items were then collated as a list, in preparation for further data analysis.

5.7 Linking outcomes in PROMs to the ICF classification

This section will describe the methods used to identify and systematically link and compare the outcomes contained in twelve shoulder region-specific PROMs, using the ICF as a reference tool (Cieza et al. 2005). Evidence of similar work which has compared measures used to assess outcomes in OA of the hand (Stamm et al. 2006) and carpal tunnel syndrome (CTS) (Jerosch-Herold, Leite & Song 2006) or measure symptoms and functional status in patients with upper limb MSK conditions (Silva Drummond et al. 2007) serves to demonstrate the rigour of methods used.

ICF categories are the building blocks of the ICF classification (Stucki et al. 2008). Categories are arranged in a stem-branch-leaf scheme with the more specific lower level categories sharing the same attributes as the less specific higher level category. The full version extends to four levels. The ICF uses an alphanumeric system in which the letters b, s, d and e are used to denote body functions, body structures, activities and participation and environmental factors, respectively. Letters are followed by a numeric code that starts with chapter number (one digit) followed by second level category (two digits) and third and forth level categories (one digit for each). For example, the component body function (b2) contains the following codes:

i) b2: sensory functions and pain

i) b280: sensation of pain

ii) b2801: pain in body part

iii) b28014: pain in upper limb

Based on the linking rules, outcomes contained in PROMs were linked to the most relevant and precise first and second level ICF categories, as recommended for the evaluation of health outcomes (WHO 2001).

The first step of analysis was to identify the outcomes, or meaningful concepts, contained in each item. A concept may be defined as a separate meaningful entity such as a body function, body structure, activity or contextual factor, pain being one such example (Stamm et al. 2006). Any item containing insufficient information to enable concepts to be identified was coded nd: not definable; any item related to a health condition was coded hc: health condition; any item related to an individual's personal characteristics was coded pf: personal factor and those concepts which were not covered by the ICF classification were coded nc: not covered.

Data on the categories to which items were linked and the frequency with which outcomes were assessed were collated. Numerical data were converted to percentages, where appropriate, to facilitate comparison within, between and across individual PROMs. Any outcome not covered by the ICF classification was documented.

Data will be used firstly to determine which outcomes are currently assessed in shoulder region-specific PROMs and secondly to compare the content of individual PROMs.

5.8 Methods used to enhance the quality of the data

This section describes the steps taken to verify the reliability and consistency of the methods used to enhance the quality of the data, including the use of the ICF to identify and categorise the outcomes currently assessed in validated shoulder region-specific PROMs. Existing evidence demonstrates both the rigour of the application of the linking rules and the ability to check the level of agreement between two raters coding health-related information independently of each other when linking PROMs to the ICF (Stamm et al. 2006; Silva Drummond et al. 2007). In this study three approaches were used.

5.8.1 Peer review

As ICF ambiguities in the linking rules may be open to different interpretation (Xiong & Hartley 2008) it was planned that any inconsistencies in linking the outcomes to the ICF as a result of the researcher's interpretation of the linking rules were identified at peer review, to ensure that a common vision might be agreed (Miles & Huberman 1994). As a result of peer review the researcher would be able to make an informed decision, to enable the final coding scheme to be systematically and consistently applied across all PROMs.

5.8.2 Estimation of inter-rater reliability

Inter-rater reliability may be defined as a measure of the level of agreement between two persons who independently assign alphanumeric codes to textual data (Miles & Huberman 1994). It was planned that two research collaborators would independently link the outcomes assessed in a sample of PROMs to the most relevant and precise categories of the ICF classification. Comparison of the two lists of ICF categories would enable the percentage level of inter-rater agreement to be determined. Where 100% would indicate perfect agreement, a 90% level of inter-rater agreement was regarded as acceptable for this study (Miles & Huberman 1994). It was thought that this method was sufficiently robust to argue that if a 90% level of agreement was reached in the sample of PROMs, then the same acceptable level of inter-rater agreement would be achieved across all PROMs.

Use of only two raters, which may be considered a limitation of this study, was offset by the fact that they were from different professional backgrounds and had an understanding of the structure of the ICF categories and prior experience of using the linking rules.

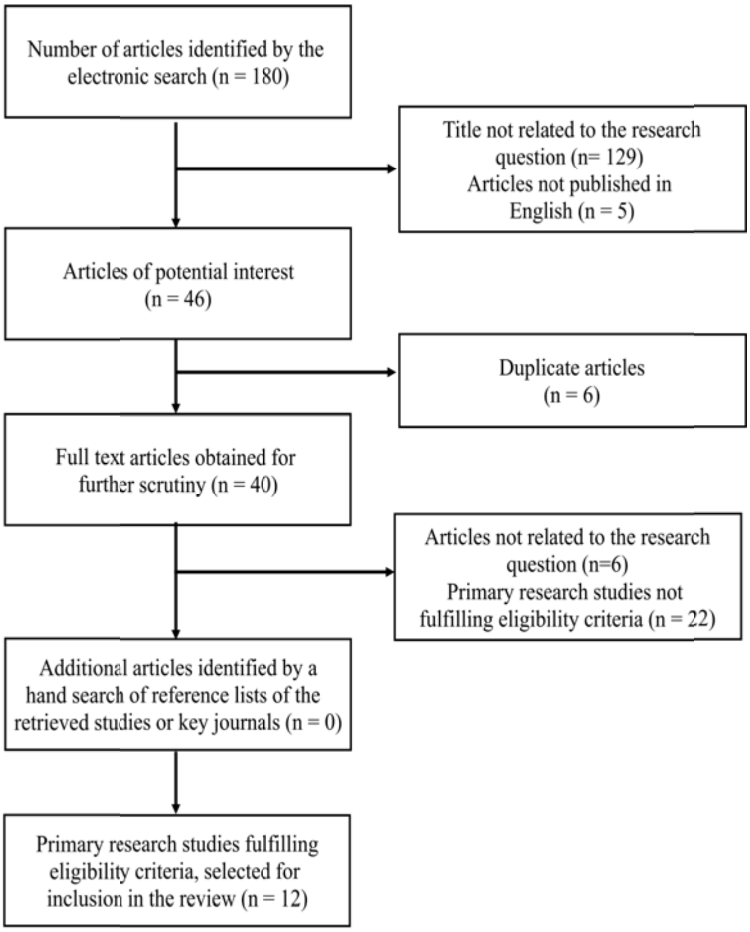
5.8.3 Provision of an audit trail

Any information integral to the research process, including examples of data analysis, not included in the main text were made available as appendices. Any reader may follow this audit trail to verify the reliability and consistency of the methods used by the researcher, to enhance the quality of the data.

5.9 Research findings

5.9.1 Results of the primary literature search

The electronic literature search produced 180 citations of potential interest. Further examination of the citations identified 40 articles, published in full in English, in peer review journals, which warranted further investigation. Examination of the full text articles of primary research studies reporting the development or empirical validation of shoulder region-specific PROMs identified 34 studies of potential interest. No additional articles were identified from a hand search of the reference lists of retrieved studies or key journals, which validated the sensitivity of the search strategy.



adapted Moher et al. 2009 @ http://www.prisma-statement.org

Figure 5-1: Results of the search for primary research studies reporting the development or empirical validation of shoulder region-specific PROMs, summarising the number of records identified, included and excluded

A flow diagram which summarises the results of the literature search, including the number of records identified, included and excluded, and the reasons for exclusions, is presented in Figure 5-1.

5.9.2 Shoulder region-specific PROMs included in the review

Examination of the 34 studies which warranted further investigation identified twelve PROMs which met the eligibility criteria. PROMs included in the review are summarised in Table 5-2. A full reference list of both included and excluded measures are summarised as Appendices 5 and 6. Ten shoulder region-specific and two upper limb region-specific PROMs, containing items on the self-assessment of impairment, physical, psychological or social functioning, in musculoskeletal shoulder conditions were included in this study. Measures were developed in a number of different countries, Australia, Canada, Germany, NL, UK and USA, between 1991 and 2006.

Table 5-2: Validated shoulder region-specific PROMs included in the study

PROM	Patient Reported Outcome Measure	1st author (year, country)
SPADI	Shoulder Pain and Disability Index	Roach (1991, USA)
SST	Simple Shoulder Test	Lippitt (1993, USA)
SDQ-UK	Shoulder Disability Questionnaire	Croft (1994, UK)
ASES	Standardized Shoulder Assessment Form	Richards (1994, USA)
OSS	Oxford Shoulder Score	Dawson (1996, UK)
DASH**	Disabilities Arm, Shoulder & Hand	Hudak (1996, Canada)
SSRS	Subjective Shoulder Rating System	Kohn (1997, Germany)
SRQ	Shoulder Rating Questionnaire	L'Insalata (1997, USA)
SDQ-NL	Shoulder Disability Questionnaire	van der Windt (1998, NL)
PSS	Pennsylvania Shoulder Score	Leggin (1999, USA)
FLEX-SF*	Flexilevel Scale Shoulder Function	Cook (2003, USA)
ULFI**	Upper Limb Functional Index	Gabel (2006, Australia)

* FLEX-SF deconstructed into 3 component scales
** Upper limb region-specific PROM

5.10 Evaluation of the measurement properties of PROMs

This section presents the results of the appraisal and synthesis of existing evidence on the measurement properties of the shoulder region-specific PROMs included in this study, using clearly defined criteria. Information on the content validity of PROMS is summarised in Appendix 7. In Appendix 8 six measurement properties i.e. internal consistency, test-retest reliability, standard error of measurement, responsiveness, minimal detectable change and interpretability have been rated, minimum = 0, maximum = 6, to facilitate comparisons between PROMS. This information may be used by clinicians and clinical researchers in their evidence based selection of the most appropriate PROMs to use, for their different purposes, in future clinical practice and research studies.

5.10.1 Intended application of PROMs

Explicit information on the intended application of 3 PROMs was available i.e. the DASH, FLEX-SF and ULFI. It was proposed that these measures should be used across a variety of clinical and research settings. Typically Cook et al. (2003) concluded that “the FLEX-SF can be used as a primary endpoint in clinical trials ... the scale also has excellent properties for use in clinical settings, tracking changes in individuals over time”. This information is important for clinicians and clinical researchers wishing to identify a measure which is fit for their purpose.

5.10.2 Validity

5.10.2.1 Content validity

Five PROMs purported to assess different aspects of shoulder function, including pain sensations, sleep functions and movement-related functions. All PROMs also purported to assess different aspects of physical functioning and disability, including hand and arm use, personal care, activities of daily living work and recreation. Whilst five PROMs, the SDQ-UK, DASH, SSRS, SDQ-NL and ULFI purported to assess different aspects of psychological functioning only one PROM, the DASH, purported to assess different social, family and intimate interpersonal relationships. Information is summarised in Table 5-3.

This information is important as PROMs appear to assess different aspects of shoulder function or health-related physical, psychological or social functioning related to a MSK shoulder condition. This evidence suggests PROMs were developed using a BPS approach, some more so than others depending on their included content.

Table 5-3: Outcomes purported to be assessed by PROMs

PROM	**Outcome**
SPADI	Pain and disability
SST	Physical function
SDQ-UK	Functional activities
ASES	Pain and functional limitations
OSS	Functional activities
DASH	Symptoms, functional status, social function and emotional function
SSRS	Pain, movement, instability, functional activities & overhead working
SRQ	Functional activities and satisfaction
SDQ-NL	Functional activities
PSS	Pain, function and satisfaction
FLEX-SF	Functional limitation
ULFI	Functional limitation, overall status and patient specific index

5.10.2.2 Selection of items

Methods of investigation used in the generation of the item pool or the selection of items included in the questionnaires were not always justified or reported in full. Lack of information makes it difficult to judge the relevance and comprehensiveness of the items included in a questionnaire.

5.10.2.3 Construct validity

Information on construct validity was available for 4 PROMs, the SPADI, SST, DASH and ASES. Limited information on the assessment of construct validity, including factor analysis was available. Overall PROMs assessed 21 theoretical constructs contained within a range of 15 diverse measurement scales, which suggests that it may not always be clear what outcomes are being assessed in PROMs.

The SPADI (Roach et al. 1991) consists of 13 items contained in two scales; reflecting two constructs, pain and disability. Evidence suggests that items may assess 1-2 underlying constructs, depending on the patient group studied (Roach et al. 1991; Roddey et al. 2000). The SST (Lippitt, Harryman & Matsen 1993) which purports to measure one construct, functional ability in activities of daily living, was found to assess two constructs, pain and functional ability (Roddey et al. 2000). It was found that the DASH (Hudak, Amadio & Bombardier 1996), which contains 30 items within a single scale, does assess a single construct i.e. disability. Factor analysis confirmed that the ASES (Richards et al. 1994) assesses two constructs, pain and function.

This information is important in determining which outcomes are assessed in individual PROMs.

5.10.2.4 Patient involvement in the development of PROMs

Information on patient involvement in the development of measures was available for 7 PROMs, the SST, SDQ-UK, OSS, DASH, SRQ, FLEX-SF and ULFI. However the nature and extent of this involvement and the robustness of methods used were not always reported in full. Whilst L'Insalata (1997) reported that “a preliminary questionnaire was developed and completed by 30 patients … a subset of these patients was interviewed and each question was assessed for clinical relevance”, other authors Hudak (1996) and Cook (2003) reported in full the methods used to ensure that the final items comprehensively covered all issues which were important to the target population. Overall it is difficult to judge from the information provided how relevant and meaningful the outcomes may be, from the patient’s perspective.

5.10.3 Reliability

5.10.3.1 Test-retest reliability

Information on test-retest reliability was available for 9 PROMs, the SPADI, SST, ASES, DASH, SSRS, SRQ, PSS, FLEX-SF and ULFI. All PROMs, except the SPADI (ICC=0.65) and SSRS (ICC = 0.71) achieved an acceptable level of reliability. This is important as an unreliable measure may underestimate the size of an effect from an intervention.

5.10.3.2 Standard error of measurement

Information on the error measure (SEM) was available for 6 PROMs, the SPADI, SST, ASES, DASH, PSS and ULFI. This information is important as it may be used to define that amount of change which is of clinical benefit to patients.

5.10.3.3 Internal consistency

Information on internal consistency was available for 9 PROMs, the SPADI, SST, ASES, OSS, DASH, SRQ, PSS, FLEX-SF and ULFI. Scores ranged between 0.85 and 0.97. The SST, ASES, OSS, SRQ, PSS, Flex-SF and ULFI demonstrated an acceptable level of internal consistency, with alpha scores between 0.85 and 0.93. However it is suggested that the SPADI and DASH, with alpha scores of 0.95 and 0.97 respectively, contain items which may be redundant (Portney & Watkins 2009).

5.10.4 Responsiveness

Information on the minimal detectable change (MDC) i.e. the smallest amount of change which would be statistically significant was available for 4 PROMs, the DASH, ASES, PSS and ULFI.

Information on responsiveness as defined by the ES statistic or SRM was available for all PROMs. However as responsiveness is not an inherent property of an instrument but related to a specific application, the interpretation of responsiveness is a subjective one (Fitzpatrick et al. 1998).

5.10.5 Interpretability

Information on the MCID in those patients who perceive to be improved was available for 7 PROMs, the SPADI, ASES, OSS, DASH, SRQ, PSS and FLEX-SF. Data are summarised in Table 5-4, in relation to SEM and MDC to enable meaningful comparisons between measures to be made. Interpretation of the MCID should be made with reference to the patient group or subgroup, intervention and research context (Portney & Watkins 2009).

Table 5-4: The relationship of the MCID to the SEM and MDC, in that group of patients who experienced important change in their health status (adapted Bot et al. 2004)

PROM	SEM	MDC	MCID
SPADI	+/- 9.3 pts (95% CI)	-	> 10 pts
SST	+/- 22.8 pts (95% CI)	-	-
ASES	6.7 pts +/- 11.0 pts	9.7 pts +/- 15.5 pts	6.4 pts
OSS	-	-	½ SD change score
DASH	7.6 pts (90% CI)	12.8 pts (90% CI)	10 pts
PSS	+/- 8.5 pts (90% CI)	+/- 12.1 pts	11.4 pts
ULFI	1.13 pts (95% CI)	2.6 pts (95% CI)	-

Key: CI = Confidence intervals; SD = Standard deviation

Criteria have been defined to guide clinicians and clinical researchers in their selection of relevant PROMs, for their different purposes (Bot et al. 2004; Terwee et al. 2007). Based on the measurement properties of existing PROMs there is no substantial evidence to recommend one patient-based measure over the others. Comparisons of measurement properties are subjective and should be made with reference to the patient group or subgroup, intervention and research context in which the PROM will be used. This will enable meaningful comparisons to be made across similar clinical populations (Portney & Watkins 2009). Findings have identified gaps in existing knowledge on the criteria which should be used to judge the measurement properties of PROMs, which should be evaluated in future research studies.

5.11 Results of collating items contained in PROMs

Twelve validated shoulder region-specific PROMs met the eligibility criteria. For the purpose of this study the FLEX-SF (Cook 2003) was deconstructed into three measures assessing easy, medium and hard upper limb dysfunction. Fourteen measures were therefore subjected to further analysis.

On the face of it not all constructs appeared to be measured using a separate subscale. PROMs contained differing number of items, range 5-30. Items were contained within a variety of different measurement scales, most commonly numerical rating scales or 3/ 5-point Likert scales, designed to capture captured nominal, ordinal or continuous data. Collating items in individual measures resulted in a list of 234 items ready for further data analysis.

5.12 Linking the outcomes assessed in PROMs to the ICF

This section reports the results of linking the outcomes, or meaningful concepts, identified in individual items in self-assessment questionnaires to the most relevant and precise first and second level ICF categories. The extent to which outcomes assessed in PROMs were reflected in ICF components and first and second level ICF categories will then be presented.

5.12.1 Linking individual items in questionnaires to the ICF

Linking some items to the ICF required no interpretation:

Item	Concept	ICF code	ICF category
"How severe is your pain at its worst?" (Roach 1991)	Pain severity	b280	Sensation of pain
"Please rate your ability to wash your back (Hudak 1996)"	Washing	d510	Washing oneself

Where necessary the content of the item was contextualised using the range of possible responses:

Item	Concept	ICF code	ICF category
"Is your activity limited by shoulder complaints? (No ... Sports and work are slightly limited ... I had to change sports or work ... I gave up sports or quit work)" (Kohn 1997)	Work	d850	Remunerative employment
	Sports	d920	Recreation and leisure

Some items were linked to one or more different ICF categories:

Item	Concept	ICF code	ICF category
"Considering all the ways you use your shoulder during daily personal and household activities (i.e. dressing, washing, driving, household chores etc.) how would you describe your ability to use your shoulder? (L'Insalata 1997)"	Dressing	d540	Dressing
	Washing	d510	Washing oneself
	Driving	d475	Driving
	Household chores	d640	Doing housework

Items in an individual PROM were coded to the same ICF categories:

Item	Concept	ICF code	ICF category
“My shoulder hurts when I bring my hand towards my buttocks” (van der Windt 1998)	Pain	b280	Sensation of pain
	Reaching	d445	Hand and arm use
“My shoulder hurts when I bring my hand towards my lower back” (van der Windt 1998)	Pain	b280	Sensation of pain
	Reaching	d445	Hand and arm use
“My shoulder hurts when I bring my hand towards the back of my head” (van der Windt 1998)	Pain	b280	Sensation of pain
	Reaching	d445	Hand and arm use

Concepts in some items could not be linked to the ICF:

Item	Concept	ICF code	ICF category
“Are you afraid of shoulder dislocation?” (Kohn 1997)	Fear	b152	Emotional functions
	Shoulder dislocation	nc	not covered

Concepts in some items could not be defined:

Item	Concept	ICF code	ICF category
“**Due to my arm:** I use the other arm more often *(Gabel 2006)”*	-	nd	not definable

It would have been possible for the researcher to compare each item in a questionnaire with the qualitative themes to see if they related to the same content. However the use of established rules to systematically link the meaningful concepts contained in PROMs to the ICF made it transparent where items were sometimes ambiguous and difficult to interpret or where outcomes could not be linked to the ICF. The result of the linking process is a list of ICF codes, which may be said to equate in content to the original health-related information, and a list of meaningful concepts which could not be linked to the ICF classification.

5.12.2 Linking the outcomes assessed in PROMs to the ICF

Outcomes assessed in twelve PROMs were linked to the ICF classification. The results of linking one measure, the SPADI (Roach et al. 1991), which typifies the manner in which the linking rules were applied, may be found as Appendix 9. Using similar methods each patient-reported measure in turn was linked to first and second level ICF categories; the frequency with which each outcome was reflected is represented in tabular form, as Appendix 10. Numerical data were converted to percentages to facilitate comparisons within, between and across measures.

In total one hundred and fifty five concepts, in two hundred and thirty four items, were assessed three hundred and thirty times; of these ninety three percent were linked to the ICF. This information is summarised in Table 5-5.

Table 5-5: Total number, frequency and proportion of outcomes reflected in PROMs, which were linked to the ICF classification

	Number	**Proportion (%)**
Number of items	234	-
Number of outcomes identified	155	-
Frequency outcomes were assessed	330	-
Number of concepts linked to ICF	144	93%
Number of concepts not linked to ICF	11	7%

Findings suggest that individual PROMs may assess some outcomes a number of times by asking the same question in different ways; this would in turn suggest that some items may be redundant.

Table 5-6: Number of ICF categories to which outcomes assessed in PROMs were linked

ICF category	**Number of categories**
First level category	11
Second level category	37
Body functions component	9
Activities and participation component	28

Outcomes assessed in PROMs were linked to 11 first-level and 37 second-level ICF categories, the latter including 9 of the body functions component and 28 of the activities and participation component. Information is summarised in Table 5-6.

A list of the first and second level ICF categories to which outcomes in PROMs were linked is presented as Appendix 11. This evidence suggests, because of the wide range of different outcomes reflected in PROMs as a whole, that whilst existing measures may not have been modelled using the ICF conceptual framework, they adopt a BPS approach to the assessment of outcome for MSP.

As reported above a minority i.e. 7% of concepts contained in 11 items, could not be linked to the ICF classification. Seven concepts e.g. ‘I have difficulty with normal home or family duties and chores’ (Gabel et al. 2006), too broad to be defined, were coded nd: not definable. Three concepts e.g. ‘Because of your shoulder do you have more minor accidents?’ (Croft et al. 1994) were coded nc: not covered by the ICF and one concept relating to shoulder dislocation (Kohn & Geyer 1997) was coded hc: healthcare condition.

As anticipated none of the outcomes in PROMs, which purported to assess impairment or physical, psychological or social functioning related to a MSK shoulder condition, were linked to the ICF components body structures or environmental factors. This is consistent with the aims of the research. Clinicians and clinical researchers may wish to use additional questionnaires or clinically-based measures of physical performance to capture this type of data.

5.13 Evaluation of outcomes currently assessed in PROMs

The next section will detail the extent to which the outcomes assessed in PROMs as a whole were reflected in ICF components and first and second level ICF categories. Results will be presented using graphs and tables supported by narrative text for ease of reading.

5.13.1 ICF components

The proportion of outcomes reflected in the ICF components body functions and activities and participation are summarised in Figure 5-2.

Five PROMs, the SDQ-UK, ULFI, SPADI, OSS and DASH, reflected the profile of the ‘average’ measure in which 26% of outcomes assessed different aspects of shoulder function and 74% assessed different aspects of health-related functioning related to a MSK shoulder condition.

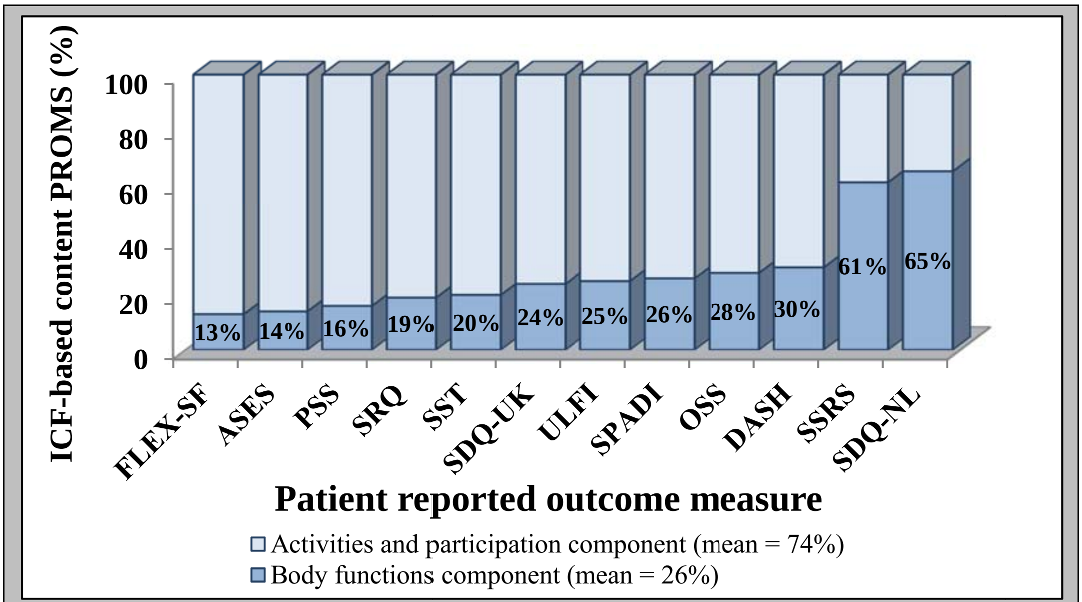


Figure 5-2: The extent to which the outcomes assessed in PROMs was reflected in ICF components body functions and activities and participation

Two PROMs, the SSRS and SDQ-NL, focussed on the assessment of shoulder function (61-65%) and five, the FLEX-SF, ASES, PSS, SRQ and SST focussed on the assessment of different aspects of functioning or disability (13-20%), related to a MSK shoulder condition.

5.13.2 First level ICF categories

Table 5-7: First level ICF categories reflected in PROMs

ICF code	Category
Body functions component	
b1	Mental functions
b2	Sensory functions and pain
b7	Neuromusculoskeletal and movement-related functions
Activities and participation component	
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

As reported above 93% of outcomes assessed in PROMs were mapped to eleven first level ICF categories, which are listed in Table 5-7.

The extent to which outcomes were reflected in each category is summarised in Figure 5-3. The DASH is the most comprehensive measure, reflecting all ICF categories. Of the remainder five PROMs, the SDQ-UK, ULFI, SRQ, PSS and OSS reflect ¾, four, the ASES, SSRS, SDQ-NL and SST ½ and two, the FLEX-SF and SPADI ¼ first level ICF categories.

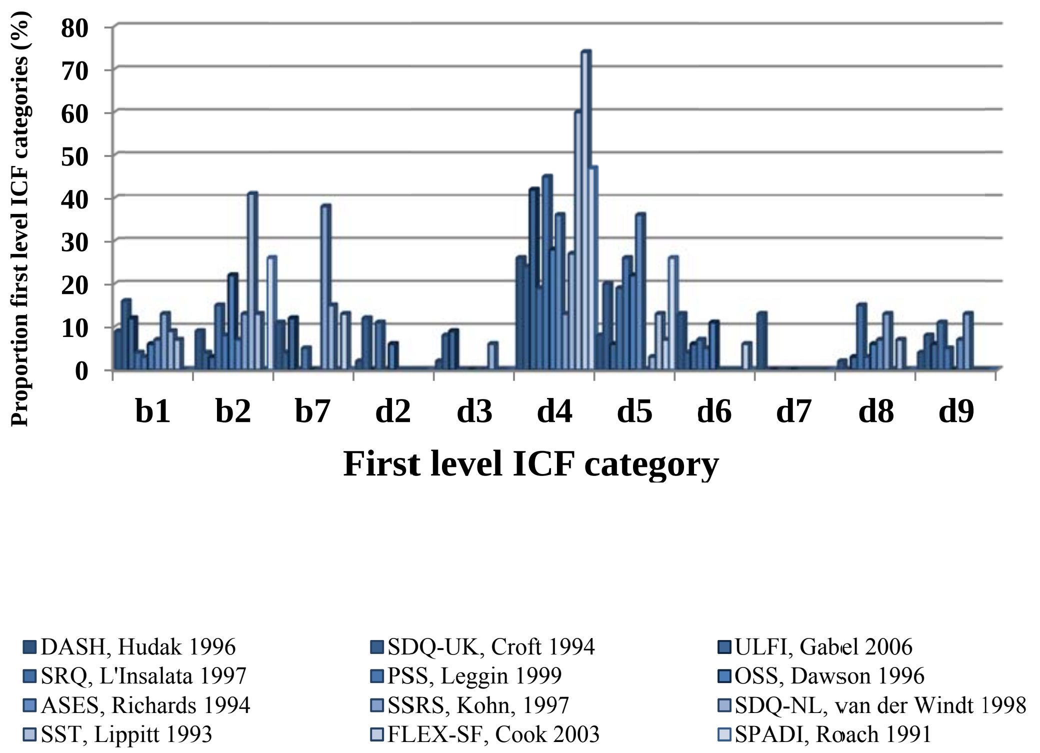


Figure 5-3: Extent to which outcomes assessed in PROMs was reflected in first level ICF categories

Data on the number of first level ICF categories to which outcomes assessed in PROMs were mapped is represented in Figure 5-4.

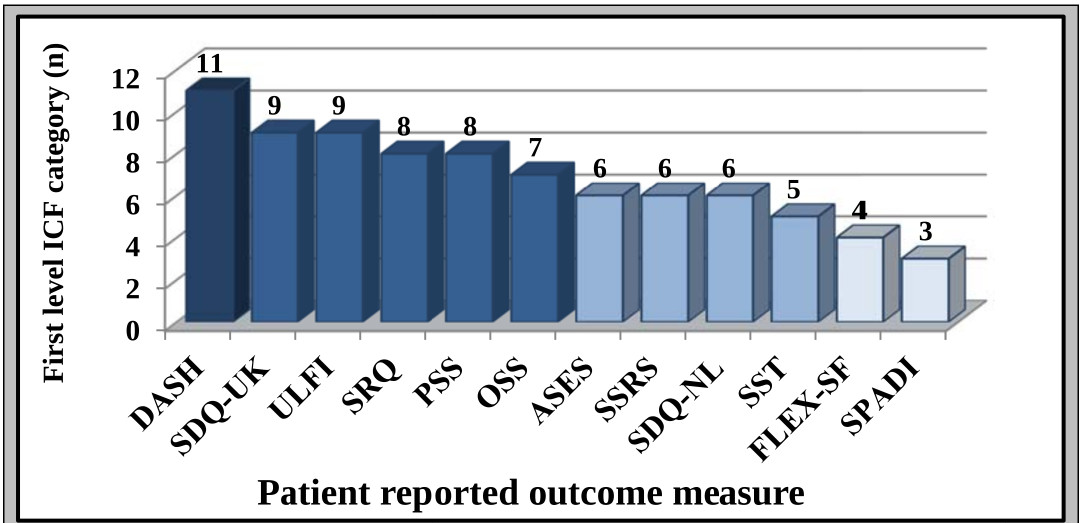


Figure 5-4: Number of first level ICF categories which outcomes assessed in PROMs were mapped

5.13.3 Outcomes assessed in individual PROMs

Having deconstructed the self-assessment questionnaires to determine which ICF-based outcomes are reflected in PROMs as a whole, the ICF may also be used to enable meaningful comparisons of the outcomes assessed in individual measures to be made. The ICF-based outcomes reflected in individual PROMs is represented in Figures 5-5 to 5- 16 below.

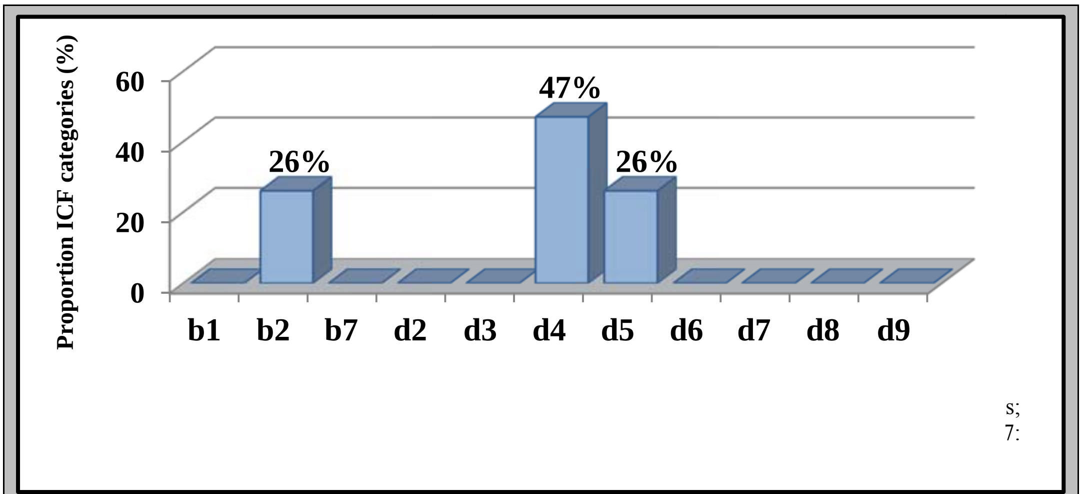


Figure 5-5: ICF-based outcomes reflected in the SPADI (Roach et al. 1991)

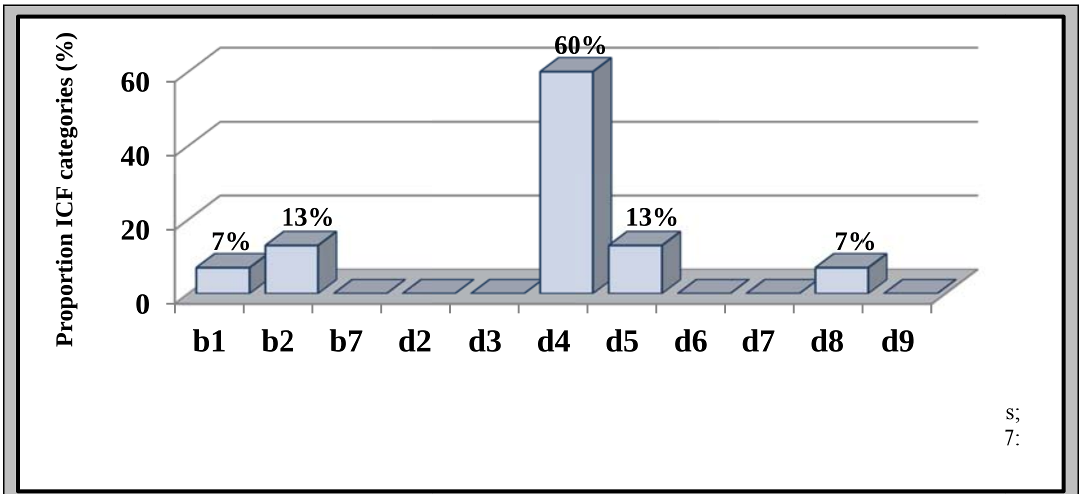


Figure 5-6: ICF-based outcomes reflected in the SST (Lippitt, 1993)

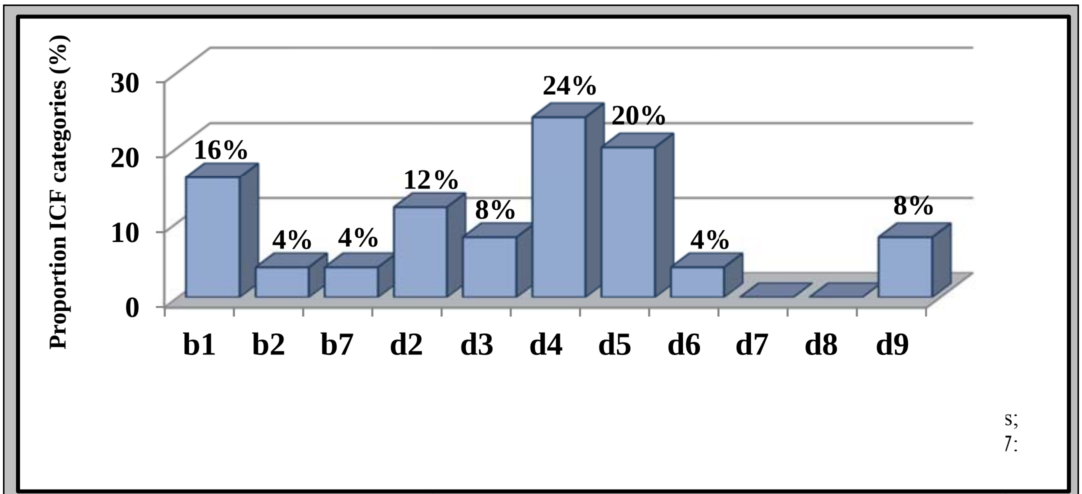


Figure 5-7: ICF-based outcomes reflected in the SDQ-UK (Croft, 1994)

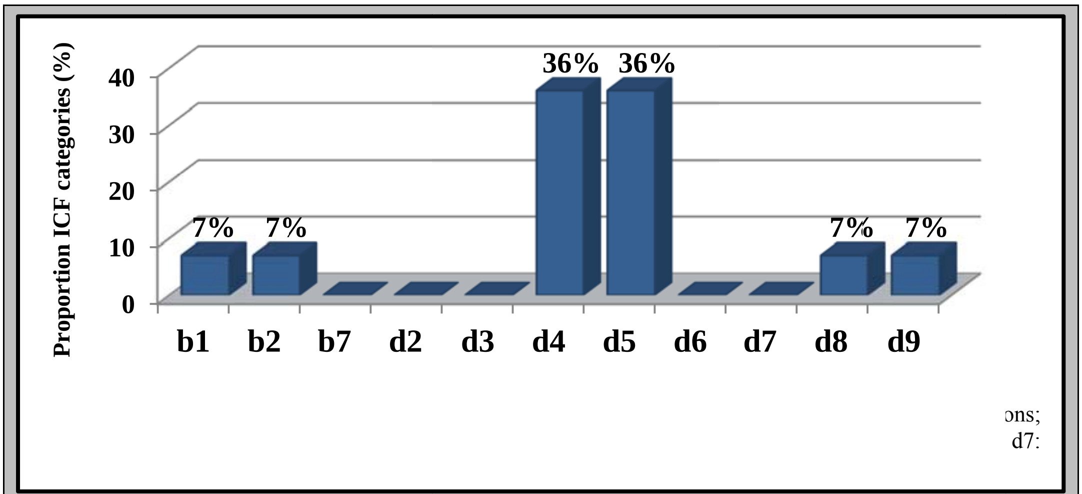


Figure 5-8: ICF-based outcomes reflected in the ASES (Richards, 1994)

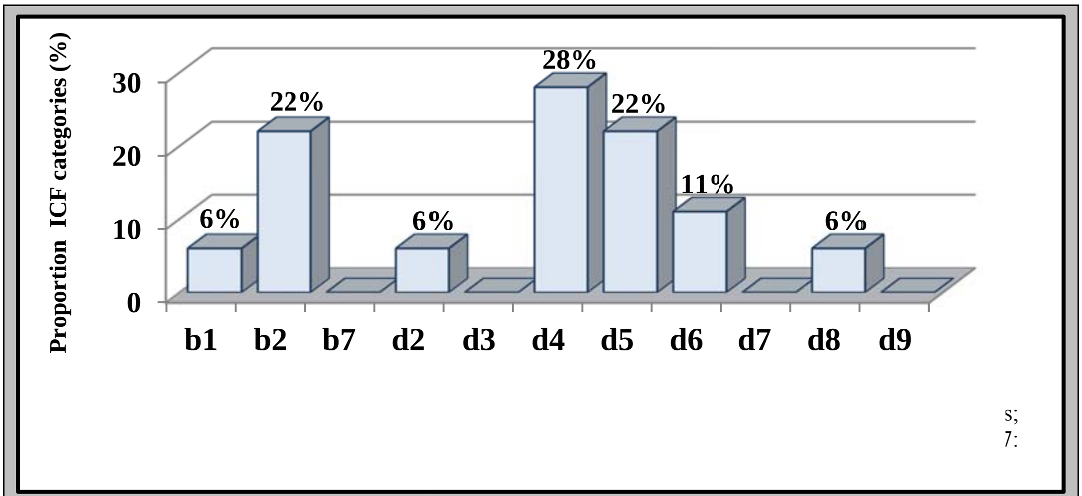


Figure 5-9: ICF-based outcomes reflected in the OSS (Dawson, 1996)

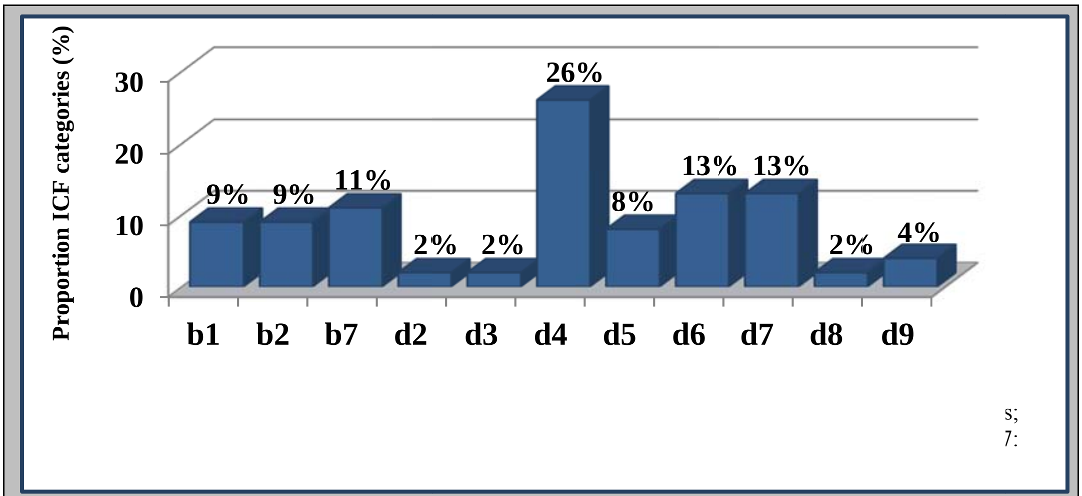


Figure 5-10: ICF-based outcomes reflected in the DASH (Hudak, 1996)

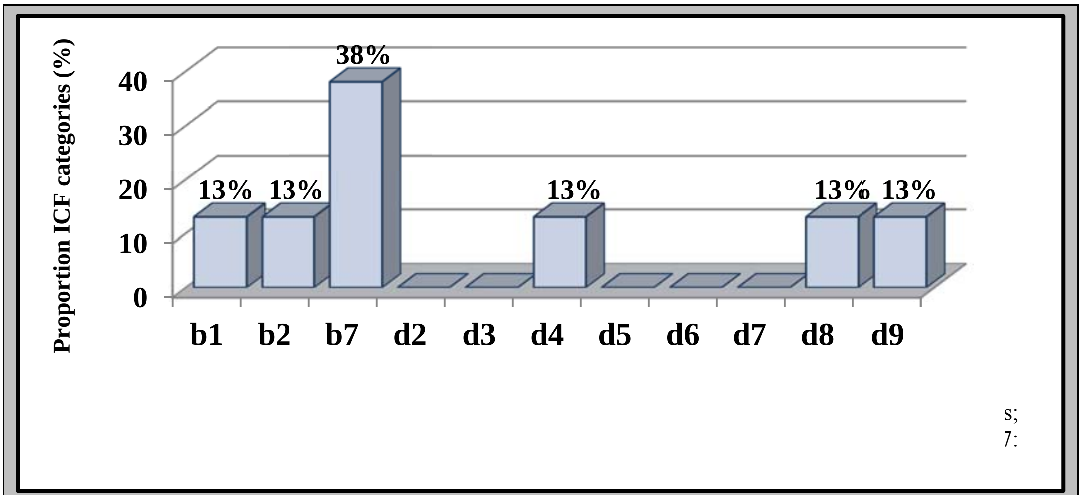


Figure 5-11: ICF-based outcomes reflected in the SSRS (Kohn, 1997)

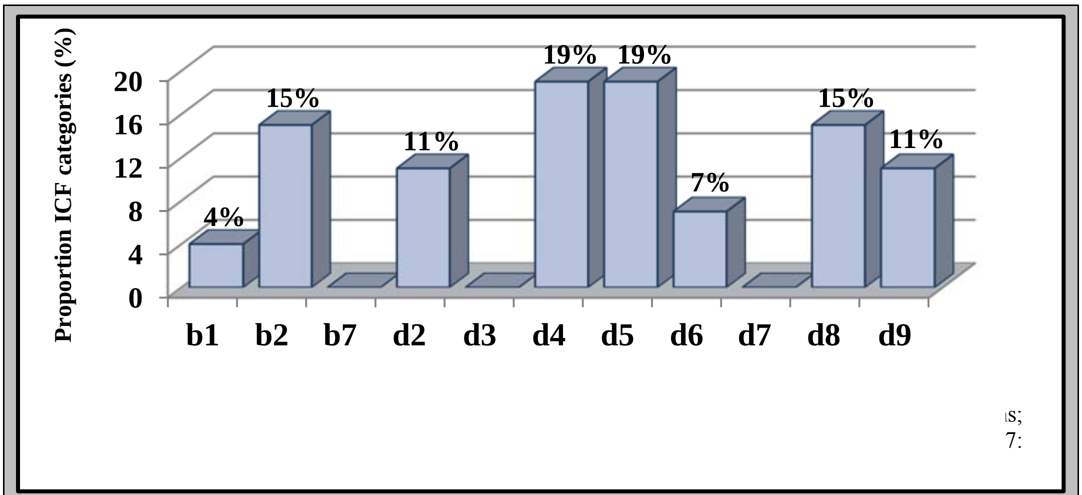


Figure 5-12: ICF-based outcomes reflected in the SRQ (L'Insalata, 1997)

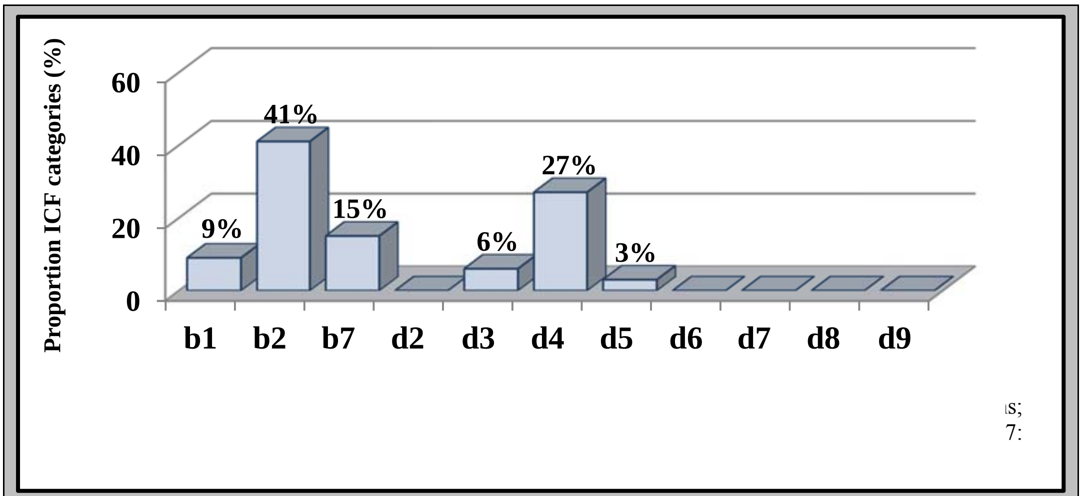


Figure 5-13: ICF-based outcomes reflected in the SDQ-NL (van der Windt, 1998)

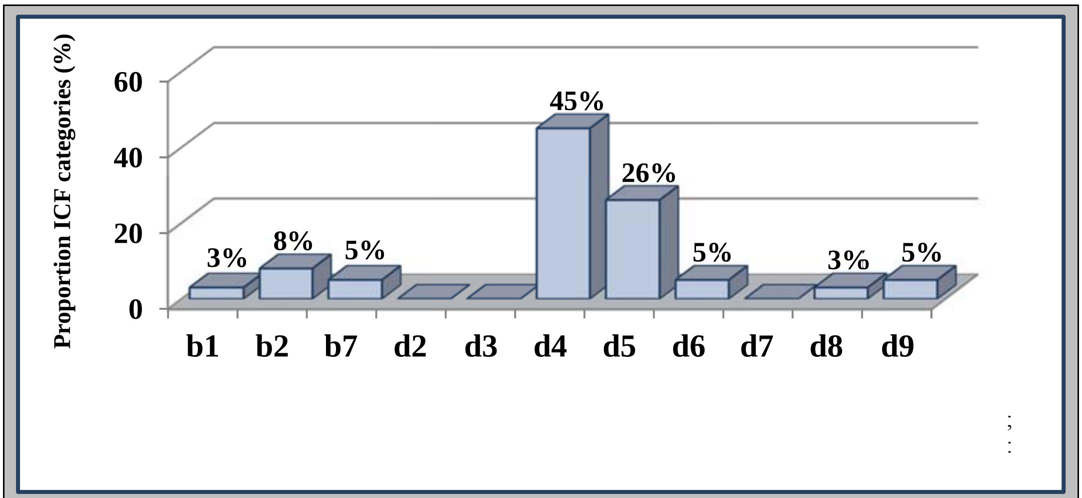


Figure 5-14: ICF-based outcomes reflected in the PSS (Leggin, 1999)

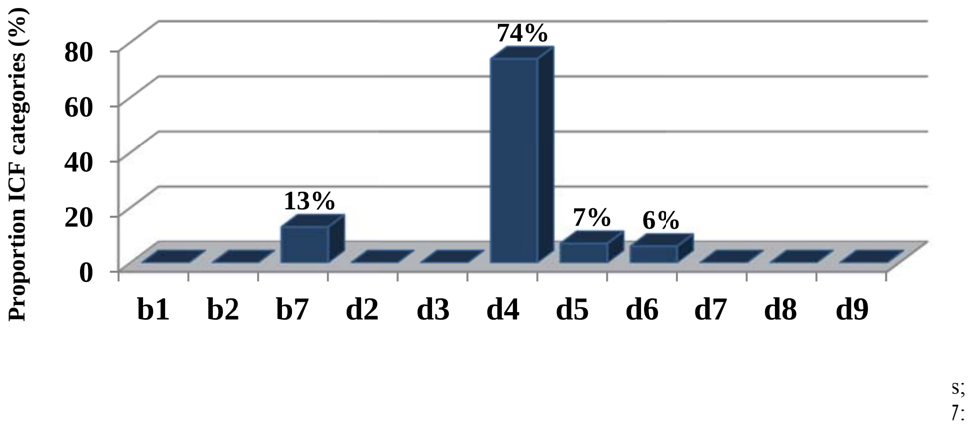


Figure 5-15: ICF-based outcomes reflected in the FLEX-SF (Cook, 2003)

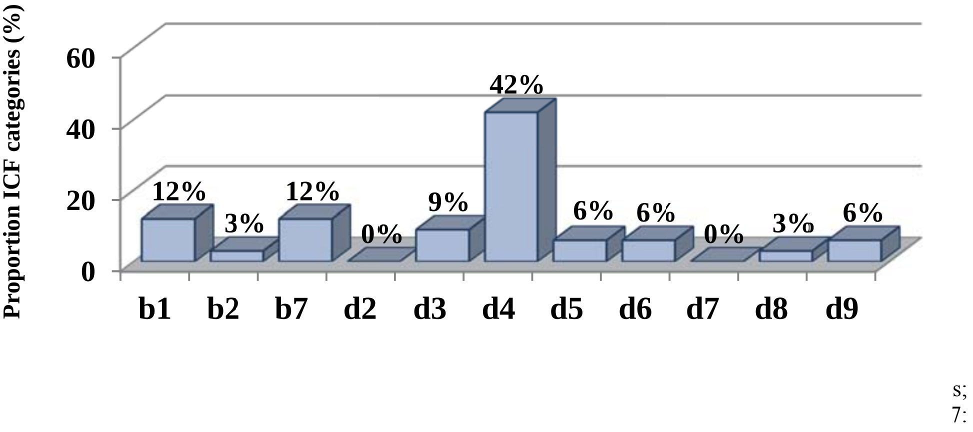


Figure 5-16: ICF-based outcomes reflected in the ULFI (Gabel, 2006)

5.13.4 Comparison of outcomes assessed in PROMs

Data on the content of validated shoulder region-specific PROMs may be used by clinicians and clinical researchers who wish to include patients' perspectives, in their selection of one or a combination of more than one PROM which covers the intended content. One such example is the comparison of the content of the DASH (Hudak, 1996) and SPADI (Roach 1991), represented in Figure 5-20.

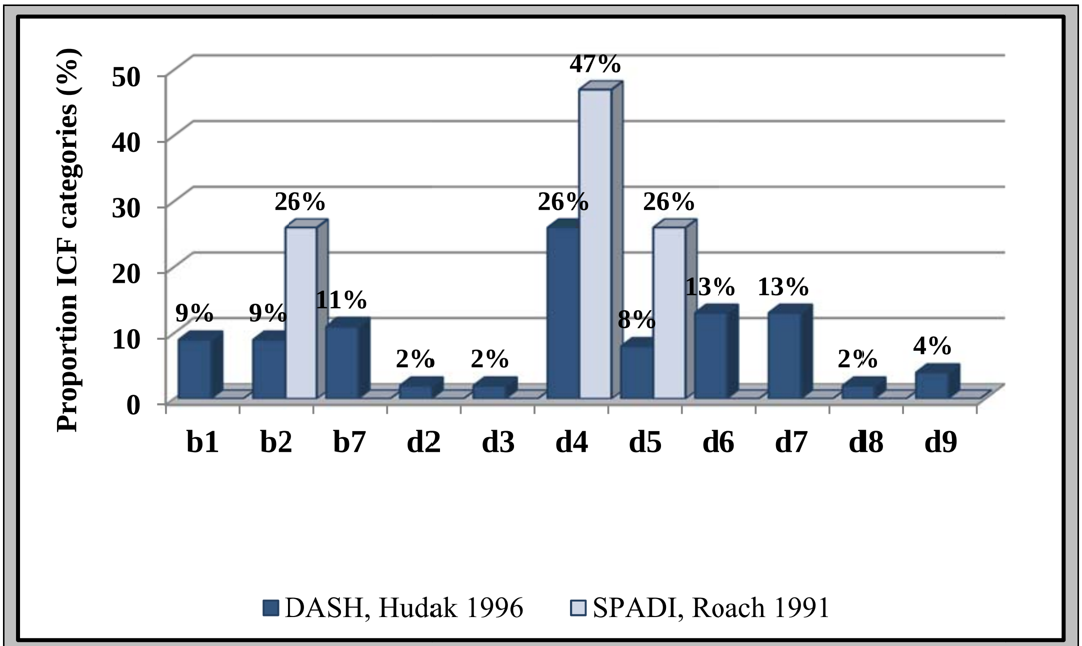


Figure 5-17: Outcomes assessed in the DASH and SPADI

Four PROMs, the DASH, SST, ASES and SPADI, have been shown to be sufficiently psychometrically robust to be able to differentiate between different patient groups or subgroups, different interventions, across a variety of different clinical and research settings (Roy et al. 209). Comparative data on the outcomes assessed in these measures is summarised in Figure 5-18.

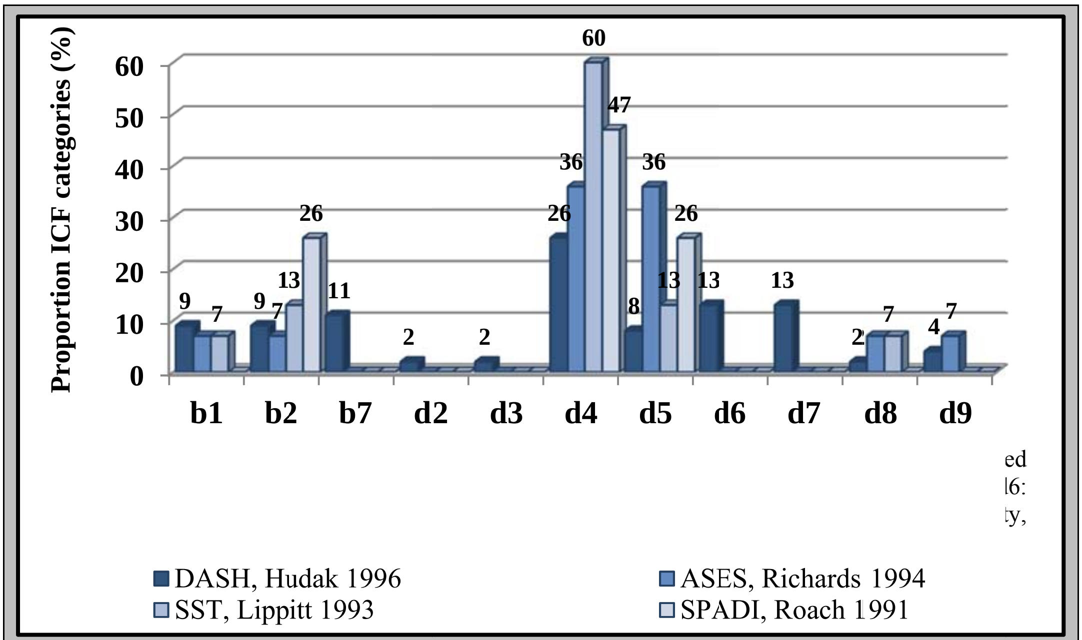


Figure 5-18: Outcomes assessed in the DASH, SST, ASES and SPADI

5.13.5 Second level ICF categories

As previously reported above the outcomes assessed in PROMs were reflected in 37 second level ICF categories, listed in Appendix 11.

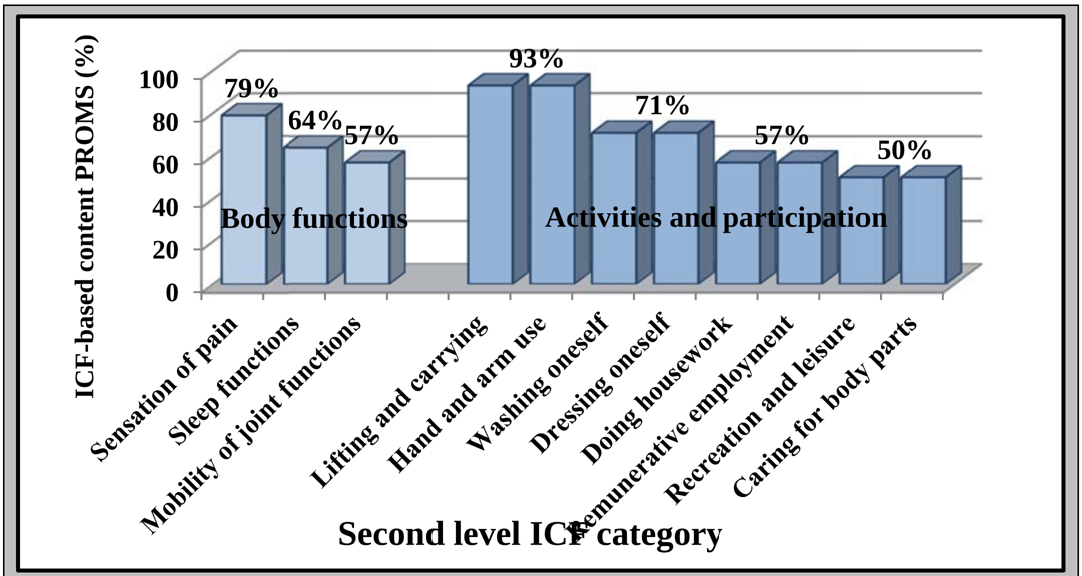


Figure 5-19: Proportion of outcomes most commonly assessed in PROMs, reflected in second level ICF categories

The proportion of outcomes linked to each second level ICF categories is detailed in Figure 5-19 and Table 5-8.

Comparative data on the extent to which second level ICF-based outcomes are reflected in individual PROMs is summarised in Appendix 12.

Table 5-8: Proportion of outcomes most commonly assessed in PROMs, reflected in first and second level ICF categories

Body functions component		
b1: Mental functions		
	b152: Emotional functions	36%
	b134: Sleep functions	64%
b2: Sensory functions and pain sensations		
	b280: Sensation of pain	79%
b7: NMSK and movement-related functions		
	b710: Mobility of joint functions	57%

Activities and participation component		
d2: General tasks and demands		29%
d3: Communication		29%
d4: Mobility		
	d430: Lifting and carrying	93%
	d445: Hand and arm use	93%
d5: Self-care		
	d510: Washing oneself	71%
	d540: Dressing	71%
	d520: Caring for body parts	50%
d6: Domestic life		
	d640: Doing housework	57%
d7: Interpersonal relationships		7%
d8: Major life areas		
	d850: Remunerative employment	57%
d9: Community, social & civic life		
	d920: Recreation and leisure	50%

5.14 Methods used to enhance the quality of the data

This section evaluates the success of the steps taken to verify the reliability and consistency of the methods used to enhance the quality of the data.

5.14.1 Peer review

Peer review was used in this study to enable any dilemmas, which arose as a result of ambiguities in the linking rules, to be resolved to everyone's satisfaction. One such dilemma was to determine if emotions, such as feeling irritable and bad tempered, should be linked to b1: Mental functions and b152: Emotional functions. It was argued that such feelings are not a mental impairment, but a natural consequence of having a health condition such as MSP, which related to an individual's personal characteristics. However, it was agreed to link emotions to b1: Mental functions, in line with existing evidence (Silva Drummond et al. 2007). Another example was to determine if overhead working was covered by the ICF; it was agreed that it should be coded to d445: Hand and arm use, which includes reaching activities.

5.14.2 Estimation of inter-rater reliability

The researcher independently linked the DASH, the only shoulder region-specific measure to have been linked to the ICF, to the most relevant and precise categories and then compared results with those reported by Silva Drummond et al. (2007). Two research collaborators each independently coded an individual PROM, either the SSRS or the SST neither of which had previously been linked to the ICF, and the results were compared with those of the researcher. The percentage agreement between two raters independently coding PROMs to the ICF classification is summarised in Table 5-9.

Whilst some PROMs appeared to map to the ICF more easily than others, the average percentage level of agreement reached in this sample was 89%. Having achieved an acceptable level of agreement (Miles & Huberman 1994) in a 25% sample of measures, it was proposed that this level of inter-rater agreement would be achieved across all PROMs.

Table 5-9: Percentage agreement between two raters independently coding three PROMs, the DASH, SSRS and SRQ, to the ICF classification

	Rater 2 DASH	**Rater 3 SSRS**	**Rater 4 SST**
Rater 1 DASH	89%	-	-
Rater 1 SSRS	-	82%	-
Rater 1 SRQ	-	-	96%
Total	89%	82%	96%

Percent agreement (%) $= \frac{\text{Number agreements between two raters}}{\text{Total number scores}} \times 100$

Peer review, the independent coding of a sample of PROMs to the ICF by research collaborators and provision of an audit have served to demonstrate the rigour of the methods used in this study to enhance the quality of the data. As a result other researchers may judge if the researcher's interpretation of the research findings is a reasonable one to make.

5.15 Discussion

This study set out to make an ICF-based comparison of the outcomes assessed in validated, shoulder region-specific PROMs, firstly to determine the extent to which individual measures reflect the same content and secondly to facilitate comparison of the views of patients and the content of patient-based measures, in a subsequent study. A secondary purpose was to synthesise existing evidence on the measurement properties of selected PROMs, to assist clinicians in their evidence-based selection of relevant and meaningful PROMs, for their different purposes.

5.15.1 Methodological considerations

Of the large number of measures available, twelve validated shoulder region-specific PROMs met the eligibility criteria, and were included in the review. No additional measures were identified from a hand search of reference lists and key journals, which validated the sensitivity of the electronic search strategy. Application of the eligibility criteria ensured that PROMs, which had a limited application across different patient subgroups or different clinical and research settings, were successfully excluded from the review. Of the twelve eligible PROMs, two were measures of upper limb function and disability, however as the function of the shoulder is subservient to that of the upper limb (Trew & Everett 2005), they were included in the review.

Ninety three percent of the meaningful concepts, identified in the items contained in PROMs, were successfully mapped to first and second level ICF categories, using the linking rules (Cieza et al. 2005). Some concepts which appeared to overlap i.e. lying on the affected side/ shoulder, gardening and DIY and childcare activities, and could be linked to different ICF categories; however such dilemmas were successfully resolved through peer review.

Concepts reflecting emotional wellbeing were also discussed at peer review, where it was emotions should be categorised as a mental impairment, in keeping with existing evidence (Silva Drummond et al. 2007). It was clear where the linking rules could not be applied i.e. where concepts could not be defined or, in one instance, where the item related to a health condition i.e. shoulder dislocation, which is not covered by the ICF. That the majority of concepts could be mapped to ICF categories, together with evidence that measures put in place successfully addressed any ambiguities in applying the linking rules, justified the use of the ICF classification in this study, to compare the content of shoulder region-specific PROMs.

5.15.2 Significance of the findings

That PROMs were linked to four first level ICF categories, reflecting a range of impairments, and seven first level ICF categories, reflecting a wide range of activity and participation limitations, would indicate that PROMs capture data on a wide range of different aspects of shoulder function or physical, emotional or social functioning, related to a MSK shoulder condition. Individual PROMs assessed a wide range of different outcomes, depending on the included content. The DASH was the most comprehensive PROM reflecting all ICF categories. It was also the only measure to assess interpersonal interactions and relationships.

Of the PROMs which have been most extensively investigated in validation studies the DASH is recommended for use as a primary outcome measure for the assessment of functioning and disability for MSP, for discriminative and evaluative purposes. The SST, ASES and SPADI, which were sufficiently robust to be able to differentiate between different patient groups, different interventions, across a variety of different clinical and research settings, should be considered as secondary outcome measures, with the SPADI being recommended for the assessment of pain.

The findings of this study may assist clinicians and clinical researchers in their selection of one or a combination of more than one relevant PROM, which covers the intended content, which may in turn assist in the evidence-based selection of PROMs, for discriminative and evaluative purposes.

5.15.3 Generalisability of the findings

Whilst it is accepted that region-specific PROMs are less responsive, which may have implications for larger sample size in RCTs (Streiner & Norman 2003), because of their greater applicability PROMs included in this study have the potential to be administered face-to-face, by telephone or post, to patients with different types of shoulder pathology, receiving a variety of interventions across different clinical and research settings.

Evidence related to MSP, would suggest that the unifying terminology and conceptual framework of the ICF may be used to conceptualise health-related physical, emotional and social functioning, related to MSK conditions.

5.15.4 Relationship of findings to trends in the literature

No study to date has compared the content of existing validated shoulder region-specific PROMs, using the ICF as a reference tool, as has been done in other

MSK conditions of the upper limb (Jerosch-Herold, Leite & Song 2006; Stamm et al 2006).

Jerosch-Herold, Leite & Song (2006) linked the outcomes used in high quality clinical trials on the effectiveness of surgical interventions for CTS and Stamm et al. (2008) identified and compared the content of six questionnaires commonly used for the assessment of OA hand. Outcomes in shoulder region-specific PROMs reflected the same three ICF categories i.e. b1: Mental functions, b2: Sensory functions and pain and b7: NMSK and movement related functions, as the outcomes used to assess impairments of body functions in CTS and OA hand, including sleep disturbance, pain and joint stiffness and muscle weakness. Outcomes in shoulder region-specific PROMs reflected the same four ICF categories i.e. d4: Mobility, d5: Self-care, d6: Domestic life and d8: Major life areas, as the outcomes used to assess different activities and participation limitations in CTS and OA hand, including washing and dressing, household chores and work-related issues.

This suggests that findings in this study are consistent with existing evidence from similar work done in other MSK conditions of the upper limb.

Conclusion

This research has demonstrated that shoulder region-specific PROMs capture data on a wide range of different aspects of shoulder function or physical, emotional or social functioning, as conceptualised by the ICF, depending on the included content. The DASH was the most comprehensive measure reflecting all ICF-based categories. Whilst there may be a superior measure, of those PROMs which have been most extensively investigated in primary validation studies, the DASH is recommended for use as the primary outcome measure for the assessment of functioning and disability for MSP, for discriminative and evaluative purposes. The SST, ASES and the SPADI should be considered as secondary outcome measures, with the SPADI being recommended for the assessment of pain. This information may be used by clinicians and clinical researchers in their evidence-based selection of relevant and meaningful measures, for their different purposes.

Within the context of the research project, this study has justified the use of the ICF classification in comparing the outcomes assessed in shoulder region-specific PROMs, which in turn justifies its use to compare the content of PROMs and the views of patients, on the important outcome of intervention for MSP. This third component study, which seeks to determine the extent to which PROMs reflect the patient’s perspective, is reported in the next chapter.

CHAPTER SIX

AN ICF BASED COMPARISON OF THE OUTCOMES PATIENTS CONSIDER IMPORTANT AND THE CONTENT OF PATIENT REPORTED MEASURES

6.0 Introduction

Evidence suggests that MSP may not only impact on an individual’s shoulder function but also on an individual's ability to perform a wide range of different activities of daily living, work and recreation (Bongers 2001; Mitchell et al. 2005). Clinically based measures of impairment may therefore not capture all aspects of the impact of shoulder pain on an individual (Roddey et al. 2005). PROMs by design use a biopsychosocial approach, to assess different aspects of physical, psychological or social functioning, related to a MSK shoulder condition, depending on what content is included (Terwee et al. 2007). Whilst the content of some PROMs was generated with patient's input most were developed by experts (Terwee et al. 2007). Therefore the extent to which existing shoulder region-specific PROMs reflect patients’ perspectives is not known. This study set out to investigate this key issue.

6.1 Research question

The research question posed in this study was ‘to what extent are the ICF-based outcomes, patients consider important, currently reflected in validated shoulder region-specific patient reported measures’?

6.2 Purpose of the study

The purpose of this study was to use the unifying language of the ICF, which adopts a biopsychosocial approach, to compare important outcomes for patients and the content of existing validated shoulder region-specific PROMs, to determine how adequately PROMs currently reflect patients' perspectives.

Clinicians and clinical researchers may use this information in the selection of PROMs which most adequately reflect patients' perspectives, for their different purposes. This information may also be used to conceptualise one, or a combination of more than one psychometrically robust PROM, which most adequately reflects patients' perspectives and which should be adopted as a gold standard of practice for the assessment of outcome for MSP, in future clinical practice and research studies (Gabel et al. 2006).

This may in turn facilitate the pooling of data in future meta-analyses, which is integral to the provision of patient-centred evidence based practice. This research therefore has the potential to enable patients with a MSK shoulder condition to make an important contribution towards evaluating and improving the quality of their own future healthcare.

6.3 Methodological framework

As detailed above the purpose of this study was to compare the views of patients and the outcomes assessed in validated shoulder region-specific PROMs, using the ICF as a reference tool, to determine how adequately PROMs currently reflect patients' perspectives. Therefore a method had to be identified to facilitate comparison of the outcomes, which patients consider important, and the ICF-based content of PROMs, which were identified in the two preceding studies. The purpose of this section is not to provide the rationale for the use of a quantitative approach, to answer the research question, as these arguments have been presented elsewhere in the thesis, in section 5.3. Neither is it the purpose of this section to provide the rationale for the use of the unifying language of the ICF, which adopts a BPS approach, to conceptualise health-related information by linking it to the most relevant and precise ICF categories, in a systematic and rigorous manner (Cieza et al. 2005), as these arguments have also been presented in section 5.3.

The preceding study provided evidence, which already existed in other MSK conditions of the upper limb, (Jerosch-Herold, Leite and Song 2006; Stamm et al. 2006), that the ICF may be used to conceptualise the outcomes assessed in patient reported measures for MSP. However, there is no existing evidence that the ICF has been used to conceptualise qualitative data on peoples' experiences and views of a MSK shoulder condition, to facilitate comparison with quantitative data on the content of PROMs, as has been conducted in OA hand conditions (Stamm et al. 2008). Whilst it would have been possible to compare the qualitative codes with the ICF-based outcomes assessed in PROMs, in this study the qualitative codes were linked to ICF categories and the frequency with which concepts were reflected were counted, to facilitate comparison of the patient-based interview data with the quantitative ICF-based content of PROMs.

6.4 Aims of the study

The aims of this study are:

i) to link the outcomes patients identified as important to the most relevant and precise first and second level categories of the ICF classification, using established rules

ii) to compare the ICF-based patient outcomes and the content of PROMs to determine the extent to which measures currently reflect patients' perspectives

iii) to identify any outcomes patients considered important not currently assessed in PROMs

6.5 Methods of investigation

6.5.1 Linking important outcome for patients to the ICF

The outcomes patients identified as important in in-depth individual interviews in a preceding study, reported in Chapter 4, were linked to the ICF Classification using established linking rules.

A phenomenological approach was used to gain patients' perspectives on the outcomes which should be used for MSP. Meaningful concepts i.e. a word, phrase or paragraph in the interview transcript which was thought to be significant were identified and assigned a descriptive code. Development of the codes, which was an iterative process, was refined and revised as more transcripts were analysed. The final coding scheme was then applied across all interview transcripts. The list of qualitative codes (Appendix 3) was used in this present study to link the outcomes which patients identified as important to the most relevant domains and most precise first and second level ICF categories, in a systematic and rigorous manner. Where necessary reference was made to the original interview transcript to contextualise the patient's experience to facilitate the decision making process.

Established linking rules have been shown to increase the reliability of methods used when comparing the content of PROMs (Cieza et al. 2005). However it has been suggested that additional applications of the rules i.e. to link patient-based interview data to the ICF, may pose a challenge (Xiong & Hartley 2008). Therefore any inconsistencies in the data, as a result of the researcher's interpretation of the linking rules, were identified at peer review to ensure that a common vision might be agreed (Miles & Huberman 1994).

The result was a list of ICF categories which may be said to equate in content to the original health-related information (Stucki et al. 2008). Any patient-based outcome not covered by the ICF classification was documented.

6.5.2 Identifying outcomes reflected in validated PROMs

In a preceding study, reported in Chapter 5, the outcomes reflected in twelve validated shoulder region-specific PROMs were identified and linked to the most relevant and precise first and second level ICF categories. Ninety three percent of outcomes were linked to the body functions and activities and participation ICF components.

Table 6-1: List of the first level ICF categories to which the outcomes assessed in PROMs were linked

ICF code:	**Category**
Body functions component	
b1	Mental functions
b2	Sensory functions and pain
b7	NMSK and movement-related functions
Activities and participation component	
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 wide range of diverse first level ICF categories, to which the outcomes reflected in PROMs were linked, are itemised in Table 6-1. The first and second level ICF categories to which the outcomes were linked are summarised in tabular form in Appendix 11.

6.5.3 Comparison of the views of patients and PROMs

The ICF-based patient outcomes and content of PROMs were compared to determine the extent to which they reflect same first and second level ICF categories. The percentage level of agreement between the two datasets was calculated. Data were represented in tabular form for ease of reading. Any outcomes patients considered important not currently reflected in PROMs were identified.

6.6 Research findings

6.6.1 Important outcomes for patients covered by the ICF

This section will report the results of linking important outcomes from the patient's perspective to the ICF classification, using established linking rules. The first and second level ICF categories to which important outcomes for patients were linked are summarised in Table 6-2.

Table 6-2: First and second level ICF categories to which important outcomes for patients were linked

First level ICF category	**Second level ICF code/ category**	
Body functions component		
Mental functions (b1)	b130	Energy and drive functions
	b134	Sleep functions
	b152	Emotional functions
Sensory functions and pain (b2)	b265	Touch function
	b280	Sensation of pain
NMSK and movement-related functions (b7)	b710	Mobility of joint functions
	b715	Stability of joint functions
	b720	Mobility of bone functions
	b730	Muscle power functions
	b755	Involuntary movement reaction functions
	b760	Control of voluntary movement functions
	b780	Sensations related to muscles and movement functions
Activities and participation component		
General tasks and demands (d2)	d230	Carrying out daily routine
Communication (d3)	d335	Producing non verbal messages
	d345	Writing messages
	d360	Using writing machines
Mobility (d4)	d410	Changing basic body position
	d415	Maintaining a body position
	d430	Lifting and carrying objects
	d440	Fine hand use
	d445	Hand and arm use
	d450	Walking
	d455	Moving around
	d470	Using transportation
	d475	Driving
Self-care (d5)	d510	Washing oneself
	d520	Caring for body parts
	d530	Toileting
	d540	Dressing
	d550	Eating
	d560	Drinking
Domestic life (d6)	d620	Acquisition of goods and services
	d630	Preparing meals
	d640	Doing housework
	d650	Caring for household objects
Interpersonal interactions and relationships (d7)	d750	Informal social relationships
	d760	Family relationships
Major life areas (d8)	d850	Remunerative employment
Community, social and civic life (d9)	d920	Recreation and leisure
Environmental factors		
Products and technology (e1)	e110	Products or substances for personal consumption
	e115	Products/ technology for personal use ADL
Support and relationships (e3)	e355	Health professionals
Attitudes (e4)	e410	Individual attitudes of immediate family members

The fourteen first level and forty three second level ICF categories to which important outcomes for patients were linked are summarised in Table 6-3.

Table 6-3: Number of first level and second level ICF categories to which the outcomes patients identified as important were linked

Total number of first level ICF categories	14
Body functions component	3
Activities and participation component	8
Environmental factors component	3
Total number of second level ICF categories	43
Body functions component	12
Activities and participation component	27
Environmental factors component	4

Whilst of interest, it was not anticipated that the environmental factors, which contextualised the patients' experiences of MSP, would be reflected in validated shoulder region-specific PROMs.

Decisions as to which ICF category each meaningful concept should be linked was made with reference to the original qualitative interview data, where necessary, to contextualise the patient's experience. Three concepts were found to overlap:

iv) Lying on the affected side/ shoulder was linked to b134: Sleep or d415: Maintaining a body position, depending on the context:

Natural meaning unit in interview transcript	Qualitative code	Second level ICF code/category
"when I go to bed if I lay on it I can do that for say half an hour ... after that I've got to turn over" (Alan: lines 142-144)	SAS: Sleep Affected Side	b134: Sleep functions
"I used to do these leg exercises ... but I can't do that now because I can't lie on me shoulder" (Gaye: lines 237-238)	LWBC: Loss Weight bearing Capacity UL	d415: Maintaining a body position

v) Childcare activities were linked to d430: Lifting and carrying objects or d760: Family relationships, depending on the context:

Natural meaning unit in interview transcript	Qualitative code	Second level ICF code/category
"I look after my grandchild and I	CC: Childcare	d430: Lifting and

haven't been able to lift him up"(Daisy: lines: 153-154)		carrying objects
"... for me personally that was an important one to be able to look after my daughter" (Frank: lines 473-475)	CC: Childcare	d760: Family relationships

vi) Gardening and DIY, including carpentry and metalwork, as conceptualised by the ICF relate to different aspects of Domestic life (d6). However whilst some concepts were linked to d650: Caring for household objects others were linked to d920: Recreation and leisure, depending on the context:

Natural meaning unit in interview transcript	**Qualitative code**	**Second level ICF code/category**
"I'm not a keen gardener I must admit but I'd like to cut the grass ... that's what I'd like to achieve" (Barry: lines 459-461)	GAR: Gardening	d650: Caring for household objects
"Not being able to get in my garden, doing things physically it's quite therapeutic ... my garden has just gone to pot" (Daisy: 176-178)	GAR: Gardening	d920: Recreation and leisure

6.6.2 Outcomes not covered by the ICF classification

Initially the researcher identified four meaningful concepts which, on the face of it, appeared not to be covered by the ICF classification. These were one-handedness, including muscle imbalance and loss of manual dexterity, overhead use of the upper limbs, as distinct from reaching activities, two work-related issues and gardening or DIY as leisure activities.

Natural meaning unit in interview transcript	**Qualitative code**	**Second level ICF code/category**
"I've got a pull switch just above my head which switches the light on ... I cannot do that (Neil: lines 253-255)"	OHU: Overhead use	d445: Hand and arm use

However further discussion, at peer review, which included reference to the interview transcripts, resulted in both overhead use and reaching activities being linked to d445: Hand and arm use.

The two work-related issues, taking time off work or returning to work, were coded to d850: Remunerative employment.

Natural meaning unit in interview transcript	Qualitative code	Second level ICF code/category
“I mean I never have any time off sick and I was off twice” (Kate: line 203)	TOW: Time off work	d850: Remunerative employment
“I am going to start doing a couple of evenings light duties on office cleaning” (Marie: line 101)	RTW: Return to work	d850:Remunerative employment

Gardening or DIY as leisure activities were coded to d920: Recreation and leisure, as outlined in the previous section.

One-handedness is therefore the only outcome patients identified as important which is not currently covered by the ICF classification. The following examples are used to illustrate decisions made:

Natural meaning unit in interview transcript	Qualitative code	Second level ICF code/category
“... my whole body is sort of out of sync because I can't use one arm” (Gaye: lines 104-105)"	ONE: One-handedness	nc: not covered by the ICF
“I’ve been wrestling with being unbalanced because one shoulder is more powerful than the other” (Eric: lines 454-455)	MIB: Muscle Imbalance	nc: not covered by the ICF
“I can’t sort of manoeuvre me arm to (pause) get my coat on ... those sort of things (Owen: lines 317-318)”	LMAN: Loss of Manoeuvrability UL	nc: not covered by the ICF

6.6.3 Comparison of the views of patients and PROMs

This section will report the results of comparing the ICF-based patient outcomes and the content of PROMs to determine the extent to which they reflect same first and second level ICF categories. The percentage level of agreement between the two datasets was calculated. Any outcomes which patients identified as important, not currently assessed in PROMs, were identified. Data are presented in tabular form for ease of reading. The first and second level ICF categories to which outcomes identified as important by patients and reflected in PROMs is summarised in Table 6-4.

Outcomes patients identified as important and the outcomes assessed in PROMs reflected the same eleven first level ICF categories, body functions and activities and participation components. As anticipated environmental factors, which contextualised the patients' experiences of MSP, were not reflected in PROMs.

Outcomes patients identified as important and the outcomes assessed in PROMs were linked to twenty nine second level ICF categories, body functions and activities and participation components.

The majority, 83%, of outcomes important to patients were reflected in PROMs. Three outcomes, related to NMSK and movement-related shoulder functions and one outcome linked to d335: Producing non verbal messages, important to patients were not reflected in PROMs. Three outcomes, d210: Undertaking a single task, d630: Preparing meals and d770: Intimate relationships reflected in PROMs were not identified as important by patients.

Table 6-4: ICF-based comparison of the outcomes patients considered important and the content of PROMs

Code	**Second level ICF category**	**PP**	**PROMs**
Body functions component			
b130	Energy and drive functions	Yes	Yes
b134	Sleep functions	Yes	Yes
b152	Emotional functions	Yes	Yes
b265	Touch functions	Yes	Yes
b280	Sensation of pain	Yes	Yes
b710	Mobility of joint functions	Yes	Yes
b715	Stability of joint functions	Yes	Yes
b720	Mobility of bone functions	Yes	No*
b730	Muscle power functions	Yes	Yes
b755	Involuntary movement reaction functions	Yes	No*
b760	Control of voluntary movement functions	Yes	Yes
b780	Sensations related to muscles	Yes	No*
Activities and participation component			
d210	Undertaking a single task	No	Yes**
d230	Carrying out daily routine	Yes	Yes
d335	Producing non verbal messages	Yes	No*
d345	Writing messages	Yes	Yes
d360	Using writing machines	Yes	Yes
d410	Changing basic body position	Yes	Yes
d415	Maintaining a body position	Yes	Yes
d430	Lifting and carrying objects	Yes	Yes
d440	Fine hand use	Yes	Yes
d445	Hand and arm use	Yes	Yes
d450	Walking	Yes	Yes
d455	Moving around	Yes	Yes
d470	Using transportation	Yes	Yes
d475	Driving	Yes	Yes
d510	Washing oneself	Yes	Yes
d520	Caring for body parts	Yes	Yes
d530	Toileting	Yes	Yes
d540	Dressing	Yes	Yes
d550	Eating	Yes	Yes
d560	Drinking	Yes	Yes
d620	Acquisition of goods and services	Yes	Yes
d630	Preparing meals	No	Yes**
d640	Doing housework	Yes	Yes
d650	Caring for household objects	Yes	Yes
d750	Informal social relationships	Yes	Yes
d760	Family relationships	Yes	Yes
d770	Intimate relationships	No	Yes**
d850	Remunerative employment	Yes	Yes
d920	Recreation and leisure	Yes	Yes
Environmental factors			
e110	Products/ substances for personal consumption	Yes	No*
e115	Products/technology for personal use ADL	Yes	No*
e355	Health professionals	Yes	No*
e410	Individual attitudes of immediate family	Yes	No*

PP = patient’s perspectives; *Important to patients but not assessed in PROMs; **Assessed in PROMs but not important to patients

The extent to which the outcomes that patients with MSP consider important are reflected in PROMs is summarised in Table 6-5.

Table 6-5: Extent to which the outcomes that patients with MSP consider important are reflected in PROMs

ICF category	**Proportion of important outcomes for patients, reflected in PROMs** (%)
First level category (n=11)	100%
Second level category (n=29)	83%
Body functions component	75%
Activities and participation component	86%

6.6.4 Extent that patients' views are reflected in PROMs

Validated shoulder region-specific PROMs satisfactorily reflect the outcomes considered important by patients, some more so than others depending on the included content. The DASH was the most comprehensive of the PROMs, as it assessed all important outcomes, from the patient's perspective. The remaining PROMs assessed 27-82% of outcomes important to patients. The extent to which individual PROMs currently reflect outcomes that patients with MSP consider important is summarised in Table 6-6.

Table 6-6: Extent to which the outcomes, which patients with MSP identified as important, are currently assessed in individual shoulder region-specific PROMs

PROM (1st author, date of publication)	**Proportion (%) of outcomes, patients consider important, assessed in individual PROMs**
DASH (Hudak, 1996)	100%
SDQ-UK (Croft, 1994)	82%
ULFI (Gabel, 2006)	82%
SRQ (L'Insalata, 1997)	73%
PSS (Leggin, 1999)	73%
OSS (Dawson, 1996)	64%
ASES (Richards, 1994)	55%
SSRS (Kohn, 1997)	55%
SDQ-NL (van der Windt, 1998)	54%
SST (Lippitt, 1993)	45%
FLEX-SF (Cook, 2003)	36%
SPADI (Roach, 1994)	27%

6.7 Measures used to enhance the quality of the data

The researcher was able to demonstrate, through peer review, that the patient-based interview data had been linked to the ICF classification in a systematic and rigorous manner, which was consistent with that used in the preceding study to link the outcomes in PROMs to the ICF classification. One dilemma was to determine if patients' feelings of frustration, annoyance, anxiety or fear, arising as a consequence of MSP, should be linked to the ICF category b152: Emotional functions. Whilst it was agreed that such emotions were not an impairment of mental functions it was decided that coding should be consistent with existing evidence (Cieza et al. 2005) and so the ICF code b152: Emotional functions was used. Additional examples have been provided in relevant sections to enable the reader to assess the reliability and consistency of the methods used by the researcher to enhance the quality of the data.

6.8 Selection of PROMs for different purposes

Once one or more PROMs, which appear to sample all relevant outcomes of interest to patients, have been identified, clinicians and clinical researchers should evaluate the other measurement properties to determine which PROMs may be suitable, for their different purposes.

Table 6-7: ICF-based outcomes included in the DASH, SST, ASES and SPADI

PROM	PP (%)	Body functions	Activities and participation
DASH	100%	Pain Sleep Pins & needles Emotion	Physical Social, inc. work & leisure
ASES	55%	Pain	Physical Social, inc. work & sport
SST	45%	Pain Sleep	Physical Social, inc. work
SPADI	27%	Pain	Physical

PP (%); Extent to which patients' perspectives are reflected in PROMS

As reported in the previous study evidence suggests that the DASH, SST, ASES and SPADI are sufficiently psychometrically robust to capture important change either on a case-by-case basis in clinical practice or to measure the endpoint in a clinical trial (Roy, MacDermid & Woodhouse 2009, Mokkink et al. 2010). Table 6-7 summarises the ICF-based content of the DASH, SST, ASES and SPADI, together with the proportion of outcomes that patients consider important reflected in each measure.

6.9 Discussion

The purpose of this study was to use the unifying language of the ICF to compare the views of patients and the content of existing validated shoulder region-specific PROMs, to determine how adequately PROMs currently reflect patients' perspectives.

6.9.1 Methodological considerations

The majority i.e. eighty three percent, of the meaningful concepts in the qualitative patient-based interview data were successfully mapped to eleven first and forty three second level ICF categories, using established linking rules. Three concepts i.e. lying on the affected side/ shoulder, gardening and DIY and childcare activities appeared to overlap and could be linked to different ICF categories, depending on the context. However such dilemmas were resolved through peer review, with reference to the original interview transcripts, which contextualised the patient's experience. This information is consistent with that found in the preceding study, which not only highlights some ambiguities in the linking rules but also suggests that measures put in place, to enhance the quality of the data, were successful. Methods adopted also enabled the concepts, underpinning the outcomes patients considered important i.e. one-handedness and overhead activities, which were not covered by the ICF classification, to be identified. As the frequency with which the concepts were linked to the ICF could also be counted, the unifying language and conceptual framework of the ICF enabled the outcomes patients considered important and the content of shoulder region-specific PROMs to be compared, using quantitative methods. This justified the use of the ICF classification in this study to determine the adequacy with which PROMs currently reflect the patients' perspectives.

6.9.2 Significance of the findings

The important outcomes for patients, in this study, were linked to three first level ICF categories, reflecting body functions, and eight, reflecting activity and participation. This provides further evidence that MSP impacts on an individual’s shoulder function and ability to perform a wide range of activities of daily living, work and recreation (Bongers 2001; Mitchell et al. 2005).

The important outcomes patients considered important were linked to the same eleven first level categories, reflecting body functions and activity and participation, as the twelve validated shoulder region-specific PROMs investigated in the preceding study. This would suggest that PROMs satisfactorily reflect patients’ perspectives, some more so than others, depending on the included content. The DASH was the most comprehensive measure reflecting all ICF-based outcomes patients considered important. The remainder reflected 27-82% of patients’ perspectives.

However, the eighty three percent level of agreement, at the second level ICF classification, would suggest that whilst PROMs broadly reflected patients’ perspectives, individual PROMs may assess different aspects of the same construct. Some aspects of movement-related shoulder functions and non-verbal communication, important to patients, were not reflected in PROMs.

This research has provided evidence on the wide range of different aspects of shoulder function or physical, emotional or social functioning, related to a MSK shoulder condition, reflected in PROMs. Clinicians and clinical researchers may use this information in the selection of one or a combination of more than one relevant and meaningful PROM, which most adequately reflect patients' perspectives, for their different purposes. Existing evidence, which suggests that the DASH, SST, ASES and SPADI are sufficiently psychometrically robust to capture important change either on a case-by-case basis in clinical practice or to measure the endpoint in a clinical trial (Roy, MacDermid & Woodhouse 2009, Mokkink et al. 2010), warrant further investigation.

This study has provided evidence that the unifying language and the framework of the ICF uses a BPS approach to the conceptualisation of function and functioning, related to a MSK shoulder condition. It has also justified its novel use to integrate the experiences and views of patients with MSP and the content of shoulder region-specific PROMs, to determine how adequately PROMs currently reflect patients’ perspectives.

It has also highlighted two important areas for future research. Ambiguities in the linking rules exist. Future research should investigate the challenges in linking the concepts of lying on the affected side/ shoulder, gardening and DIY and childcare activities, which could be linked to different ICF categories, depending on the context. At first glance two outcomes important to patients i.e. one-handedness and overhead activities, appeared not to be covered by the ICF classification. At peer review it was decided that overhead activities should be subsumed under the category, reaching activities; however it may be deserving of a separate ICF category. Clinicians and clinical researchers may wish to identify alternative methods of capturing data on these constructs. Researchers may use this information to inform future development of the ICF classification.

6.9.3 Generalisability of the findings

Evidence suggests that the patients in this study reflect sociodemographic characteristics which typify MSP. Therefore, whilst findings from a purposive sampling strategy are not intended to be transferable, there is no reason to suggest that the validated shoulder region-specific PROMs, identified in this study should not be used in similar clinical settings and research contexts.

6.9.4 Relationship of findings to trends in the literature

Lack of evidence, on the extent to which patient reported measures reflect important outcomes of intervention for patients, with MSK conditions of the upper limb, prevent meaningful comparisons of study findings with trends in the scientific literature. Whilst PROMs were found to satisfactorily reflect ICF-based outcomes, which patients with MSP identified as important, similar work conducted by Stamm et al. (2008) found that instruments commonly used for the assessment of OA hand did not fully represent psychological consequences, pain sensations, aesthetic changes and leisure activities, which patients considered important.

Conclusion

Shoulder region-specific PROMs satisfactorily reflect patients' perspectives, some more so than others depending on the included content. The DASH is the most comprehensive measure reflecting all ICF-based outcomes patients considered important. Of the remainder five PROMs included three-quarters, four one half and two one quarter of important outcomes for patients. Clinicians and clinical researchers may use this information in the selection of PROMs which most adequately reflect patients' perspectives, for their different purposes.

Empirical evidence that existing PROMs do adequately reflect the patients' perspectives is important as this information may be used to conceptualise one, or a combination of more than one psychometrically robust PROM, which should be widely adopted as a gold standard of practice for the assessment of outcome for MSP, in future clinical practice and research studies. Involving patients, as service users, therefore has the potential to enable patients, with a MSK shoulder condition, to make an important contribution towards evaluating and improving the quality of their own future healthcare (Haywood 2006).

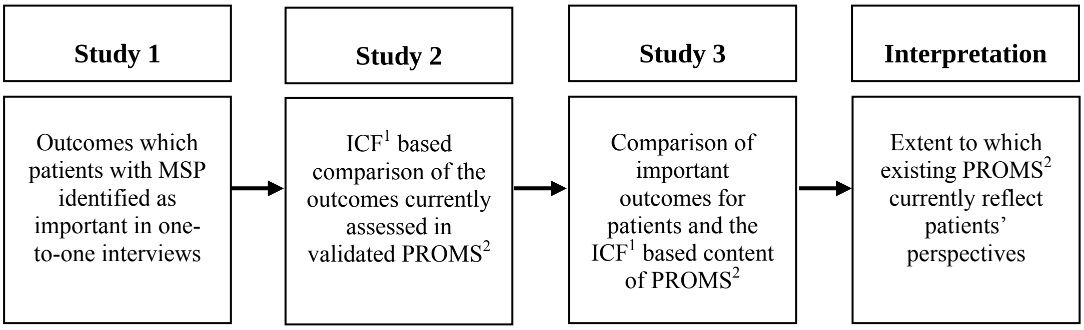
CHAPTER SEVEN

DISCUSSION

7.0 Introduction

The purpose of this chapter is firstly to discuss the extent to which the purpose of each of the three component studies was fulfilled to enable to overall research question to be answered. It will then discuss how consistent research findings are with existing knowledge. Next it will discuss how research findings may resonate with clinicians and clinical researchers in their selection of relevant outcomes, for their different purposes in future practice and research studies. Finally it will present a short critique of the research and make recommendations for future research, grounded in the new knowledge.

Although inter-related each component study was designed to stand alone with data being collected, analysed, interpreted and reported independently of one another. The temporal relationship between the three studies, first introduced in section 3.4, is reprised as Figure 7-1, for ease of reading.



[1] International Classification of Functioning, Disability and Health @ http://www.who.int/classifications/icf
[2] Shoulder region-specific patient reported outcome measures

Figure 7-1: Temporal relationship between component studies

7.1 Study 1: Exploration of patients' perspectives

The purpose of this phenomenological study was to explore the lived experience of patients, reflecting a typical range of characteristics and with relevant experiences of MSP, to identify which outcomes of intervention are considered important, from the patient's perspective. Patients articulated personally relevant and important outcomes which they may use to judge treatment success. They expected to be symptom free, regain their former level of upper limb use, resume their usual activities, regain a sense of emotional well-being, resume their former family relationships and social interactions and independently manage their own healthcare condition. These outcomes should be included in patient reported measures used in the assessment of MSP, in future clinical practice and research studies.

7.1.1 Significance of research findings

No study to date has explored in depth patients' experiences of MSP using a phenomenological approach. However, as the shoulder is primarily concerned with accommodating the demands of the upper limb (Peat 1986; Trew & Everett 2005), the impact of MSP on an individual's ability to perform a wide range of activities of daily living, work and recreation may be similar to that of MSK hand and wrist conditions e.g. wrist disorders (Bialocerkowski 2002), Carpal tunnel syndrome (CTS) (Jerosch-Herold, Mason & Chojnowski 2008), OA hand (Stamm et al. 2008) and Dupuytren's disease (Pratt & Byrne 2009). All patients with a MSK shoulder condition experienced pain and sleep disturbance in common with those with wrist disorders and CTS. MSP commonly impacts on different aspects of mobility, personal care, domestic life, work and recreation, which were also experienced by patients with hand and wrist disorders. Patients also reported emotional issues as a result of MSP in common with patients with Dupuytren's disease and OA hand. Problems with communication, socialising and interpersonal relationships typify the experiences of patients with MSP and hand and wrist disorders. One-handedness was perceived to be a problem for patients with MSP, which was described as feeling "out of sync" or "unbalanced" in that one shoulder was more powerful than the other. Patients with wrist disorders had similar issues with "anything which required the co-ordinated use of both hands" (Bialocerkowski 2002).

Patient with MSP were not only able to articulate important outcomes but were also able to prioritise their expectations of treatment. Patients may expect to be symptom free and have their physical, emotional and social needs addressed. This is similar to the findings of Jerosch-Herold, Mason & Chojnowski (2008) who found that patients with CTS often expect to be symptom free and to resume their usual daily activities.

MSP may therefore result in impairments in shoulder function or impact on an individual's physical, psychological or social functioning, which is consistent with existing knowledge in hand and wrist disorders.

7.2 Study 2: Comparison of the content of PROMs

The purpose of the second component study was to compare the outcomes currently assessed in validated shoulder region-specific PROMs, using the ICF as a reference tool. A secondary purpose was to synthesise existing evidence to determine which existing PROMs have acceptable measurement properties across all subgroups of patients with MSP. Individual PROMs were found to assess a wide range of different ICF-based outcomes reflecting shoulder functions and physical, emotional and social functioning and disability. The DASH was found to be the most comprehensive measure reflecting all relevant ICF categories. Of the PROMs which have been most extensively investigated in empirical validation studies the DASH, SST, ASES and SPADI are sufficiently robust to be able to differentiate between different patient groups across a variety of different clinical and research contexts.

7.2.1 Significance of research findings

No study to date has compared the content of existing validated shoulder region-specific PROMs, using the ICF as a reference tool, as has been done in other MSK conditions of the upper limb (Jerosch-Herold, Leite & Song 2006; Stamm et al 2006).

Jerosch-Herold, Leite & Song (2006) linked the outcomes used in high quality clinical trials on the effectiveness of surgical interventions for CTS and Stamm et al. (2008) identified and compared the content of six questionnaires commonly used for the assessment of OA hand. Outcomes in shoulder region-specific PROMs reflected the same three ICF categories i.e. b1: Mental functions, b2: Sensory functions and pain and b7: NMSK and movement related functions, as the outcomes used to assess impairments of body functions in CTS and OA hand, including sleep disturbance, pain and joint stiffness and muscle weakness.

Outcomes in shoulder region-specific PROMs reflected the same four ICF categories i.e. d4: Mobility, d5: Self-care, d6: Domestic life and d8: Major life areas, as the outcomes used to assess different activities and participation limitations in CTS and OA hand, including washing and dressing, household chores and work-related issues.

This suggests that findings in this study are consistent with existing evidence from similar work done in other MSK conditions of the upper limb.

PROMs by design use a BPS approach to capture data on the impact of MSP on shoulder function and activities and participation limitations. The ICF, which also uses a BPS, was therefore used to categorise the outcomes in PROMs to enable meaningful comparisons of the content of measures to be made. That the DASH mapped easily to the ICF was not surprising, as it was developed using the International Classification of Impairments, Disabilities and Handicaps (ICDIH) (WHO 1980) as a reference tool. The ICDIH, which assumes a linear relationship between components, is a precursor of the ICF expanded model of functioning, disability and health. Findings that some PROMs could be linked to the ICF more easily than others, suggests not all were developed using a BPS approach.

Evidence on the content of individual PROMs e.g. that the DASH is the only questionnaire to assess interpersonal interactions and relationships (d7), a category not assessed by any other PROM, facilitates choice between measures. Therefore clinicians and clinical researchers wishing to capture meaningful and important change either in the same subject over time or to measure differences between subjects at the endpoint of a clinical trial may now select one or more PROMs which capture the intended content.

7.3 Study 3: Comparison of patients' views and PROMs

The purpose of the third component study was to use the unifying language of the ICF to determine the extent to which validated shoulder region-specific PROMs reflect the outcomes patients consider important. Whilst individual PROMs were found to assess a wide range of different outcomes, the DASH alone reflected all outcomes patients considered important. Of the remainder five PROMs, the SDQ-UK, ULFI, SRQ, PSS and OSS, included three-quarters, four, the ASES, SSRS, SDQ-NL and SST, one half and two, the FLEX-SF and SPADI, one quarter of important outcomes for patients.

7.3.1 Significance of research findings

No study to date has determined how adequately validated shoulder region-specific PROMs reflect the patient's perspective, using the ICF as a reference tool. Similar work however was conducted by Stamm et al. (2008) who found that psychological consequences, different qualities of pain sensations, aesthetic changes and leisure activities, which patients considered important, were not fully represented in the instruments routinely used for the assessment of OA hand.

However, in this research validated shoulder region-specific PROMs were found to satisfactorily reflect all outcomes important to patients, some more so than others depending on the included content. Of the twelve PROMs with acceptable measurement properties in generic populations of patients with MSP, the DASH was the most comprehensive measure, reflecting all important outcomes from the patient's perspective. This together with evidence of its robust psychometric properties would suggest that the DASH should be used as the primary outcome measure for the assessment of functioning and disability for MSP, for discriminative and evaluative purposes.

Of the remaining PROMs which have been most extensively investigated in primary validation studies the Simple Shoulder Test (SST), American Surgeons and Elbow Surgeons assessment standardized assessment form (ASES) and the Shoulder Pain and Disability Index (SPADI) should be considered as secondary outcome measures, with the SPADI being recommended for the assessment of pain.

Clinicians and clinical researchers may now select one or a combination of more than one psychometrically robust PROM, which most adequately reflects the patient's perspective, for their different purposes.

7.4 The ICF model of disability and health

The purpose of this research was to use the unifying language of the ICF as a reference tool, to facilitate comparison of the content of PROMs and the views of patients. Established rules were used to link the outcomes in shoulder region-specific PROMs to relevant ICF categories, in a systematic and rigorous manner (Cieza et al. 2005). Evidence of similar work which compared measures used to assess outcomes in OA hand (Stamm et al. 2006) or measure symptoms and functional status in patients with upper limb MSK conditions (Silva Drummond et al. 2007) serves to demonstrate the rigour of methods used.

Whilst linking some items to the ICF required no interpretation, where necessary the content was contextualised using the range of response options. Findings show that PROMs may sample a wide range of different, often overlapping outcomes, with different levels of precision. PROMs may also over-represent some outcomes by asking the same questions a number of times in different ways, which suggests some items may be redundant.

It has been suggested that additional applications of the rules e.g. to link patient-based interview data to the ICF, may pose a challenge (Xiong & Hartley 2008). Where necessary reference to the original interview transcripts was made to contextualise the patient's experience and any inconsistencies in the data were identified and discussed at peer review.

Two concepts were found to overlap depending on the circumstances:

i) lying on the affected side/ shoulder could be linked to both b134: Sleep or d415: Maintaining a body position

ii) childcare activities were linked to d430: Lifting and carrying objects or d760: Family relationships

Overhead hand and arm use was very important to patients who separated it quite distinctly from other reaching activities. Whilst applying the linking rules with a systematic objectivity enabled this activity to be coded to d445: Hand and arm use, future developments of the ICF may consider overhead hand and arm use worthy of a separate category.

Gardening and DIY, including carpentry and metalwork, were linked to d650: Caring for household objects. However for patients these activities were most often considered to be recreation and leisure pursuits rather than "chores", as presently conceptualised by the ICF. Future developments may like to consider developing separate categories, within d9: Community, social and civic life, under d920: Recreation and leisure activities.

Whilst it may be argued that emotional issues, such as feeling irritable and bad tempered, are not a mental impairment, but a natural consequence of having a health condition such as MSP, these concepts were linked to b1: Mental functions and b152: Emotional functions, in line with existing evidence (Cieza et al. 2005; Silva Drummond et al. 2007).

One-handedness was therefore the only concept not covered by the ICF classification. As previously mentioned this is a multidimensional construct; patients described as feeling "out of sync" or "unbalanced", in that one shoulder was more powerful than the other. Evidence suggests that patients who have a neurological disorder e.g. stroke may have similar feelings (Edwards 2002; Donatelli 2004), therefore this issue is worthy of further investigation.

Whilst the ICF facilitated comparison of the content of PROMs and the views of patients, it has been acknowledged that the ICF Classification is under development. This research has highlighted some areas which need clarification in future research studies.

7.5 Mixed methods research

The purpose of this mixed methods study was to facilitate the integration of qualitative and qualitative data, within a series of three independent but inter-related studies, each designed to answer a different component of the overarching research question. An exploratory sequential design was used in recognition that a more comprehensive understanding of the PROMs, which should be used in the assessment of outcome for MSP, can only be achieved if the quantitative methods are underpinned by an initial qualitative exploration, based on patients' perspectives. Each study was designed to stand alone with data being collected, analysed, interpreted and reported independently of one another. However each qualitative and quantitative data set contributed equally in answering the overarching research question.

An interpretive approach was used to gain multiple subjective perspectives on which outcomes should be included in the assessment of MSP before a positivist approach was used in two successive studies to determine, with a systematic objectivity, how adequately the outcomes which patients considered important were reflected in the content of validated shoulder region-specific PROMs. Unlike Stamm et al. (2008) who used the ICF as a theoretical framework to analyse patient-based interview data on experiences of OA hand, the in-depth, rich narrative data in the qualitative study were analysed using an inductive approach, with codes, categories and themes being derived systematically, from the data itself. Therefore whilst the ICF facilitated comparison of the content of PROMs and the views of patients the mixed methods approach respected both the qualitative and quantitative data and the different philosophical approached from which they were derived.

As rigour is not assessed in the same way in qualitative and quantitative research (Bowling 2004), a range of measures were put into place to enhance the trustworthiness of the qualitative data and the reliability of the quantitative data. In the qualitative research the researcher made explicit her personal stance to demonstrate to the reader that her interpretation of the patients' experiences was credible and accurate and in the quantitative research the researcher took steps to guard against bias by applying the established linking rules when mapping data to the relevant ICF categories. Research collaborators independently linked a random sample of items in PROMs to the ICF to check the consistency of methods used.

The value of using qualitative and quantitative approaches to answer different components of the overarching research question within a mixed methods study was to gain a more comprehensive understanding of the assessment of outcome for MSP, from the patient's perspective; the same outcome would not have been achieved by either qualitative or quantitative approaches used alone.

7.6 Implications for practice and research

MSP may lead to an individual's inability to perform a wide range of different activities of daily living, work or recreation (Bongers 2001; Mitchell et al. 2005). Clinically based measures of impairment therefore may not capture all aspects of the impact of MSP, from the patient's perspective (Roddey et al. 2005). PROMs therefore represent a fundamental shift, away from the assessment of impairment, towards the self-assessment of the impact of MSP on activities and participation (Wright 2000). Including the outcomes patients consider important in the measures used for the assessment of MSP in future clinical practice and research studies may increase the acceptability of PROMs to patients. In turn this may reduce the number of missing values or incomplete responses in questionnaires, which may increase the reliability of the data (Streiner & Norman 2003).

The management of MSP is a complex issue which presents challenges for clinicians and clinical researchers wishing to implement EBP (Grimmer et al. 2004). Although research is extensive, the evidence on common interventions for MSP is inconclusive; one reason put forward for this is that there are a number of methodological limitations in existing RCTs, which may limit the generalisability of research findings to clinical practice (Green, Buchbinder & Hetrick 2003). Other issues which may reduce the external validity of research findings include the clinical relevance of the interventions investigated, the definition of the clinical diagnostic criteria and the clinical relevance of the outcome measures to all stakeholders and across all subgroups of patients with the same condition (Grimmer et al. 2004). Therefore identifying the relevant and meaningful PROMs which should be used for the assessment of MSP has addressed an important issue for those evaluating the effects of treatment on a case-by-case basis or those planning an effectiveness trial in the future. Whilst it is acknowledged that other problems in designing good quality RCTs would still exist this research has made an important contribution towards increasing the capacity of future RCTs to produce high quality clinically applicable evidence (Grimmer et al. 2004). Evidence on the criteria which clinicians and clinical researchers may use to measure treatment success in RCTs may therefore in turn facilitate the pooling of data in future meta-analyses (Green, Buchbinder &

Hetrick 2003; Grimmer et al. 2004), which is integral to the implementation of EBP.

7.7 Strengths and limitations of the research

7.7.1 Strengths of the research

The management of MSP is a complex issue, which presents challenges for clinicians and clinical researchers, wishing to implement patient-centred, evidence based practice. One reason put forward is that there appears to be little agreement amongst clinicians and clinical researchers on which measures should be used for the assessment of outcome for MSP, from the patient's perspective. This mixed methods research, which compared the views of patients and the outcomes assessed in patient reported measures, using the ICF as a reference tool, has provided new insight into an under-researched clinical and conceptual area:

i) This research has demonstrated the importance of the contribution of patients, as service users, rather than participants in research, in determining the criteria, which they may use to judge treatment success for MSP. Gaining patients' perspectives may in turn therefore enable patients to participate in evaluating and improving the quality of their own future healthcare.

ii) From the large number of diverse PROMs available, this research identified four shoulder region-specific measures, the DASH (Hudak 1996), SST (Lippitt 1993), ASES (Richards 1994) and SPADI (Roach 1991), which are sufficiently psychometrically robust to be recommended for use across different subgroups of patients with MSP, different interventions, and across a variety of different clinical and research contexts, in future clinical practice and research studies.

iii) This research has provided evidence that PROMs satisfactorily reflect patients' perspectives, some more so than others, depending on the included content. The DASH was the most comprehensive measure reflecting all ICF-based outcomes patients considered important. The remainder reflected between 27-82%, of patients' perspectives. This information may be used in the selection of one or a combination of more than one relevant and meaningful PROM, which most adequately reflect patients' perspectives, for evaluative or discriminative purposes.

iv) This research has demonstrated that conducting three independent, but inter-related component studies, within an exploratory, sequential mixed methods design, supported the need to integrate patients' subjective views and experiences with objective ICF-based data, on the outcomes assessed in validated PROMS. The same outcome would not have been achieved by using qualitative or quantitative approaches alone.

v) This research provided important evidence that the biopsychosocial approach of the ICF may be used to conceptualise health-related physical, emotional and social functioning, related to a MSK shoulder condition. Research on MSP, has also provided a further example of how the ICF is a beneficial framework for PROMS development. The ICF has also supported the conceptualisation of patients' experiences and expectations of treatment, to determine the adequacy with shoulder region-specific PROMs currently reflect patients' perspectives. This research has provided important evidence which may be used to inform future developments of the ICF; two important outcomes for patients i.e. one-handedness and overhead activities, do not appear to be covered by the ICF and this research has uncovered ambiguities in the application of the linking rules.

vi) As an expert clinician, the researcher has been able to utilise her well developed clinical reasoning skills to demonstrate the extent to which qualitative research findings may be mirrored in clinical practice (Jones, Edwards & Gifford 2002; May et al. 2008). Findings may therefore resonate with other clinicians and clinical researchers, wishing to include the patient's perspective in the measures used in the assessment of outcome for MSP, in future clinical practice and research studies.

7.7.2 Limitations of research

This work also has a number of limitations, which need to be taken into consideration when interpreting the main findings and drawing conclusions:

i) Whilst it would have been possible to have conducted more than one interview in a longitudinal study patients were interviewed once, at the outset of their current treatment for MSP. This was to avoid any modification of their expectations of the outcome of treatment either because of the professional advice or exposure to self-assessment questionnaires during their treatment.

ii) It would have been possible to return the findings to participants as a means of validating the researcher's interpretation of the patient-based interview data. However as patients were undergoing treatment which once again might result in modification of their expectations a decision was made to ensure the rigour of the data in other ways. This included the use of research collaborators who independently coded a sample of interview transcripts and checked that the researcher's interpretation was a reasonable one to make.

iii) Disease specific PROMs may be more responsive and therefore justify smaller sample sizes in effectiveness trials. However, in this study, a decision was made to compare the content of region-specific PROMs with the views of patients. This was to identify one or more than one measure, which should be adopted as a standard of practice, for use across different subgroups of patients to increase the generalisability of research findings.

iv) Whilst there may be a superior measure a decision was made to investigate the psychometric properties of the four PROMs which had been most extensively investigated in primary validation studies.

7.8 Recommendations for future research

i) Future research should seek to gain a widely accepted expert consensus on a 'core set' of psychometrically robust PROMs, which are relevant and meaningful to patients, and which should be adopted as a standard of practice. This would satisfy the need to standardise the assessment of outcome across all subgroups of patients with MSP in future clinical practice and research studies.

ii) High quality research studies should either address gaps in knowledge or determine more precise estimates for the criteria used to rate measurement properties of the DASH, SST, ASES and SPADI e.g. the interpretability of the SST. This work would assist clinicians and clinical researchers in the evidence based selection of a core set of shoulder region-specific PROMs, suitable for use across different patient groups and a variety of clinical and research contexts (Portney & Watkins 2009).

iii) High quality research studies should address existing methodological limitations in RCTs, including inadequate allocation concealment, inadequate blinding of patients, clinicians or assessors and small sample sizes. It should also seek an expert consensus on the clinical relevance of the interventions investigated and the clinical diagnostic criteria, which should be used to define different subgroups of patients with MSP.

iv) Future developments of the ICF should clarify ambiguities in the interpretation of the linking rules related to four important concepts i.e. emotional issues, lying of the affected side, childcare and gardening and DIY. It should also consider the issue of one-handedness, which does not appear to be covered, and overhead activities, which may be deserving of a separate ICF category.

CONCLUSION

This mixed methods research has identified which validated shoulder region-specific PROMs should be used in the self-assessment of MSP, from the patient's perspective, using the International Classification of Functioning, Disability and Health (ICF) as a reference tool.

Patients with MSP articulated personally relevant and important outcomes which they may use to judge treatment success. They often expect to be symptom free and to have their physical, emotional and social needs addressed, so that they may independently manage their own MSK shoulder condition. Existing validated shoulder region-specific PROMs capture data on impairment of shoulder function and the impact of MSP on an individual's ability to perform a wide range of different activities of daily living work and recreation, as defined by the ICF. Individual PROMs assessed a wide range of different outcomes, depending on the included content; the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire being the most comprehensive measure. PROMs satisfactorily reflected patients' perspectives, some more so than others, however only the DASH included all the outcomes patients considered important.

Of the PROMs which have been most extensively investigated in validation studies it is recommended that the DASH be used as the primary outcome measure for the assessment of functioning and disability for MSP, for discriminative and evaluative purposes. The Simple Shoulder Test (SST), American Surgeons and Elbow Surgeons standardized assessment form (ASES) and the Shoulder Pain and Disability Index (SPADI) should be considered as secondary outcome measures, with the SPADI being recommended for the assessment of pain.

Clinicians and clinical researchers, wishing to capture meaningful and important change either in the same subject over time or to measure differences between subjects in clinical trials, may now select the meaningful and relevant PROMs, which most adequately reflect the patient's perspective.

Future research, grounded in this new knowledge, should seek to gain a widely accepted expert consensus on a 'core set' of psychometrically robust shoulder region-specific PROMs, which are relevant and meaningful to patients, and which should be adopted as a standard of practice. Whilst methodological limitations of RCTs would still exist findings have the potential to facilitate the pooling of data in future meta-analyses, which is integral to the provision of evidence based healthcare. Gaining patients' perspectives, on the important outcomes of intervention for MSP, therefore may ultimately enable patients to participate in evaluating and improving the quality of their own future healthcare.

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APPENDICES

Appendix 1

Patient information sheet and consent form

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

epartment
tients East
ty Hospital
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NR4 7UY
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03 287369
uh.nhs.uk

Patient Information Leaflet

Important outcomes of intervention for shoulder pain

I would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish.

Please contact me if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Shoulder pain is a very common reason for patients to be referred to the hospital for a consultation. It is very important to be able to measure which treatments are most successful in treating shoulder pain. In the past it was the person who treated you who decided which outcome measures to use. However, we have come to realise that what experts think is not necessarily the same as what patients think is important. This research sets out to interview patients and ask them about their experiences of shoulder pain. The purpose of this research is to find out what patients think are important outcomes of treatment for their shoulder pain.

Why is this research being done?

I am a postgraduate research student at the University of East Anglia. I am doing this research as part of obtaining a doctoral degree. I am being supervised in the hospital by Mr Simon Donell, Orthopaedic Consultant Surgeon.

Appendix 1

Why have I been invited?

You have been invited to take part because you have been referred to the hospital for a consultation for your shoulder pain.

Do I have to take part?

It is up to you to decide. This information sheet explains about the study. You are asked to sign and return the consent form to me in the envelope provided, within **one week** of attending the hospital, to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

What will happen to me if I take part?

You will be interviewed and asked some questions about your shoulder pain. Once the interview has been transcribed you will be asked to check that it is an accurate record of what you said on the day. You will be asked to return it to me in the post. You will not be expected to do anything else as part of this research.

How will this be done?

I will contact you to arrange a mutually convenient appointment either in the hospital or at your home or work. You will be able to rebook the appointment if necessary because of an illness or similar. I will send you a letter confirming the details of your appointment. The interview should last approximately 40 minutes but please set aside 1 hour in case it takes a little longer. This will be tape recorded. I will take notes.

I will then get the interview transcribed and I will then send this record to you. You will be asked to check that it is an accurate transcript of the interview as you remember it. You will be able to add any comments you may have before signing the transcript and returning it to me in the envelope provided.

If you attend at the hospital your travel expenses will be reimbursed at public transport rate. Please make a note of how many miles you travelled or the cost of your bus fare so I can arrange for payment to be made. If you park at the hospital you will not have to pay a car parking charge.

What are the possible disadvantages and risks of taking part?

There is very little risk to you in taking part as all I am doing is asking you about is what you think are the important outcomes of your treatment. However there is a possibility that you may get upset as a result of talking about your experiences of having shoulder pain.

What are the possible benefits of taking part?

There is no direct benefit to you of taking part in this study. The information that you give me may help with finding the best treatment for shoulder pain in the future.

What if there is a problem?

If you have a concern about any aspect of this study you should speak with me (01603 286990) or my clinical supervisor Mr Simon Donell (01603 286578) and we will do our best to answer your questions. If you remain unhappy and wish to complain formally you can do this through the NHS Complaints Procedure. Details can be obtained from the Complaints and Legal Services department (01603 289684) or by writing to:

The Chief Executive
Norfolk and Norwich University Hospital NHS Trust
Colney Lane
Norwich
Norfolk NR4 7UY

Will my taking part in the study be kept confidential?

Yes. All information which is collected about you during the course of the research will be kept securely, under lock and key, and treated in the strictest confidence.

The cassette tapes will be destroyed once the interview has been typed and you have agreed that it is an accurate record of what you said on the day. Only members of the research team will have access to the research information. This will be kept for five years after the study is over and then will be disposed of securely in the confidential waste, in line with Hospital policy.

Any personal records that I keep to contact you during the study will be destroyed once it is finished. All research documents will have your name and address removed. This means that your identity will not be able to be recognised either in the written research report or in any publications.

What will happen if I don’t want to carry on with the study?

You may withdraw from this study, or stop the interview at any point, without having to give me reason.

What will happen to the results of the research study?

The results of this study will form part of my doctoral thesis. I will also seek to publish a report of the study in a scientific journal. If you wish I will send you a summary of the research findings once the study has been completed.

Who has reviewed the study?

The project idea and methods have been reviewed at the University, by my supervisory team who are experts in this field.

All research in the NHS is looked at by an independent group of people in order to protect your safety, rights, wellbeing and dignity. This study has been reviewed and approved by the Norfolk Research Ethics Committee. As well as this information sheet you will be given a copy of the signed consent form for you to keep.

Further information and contact details

If you have any questions about this study please contact me on 01603 286990. If you want independent advice about taking part in a research study please contact the Research & Development Department, Norfolk and Norwich University Hospital NHS Trust (01603 287408).

What do I do now?

If you decide to take part please sign the consent form and fill in your personal details. You should send it to me in the envelope provided within **one week** of attending the hospital.

Thank you very much for taking time to read this information sheet.

Carol Payne MCSP, DipPhys, MSc
Postgraduate Research Student

Appendix 1

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

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ity Hospital
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CONSENT FORM

Title of study: Important outcomes of intervention for shoulder pain

Chief investigator: Carol Payne MCSP, DipPhys, MSc

		Please initial the box
1	**I confirm that I have read and understand the information sheet (version number and date) and that I have had the opportunity to ask questions.**	
2	**I understand that I am participating voluntarily. I am free to withdraw from the study at any time without having to give a reason. This will not affect the course of my treatment in any way.**	
3	**I have agreed that the research information can be recorded but that no one, other than the members of the research team, will have access to this information.**	
4	**I understand that all the information related to this research will kept strictly confidential and be anonymous, so that I will not be able to be identified in any report.**	
5	**I agree to take part in the above study. I understand that I will be given a copy of the consent form when it has been completed.**	

PRINT YOUR NAME: **DATE:** **YOUR SIGNATURE:**

Chief Investigator: **Date:** **Signature:**

Appendix 1

PLEASE COMPLETE THE FOLLOWING:

Title	
Christian Name	
Surname	
Address1	
Address 2	
Address 3	
Postcode	
Daytime telephone number	
Home telephone number	
Date of birth	
Name of GP	
GP's Surgery	

Please send this form in the envelope provided within <u>one week</u> to the Chief investigator, Carol Payne.

Thank you

Appendix 2

Interview Guide

Patient code number	**Date of interview**
Gender	Male/ Female
Age	Years/ Months
Place of interview	Hospital/ Home / Work

Introduction:

Thank you for agreeing to talk to me today about what it's like to have shoulder pain. You may find that I say very little unless I want to ask you a bit more about something you raise or I think that I haven't understood clearly something you have said. If there are any things that you don't want to talk about that’s fine - we'll just move on.

Anything you do say will be confidential. Although this interview is being recorded I'm sure you'll quickly forget it’s there. This will make sure that I get everything down accurately. I may also take a few notes but don't let that put you off. If for any reason you wish to stop the interview at any stage you just have to tell me and we will stop. OK? Just some general questions to start with.

Socio-demographic data:

Which shoulder is affected?	Right / Left
Are you right or left handed?	Right / Left
Is this the first time you have had a shoulder problem?	Yes /No
Is this the result of an incident or accident?	Yes /No
Do you have bouts of shoulder pain?	Yes /No
How long have you had your symptoms (this time)?	
Did it start suddenly or gradually (this time)?	Yes /No
What work do you do?	
Have you lost any time off because of your shoulder?	Yes /No
How long have you been off work (this time)?	
Are you retired/ unemployed/ a housewife/ student?	Other?
How do you like to spend your spare time?	
Are you able to take part in your hobbies at present?	Yes /No

Interview questions:

Question 1	**How would you describe your shoulder problem?**
Possible probes	*What words would you use to describe your symptoms? When are your symptoms most noticeable?*
Question 2	**How do you find your shoulder problem affects your ability to carry out everyday activities?**
Possible probes	*How does your shoulder pain affect your ability to do things? Think of a typical day from morning to evening; what about at night?*

Appendix 2

Question 3	**How do you cope with having a shoulder problem on a day to day basis?**
Possible probes	*How have you had to change the way you do things? How do you get round problems? I was wondering what impact, if any, it has had on your ability to work and; what about socialising?*
Question 4	**Is there anything else that you think affects your ability to cope with the everyday problems of your shoulder pain?**
Possible probes	*How is your general health? Do you mind telling me if you have any other medical conditions? What impact, if any, does this (they) have on your shoulder pain?*
Question 5	**How does having a shoulder problem make you feel? Have you noticed any changes in yourself?**
Question 6	**What do you hope will be the result of having treatment?**
Possible probes	*Which problems do you expect to change with treatment? Which do you expect to change first; take the longest? How much overall improvement do you expect there to be?*
Question 7	**If you had to choose just one of those things to get better which one would it be?**
Possible probes	*Of all these which is most important; which is less important'? Which bothers you most? Which could you live with?*
Question 8	**Is there is anything else that you feel should happen as a result of your treatment?**
Purpose	*To allow the participant to explore any issues that haven't already been covered*

Conclusion:

Thank you very much for agreeing to take part in my research and for sharing with me your experiences of having shoulder pain.

Just to remind you that once our conversation has been typed I'll send you a copy in the post. Don't be concerned if it all looks like gobbledegook as I'm not going to ask you to make any corrections. All I want you to do is to check that you think it is an accurate record of our conversation today. I'll send you a self addressed envelope so you can send it back to me with any comments you have as soon as you can. Is there anything else about the research that you want to ask?

Appendix 3

Final coding scheme

Theme 1: Range of Symptoms

Category	Code	Descriptor
Pain Symptoms	PS	Pain
	ACH	Ache
	DISH	Discomfort/ Hurt
	TS	Tenderness/ Soreness
	SPS	Secondary Pain Symptoms
Sleep	DOS	Difficulty Getting off to Sleep
	WBP	Woken by Pain
	SAS	Sleep Affected Side
	TOB	Turning Over Bed
Tiredness	TRD	Tiredness
Sensory Disturbance	PAN	Pins and Needles
	NUM	Numbness
Cosmetic Appearance	CA	Cosmetic Appearance
Movement Disorder	LJM	Loss of Joint Movement
	LJS	Loss of Joint Stability
	LMS	Loss UL Muscle Strength
	MST	Muscle Stiffness/ Tension
	LPR	Loss Protective Reactions
	LWBC	Loss Weight-bearing Capacity UL
One-handedness	ONE	One-handedness
	LMD	Loss Manual Dexterity
	LMAN	Loss Manoeuvrability UL
	MIB	Muscle Imbalance

Theme 2: Impact on Upper Limb Use

Category	Code	Descriptor
Lifting and Carrying	LA	Lifting Activities
	CHA	Carrying in Hands
	CAA	Carrying in Arms
	CSA	Carrying on Shoulder
	MAH	Moving & Handling
Hand and Arm Use	MD	Manual Dexterity
	RA	Reaching Activities
	PAPA	Pushing & Pulling Activities
	TATA	Twisting & Turning Activities
	OHU	Overhead Use

Theme 3: Impact on Personal Care, Activities of Daily Living, Work & Recreation

Category	Code	Descriptor
Personal Care	WBS	Washing/ Bathing/ Showering
	HC	Hair Care
	CT	Cleaning Teeth
	TOIL	Toileting
	DRES	Dressing
	EAD	Eating & Drinking
Activities of Daily Living	SHOP	Shopping
	HW	Housework
	CC	Childcare
	DRIV	Driving
	CYCL	Cycling
	WAR	Walking and Running
	SC	Stair Climbing
	UPT	Using Public Transport
	WAT	Writing and Typing
Work	WFC	Working Full Capacity
	CWP	Change Working Practices
	TOW	Time Off Work
	RTW	Return To Work
Recreation	SAE	Sports & Exercise
	DIY	Do-it-Yourself
	PMI	Music
	GAR	Gardening

Abbreviations:

UL = Upper Limb; MED = Medical; MH = Mental Health; MSK = Musculoskeletal

Appendix 3

	SWIM	Swimming

Theme 4: Impact on Personal Relationships

Category	Code	Descriptor
Family Relationships	CFO	Concern For Others
	OW	Others Worry
Social Interactions	PSO	Participation Socialising
	CWO	Communicating With Others

Theme 5: Emotional Impact of MSK Shoulder Pain

Category	Code	Descriptor
Emotional Impact	PRO	Protective
	FR	Frightened
	INS	Insecure
	UPS	Upset
	FRA	Frustrated/ Annoyed
	ISWA	Wary/ Cautious
	ISWO	Worried / Anxious
	DEP	Depressed
	AWK	Awkward/ Clumsy
	SHK	Shocked
	CON	Confident/ Positive
	HSP	Happy/ Surprised/ Pleased

Theme 6: Strategies for Coping with MSK Shoulder Pain

Category	Code	Descriptor
Use Adaptive Strategies	MLA	Make Lifestyle Adaptations
	TIO	Test It Out/ Risk Assessment
	IP	Ignore Pain/ Cope
Need for Assistance	GAS	General Assistance
	PHYS	Physical Assistance
	SUP	Support (Sling/ Pillows etc)
	UGM	Use of a Gadget/ Machine
	SPA	Seek Professional Advice
Medication	POM	Prescribed Medicine
	SEM	Side Effects Medication
	SFM	Self Medication
	MEM	Measure Effect Medication
	EIM	Emotional Impact of Medication
Use Avoidance Strategies	AVS	Use of Avoidance Strategies
Attend Gym/ Exercise/ Massage	GEM	Attend Gym/ Exercise/ Massage
Put Into Perspective	OWO	Others Worse Off
	ARC	Age Related Changes
	CMC	Co-existing MED/ MH Condition
	FH	Family History MSK Condition
	MCC	Measure Change Condition

Theme 7: Expectations of Outcome of Intervention for MSK Shoulder Pain

Category	Code	Descriptor
Identification Specific Outcomes	RS	Relieve Symptoms
	RNA	Resume Normal Activities
	IJE	Improve Job Expectations
	RR	Regain Role
	ESI	End Social Isolation
	REI	Reduce Emotional Impact
	BSR	Be Self-responsible
	AMED	Avoid Prescribed Medication
Prioritisation Specific Outcomes	PSO	Prioritisation Specific Outcomes
Expected Level of Recovery	EFR	Expects Full Recovery
	DEFR	Doesn't Expect Full Recovery
	OTU	Outcome Treatment Uncertain
Expected Rate of Recovery	RTT	Recovery Takes Time
	RSCD	Rate Symptoms Change Differs

<u>**Abbreviations**</u>**:**

UL = Upper Limb; MED = Medical; MH = Mental Health; MSK = Musculoskeletal

Primary data analysis: overarching themes, categories, codes and frequency counts

Theme 1: Range of Symptoms																	
Category	**Code**	**Frequency Count**															**Number (%) Participants**
		A01	**A02**	**A03**	**A04**	**A05**	**A06**	**A07**	**A08**	**A09**	**A10**	**A11**	**A12**	**A13**	**A14**	**A15**	
Pain Symptoms																	
Pain	PS	13	7	5	10	4	7	12	11	17	26	21	10	6	21	10	15 (100%)
Ache	ACH	5		5	3	6	8		12	2	1	1	10		1		11 (73%)
Discomfort/ Hurt	DISH		2	4		3	2		2	8		5	2		9		9 (60%)
Tenderness/ Soreness	TS							2			8	1		2	7		5 (33%)
Secondary Pain Symptoms	SPS	3	2	4	3	9		4	3	3	3	2	2	5	3		13 (87%)
Total Pain Symptoms Category		21	11	18	16	22	17	18	28	30	38	30	24	13	41	10	15 (100%)
Sleep																	
Difficulty Getting off to Sleep	DOS		1		2		6		3	1	5			2			2 (13%)
Woken by Pain	WBP	3	3	1	3	2		5		2		6	3		1	2	11 (73%)
Sleep Affected Side	SAS	2	9	5	1		19	8	1		12	2	3	7	4	4	13 (87%)
Turning Over Bed	TOB	2								4							2 (13%)
Total Sleep Category		7	13	6	6	2	25	13	4	7	17	8	6	9	5	6	15 (100%)
Tiredness																	
Tiredness	TRD	2			2	2				2			8			3	6 (40%)
Sensory Disturbance																	
Pins and Needles	PAN				3		3				2	1			2		5 (33%)
Numbness	NUM		3						9		2			2	4		5 (3%)
Total Sensory Disturbance Category			3		3		3		9		4	1		2	6		8 (53%)

Cosmetic Appearance																	
Cosmetic Appearance	CA							4			3		3		5		4 (27%)
Movement Disorder																	
Loss of Joint Movement	LJM	5	10	2	8	4	11	22	8	5	9	8	9	7	11	6	15 (100%)
Loss of Joint Stability	LJS			1			4		5		13	3					5 (33%)
Loss UL Muscle Strength	LMS			3			8	2	8		3		7	1	1	6	9 (60%)
Muscle Stiffness/ Tension	MST		1	10	3	4	5		9	5	11			3			9 (60%)
Loss Protective Reactions	LPR		5	3			13	5	2	6							6 (40%)
Loss Weight-bearing Capacity UL	LWBC	1		3	1		1	1	5	3	5			1		1	10 (67%)
Total Movement Disorder Category		6	16	22	12	8	42	30	37	19	41	8	15	12	12	13	15 (100%)
One-handedness																	
One-handedness	ONE					4	6	4	2				5	3		6	7 (47%)
Loss Manual Dexterity	LMD					2		1					1				3 (20%)
Loss Manoeuvrability UL	LMAN						4	3					1			3	4 (27%)
Muscle Imbalance	MIB			3	3	3											3 (20%)
Total One-handedness Category				3	3	9	10	8	2				7	3		9	9 (60%)
		A01	A02	A03	A04	A05	A06	A07	A08	A09	A10	A11	A12	A13	A14	A15	
Theme 2: Impact on Upper Limb Use																	
Category	**Code**	**Frequency Count**															**Number (%) Participants**
		A01	**A02**	**A03**	**A04**	**A05**	**A06**	**A07**	**A08**	**A09**	**A10**	**A11**	**A12**	**A13**	**A14**	**A15**	
Lifting and Carrying																	
Lifting Activities	LA	7	3	2	7	1	2		1	3	1		10		1	8	12 (80%)
Carrying in Hands	CHA						3	1			2	1		1			5 (33%)
Carrying in Arms	CAA						5	1			1						3 (20%)
Carrying on Shoulder	CSA						2	4			1		1	1			5 (33%)

Moving & Handling	MAH				4					1			1				3 (20%)
Total Lifting & Carrying Category		7	3	2	11	1	12	6	1	4	5	1	12	2	1	8	15 (100%)
Hand & Arm Use																	
Manual Dexterity	MD					3	9	1			1		1				5 (33%)
Reaching Activities	RA			4	3		1		5			3	4	2			7 (47%)
Pushing & Pulling Activities	PAPA	1			4		3		1				1	3		2	7 (47%)
Twisting & Turning Activities	TATA	6				4	1		1						1		5 (33%)
Overhead Use	OHU	1			2		1	1					2	1	1	2	8 (53%)
Total Hand & Arm Use Category		8		4	9	7	15	2	7		1	3	8	6	2	4	13 (87%)
		A01	A02	A03	A04	A05	A06	A07	A08	A09	A10	A11	A12	A13	A14	A15	

Theme 3: Impact on Personal Care, Activities of Daily Living, Work & Recreation

Category	**Code**	**Frequency Count**															**Number (%) Participants**
		A01	**A02**	**A03**	**A04**	**A05**	**A06**	**A07**	**A08**	**A09**	**A10**	**A11**	**A12**	**A13**	**A14**	**A15**	
Personal Care																	
Washing/ Bathing/ Showering	WBS				1	1	3	1	6		5					1	7 (47%)
Hair Care	HC		1					4							1	1	4 (27%)
Cleaning Teeth	CT		1				1										2 (13%)
Toileting	TOIL		2														1 (7%)
Dressing	DRES		2	2	2	1	5	2	3	1	1	1	1	3		3	14 (93%)
Eating & Drinking	EAD		1										1				2 (13%)
Total Personal Care Category			7	2	3	2	9	7	9	1	6	1	2	3	1	5	15 (100%)
Activities of Daily Living (ADL)																	
Shopping	SHOP						3	2			2						3 (20%)
Housework	HW		4		3	4	3		3	4	1	2	4	3			10 (67%)
Childcare	CC				1		3			1	1						4 (27%)

Driving	DRIV		2		2		5						5				4 (27%)
Cycling	CYCL	5						4			2						3 (20%)
Walking and Running	WAR		1	1		1	1			1			1				6 (40%)
Stair Climbing	SC						4	3	3								3 (20%)
Using Public Transport	UPT		2					1									2 (13%)
Writing and Typing	WAT					2	5										2 (13%)
Total ADL Category		5	9	1	6	7	24	10	6	6	6	2	10	3			13 (73%)
Work																	
Working Full Capacity	WFC	1		2			1		N/A						N/A	N/A	3/ 12 (25%)
Change Working Practices	CWP				2				N/A		3	2	8	2	N/A	N/A	5/ 12 (42%)
Time Off Work	TOW	1			5	2	1	2	N/A	1	4		1		N/A	N/A	8/ 12 (67%)
Return To Work	RTW								N/A				1	2	N/A	N/A	2/ 12 (17%)
Total Work Category		2		2	7	2	2	2	N/A	1	7	2	10	4	N/A	N/A	11/12 (92%)
Recreation																	
Sports and Exercise	SAE			6				6	6		16		6		4		6 (40%)
DIY	DIY	6															1 (7%)
Music	PMI			2													1 (7%)
Gardening	GAR		4		3		5		3			4	3	1			7 (47%)
Swimming	SWIM	3													2		2 (13%)
Total Recreation Category		9	4	8	3		5	6	9		16	4	9	1	6		12 (80%)
		A01	A02	A03	A04	A05	A06	A07	A08	A09	A10	A11	A12	A13	A14	A15	
Theme 4: Impact on Personal Relationships																	
Category	**Code**	**Frequency Count**															**Number (%) Participants**
		A01	**A02**	**A03**	**A04**	**A05**	**A06**	**A07**	**A08**	**A09**	**A10**	**A11**	**A12**	**A13**	**A14**	**A15**	
Family Relationships																	

Concern For Others	CFO		5		3		2				8	1	5	2	1		8 (53%)
Others Worry	OW		2		1		1		3		2	1	4	1			8 (53%)
Total Family Relationships			7		4		3		3		10	2	9	3	1		9 (60%)
Social Interactions																	
Participation Socialising	PSO		6					2					3				3 (20%)
Communicating with Others	CWO										1			1			2 (13%)
Total Social Interactions			6					2			1		3	1			5 (33%)
Total Personal Relationships			13		4		3	2	3		11	2	12	4	1		10 (67%)
		A01	**A02**	**A03**	**A04**	**A05**	**A06**	**A07**	**A08**	**A09**	**A10**	**A11**	**A12**	**A13**	**A14**	**A15**	
Theme 5: Emotional Impact of MSK Shoulder Pain																	
Category	**Code**	**Frequency Count**															**Number (%) Participants**
		A01	**A02**	**A03**	**A04**	**A05**	**A06**	**A07**	**A08**	**A09**	**A10**	**A11**	**A12**	**A13**	**A14**	**A15**	
Emotional Impact																	
Protective	PRO			4	1		5		3		5	5					6 (40%)
Frightened	FR		2		1			14	1		15	3					6 (40%)
Insecure	INS		5								3						2 (13%)
Upset	UPS				2			2			10					1	4 (27%)
Frustrated/ Annoyed	FRA	2		1		1			4	1	2	1	1	1	2		10 (67%)
Wary/ Cautious	ISWA			3	8		7	2	2	2	1						7 (47%)
Worried / Anxious	ISWO				1		6		1				3				4 (27%)
Depressed	DEP	2			4					3			1				4 (27%)
Awkward/ Clumsy	AWK					3							1	8			3 (20%)
Shocked	SHK							2	3		1						3 (20%)
Confident/ Positive	CON			3		1	1		1		3	2	4			1	8 (53%)
Happy/ Surprised/ Pleased	HSP	4						1			2		6		2		5 (33%)
Total Emotional Impact Category		8	7	11	17	5	19	21	15	6	42	11	16	9	4	2	15 (100%)
		A01	A02	A03	A04	A05	A06	A07	A08	A09	A10	A11	A12	A13	A14	A15	

Theme 6: Strategies for Coping with MSK Shoulder Pain																	
Category	**Code**	**Frequency Count**															**Number (%) Participants**
		A01	**A02**	**A03**	**A04**	**A05**	**A06**	**A07**	**A08**	**A09**	**A10**	**A11**	**A12**	**A13**	**A14**	**A15**	
Use of Adaptive Strategies																	
Make Lifestyle Adaptations	MLA		1	3	12	1	11		11	3	24	4	5	3	2		12 (80%)
Test It Out	TIO			7	2	4	4	1	1		8						7 (47%)
Ignore Pain/ Cope	IP					5			10	5	18			6	7	4	7 (47%)
Total Adaptive Category			1	10	14	10	15	1	22	8	50	4	5	9	9	4	14 (93%)
Use of Assistance																	
General Assistance	GAS		3		2	1	1	5	2								6 (40%)
Physical Assistance	PHYS								6		6			2	8		4 (27%)
Support (Sling/ Pillows etc)	SUP		2	1			4		3		9			3	2		7 (47%)
Use of a Gadget/ Machine	UGM	1	1		5	2											4 (27%)
Seek Professional Advice	SPA	1	1		7			1			9	2		7			7 (47%)
Total Assistance Category		2	7	1	14	3	5	6	11		24	2		12	10		12 (80%)
Medication																	
Prescribed Medicine	POM	3			1	5		6	2	7	3	4	4	2	2	3	12 (80%)
Side Effects Medication	SEM					2		3		4	2			3			5 (33%)
Self Medication	SFM					4	2					3		1			4 (27%)
Measure Effect Medication	MEM				3			1			3	1	1	1	1	3	8 (53%)
Emotional Impact of Medication	EIM							1		1				1			3 (20%)
Total Medication Category		4			5	13	2	14	2	16	10	8	5	8	3	6	13 (73%)
Use of Avoidance Strategies																	
Use of Avoidance Strategies	AVS	6	8	6	10	5	6	5		2	7		4	8	6	1	13 (73%)

Attend Gym/ Exercise/ Massage																	
Attend Gym/ Exercise/ Massage	GEM		3	5			5	8	2		7	6	3	4			9 (60%)
Put Into Perspective (PIP)																	
Others Worse Off	OWO								3		5	2					3 (20%)
Age Related Changes	ARC				3				4								2 (13%)
Co-existing MED/ MH Condition	CMC					3		2						3		4	4 (27%)
Family History MSK Condition	FH			3								5					2 (13%)
Measure Change Condition	MCO	2	9		1	3	4			1	3	3	12		8	5	11 (73%)
Total PIP Category		2	9	3	4	6	4	2	7	1	8	10	12	3	8	9	15 (100%)
		A01	A02	A03	A04	A05	A06	A07	A08	A09	A10	A11	A12	A13	A14	A15	
Theme 7: Expectations of Outcome of Intervention for MSK Shoulder Pain																	
	Code	**Frequency Count**															**Number (%)**
Category		**A01**	**A02**	**A03**	**A04**	**A05**	**A06**	**A07**	**A08**	**A09**	**A10**	**A11**	**A12**	**A13**	**A14**	**A15**	**Participants**
Identification Specific Outcomes																	
Relieve Symptoms	RS	5	2	5	7	1	3	11	3	11	1	4	7	2	6	6	15 (100%)
Resume Usual Activities	RUA	6		4	3		2		4		3		2				7 (47%)
Improve Job Expectations	IJE		6		11	2											3 (20%)
Regain Role	RR		9				2							1			3 (20%)
End Social Isolation	ESI		2										2				2 (13%)
Be Self-responsible	BSR				3	1	3	6	3			7	3				7 (47%)
Avoid Prescribed Medication	AMED	1			1	2		3		4	2						6 (40%)
Total Specific Outcomes Category		11	19	9	25	6	10	20	10	15	6	11	12	3	6	6	15 (100%)
Prioritisation Specific Outcomes																	
Prioritisation Specific Outcomes	PSO	2	2	1	1	1	2	1	2	2	1		4	1	6	4	14 (93%)

Expected Level of Recovery																	
Expects Full Recovery	EFR		3		1			3		3	1		3	1			7 (47%)
Doesn't Expect Full Recovery	DEFR	3	3	1	3			1							4		6 (40%)
Outcome Treatment Uncertain	OTU	4	2	2		4	2	3				2	1	2	1	1	11 (73%)
Total Expected Level of Recovery		7	8	3	4	4	2	7		3	1	2	4	3	5	1	14 (93%)
Expected Rate of Recovery																	
Recovery Takes Time	RTT	3		2	3	2	2	2	1		5	2		3	3		11 (73%)
Rate Symptoms Change Differs	RSCD			3					1							1	3 (20%)
Total Expected Rate of Recovery		3		5	3	2	2	2	2		5	2		3	3	1	12 (80%)
		A01	**A02**	**A03**	**A04**	**A05**	**A06**	**A07**	**A08**	**A09**	**A10**	**A11**	**A12**	**A13**	**A14**	**A15**	

Appendix 5

PROMS, published 1991-2006, included in the review

Shoulder Pain and Disability Index (SPADI)
SPADI was developed to measure the impact of shoulder pathology in terms of pain and disability. Roach, KE, Budiman-Mak, E, Songsiridej, N & Lertratanakul, Y 1991, 'Development of a shoulder pain and disability index', *Arthritis Care Res*, vol. 4, pp. 143–149.
Simple Shoulder Test (SST)
SST was developed to assess the functional limitations of the affected shoulder in the context of the patient's activities of daily living. Lippitt, SB, Harryman, DTI & Matsen, FAI, 1993, 'A practical tool for evaluation of function: the simple shoulder test', pp. 501–518, in FA, Matsen, III, FH, Fu & Hawkins, RJ (eds), *The shoulder: a balance of mobility and stability*, The American Academy of Orthopaedic Surgeons, Rosemont, USA.
Shoulder Disability Questionnaire (SDQ-UK)
SDQ was designed for the assessment of restriction in everyday activities from shoulder symptoms. Croft, P, Pope, D, Zonca, M, O'Neill, T & and Silman, A 1994, 'Measurement of shoulder related disability: results of a validation study', *Ann Rheum Dis*, vol. 53, pp. 525–528.
American Shoulder and Elbow Surgeon's Standardized Shoulder Assessment: Patient Self-evaluation Form (ASES)
The patient self-evaluation section of the ASES was developed to measure functional limitations and pain of the shoulder. Richards, RR, An, KN, Bigliani, LU, Friedman, RJ, Gartsman, GM, Gristina, AG, Iannotti, JP, Mow, VC, Sidles, JA & Zuckerman, JD 1994, 'A standardized method for the assessment of shoulder function', *J Should Elbow Surg*, vol. 3, pp. 347–352.
Oxford Shoulder Score (OSS)
OSS was developed for the assessment of outcomes of shoulder surgery, excluding stabilisation, in randomised trials. Dawson, J, Fitzpatrick, R & Carr, A 1996, 'Questionnaire on the perceptions of patients about shoulder surgery', *J Bone Joint Surg [Br]*, vol. 78, pp. 593-600.
Disabilities of the Arm, Shoulder and Hand Questionnaire (DASH)
DASH was designed to evaluate symptoms and functional status in patients with upper extremity musculoskeletal conditions for use by clinicians in daily practice and as a research tool. Hudak, PL & Amadio, PC & Bombardier, C 1996, 'Development of an upper extremity outcome measure: the DASH (disabilities of the arm, shoulder and hand): The Upper Extremity Collaborative Group (UECG), *Am J Ind Med*, vol. 29, pp. 602–608.

Appendix 5

Subjective Shoulder Rating System (SSRS)

SSRS was designed as an easy-to-perform, examiner-independent scoring system for the evaluation of patients with different shoulder problems.

Kohn, D & Geyer, M 1997, 'The subjective shoulder rating system', *Arch Orthop Trauma Surg*, vol. 116, pp. 324–328.

Shoulder Rating Questionnaire (SRQ)

SRQ was designed to evaluate the severity of symptoms related to and the functional status of a broad range of disorders related to the shoulder.

L'Insalata, JC, Warren, RF, Cohen, SB, Altchek, DW & Peterson, MG 1997, 'A self-administered questionnaire for assessment of symptoms and function of the shoulder', *J Bone Joint Surg (Am),* vol. 79, pp. 738–748.

Shoulder Disability Questionnaire (SDQ-NL)

SDQ-NL was developed to evaluate the functional status limitations in patients with soft tissue disorders.

van der Windt, DA, van der Heijden, GJ, de Winter, AF, Koes, BW, Devillé, W & Bouter, LM 1998, 'The responsiveness of the Shoulder Disability Questionnaire', *Ann Rheum Dis*, vol. 57, no. 2, pp. 82-87.

Penn Shoulder Score (PSS)

PSS was developed to evaluate the pain, satisfaction and function in patients with shoulder disorders.

Leggin, BG & Iannotti, JP 1999, 'Shoulder Outcome Measurement ', eds JP Iannotti & GR Williams, *Disorders of the Shoulder: Diagnosis and Management*, Lippincott, Williams & Wilkins, Philadelphia.

Flexilevel Scale of Shoulder Function (FLEX-SF)

FLEX-SF, an adaptive scale in which patients respond only to items that are targeted at their level of shoulder function, was developed to evaluate the full range of shoulder function in clinical practice and clinical research.

Cook, KF, Roddey, TS, Gartsman, GM & Olson, SL 2003, 'Development and psychometric evaluation of the Flexilevel Scale of Shoulder Function (FLEX-SF)', *Med Care*, vol. 41, pp. 823–835.

Upper Limb Functional Index (ULFI)

ULFI was developed to evaluate the health related quality of life and upper extremity dysfunction for use in patient populations across a variety of clinical and research situations.

Gabel, CP, Michener, LA, Burkett, B & Neller, A 2006, The Upper Limb Functional Index: development and determination of reliability, validity, and responsiveness, *J Hand Ther*, vol.19, no. 3, pp. 328-348.

Appendix 6

PROMS excluded from the review

Single Construct Measures (1996-2007)

1 **Subjective Shoulder Value**

Gilbart, MK & Gerber, C 2007, 'Comparison of the subjective shoulder value and the Constant score', *J Shoulder Elbow Surg*, vol. 16, no. 6 pp. 717-721.

2 **Single Assessment Numeric Evaluation**

Williams, GN, Gangel, TJ, Arciero, RA, Uhorchak, JM & Taylor, DC 1999, 'Comparison of the Single Assessment Numeric Evaluation method and two-shoulder rating scales. Outcomes measures after shoulder surgery', *Am J Sports Med*, vol. 27, pp. 214–221.

3 **Shoulder Pain Score**

Winters, JC, Sobel, JS, Groenier, KH, Arendzen, JH & Meyboom-De Jong, B 1996, 'A shoulder pain score: a comprehensive questionnaire for assessing pain in patients with shoulder complaints', *Scand J Rehabil Med*, vol. 3, pp. 163-167.

Combined Patient Report & Clinician Rated Measures (1981- 2001)

4 **University of California Los Angeles Shoulder Score**

Amstutz, HC, Sew Hoy, AL & Clarke, IC 1981, 'UCLA anatomic total shoulder arthroplasty', *Clin Orthop*, vol. 155, pp. 7–20.

5 **Constant Murley Shoulder Score**

Constant, CR & Murley, AH 1987, 'A clinical method of functional assessment of the shoulder, *Clin Orthop*, vol. 214, pp. 160–164.

6 **Functional Impairment Test-Hand & Neck/Shoulder/Arm**

MacDermid, JC, Ghobrial, M, Quiron, KN, St-Amour, M, Tsui, T, Humphreys, D, McCluskie, J, Shewayhat, E & Galea, V 2007, *'Validation of a new test that assesses functional performance of the upper extremity and neck (FIT-HaNSA) in patients with shoulder pathology'*, BMC Musculoskelet Disord, viewed 7th Jan 2009, < http://www.biomedcentral.com/1471-2474/8/42>

Shoulder Disease Specific Measures (1975-2005)

7 **Oxford Instability Questionnaire**

Dawson, J, Fitzpatrick, R & Carr, A 1999, 'The assessment of shoulder instability. The development and validation of a questionnaire', *J Bone Joint Surg [Br]*, vol. 81, pp. 420–426.

8 **Rotator Cuff Quality of Life Measure**

Hollinshead, RM, Mohtadi, NG, Vande Guchte RA & Wadey, VM 2000, 'Two to six-year follow-up studies of large and massive rotator cuff tears: comparison of outcome measures', *J Shoulder Elbow Surg*, vol. 9, pp. 373–381.

9 **Acromioclavicular joint dislocation**

Imatani, RJ, Hanlon, JJ & Cady, GW 1975, 'Acute, complete acromioclavicular separation', *J Bone Joint Surg [Am],* vol. 57, no. 3, pp. 328–332.

10 **Western Ontario Shoulder Instability Index**

Kirkley, A, Griffin, S, McLintock, H & Ng, L 1998, 'The development and evaluation of a disease-specific quality of life measurement tool for shoulder instability', *Am J Sports Med*, vol. 26, pp. 764–772.

11 **Western Ontario Rotator Cuff Index**

Kirkley, A, Alvarez, C & Griffin, S 2003, 'The development and evaluation of a disease-specific quality-of-life questionnaire for disorders of the rotator cuff: The Western Ontario Rotator Cuff Index', *Clin J Sport Med*, vol. 13, pp. 84–92.

12 **Western Ontario Osteoarthritis of the Shoulder Index**

Lo, IK, Griffin, S & Kirkley, A 2001, 'The development of a disease-specific quality of life measurement tool for osteoarthritis of the shoulder: The Western Ontario Osteoarthritis of the Shoulder (WOOS) index', *Osteoarthritis Cartilage*, vol.9 pp. 771–778.

Appendix 6

13 Neer Rating Scale

Neer, CS 2nd, Watson, KC & Stanton, FJ 1982, 'Recent experience in total shoulder replacement', *J Bone Joint Surg [Am],* vol. 64, pp. 319–337.

14 Rowe Rating Sheet for Bankart Repair

Rowe, CR, Patel, D & Southmayd, WW 1978, 'The Bankart procedure: a long-term end-result study', *J Bone Joint Surg [Am],* vol. 60, pp. 1–16.

15 Shoulder Functional Assessment Scale Rheumatoid Arthritis

van den Ende, CH, Rozing, PM, Dijkmans, BA, Verhoef, JA, Voogt-van der Harst EM & Hazes, JM 1996, 'Assessment of shoulder function in rheumatoid arthritis', *J Rheumatol*, vol. 23, pp. 2043–2048.

16 Melbourne Instability Shoulder Score Questionnaire

Watson, L, Story, I, Dalziel, R, Hoy, G, Shimmin, A & Woods D 2005, 'A new clinical outcome measure of glenohumeral joint instability: the MISS questionnaire', *J Shoulder Elbow Surg*, vol. 14, no. 1, pp. 22-30.

Specific Patient Subgroups (1995-2001)

Occupational Groups:

17 Upper Extremity Function Scale

Pransky, G, Feuerstein, M, Himmelstein, J, Katz, JN & Vickers-Lahti, M 1997, 'Measuring functional outcomes in work-related upper extremity disorders. Development and validation of the Upper Extremity Function Scale', *J Occup Environ Med*, vol. 39, 1195–1202.

18 Upper Extremity Questionnaire

Salerno, DF, Franzblau, A, Armstrong, TJ, Werer, RA & Becker, MP 2001, 'Test-retest reliability of the Upper Extremity Questionnaire among keyboard operators, *Am J Ind Med*, vol. 40, no. 6, pp. 655-666.

19 Upper and Lower Functional Limitation Scale

Simonsick, EM, Kasper, JD, Guralnik, JH, Bandeen-Roche, K, Ferrucci, L & Hirsch, R 2001, 'WHAS Research Group Women's Health and Aging Study, Severity of upper and lower extremity functional limitation: scale development and validation with self-report and performance-based measures of physical function', *J Gerontol B Psychol Sci Soc Sci*. vol. 56, pp. S10–S19.

Malignancy:

20 Toronto Extremity Salvage Score: Sarcoma (TESS)

Davis, AM, Wright, JG, Williams, JI, Bombadier, C, Griffin, A & Bell RS 1996, 'Development of a measure of physical function for patients with bone and soft tissue sarcoma', *Qual Life Res*, vol. 5, pp. 508–516.

Wheelchair Users:

21 Wheelchair Users Shoulder Pain Index

Curtis, KA, Roach, KE Applegate, EB, Amar, T, Benbow, CS & Genecco, TD 1995, 'Development of the Wheelchair User's Shoulder Pain Index (WUSPI)', *Paraplegia*, vol. 33, pp. 290–293.

Tetraplegia:

22 Capabilities Upper Extremity Instrument

Marino, RJ, Shea, JA & Stineman, MG 1998, 'The Capabilities of Upper Extremity instrument: reliability and validity of a measure of functional limitation in tetraplegia', *Arch Phys Med Rehabil*, vol. 79, pp. 1512–1521.

Appendix 7

Content validity of PROMS

PROM	First author (date/ country)	Target population	Involvement of patients, experts or researchers	Number of items	Number of scales/ subscales	Constructs measured	Response options	Range possible scores
SPADI	Roach (1991, USA)	Shoulder pathology	Experts	5 8	**2**	Pain Disability	11-pt NRS	0 - 100
SST	Lippitt (1993, USA)	Shoulder problems	Patients Researchers	12	**1**	Physical Function	Yes/ No	0 -12
SDQ-UK	Croft (1994, UK)	Shoulder symptoms	Patients Experts/ researchers	22	**1**	Functional activities	Yes/ No	0 - 22
ASES	Richards (1994)	Shoulder pathologies	Experts/ researchers	1 10	**2**	Pain Functional limitations	10-cm VAS	0-100
OSS	Dawson (1996, UK)	Range of shoulder disorders	Patients Researchers	12	**1**	Functional activities	5-pt Likert scale	0 - 48
DASH	Hudak (1996,Canada)	MSK disorders of the upper extremity	Patients Experts/ researchers	30	**1**	Functional status Social function Symptoms Emotional function	5-pt Likert scale	0 -100
SSRS	Kohn (1997, Germany)	Shoulder problems	Researchers	5	**1**	Pain, movement, instability, functional activities & overhead working	3/ 5-pt Likert scale	0 - 100
SRQ	L'Insalata (1997, USA)	Range of shoulder disorders	Patients Researchers	17 1	**5** **1**	Functional activities Satisfaction	Yes/ No	0-12
SDQ-NL	van der Windt (1998, NL)	Shoulder disorders	Experts	16	**1**	Functional activities	NA /Yes / No	0 - 100
PSS	Leggin (1999, USA)	Shoulder disorders	Not reported	20 3 1	**3**	Function Pain Satisfaction	5-pt Likert scale 0-10 NRS 0-10 NRS	17 - 100
FLEX-SF	Cook (2003, USA)	Functionally limited shoulder disorders	Patients Experts/ researchers	1 branching question + 15 each scale*	**1**	Functional limitation	5-pt Likert scale	1 - 50
ULFI	Gabel (2006, Australia)	Dysfunction upper extremity	Patients Experts/ researchers	25	**1** **1** **1**	Functional limitation Overall status Patient specific index	Yes/ No 6-pt Likert scale 11-pt VAS	0 - 100

Abbreviations: **NA**: Not Applicable; **NRS**: Numeric Rating Scale; **VAS**: Visual analogue scale
*FLEX-SF: 3 scales with easy, medium difficulty and hard items

Appendix 8

Reliability, responsiveness and interpretability of PROMS

Outcome Measure	Time to Complete	Internal Consistency	Test-retest Reliability	Standard Error Measurement	Responsiveness	Minimal Detectable Change	Minimally Clinically Important Difference
SPADI (Roach 1991)	5-10 min a	α = 0.95 a	ICC: 0.65 a	SEM ± 9.3 pts (95% CI) a	SRM: 1.23 (95% CI 0.88, 1.58) c	DNA	MCID: > 10 points b
*****							
SST (Lippitt 1993)	< 3 min c	α = 0.85 d	ICC: 0.99 c	SEM ± 22.8 pts (95% CI) d	SRM: 0.87 (95% CI 0.52, 1.22) c	DNA	DNA
****							
SDQ-UK (Croft 1994)	3 (1-8) min h	DNA	DNA	DNA	SRM: 0.78 h ES: 0.91 h	DNA	DNA
*							
ASES (Richards 1994)	3 min a	α = 0.86 m	ICC: 0.84 95%CI 0.75, 0.91) m	SEM 6.7 ± 11.0 m	SRM: 1.54 m ES: 1.39 m	MDC 9.7 pts ± 15.5 m	MCID: 6.4 pts m
******							
OSS (Dawson 1996)	DNA	α = 0.89-0.92 a	DNA	DNA	ES: 1.2 a	DNA	½ SD change score a
***							
DASH (Hudak 1996)	6 min f	α = 0.97 c	ICC: 0.96 (95% CI 0.93, 0.98) c	SEM: 7.6 pts (90% CI) j	SRM: 0.6 c ESS: 0.5 c	MDC: 12.8 (90% CI) j	MCID: 10 pts c
******							
SSRS (Kohn 1997)	55 (20-310) sec a	DNA	ICC: 0.71 c	DNA	SRM: 0.65 (95% CI 0.3, 1.0) c	DNA	DNA
**							
SRQ (L'Insalata 1997)	4 (1-16) min h	α = 0.86 a	Weighted Kappa = 0.73-0.97 a	DNA	SRM: 1.9 a GIR: 1.58	DNA	MCID: 12 pts a
****							
SDQ-NL (van der Windt 1998)	5-10 min g	DNA	DNA	DNA	GIR 1.89-2.22 a SRM: 0.95 h ES: 1.56 h	DNA	DNA
*							
PSS (Leggin 1999)	8 min f	α = 0.93 a	ICC: 0.94 (95% CI 0.89, 0.97) a	SEM ± 8.5 pts (90% CI) a	SRM = 1.27 a ES = 1.01 a	MDC: ± 12.1 pts a	MCID: 11.4 pts a
******							
FLEX-SF (Cook 2003)	DNA	α > 0.90 a	ICC: 0.90 (95% CI 0.84, 0.94) a	DNA	GIR 1.12 a	DNA	MCID: 3.02pts a
****							
ULFI (Gabel 2006)	<3min a	α = 0.89 a	ICC: 0.96 (95%CI) a	1.13 pts (95%CI) a	SRM: 1.87 a ES: 1.28 a	MDC: 2.6 pts (95% CI) a	DNA
******							

Abbreviations: DNA = Data not available; SD = Standard Deviation; Internal Consistency (Cronbach's alpha (α)); Reliability (Intraclass correlation coefficient (ICC); Standard Error Measurement (SEM); Standardised response mean (SRM); Effect Size (ES); Guyatt Index Responsiveness (GIR); Minimal Detectable Change (MDC) and; Minimal Clinically Important Difference (MCID)

Adapted from: a Original author; b Williams, Holleman & Simnel 1995, c Beaton & Richards 1998; d Roddey et al. 2000; e van der Heijden, Leffers & Bouter 2000, f Michener & Leggin 2001; g Bot et al. 2004, h Paul et al. 2004, j Leggin et al. 2006, I Cloke et al. 2005 and m Michener, McClure & Sennett 2002

*Overall rating of six measurement properties i.e. internal consistency, test-retest reliability, standard error of measurement, responsiveness, minimal detectable change and interpretability of PROMS (min = 0, max = 6), are presented to facilitate comparisons between individual measures.

Example of linking an individual PROM, the SPADI (Roach 1991), to the ICF

Shoulder Pain and Disability Index (SPADI) (Roach 1991)
2 scales: 13 items (rated 11-point visual analogue scale)

Items SPADI	Meaningful Concept	ICF Code	ICF Category	Additional Information
How severe is your pain				
At its worst?	Pain	b280	Sensation of pain	Pain severity
When lying on the involved side?	Pain	b280	Sensation of pain	Pain severity
	Lying involved side	d415	Maintaining a body position	
Reaching for something on a high shelf?	Pain	b280	Sensation of pain	Pain severity
	Reaching	d445	Hand and arm use	High shelf
Touching the back of your neck?	Pain	b280	Sensation of pain	Pain severity
	Reaching	d445	Hand and arm use	Back of neck
Pushing with the involved arm?	Pain	b280	Sensation of pain	Pain severity
	Pushing involved arm	b445	Hand and arm use	
How much difficulty do you have				
Washing your hair?	Washing hair	d520	Caring for body parts	
	Reaching	d445	Hand and arm use	Overhead
Washing your back?	Washing oneself	d510	Washing oneself	Back
	Reaching	d445	Hand and arm use	Back
Putting on an undershirt/ pullover sweater?	Dressing	d540	Dressing	Undershirt/ sweater
	Reaching	d445	Hand and arm use	Overhead
Putting on a button down the front shirt?	Dressing	d540	Dressing	Front fastening shirt
	Reaching	d445	Hand and arm use	Across front of body
Putting on your pants?	Dressing	d540	Dressing	Pants
Placing an object on a high shelf?	Lifting	d430	Lifting and carrying objects	High shelf
	Reaching	d445	Hand and arm use	Overhead
Carrying a heavy object of 10 pounds?	Carrying in hands	d430	Lifting and carrying	10lb weight
	Carry in arms	d430	Lifting and carrying	10lb weight
Removing something from your back pocket?	Reaching	d445	Hand and arm use	Back
	Dexterity	d440	Fine hand use	Removing item back pocket

Appendix 10

Frequency with which outcomes, contained in PROMS, were reflected in the ICF classification

Second-level ICF category (N)	ICF Code	Frequency outcome assessed in PROM (N)														N (%) PROMS
		SPADI	SST	SDQ-UK	ASES	OSS	DASH	SSRS	SRQ	SDQ-NL	PSS	FLEX-E	FLEX-M	FLEX-H	ULFI	
Body functions component																
Energy and drive functions	**b130**	0	0	1	0	0	0	0	0	0	0	0	0	0	1	2 (14%)
Sleep functions	**b134**	0	1	1	1	1	1	0	1	1	1	0	0	0	1	9 (64%)
Emotional functions	**b152**	0	0	2	0	0	3	1	0	2	0	0	0	0	2	5 (36%)
Mental functions	**b1**	0	1	5	1	1	4	1	1	3	1	0	0	0	4	10 (71%)
Touch functions	**b265**	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1 (7%)
Sensation of pain	**b280**	5	2	1	1	4	3	1	4	14	3	0	0	0	1	11 (79%)
Sensory functions & pain sensations	**b2**	**5**	**2**	**1**	**1**	**4**	**4**	**1**	**4**	**14**	**3**	**0**	**0**	**0**	**1**	**11 (79%)**
Mobility of joint functions	**b710**	0	0	1	0	0	4	2	0	4	2	3	0	2	3	8 (57%)
Stability of joint functions	**b715**	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1 (7%)
Muscle power functions	**b730**	0	0	0	0	0	1	0	0	0	0	0	0	0	1	2 (14%)
Control voluntary movement	**b760**	0	0	0	0	0	0	0	0	1	0	1	1	0	0	3 (21%)
Movement-related functions	**b7**	**0**	**0**	**1**	**0**	**0**	**1**	**3**	**0**	**5**	**2**	**4**	**1**	**2**	**4**	**9(64%)**
Activities and participation component																
Undertaking a single task	**d210**	0	0	1	0	1	0	0	0	0	0	0	0	0	0	2 (14%)
Carrying out daily routine	**d230**	0	0	2	0	0	1	0	3	0	0	0	0	0	0	3 (21%)
General tasks and demands	**d2**	**0**	**0**	**3**	**0**	**1**	**1**	**0**	**3**	**0**	**0**	**0**	**0**	**0**	**0**	**4 (29%)**
Writing messages	**d345**	0	0	1	0	0	1	0	0	1	0	0	0	0	1	4 (29%)
Using writing machines	**d360**	0	0	1	0	0	0	0	0	1	0	0	0	0	2	3 (21%)
Communication	**d3**	**0**	**0**	**2**	**0**	**0**	**1**	**0**	**0**	**2**	**0**	**0**	**0**	**0**	**3**	**4 (29%)**
Changing basic body position	**d410**	0	0	1	0	1	0	0	0	0	0	0	0	0	1	3 (21%)
Maintaining a body position	**d415**	1	0	2	1	0	0	0	0	1	1	0	0	0	0	5 (36%)
Lifting and carrying objects	**d430**	2	4	1	1	1	3	0	1	1	7	3	2	4	3	13 (93%)
Fine hand use	**d440**	1	0	2	0	0	1	0	0	1	0	0	0	0	1	5 (36%)
Hand and arm use	**d445**	5	5	0	3	2	5	1	3	6	8	7	14	10	5	13 (93%)

Second-level ICF category (N)	**Code**	**SPADI**	**SST**	**SDQ-UK**	**ASES**	**OSS**	**DASH**	**SSRS**	**SRQ**	**SDQ-NL**	**PSS**	**FLEX-E**	**FLEX-M**	**FLEX-H**	**ULFI**	**N (%)**
Walking	**d450**	0	0	0	0	0	1	0	0	0	0	0	0	0	2	2 (14%)
Moving around	**d455**	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1 (7%)
Using transportation	**d470**	0	0	0	0	1	1	0	0	0	0	0	0	0	1	3 (21%)
Driving	**d475**	0	0	0	0	0	1	0	1	0	0	0	0	0	1	3 (21%)
Mobility	**d4**	**9**	**9**	**6**	**5**	**5**	**12**	**1**	**5**	**9**	**17**	**10**	**16**	**14**	**14**	**14 (100%)**
Washing oneself	**d510**	1	1	1	1	1	1	0	2	0	3	1	0	0	1	10 (71%)
Caring for body parts	**d520**	1	0	0	1	1	1	0	1	0	1	1	0	0	0	7 (50%)
Toileting	**d530**	0	0	0	1	0	0	0	0	0	1	0	0	0	0	2 (14%)
Dressing	**d540**	3	1	4	2	1	1	0	2	1	4	1	0	0	0	10 (71%)
Eating	**d550**	0	0	0	0	1	1	0	0	0	1	0	0	0	1	4 (29%)
Drinking	**d560**	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1 (7%)
Self-care	**d5**	**5**	**2**	**5**	**5**	**4**	**4**	**0**	**5**	**1**	**10**	**4**	**0**	**0**	**2**	**11 (79%)**
Acquisition of goods and services	**d620**	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1 (7%)
Preparing meals	**d630**	0	0	0	0	0	1	0	0	0	1	0	0	0	0	2 (14%)
Doing housework	**d640**	0	0	1	0	1	4	0	1	0	1	0	2	1	1	8 (57%)
Caring for household objects	**d650**	0	0	0	0	0	1	0	1	0	0	0	0	0	1	3 (21%)
Domestic life	**d6**	**0**	**0**	**1**	**0**	**1**	**6**	**0**	**2**	**0**	**2**	**0**	**2**	**1**	**2**	**8 (57%)**
Informal social relationships	**d750**	0	0	0	0	0	4	0	0	0	0	0	0	0	0	1 (7%)
Family relationships	**d760**	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1 (7%)
Intimate relationships	**d770**	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1 (7%)
Interpersonal relationships	**d7**	**0**	**0**	**0**	**0**	**0**	**6**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1 (7%)**
Remunerative employment	**d850**	0	1	0	1	1	1	1	4	0	1	0	0	0	1	8 (57%)
Major life areas	**d8**	**0**	**1**	**0**	**1**	**1**	**1**	**1**	**4**	**0**	**1**	**0**	**0**	**0**	**1**	**8 (57%)**
Recreation and leisure	**d920**	0	0	2	1	0	2	1	3	0	2	0	0	0	2	7 (50%)
Community, civic and social life	**d9**	**0**	**0**	**2**	**1**	**0**	**2**	**1**	**3**	**0**	**2**	**0**	**0**	**0**	**2**	**7 (50%)**

Appendix 11

First and second level ICF categories reflected in PROMS

First level ICF code and category	Second level ICF code and category
Body functions component	
b1 Mental functions	b130 Energy and drive functions b134 Sleep functions b152 Emotional functions
b2 Sensory functions and pain	b265 Touch function b280 Sensation of pain
b7 NMSK and movement related functions	b710 Mobility of joint functions b715 Stability of joint functions b730 Muscle power functions b760 Control of voluntary movement functions
Activities and participation component	
d2 General tasks and demands	d210 Undertaking a single task d230 Carrying out daily routine
d3 Communication	d345 Writing messages d360 Using writing machines
d4 Mobility	d410 Changing basic body position d415 Maintaining a body position d430 Lifting and carrying objects d440 Fine hand use d445 Hand and arm use d450 Walking d455 Moving around d470 Using transportation d475 Driving
d5 Self-care	d510 Washing oneself d520 Caring for body parts d530 Toileting d540 Dressing d550 Eating d560 Drinking
d6 Domestic life	d620 Acquisition of goods & services d630 Preparing meals d640 Doing housework d650 Caring for household objects
d7 Interpersonal interactions and relationships	d750 Informal social relationships d760 Family relationships d770 Intimate relationships
d8 Major life areas	d850 Remunerative employment
d9 Community, social & civic life	d920 Recreation and leisure

Appendix 12

Extent which PROMS were reflected in second level ICF categories

The proportion (%) of outcomes assessed in PROMS, which were reflected in second level ICF categories are presented, ICF chapter by ICF chapter.

b1: Mental functions

Information on 10 PROMS, the DASH, SDQ-UK, ULFI, SRQ, PSS, ASES, OSS, SDQ-NL, SST and SSRS, which assessed different aspects of b1: Mental functions is summarised in Figure 1.

Of these 9, the DASH, SDQ-UK, ULFI, SRQ, PSS, ASES, OSS, SDQ-NL and SST assessed sleep functions and 2, the SDQ-UK and ULFI, assessed energy and drive functions related to appetite. Four PROMS, the DASH, SDQ-UK, ULFI and SSRS, assessed emotional functions.

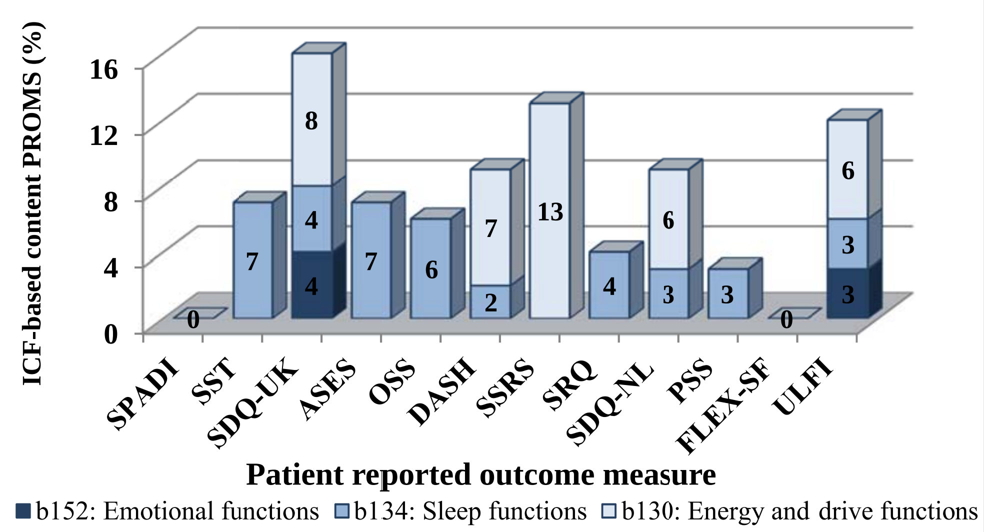

Figure 1: Proportion of PROMS which assessed different aspects of b1: Mental functions

b2: Sensory functions and pain

Information on 11 PROMS, the DASH, SDQ-UK, ULFI, SRQ, PSS, ASES, OSS, SSRS, SDQ-NL, SST and SPADI, which assessed different aspects of b2: Sensory functions and pain is summarised in Figure 2.

Ten PROMS, the SDQ-UK, ULFI, SRQ, PSS, ASES, OSS, SSRS, SDQ-NL, SST and SPADI assessed pain severity. Only the DASH assessed both pain severity and sensory disturbance i.e. pins and needles. The FLEX-SF alone did not assess this category.

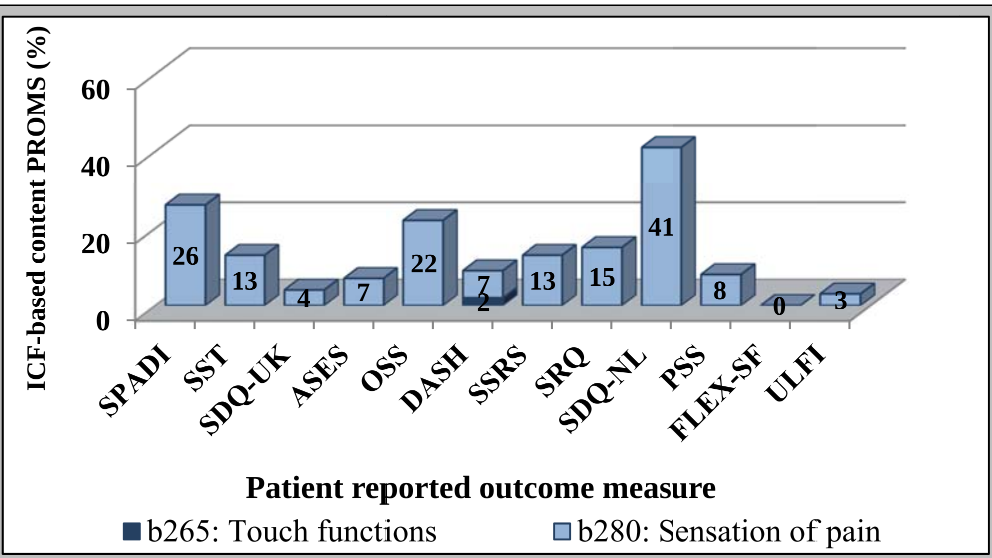

Figure 2: Proportion of PROMS which assessed different aspects of b2: Sensory functions and pain sensations

b7: NMSK and movement-related functions

Information on 7 PROMS, the DASH, SDQ-UK, ULFI, PSS, SSRS, SDQ-NL and FLEX-SF, which assessed different aspects of b7: NMSK and movement-related functions, including shoulder movement and strength is summarised in Figure 3.

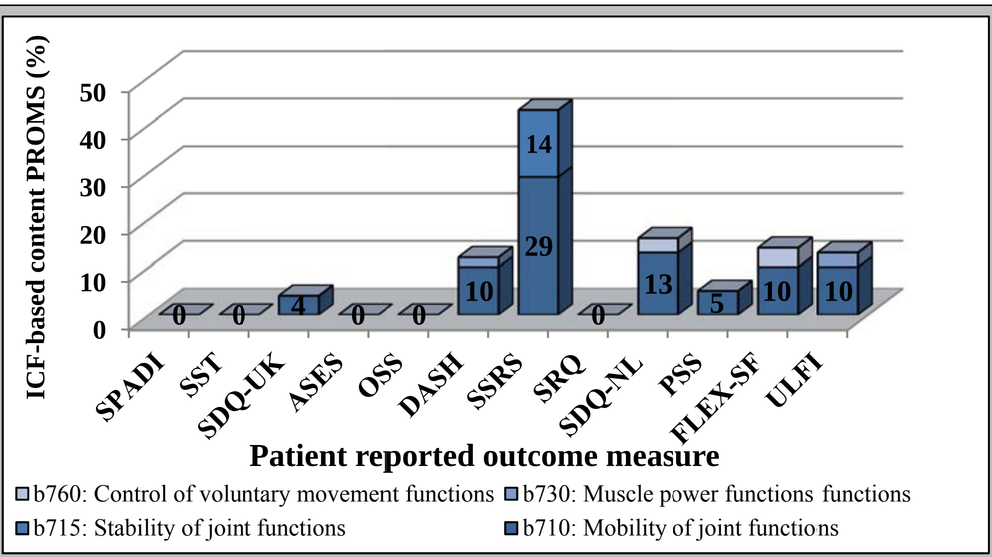

Figure 3: Proportion of PROMS which assessed different aspects of b7: NMSK and movement-related functions

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d2: General tasks and demands

Information on 4 PROMS, the DASH, SDQ-UK, OSS and SRQ, which assessed different aspects of d2: General tasks and demands is summarised in Figure 4.

The DASH, SDQ-UK and SRQ assessed different aspects of carrying out the daily routine and the SDQ-UK and OSS assessed the demands of undertaking individual tasks.

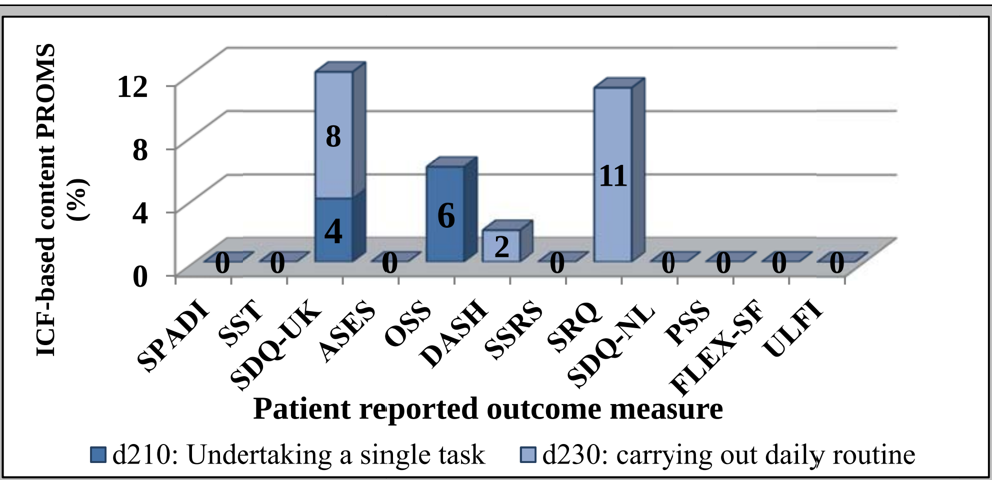

Figure 4: Proportion of PROMS which assessed different aspects of d2: General tasks and demands

d3: Communication

Information on 4 PROMS, the DASH, SDQ-UK, ULFI and SDQ-NL, which assessed different aspects of d3: Communication is summarised in Figure 5. All assessed activities involved in producing written forms of communication.

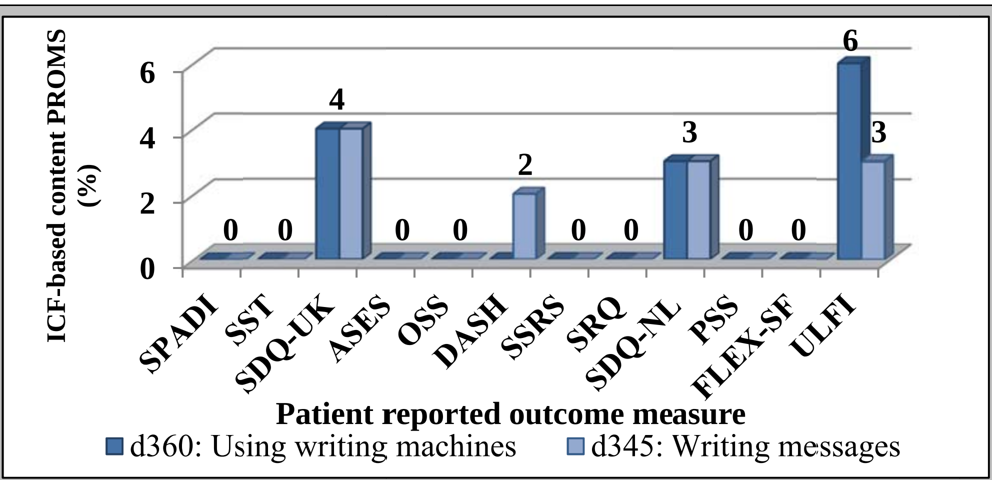

Figure 5: Proportion of PROMS which assessed different aspects of d3: Communication

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d4: Mobility

Information on 12 PROMS, the DASH, SDQ-UK, ULFI, SRQ, PSS, ASES, OSS, SSRS, SDQ-NL, SST, SPADI and the FLEX-SF, which assessed different aspects of d4: Mobility is summarised in Figure 6.

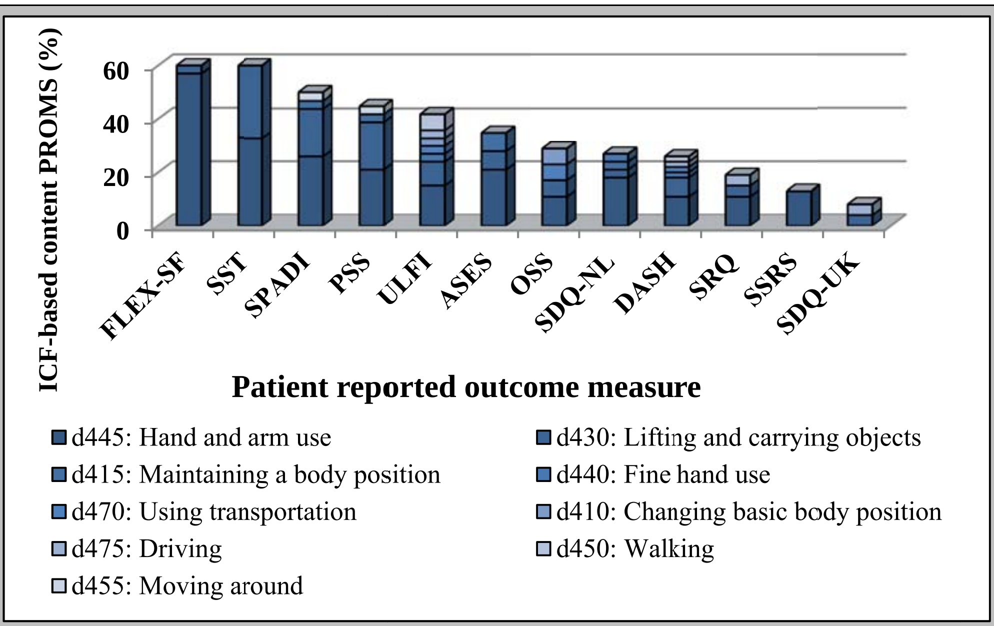

Figure 6: Proportion of PROMS which assessed different aspects of d4: Mobility

All PROMS assessed different aspects of hand and arm use, including reaching and activities involving lifting and carrying in the hands or arms. Less commonly activities involved in maintaining or changing body position, including walking, driving and using public transport were assessed.

d5: Self-care

Information on 11 PROMS, the DASH, SDQ-UK, ULFI, SRQ, PSS, ASES, OSS, SDQ-NL, SST, SPADI and FLEX-SF, which assessed different aspects of d5: self-care is summarised in Figure 7. Washing and dressing oneself, hair care, toileting and eating and drinking were the activities most commonly assessed.

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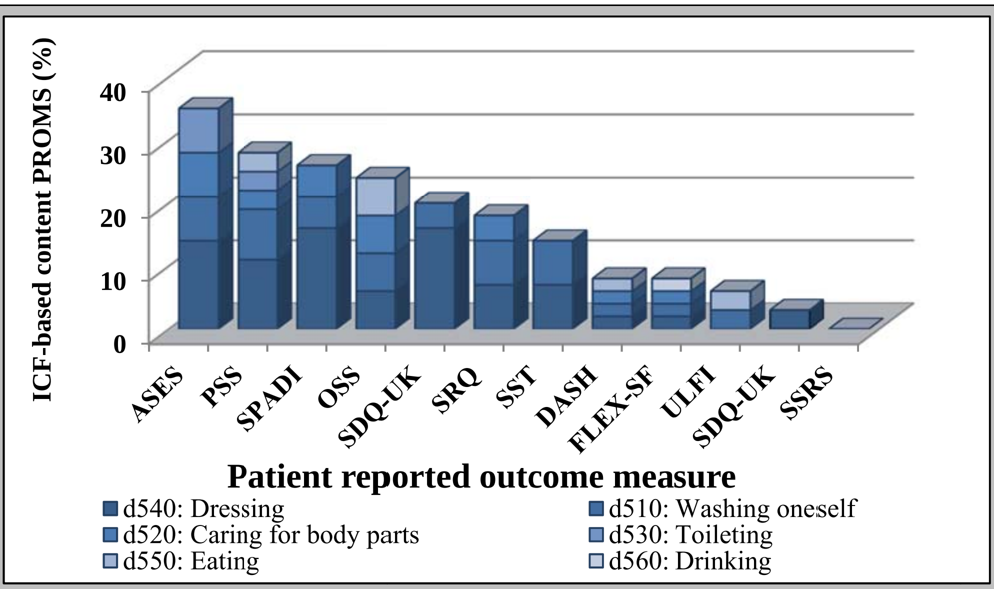

Figure 7: Proportion of PROMS which assessed different aspects of d5: Self-care

d6: Domestic life

Information on 7 PROMS, the DASH, SDQ-UK, ULFI, SRQ, PSS, OSS and FLEX-SF, which assessed different aspects of d5: Domestic life, including shopping, preparing meals, doing housework and household maintenance, including outside chores, is summarised in Figure 8.

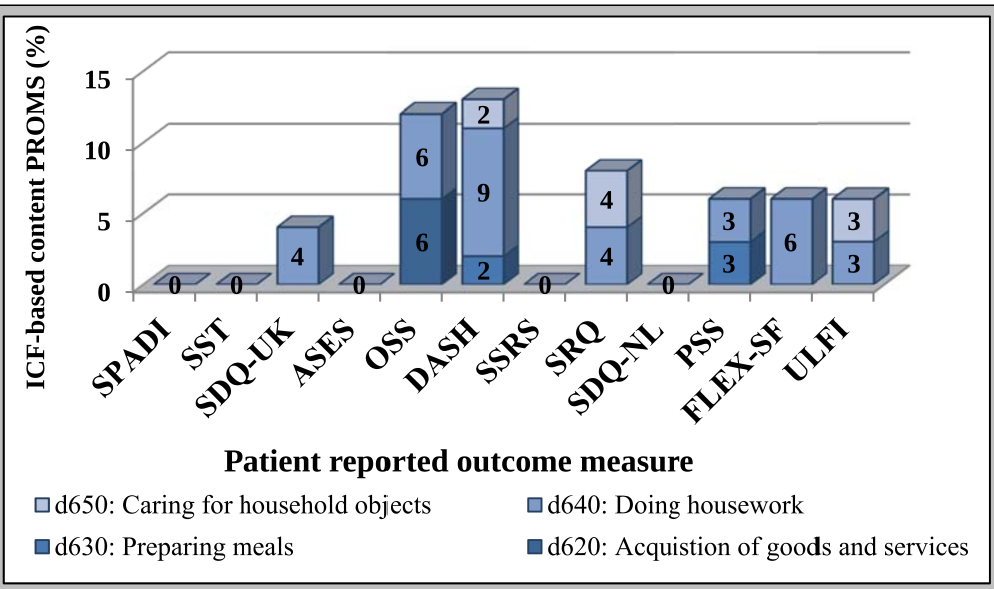

Figure 8: Proportion of PROMS which assessed different aspects of d6: Domestic life

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d7: Interpersonal interactions and relationships

Information on the only PROM, the DASH which assessed different aspects of d7: Interpersonal interactions and relationships, including social, family and intimate relationships is summarised in Figure 9.

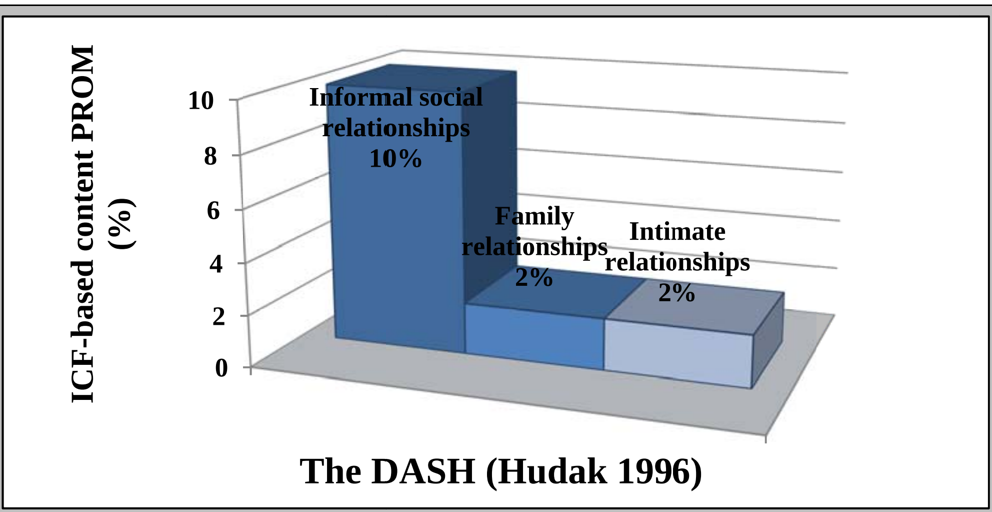

Figure 9: Proportion of PROMS which assessed different aspects of d7: Interpersonal interactions and relationships

d8: Major life areas and d9: Community, social and civic life

Information on 8 PROMS, the DASH, ULFI, SRQ, PSS, ASES, OSS, SSRS and SST which assessed one aspect of b8: Major life areas, related to participation in remunerative work is summarised in Figure 10.

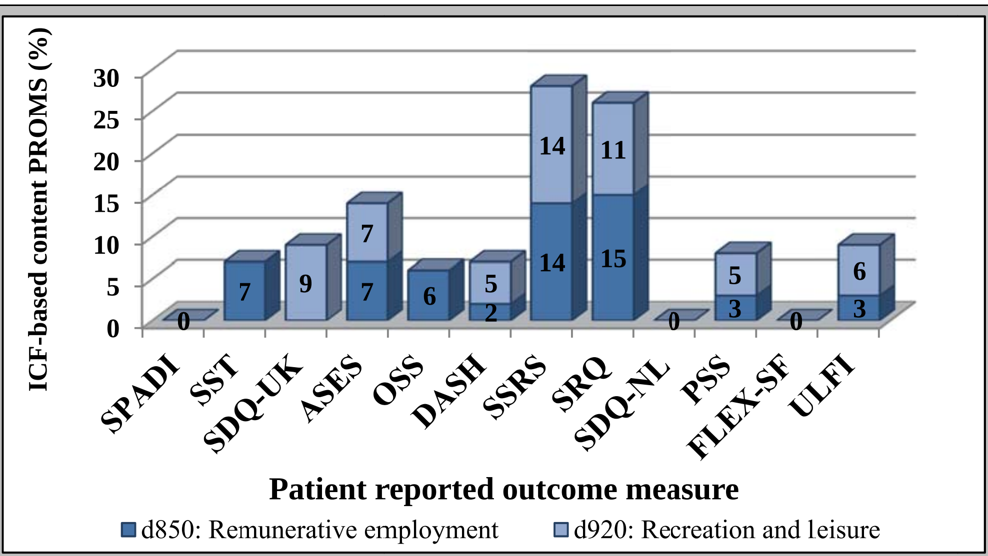

Figure 10: Proportion of PROMS which assessed different aspects of d8: Major life areas and d9: Community, social and civic life

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Information on 7 PROMS, the DASH, SDQ-UK, ULFI, SRQ, PSS, ASES and SSRS, which assessed one aspect of d9: Community, social and civic life, relating to participation in recreation and leisure activities is also summarised in Figure 10.