

**Evaluating Referral Appropriateness in Primary Care Extended
Scope Physiotherapists through the Development of Referral
Criteria for Rotator Cuff Tears**

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Conversion rates and perceived barriers to referral: Views of Extended Scope Physiotherapists in the Primary Care setting.

Abstract

Background: The ability of primary care Extended Scope Physiotherapists (ESPs) to refer appropriate patients to secondary care has not been adequately examined. Also referrals for shoulder surgery from secondary care ESPs have been shown to be misdirected in comparison to other specialties. Barriers to referral have not been investigated but the literature suggests that referral criteria may improve appropriate referrals. The high prevalence of rotator cuff disease, its impact on pain and disability, and the lack of agreement between surgeons about when to operate indicate that there is a strong case for the development of surgical referral criteria for rotator cuff tear pathology.

Method: The thesis has three stages of study. First a national survey of 99 primary care ESPs was undertaken to determine conversion to surgery rates, barriers to referral and the use of referral criteria. Secondly a national Delphi study with 20 shoulder surgeons was undertaken and surgical referral criteria for rotator cuff tear were developed. Thirdly after development, the criteria were tested on a convenience sample of 9 ESPs using 3 vignette case studies.

Results: Primary care ESPs have a mean conversion rate of 74%. There was not enough data to show differences between subspecialist groups. Most barriers to specialist referral were associated with commissioning rather than issues pertaining to the primary care environment. 50% of ESPs reported using referral criteria which may explain why barriers to referral were relatively low. Surgical referral criteria for rotator cuff tear were developed. Key areas of consensus were: severity of pain, functional limitation, identification of fat atrophy and agreement for a trial of physiotherapy before referral. When referral criteria were piloted on a surgical candidate 33% of the ESPs changed their referral behaviour appropriately.

Conclusion: ESPs in primary care have shown mean conversion rates of 74%. Surgical referral criteria to improve the appropriateness of rotator cuff tear referrals have shown promising results when piloted.

Implications: In future referral criteria may have the potential to improve the appropriateness of rotator cuff referrals and may be beneficial as a benchmark against which ESPs can independently demonstrate the appropriateness and quality of the care they provide.

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Abbreviations

ARMA:	Arthritis and Musculoskeletal Alliance
CAS:	Clinical Assessment Service
CAT:	Clinical Assessment and Treatment
CSP:	Chartered Society of Physiotherapy
CT:	Computerised axial tomography.
DH:	Department of Health
ESP:	Extended Scope Physiotherapist
GP:	General Practitioner
MRI:	Magnetic Resonance Image
MSK:	Musculoskeletal
NICE:	National Institute for Clinical Excellence
NHS:	National Health Service
SAD:	Subacromial Decompression
UK:	United Kingdom
US:	Ultrasound

Definitions

CAT Service/Interface Service: They have more recently been defined as 'any services (excluding consultant-led services) that incorporate any intermediate levels of triage, assessment and treatment between traditional Primary and Secondary Care' (DH 2010).

Conversion Rate: The conversion rate is defined by Speed and Crisp (2005) as 'the proportion of referred patients who are ultimately listed for surgery' and it is a crude measure of referral appropriateness.

ESPs: Extended Scope Physiotherapists are defined as clinical physiotherapists, working at an advanced level, after taking further training in tasks or roles which are recognised as being beyond the normal scope of practice for the physiotherapist, such as requesting X-rays, making referrals to specialists and performing some injection procedures (Ruston 2008).

Occupation Ratio: The ratio of the cross-sectional area of the supraspinatus muscle to the area of the supraspinatus fossa (occupation ratio) measured with MRI (Morag et al, 2006).

Prevalence: Prevalence being defined as 'a figure for a factor at a single point in time (Jekel et al, 2001), i.e. the percentage of patients with shoulder pain)

Quality Care: "the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (Institute of Medicine 2012).

Quality Measures: Mechanisms that enable the user to quantify the quality of a selected aspect of care by comparing it to an evidence-based criterion that specifies what is better quality (Institute of Medicine 2012).

Scapula Ratio: The scapular ratio is calculated in the sagittal oblique plane at the level of the medial coracoid process, where the supraspinatus fossa is largely encompassed by osseous boundaries. If the ratio of the cross-sectional area of the supraspinatus muscle to the area of the supraspinatus fossa

(occupation ratio) is less than 50% in the sagittal oblique plane, supraspinatus muscle atrophy is indicated (Morag et al, 2006).

Tangent Sign: One method of identifying supraspinatus muscle atrophy is the tangent sign. With use of an MR imaging plane and bone landmarks, a normal supraspinatus muscle should cross superior to a line drawn through the superior borders of the scapular spine and the superior margin of the coracoid process. This finding is not present with atrophy. When **not present** it is called a 'positive tangent sign'.

There is a significant correlation between occupation ratio / negative tangent sign, and improved strength and mobility (Morag et al, 2006).

Tear Size: Rotator cuff tears can be classified according to size. Classified on the basis of greatest dimension as either small (<1 cm), medium (1–3 cm), large (3–5 cm), or massive (>5 cm). The dimensions of rotator cuff tears may have implications for selection of treatment and surgical approach, postoperative prognosis, and tear recurrence Morag et al, (2006).

Chapter 1: Introduction

Poor orthopaedic services affect patient care. Interface services between primary and secondary care were established to improve service efficiency and deliver improved quality of care in the musculoskeletal (MSK) speciality. A small number of studies have shown that extended scope physiotherapists (ESPs) working within primary care interface services can provide improved service delivery in the form of reduced referral rates and reduced waiting lists (Maddison et al, 2004; Hattam and Smeatham 1999). However there is little evidence demonstrating that ESPs within primary care interface services can refer appropriate surgical patients to secondary care which is a key part of the ESP role and crucial to delivering high quality clinical care.

A review of ESPs working in secondary care have shown high levels of appropriate referrals in the lower limb speciality (conversion rate of 84%) (Rabey et al, 2009). However within the shoulder specialty a high level of misdirected referrals have been reported (conversion to surgery rate of 9%) (Pearse et al, 2006). Similar reviews in primary care have not been undertaken. To improve the appropriateness of referrals and thus improve the quality of MSK care there have been repeated calls to develop surgical referral criteria (Lowry et al, 1991; Speed and Crisp 2005). To date there are no detailed referral guidance criteria for patients with shoulder conditions and there is a pressing need for referral criteria in the shoulder speciality where the number of misdirected referrals is reported to be high.

The purpose of this research was therefore to investigate the level of appropriate referrals made by primary care ESPs (by specialism and by team) and to determine whether ESPs faced referral barriers which may affect their ability to refer appropriate patients to secondary care. As shoulder referrals have been shown to be misdirected, the study also aimed to develop surgical referral criteria within this specialty. Rotator cuff tears account for 50% of major shoulder injuries (Murrell and Walton 2001), and as there is little agreement within the literature or among shoulder surgeons regarding the indications for

rotator cuff surgery (Iannotti et al, 2010), the study focused on developing referral criteria in this field.

1.1 Background to the Study

This section sets out the background to the study with regard to the historical context of the NHS, the modernisation agenda and the move towards improving the quality of care in the MSK field.

The National Health Service (NHS) was created in 1948 with the aim of providing free health care at the point of access on the basis of need rather than ability to pay. The NHS in England is divided into two distinct parts, primary and secondary care. Primary care is primarily provided by independently contracted general practitioners (GPs) along with a number of other clinicians such as pharmacists, dentists, allied health professionals such as physiotherapists and community nurses. Their work usually takes place closer to the patient's home in health centres or 'cottage' hospitals. In contrast secondary care is primarily provided in one larger centralised hospital staffed by a range of specialist clinicians specifically those undertaking surgery or delivering other specialist services such as radiology.

Since its inception there has been debate with regard to whether the NHS is funded adequately (Dixon et al, 1997). Prior to 1997, funding in the NHS rose by an average of between 3%-4% each year (Dickson 2009). In the late 1990s the government identified that there had been significant funding constraints and a lack of investment in the NHS (Department of Health (DH) 1997; DH 2000). It was also noted that the NHS was in need of modernisation. In particular there were high waiting lists and significant variation in the standards and quality of care across England. Following the election of the government in 1997, and up to 2008, there was a 7% per annum increase in NHS funding (Dickson 2009). However in 2009 there was a reversal in policy and NHS funding reduced from 7% to 5.5% per year (Crump and Adil 2009). Funding is predicted to be reduced further. A reduction in funding of £21-30 billion, which is nearly 30% of the total NHS budget in England is predicted by 2016 (Crump

and Adil 2009). Despite the predicted shortfall in funding, the government has indicated that the quality of care must continue to improve (DH 2010a).

It was reported in the NHS Plan (DH 2000) that public consultation had shown that patients wanted to see reduced waiting lists and high quality care within local hospitals and surgeries. It was felt that there had been too little investment in health care professionals such that they were unable to provide the number and types of treatments necessary, an acknowledgement that the NHS lacked adequate capacity. The government at the time took the view that the NHS was over centralised, and there were few incentives to drive performance. Following the publication of *The New NHS, Modern, Dependable* (DH 1997) the first attempts to modernise the NHS focused on improving health care delivery and the quality of patient care. For example the paper outlined plans to improve information technology investment in GP surgeries, to develop fast track cancer services and to develop nurse led care (specifically the NHS Direct Helpline).

The NHS Plan (DH 2000) provided a more ambitious modernisation strategy. It was aimed at a number of key areas including disease prevention, improving patient care, improving service performance and the development of the professional workforce. Extending the scope of a range of health care professionals such as physiotherapists, nurses and pharmacists was a key part of this modernisation. The development of organisations to facilitate and oversee improvements in NHS care was also recommended. These have focused on improving the quality of care, and more recently they have influenced new models of service delivery (Dickson 2009).

Orthopaedic and MSK services were particularly noted as suffering capacity shortages and long waiting lists (DH 2006; Newey et al, 2006; Rymaszewski et al, 2005; Appleby et al, 2005; Maddison et al, 2004; Belthur et al, 2003). The Musculoskeletal Services Framework (DH 2006) was developed to improve the clinical quality of MSK care and health care delivery. Recommendations included: improving capacity with non-medical health professionals by utilising their skills and creating new roles for health care professionals, the

development of pathways of care, more focus on patient outcomes and the development of new MSK services at the interface between primary and secondary care.

The utilisation of staff to increase capacity within MSK services was possible due to the research studies that had been undertaken in the preceding years. Advanced practice roles in nursing first began to appear in the 1960s (Neville and Swift 2012). Advanced practice roles in MSK physiotherapy began in the UK in the late 1980s primarily due to long waiting lists in orthopaedics. For example Byles and Ling (1989) evaluated a pilot scheme in which a physiotherapist had worked independently and autonomously within an orthopaedic clinic, with a caseload that had originally been referred to an orthopaedic consultant. Patients were screened by the consultant before being added to the physiotherapist's list, and those selected were patients who, based on their referral letter, appeared to need conservative treatment such as physiotherapy or orthotics. Patients with a potential diagnosis of sinister pathology and those with a clear surgical need (as derived by the consultant's opinion from the referral letter) were allocated to the consultant. The physiotherapist was described as experienced and was given good clinical support. They were responsible to the consultant and had access to advice particularly when cases were considered to need emergency care. The authors concluded that the physiotherapist managed two thirds of the caseload independently (67%), with 33% of patients being referred for consultant orthopaedic review. Since this early work other pilot studies were conducted and similar findings obtained. Hourigan and Weatherley (1995) reported that physiotherapists were able to manage 70% of GP referrals to a secondary care spinal unit, and Belthur et al, (2003) reported even higher levels of independent physiotherapy care at 93% in a paediatric orthopaedic clinic.

Daker-White et al, (1999) undertook a randomised controlled trial to evaluate the effectiveness of specially trained physiotherapists in the assessment and management of defined referrals to hospital orthopaedic departments in two hospitals. Four hundred and eighty one patients with MSK problems were referred for specialist orthopaedic opinion, and then randomized into two groups

for assessment and management by either post-fellowship junior orthopaedic surgeons, or by specially trained physiotherapists working in an extended role. Patients were assessed using four outcomes: pain, functional disability, perceived handicap and patient satisfaction¹. Follow up questionnaires were completed by 383 patients (79.6%). The two groups were shown to be broadly similar at baseline with regard to demographic characteristics and primary outcome measures. The mean time to follow up was 5.6 months after randomization, with similar distributions of intervals to follow up in both arms of the trial. The only outcome for which there was a statistically significant or clinically important difference between arms was in a measure of patient satisfaction, which favoured the 'Physiotherapist' arm. The authors concluded that ESPs were as effective as post-fellowship junior staff and clinical assistant orthopaedic surgeons in the initial assessment and management of new referrals to outpatient orthopaedic departments. Cost analysis also showed that they incurred lower initial direct hospital costs. Lower costs were associated with physiotherapists ordering less radiographs and referring less patients for surgery.

Following these studies the role of the ESP began to develop. ESP roles and pilot studies were initially a feature of secondary care orthopaedic departments as this was the area where waiting lists were high. At the time of this development there were also very few primary care specialist MSK services. As the ESP role developed and became successful there was a need to define it, for both professional and legal reasons. Ruston (2008:121) defines an ESP as a clinical physiotherapist,

‘ working at an advanced level, after taking further training in tasks or roles which are recognised as being beyond the normal scope of practice for the physiotherapist, such as requesting X-rays and making referrals to specialists’.

¹ A range of validated outcome measures were used including EuroQuol; Short Form 36; Oswestry; WOMAC; VAS and HADS, but the patient satisfaction questionnaire is not discussed in detail and thus does not appear to be validated (see Appendix 1 for further explanation of outcome measures).

The formal strategy to commission services which required the utilisation of non-medical health care staff in order to create extra capacity (DH 2006) facilitated the development of ESP posts in primary as well as secondary care. The Musculoskeletal Services Framework (DH 2006) recommended the development of new services called interface services. Over the last few years interface services have been redefined and they are now defined as 'any services (excluding consultant-led services) that incorporate any intermediate levels of triage, assessment and treatment between traditional Primary and Secondary Care' (DH 2010b). Initially ESPs in primary care interface services provided a triage function only (Arthritis and Musculoskeletal Alliance (ARMA) 2009; Blackburn et al, 2009). If treatment was required it was usually provided by physiotherapists working within local physiotherapy departments or by a small team of physiotherapists within the interface service. Many primary care ESP roles now also include a treatment function as well as triage, though some are still organised so that treatment is provided by physiotherapists working within the same or a separate team, with the ESPs providing only triage. In the UK, the role of the ESP in primary care is subtly distinct from the role in secondary care. More emphasis is paid to triage and routing patients along the appropriate pathway which could be surgical or conservative. In secondary care though the role may also include components of triage this is often done in conjunction with the consultant, and in some departments referrals are first screened by the consultant team. ESPs in secondary care are also concerned with more specialist surgical planning such as arranging further investigations to differentiate optimum surgical choices and arranging procedures such as nerve root blocks which help the surgeon to plan surgery more effectively. Their role may be more akin to an orthopaedic registrar working closely alongside a consultant.

Anecdotally there has been resistance from some medical staff to the development of the ESP in primary care. GPs for example may oppose the role on the grounds that triage can delay access to care and reduce their autonomy. Consultants may oppose the role as they perceive that ESPs become 'gatekeepers' for referrals to their services. Though there is little evidence of

such opposition in the academic literature pertaining to primary care ESPs there are references to the 'gatekeeper' role associated with nurse-led telephone triage (Holmström and Dall'Alba 2002). This work adds support to the possibility that triage ESPs in primary care may be expected to perform a gatekeeper role.

Other differences relate to the environment and structure of the primary care ESP role. Anecdotally some ESPs within primary care have been reported to operate in an isolated setting and often work in a generic way similar to a GP rather than alongside a consultant like a secondary care ESP in a hospital clinic. In contrast some primary care ESPs are also reported to be very specialist and there are anecdotal reports that some primary care ESPs list for surgery or offer specific specialism in areas such a spinal orthopaedic or neurosurgical care despite having little consultant support. Despite the development of ESP roles the lack of robust research particularly in primary care brings into question the rapid growth of roles without evidence of their effectiveness, competence or safety (Kersten et al, 2007). More research to demonstrate their effectiveness and competence is thus required.

The government has continued to promote service redesign within the NHS and within MSK care. There has been more recent emphasis on improved access and reduced costs by encouraging the movement of services away from secondary care and into the community (DH 2007; DH 2008; DH 2010c; DH 2011a). Musculoskeletal services are at the forefront of such shifts. There is an acknowledgement that MSK services are suited to primary care particularly as most conditions are successfully managed conservatively (NHS Institute 2009). There has also been a recent increased focus on improving patient outcomes. It is expected that despite cost savings, the quality of care should continue to improve (DH 2010a). Again it is thus imperative to demonstrate clinical and performance outcomes.

In summary, since 1997 the modernisation agenda has brought about significant change to the NHS, including MSK services (DH 2006). There has

been service redesign, with the development of a new type of service (the interface service), and new roles for NHS staff (e.g. introduction of ESPs). There has been an emphasis on shifting MSK services from secondary to primary care and a greater focus on improving the quality of care. Recently the introduction of quality and patient outcomes has become a key part of health care delivery. These policy changes have been put in place to provide better clinical care and improvements in the delivery of MSK care (DH 2006).

1.2 Overview of the Current Problem

To improve the quality of MSK care it was recommended that local health economies should create specialist MSK “interface services”, to operate between primary and secondary care (DH 2006). The aim was to improve the quality of care by improving the appropriateness of referral, which would in turn improve the delivery of health care by freeing up capacity. Studies have shown that primary care ESPs are effective at improving health care delivery such as reducing secondary care waiting lists (Hattam and Smeatham 1999; Maddison et al, 2004). Furthermore studies have also shown that patients were highly satisfied with the care that they received from ESPs (Maddison et al, 2004; Sephton et al, 2010). However no studies were found which showed that primary care ESPs were able to select and refer patients to secondary care appropriately.

Referral appropriateness is usually measured by the surgical conversion rate which is defined as ‘the proportion of referred patients who ultimately are listed for surgery’ (Speed and Crisp 2005: 471). Anecdotally there are reports that the conversion rate may be difficult to measure due to difficulties in collecting the data and the lack of specificity used when coding data in secondary care. For example injections, biopsies and other orthopaedic treatments may be coded as surgery even if they do not fall into the realms of a standard surgical definition. Irrespective of what method is used, it is important that ESPs are able to demonstrate that they can select appropriate patients for referral, thus demonstrating their contribution to providing clinical quality. In light of the new drive to demonstrate improved quality outlined in Equity and Excellence:

Liberating the NHS (DH 2010a) and the shift of activity from secondary to primary care, it may be more important than ever that primary care ESPs are able to demonstrate their impact on the quality of care patients receive.

Low conversion rates have been reported for GPs and secondary care ESPs in some specialities (Lowry et al, 1991; Maddison et al, 2004; Pearse et al, 2006). Where conversion rates have been reported to be low, there has been little analysis of the possible reasons. Referral barriers faced by ESPs working in either primary or secondary care have not been explicitly investigated. The area where referrals appear to be most misdirected when compared to other specialties is in the shoulder specialty, though studies comparing different specialties are limited. One study has reported that the rates of conversion to surgery from secondary care ESPs to shoulder specialists are as low as 9% (Pearse et al, 2006) which questions the model of the ESP within this specialty specifically. It is possible that this area may be particularly complex or lacking in clinical expertise. Though not extensive the literature does suggest that surgical referral criteria may help to improve referral appropriateness (Lowry et al, 1991; Speed and Crisp 2005; Musila et al, 2011).

Rotator cuff pathology is the most common condition seen at the shoulder (Lin et al, 2008; Gomoll et al, 2004; Murrell and Walton 2001). It has been reported that rotator cuff tears account for almost 50% of major shoulder injuries (Murrell and Walton 2001). However referral criteria for rotator cuff tear surgery have not been published. The need for surgical referral criteria specifically to assist with appropriate referral of rotator cuff tears was shown recently (Iannotti et al, 2010). They found only 'fair' agreement between experienced shoulder surgeons when investigating the inter-rater reliability of decision-making for rotator cuff and reverse arthroplasty surgery ($k=0.31$). However the evidence underpinning which patient characteristics lead to the best surgical outcomes in rotator cuff tear pathology is of poor quality and has also been shown to be inconclusive. Ensuring appropriate surgical referral for patients with rotator cuff tear continues to be difficult and challenging.

Though the development of referral criteria is recommended, there remains doubt over whether referral criteria can be effectively implemented (Van Tulder et al, 2002; Cabana et al, 1999). Many evidence based guidelines have been shown to have little effect (Van Tulder et al, 2002; Cabana et al, 1999), which may mean that even if referral criteria are developed they do not change referral behaviour. Many factors are thought to be important with regard to practice change such as knowledge, skills, reasoning, beliefs and organisational factors (Michie et al, 2005). Optimum implementation strategies have not been identified. It remains unclear how to successfully implement referral criteria, and what the impact of such criteria might be (Grimshaw et al, 2004). It is hoped that criteria will support ESPs when making referral decisions in the shoulder specialty, ultimately leading to improved patient care. However there is a need to demonstrate the impact of referral criteria on ESP referral behaviour to determine whether introduction of referral criteria on a wider scale is beneficial.

1.3 The Problem Statement

Five key problems have been identified which underpin the whole study, these are:

1. The ability of primary care ESPs to refer appropriate patients to secondary care has not been demonstrated, particularly in the field of shoulder pathology.
2. It is possible that ESPs in primary care face referral barriers which may lead to lower conversion rates than their secondary care counterparts, such as isolation or lack of clinical support.
3. The surgical conversion rates in the shoulder speciality for ESPs working in secondary care are very low, (though it is acknowledged that there are few studies that have investigated conversion rates generally in all specialities). The low conversion rates in the upper limb speciality suggest referrals are the least appropriate and health care delivery may be poor.

4. There are no published surgical referral criteria for shoulder conditions. There is low agreement on the optimum management for rotator cuff pathology which is one of the most common shoulder conditions leading to pain and disability.
5. Even if surgical referral criteria can be developed, it is not clear whether they can be implemented or if they would change practice.

Research Questions

1. Do MSK ESPs in working primary care record their ability to refer appropriate patients to secondary care (as measured by the conversion rate)?
2. Do MSK ESPs in working primary care experience barriers to referral?
3. Can surgical referral criteria for degenerative rotator cuff tears be developed?
4. Can these criteria improve the appropriateness of ESP referrals?

Study Aims

Based on these five key problems, four study aims have been developed which are:

1. To determine whether MSK ESPs working in primary care record their ability to refer appropriate patients to secondary care (as measured by the conversion rate).
2. To determine whether MSK ESPs working in primary care experience specific barriers to onward referral which may ultimately affect their ability to refer appropriately.
3. To develop referral criteria to enable primary care ESPs to refer the most appropriate patients for rotator cuff repair surgery.
4. To determine whether referral criteria change ESP referral behaviour when assessing patients with rotator cuff tear.

1.4 The Professional Significance of the Study

Referring appropriate patients along the optimum care pathway is a key component of the ESP role and it represents high quality clinical care and efficient health care delivery. The level of appropriate referrals made by ESPs within orthopaedic secondary care units to orthopaedic consultants has been documented, however the level of appropriate referrals to orthopaedic consultants from ESPs within primary care interface services is unknown. ESPs, particularly in primary care, are poised to provide many services previously supplied in secondary care (DH 2007; DH 2008). Therefore it is important to examine whether or not they are able to make appropriate referrals which may impact on the delivery of high quality clinical care.

One of the common methods of identifying referral appropriateness is through the surgical conversion rate, though it is acknowledged that this is a complex measure (Griffiths 2012). The conversion rate is influenced not only by whether the referral is clinically appropriate but also by a range of factors that influence patient and surgeon decision-making, as well as political and organisational factors. For example patients may choose to decline surgery due to a lack of understanding of the benefits of surgery, even if the patient's condition was considered to be amenable to surgery and clinically appropriate. All of these factors are central to optimising referral appropriateness and impact on the surgical conversion rate reported.

Identifying their current conversion rates will help ESPs to benchmark their ability to refer appropriate patients to specialist services. This will include clinical appropriateness as well as the other factors which influence whether patients decide to opt for surgery or are offered surgery. Identifying the existence of referral barriers may ultimately lead to a reduction in barriers to appropriate referral and thus could deliver improved quality of care in existing services or new services in development.

The finding that secondary care ESP conversion rates in the upper limb are the lowest of all those recorded is of key professional significance for those who claim specialism in this area. Shoulder pathology, particularly rotator cuff tear,

has been reported to lead to significant pain and disability particularly for the elderly (Lin et al, 2008). Shoulder problems are a significant health burden, and rotator cuff tears account for almost 50% of major shoulder injuries (Murrell and Walton 2001). Despite this there is poor agreement between surgeons regarding which patients are most suitable for rotator cuff tear surgery (Iannotti et al, 2010). The research which supports differentiation of the best surgical outcomes is of poor quality, and is made up primarily of uncontrolled case series.

It was anticipated that by addressing the research questions identified above this study would have an impact on patient care, improve quality within the NHS and provide clinical support for ESPs.

1.5 An Overview of the Methodology

The first stage was to investigate whether MSK ESPs based in primary care recorded their ability to refer appropriate patients to secondary care and whether they experienced barriers to referral. A national questionnaire survey of ESPs working in primary care and specialising in orthopaedics was undertaken. Though the area of particular interest was the upper limb, the survey was not limited to this group because the level of specialism in this field in primary care is not yet established. The ESP Professional network (a special interest group of the Chartered Society of Physiotherapy) does not hold data regarding this level of specialism and the numbers of primary care ESPs in this field was not known before the study was undertaken. Therefore a sample of 99 primary care ESPs was recruited through the ESP professional network and information regarding their specialism was requested to enable further sub-specialism analysis. A mixture of open and closed questions was used which focused on conversion rates, referral barriers and the use of referral criteria within practice. Multiple mailing was used to give the opportunity for as many ESPs as possible to respond. See Chapter 4 for detailed methodology.

In the second stage a Delphi study was undertaken to develop surgical referral criteria for degenerative rotator cuff tears. A sample of 20 specialist shoulder surgeons was recruited through the publicly available British Orthopaedic

Association website. Primarily closed questions were used with a 5-point Likert scale. Opportunities for comments were available at the end of every section and after strategic questions concerning thresholds for surgery. Two rounds of the consensus questionnaire were undertaken and multiple mailing was used for each round (Robson 2011).

Finally the criteria were piloted to determine whether the referral criteria influenced referral behaviour. A convenience sample of 9 primary care ESPs, all banded at grade 8A⁴ was recruited from two services. ESPs from one service worked in a triage role and the others provided specialist assessment and treatment. Three extensive clinical vignettes based on real patients were used. ESPs were given the same vignettes twice with a period of six months separating each session. At each session they were asked to identify their referral choice from a set of response options, or they were allowed to choose an independent option. At the second session they were given the referral criteria and asked to make their referral choice once they had evaluated the information.

1.6 Thesis Outline

Chapter one has provided the background to the problem, highlighted the professional significance of the study and provided a brief overview of the methodology.

In Chapters 2 and 3 the literature specific to the main research aims is reviewed in detail. The following electronic databases were searched for relevant literature (date range 1960-June 2013): Research Databases including Medline, AMED, CINAHL, and The Cochrane Database of Systematic Reviews. Internet searches were conducted using the following websites: The Department of Health www.dh.gov.uk, The NHS Library www.library.nhs.uk, The Stationery Office www.tso.co.uk, British Official Publications Current

⁴ ESPs at band 8A are specialists in their field. They are required to have advanced interpersonal skills, extended diagnostic and clinical skills. The role usually encompasses audit and or teaching. Usually they are expected to hold a post-graduate qualification in MSK care (such as a Diploma in Manual Therapy, specialist ESP training or an MSc).

Awareness Service www.bopcas.com, The Office of National Statistics www.statistics.gov.uk. For details of the search strategy, key words and phrases used see Appendix 2.

Chapter 2 provides an overview of the difficulties associated with the delivery of MSK health care, and MSK redesign. Referral appropriateness within the context of MSK interface services is critically discussed and an outline of the key components is presented. Measurement of referral appropriateness is identified as a key outcome measure for the triage components of interface services and the methods to measure referral appropriateness are discussed.

Chapter 3 focuses on the appropriateness of referrals in the shoulder specialty and the possible reasons for high numbers of misdirected referrals. Rotator cuff pathology is identified as a common condition seen within the shoulder specialty and the lack of agreement surrounding the management of rotator cuff tear pathology is highlighted. Lack of surgical referral criteria for repair of rotator cuff tears is discussed and justification for the development of referral criteria in this field is presented. The evidence which underpins criteria for rotator cuff tear surgery is reviewed and the weaknesses are identified. Finally an outline of the evidence that pertains to implementing evidence-based guidelines and criteria is reviewed. The chapter ends with a summary linking the evidence to the study aims.

In Chapter 4 the methodology of the thesis is reported in detail. The methodology for each stage of the study is described separately in three sub-sections. Each sub-section begins with the justification for the methodology and is then followed by the protocol for each stage. Data analysis for each stage is reported at the end of each sub-section.

Chapter 5 reports the results of the research in detail. The first section contains the findings from the referral appropriateness questionnaire. The second part of the section reports the findings of the Delphi study and the third section contains the results of the pilot study to test the referral criteria.

In Chapter 6 the key findings are discussed in detail. The methodological limitations of the study are highlighted as well as the strengths and weaknesses of the referral criteria. Finally the thesis ends with the study conclusions and the recommendations for future study. This chapter also discusses the impact of the study on practice, clinical quality, policy and the applicability to the NHS.

Chapter 2: Referral Appropriateness

This chapter provides an overview of the difficulties associated with the delivery of MSK health care and unnecessary or misdirected referrals.

Recommendations in the Musculoskeletal Services Framework (DH 2006) to improve the delivery and quality of care by improving appropriate specialist referral are reviewed. However detailed evidence of successful implementation appears to be lacking. Appropriate referral within the context of MSK interface services is defined and the options for and importance of measurement are discussed. The literature pertaining to the appropriateness of ESP referrals is also reviewed and comparisons between subspecialist groups (upper limb, lower limb and spinal) are made. Justification of further investigation into this area, particularly with regard to referral appropriateness, is presented.

2.1 Overview of Musculoskeletal Services

Musculoskeletal disorders are common among the general population in the UK and across the world (McBeth and Jones 2007). In England, MSK conditions are a major cause of ill-health, pain and disability. It is estimated that nearly one-quarter of adults and around 12,000 children are affected by longstanding MSK problems, such as arthritis, that limit daily activities (DH 2006).

Musculoskeletal conditions contribute significantly to the workload of UK GPs and it is thought that up to 30% of all GP consultations are concerned with MSK complaints (European Bone and Joint Health Strategies Project 2005).

Musculoskeletal conditions are also reported to be the most common reason for repeat consultations with a General Practitioner (DH 2006).

Historically, within the English National Health Service (NHS), there was a continued period of under investment which led to a sustained increase in funding from 1997 onwards. Orthopaedic and MSK services specifically were noted as suffering capacity shortages and long waiting lists (DH 2006; Newey et al, 2006; Rymaszewski et al, 2005; Appleby et al, 2005; Maddison et al, 2004; Belthur et al, 2003). Some areas of England had reported excessive waiting times such as three years for an orthopaedic appointment (Lloyd et al, 2003) and five years for orthopaedic surgery (Donaldson et al, 1984). These times

should be seen in the context of the government's own target in 1997 of 13 weeks waiting time for both out-patient and in-patient procedures (DH 1997). The government's 2012-2013 target for NHS waiting times is now 18 weeks for consultant led services (DH 2012), though no justification for the arbitrary figure has been found. According to Department of Health referral to treatment waiting times statistics for England the waiting times in 2010 for all consultant led services were met, unfortunately no target was stated in the report (DH 2011b). The report illustrates that 92.2% of admitted patients and 97.6% of non-admitted patients were reported as receiving their treatment within a maximum of 18 weeks (DH 2011b). More recent data, or data specific to orthopaedic waiting times specifically is not available.

Along with the lack of investment and reduced appointment capacity, analysis of orthopaedic services showed that NHS patients with MSK problems have relied very heavily on referral to hospital for most conditions (West and McKibbin 1982; Ross et al, 1983; Lowry et al, 1991; Speed and Crisp 2005; The Kings Fund 2011). This practice has continued despite studies which identified that many patients with MSK problems do not need to be treated in orthopaedic surgical departments (West and McKibbin 1982; Ross et al, 1983; Schoch and Adair 2012). It has been shown that MSK patients can receive faster and more appropriate care in a community setting (Lowry et al, 1991; Maddison et al, 2004) or by seeing a physiotherapist (Ross et al, 1983; Byles and Ling 1989; Hockin and Bannister 1994; Hourigan and Weatherley 1995; Belthur et al, 2003).

West and McKibbin (1982) retrospectively investigated the orthopaedic outpatient caseload in South Glamorgan with a survey of all patients on the orthopaedic waiting list in March 1978. Patients were asked to report information about their present condition, previous treatments, whether they had improved with time and whether they still required orthopaedic attention. A large number of patients responded to the survey (1702 patients). After in-depth analysis of the responses they found that only one third of all patients referred needed consultant attention. West and McKibbin (1982) concluded that 46% of orthopaedic outpatients assessed by the consultant were regarded

as having chronic conditions that were not appropriate for surgery and unamenable to treatment⁵. Ross et al, (1983) found similar results when they assessed the orthopaedic waiting list referrals in North Staffordshire. Their prospective study analysed the outcomes of patients referred by their GP once they had seen the orthopaedic consultant. They found that 43% were managed conservatively with physiotherapy or surgical appliance equipment. Both studies found a high non-attendance rate for orthopaedic consultations. West and McKibbin (1982) concluded that taken with the other non-responder information, it is possible that up to 40% of patients referred to orthopaedics (in 1978) were for 'trivial conditions' (defined by West and McKibbin (1982) as those which had recovered). These trivial conditions had resolved without the need of orthopaedic intervention, questioning the appropriateness of the referral. Despite the wealth of evidence demonstrating over reliance on orthopaedic surgical departments a recent review has found that there are still many patients referred directly to secondary care without a trial of conservative management (Schoch and Adair 2012). There are also a high number of misdirected referrals (Belthur et al, 2003; Rymaszewski et al, 2005) leading to delays and poor quality care.

2.2 Review of Studies of Referral Appropriateness

The practice of referring patients to hospital, when they could be managed by referral to a conservative care pathway such as physiotherapy, has led to investigations of referral appropriateness by some surgical departments (Lowry et al, 1991; Speed and Crisp 2005). The surgical conversion rate has been identified as a marker of referral appropriateness. It was defined as 'the proportion of referred patients who ultimately are listed for surgery' (Speed and Crisp 2005:471). It has been suggested that low conversion rates demonstrate inappropriate, unnecessary or misdirected referrals, and result in poor clinical care and wasted resources (DH 2006). The construct of an appropriate referral in the MSK context will be discussed in-depth in section 2.6 page 51. These

⁵ It is not clear whether these patients would have been suitable for physiotherapy or chronic pain services.

terms relate to referrals which do not result in surgery or other treatment interventions offered by surgeons. The term misdirected is often used within the literature and may be used to suggest that referral to another professional or service such as pain clinic or physiotherapy rather than orthopaedics would have been more appropriate. For example the NICE CG88 Low Back Pain Guidelines (2009) and NICE Low back Pain Early Management Pathway (2013) indicate that a patient with non-specific low back pain should be referred to physiotherapy (or similar discipline) in the first instance to try a course of conservative treatment rather than to a spinal surgeon. Referral of such a patient to a surgical department rather than physiotherapy could be considered to be misdirected. Unnecessary may be used in similar situations or may be used when patients are re-referred for a surgical opinion even when a previous surgical opinion has been given. West and McKibbin (1982) have shown evidence of this type of unnecessary referral in their study on waiting times in orthopaedics. In this scenario, as shown in the study by West and McKibbin (1982), patients referred are often unamenable to surgery but are re-referred (perhaps because the condition is chronic and there is a lack of confidence or skill to manage these patients conservatively). The term inappropriate may also be used to describe these patients or may be used as a generic term to describe either scenario. The issue of whether a referral is appropriate is complex and relates to the referrer, to the service and to the professional to which the patient is referred (see section 2.6 page 51).

Lowry et al, (1991) investigated the number of appropriate GP referrals to an outpatient department and used the low conversion rate to indicate that a number of referrals were misdirected. During a waiting list initiative they analysed 165 patients referred by their GP to an orthopaedic department; no specialty was identified and thus it must be assumed that the sample is a group of mixed orthopaedic patients (i.e. lower limb, spinal and upper limb patients). Random sampling was not used; patients were included if they wished to change to another consultant which was a feature of the waiting list initiative. Patients who opted in were seen in a survey clinic by an orthopaedic surgeon and then allocated to one of 3 groups: waiting list for surgery, follow up or

discharge. The results showed that after their 'triage' survey appointment 35% were listed for surgery, 34% were discharged immediately and 31% were seen in a follow up clinic for advice, identifying a conversion rate of 35%.

There is some inevitable bias within this study. For example patients with more severe conditions may be more likely to switch groups to expedite their appointment because they are in more pain. Anxious patients may also be more likely to switch to the new group so that they can be seen sooner which is also likely to affect the sample balance. Despite the risk of sample bias, it could be argued that this bias would lead to a group with a higher rather than lower conversion rate. The self selecting sample may be more likely to take up surgery than a random sample, skewing the final conversion rates to a higher level than would ordinarily be the case.

Oldmeadow et al, (2007) undertook a prospective observational study in Australia and showed that orthopaedic conversion rates for non urgent, MSK GP referrals to an orthopaedic department in a teaching hospital were very low. A sample of 52 patients was recruited which was reduced to 38 patients following drop outs (the causes of drop outs were not explained but may represent patients who failed to attend). Patients were seen separately first by a physiotherapist and then by an orthopaedic surgeon so that the level of clinical agreement between consultant and therapist diagnoses could also be evaluated. Though the conversion rate was not explicitly presented, analysis of the results allows the conversion rate to be calculated independently. Using the definition identified by Speed and Crisp (2005), and that followed by Pearse et al, (2006), the conversion rate following GP referral was 18% (7 out of 38 patients were listed for surgery). Thus the majority of these non-urgent MSK GP referrals (82%) were considered unsuitable for surgical management and many could be considered to be inappropriate for referral to a secondary care hospital. It is important to acknowledge that some of these patients may have been referred for specific non-surgical or medical advice. However after considering the diagnostic agreement between therapist and surgeon, Oldmeadow et al, (2007) concluded that these patients could have been appropriately assessed and managed by experienced physiotherapists. These

findings are consistent with those found earlier in the UK (West and McKibbin 1982).

Anecdotally some services have also reported very low conversion rates of under, or around 20%, (Personal correspondence Birmingham East and North Primary Care Trust (PCT) 2005; Hammersmith and Fulham PCT 2010; Imperial NHS Trust 2011). There is also a case study by the University Hospitals of North Staffordshire, cited in the Musculoskeletal Service Framework (DH 2006:32) which reported a conversion rate of 18%, similar to that reported by Oldmeadow et al, (2007). This case study is only available in the Musculoskeletal Services Framework (DH 2006:32) and cannot be found in the academic literature. However it is not cited in the reference list of the Musculoskeletal Services Framework (DH 2006).

The range of conversion rate figures for GP referrals to orthopaedics reported in the available literature are summarised in Table 2.1. The methods of conversion rate analysis vary across the published studies. Rather than present this information some have provided raw data so that calculation can be undertaken (Lowry et al, 1991; Oldmeadow et al, 2007). However, Maddison et al, (2004), and the case study attributed to the University Hospitals of North Staffordshire (cited in DH 2006:32) did not provide raw data for independent confirmation.

Table 2.1: Summary of GP Orthopaedic Conversion Rates

Author	Conversion Rate
Lowry et al, 1991	35%
Maddison et al, 2004	37%
Oldmeadow et al, 2007	18%
University Hospitals of North Staffordshire (cited in the Musculoskeletal Services Framework DH 2006)	18%

The Musculoskeletal Services Framework (DH 2006) highlights that non-surgical referrals take up appointments which could be used for those needing surgical opinion and focuses clearly on the importance of appropriate referrals. Based on this guidance, the low surgical conversion rates reported from the GP studies summarised in Table 2.1 (range 18% to 37%) indicate that there could be a high level of 'unnecessary' or 'misdirected' GP referrals. These low surgical conversion rates indicate that a number of patients referred to orthopaedics may not require surgery which does not represent efficient health care delivery or clinical quality. This data also correlates with the earlier studies showing that many referrals to orthopaedics are misdirected and could have been managed by physiotherapists.

Although there has been a number of studies which have investigated referral appropriateness (Lowry et al, 1991; Speed and Crisp 2005) there are no studies which have explicitly investigated the main reasons for referral to orthopaedic surgical departments. One study undertaken by Raymont et al, (2008) investigated why New Zealand GPs referred patients to surgical services in general, with orthopaedic services being identified as one of the surgical services under investigation. Raymont et al, (2008) found that in more than half of the cases investigated advice on cancer control, and condition diagnosis or management, rather than surgery, were relatively frequent goals of referral. These findings suggest that GPs may refer to orthopaedics for a range of non-surgical functions and this may explain why some referrals are misdirected and why conversion rates may be low in some clinical groups such as GPs. The findings also suggest that there is a need for non-surgical and well as surgical specialists so that specialist advice about the diagnosis and management of non-surgical conditions can be given. In the MSK field the interface service may well be able to provide this level of specialist non-surgical care (PCR Society 2011).

Overall the studies investigating the appropriateness of GP referrals to orthopaedic surgical units are limited in number and methodological detail is often lacking. However they provide an indication that there are a high number

of patients referred to surgical departments who do not take up surgery, and this does represent inefficiency within the MSK pathway.

2.3 Musculoskeletal Service Redesign

High waiting lists, high non-attendance rate, reduced capacity, over reliance on hospital care and poor conversion rates contributed to the view that MSK services were of poor quality and needed to change (DH 2006; Kings Fund 2011). One aspect of the Musculoskeletal Services Framework (DH 2006) was dedicated to improving the quality and delivery of MSK care through service redesign. It recommended improvement in four key areas:

1. Increasing health care capacity with non-medical health professionals (utilising their skills and creating new roles)
2. Developing MSK pathways of care
3. More focus on patient outcomes and
4. The development of new services at the interface between primary and secondary care, providing specialist MSK care.

The recommendation to develop interface services was supported by two case studies as well as a large service redesign project conducted by Maddison et al, (2004). The case studies were undertaken by Somerset Coast Primary Care Trust and University Hospitals of North Staffordshire but neither has been published in the literature apart from the description contained within the Musculoskeletal Services Framework (DH 2006:32)⁹. Both case studies demonstrated improvements in health care delivery such as reductions in the waiting lists for orthopaedics and reduced onward referral rate.

⁹ Neither the University Hospitals of North Staffordshire case study nor the Somerset Coast PCT case study have been found independently in the literature. These cases have only been found in the Musculoskeletal Services Framework (DH 2006) and were not available on any of the research databases searched.

Maddison et al, (2004) observed a range of service performance targets before and after an extensive service redesign programme, which included the development of a new interface service staffed by ESPs and 'GPs with Special Interest' in MSK conditions. They demonstrated improvements in health care delivery with reduction in duplicate referrals, and a reduction in the waiting time for secondary care appointments. They also showed improved patient satisfaction. However there was no financial costing, cost effectiveness or capacity analysis included so it is not clear whether extra investment or extra staff could account for operational service improvements rather than service redesign alone. Although the authors were able to conclude that there had been improvements in health care delivery there was no evidence of improved clinical quality. Maddison et al, (2004) used the surgical conversion rate as an outcome measure and showed that it remained unchanged at 37% after the service redesign. There was no mention of care pathways or criteria used to improve referral appropriateness as recommended by the Musculoskeletal Services Framework (DH 2006). One of the key aims of the Musculoskeletal Services Framework (DH 2006) was to improve the quality of patient care by redesigning services to ensure that patients were seen by the most appropriate clinician as quickly as possible. Using the descriptors in the framework suggests that this service could be seen to have failed in its target to deliver 'better' orthopaedic services, by directing patients to the most appropriate clinician.

The case study by University Hospitals of North Staffordshire presented in the Musculoskeletal Services Framework (DH 2006:32) did report a change in conversion rate from 18% to 60% with the introduction of a primary care ESP interface service, however this case has not been published in the academic literature and thus further analysis is not possible. The case study by Somerset Coast Primary Care Trust (DH 2006:32) reported a final conversion rate of 75-80% but this was not measured before the pilot started so it is difficult to judge the impact of the change.

Though data regarding improvements in some aspects of health care delivery in interface services was presented from the studies in the Musculoskeletal Services Framework (DH 2006) there was limited data with regard to demonstrating improvements in clinical quality or referral appropriateness. Only one case study showed improvements in the surgical conversion rate. Though the Musculoskeletal Services Framework (DH 2006) identified that improving clinical quality was a key objective, there was little mention of how to ensure quality control within interface services.

Despite the lack of literature supporting the clinical effectiveness of interface services, they appear to have grown significantly. The Musculoskeletal Services Framework (DH 2006) indicated that interface services could be located in primary or secondary care, however it is now recommended that they should be located within the community to improve access and free up capacity in secondary care (NHS Institute 2009). The Musculoskeletal Services Framework (DH 2006) indicated that MSK interface services should have the appropriate level of expertise to enable them to deliver 'better' orthopaedic services. It is recommended that they are staffed by a range of clinicians to fulfil the service outcomes. However it is also acknowledged that ESPs have now become significant members of the interface team and provide the primary assessment (NHS Institute 2009).

For ESPs within all primary care interface services there are two key inter-dependent aims which are to select or triage appropriate patients for referral to specialist secondary care services whilst also selecting appropriate patients who do not need surgery and referring those for conservative treatment (DH 2006). The triage of MSK conditions and appropriate specialist referral is underpinned by accurate assessment, appropriate investigation and interpretation of the clinical findings (NHS Institute 2009; Ruston 2008). As well as knowledge of MSK pathology and high level assessment skills, ESPs and other professionals within interface services need adequate knowledge of conservative and surgical management in order to triage efficiently (Syme et al, 2012). Clinicians also need to be able to apply this knowledge in practice to the

patient within the consultation so that they can offer appropriate treatment options and refer appropriately.

The third key aim relates to interface services which also provide specialist treatment. As well as triage these services aim to provide high quality MSK care to those patients who are being managed conservatively. This third aim relates to those interface services which are identified as clinical assessment and treatment services (CATS or CAT services). They operate a 'see and treat' model providing a triage and treatment function (NHS Institute 2009; DH 2006)¹⁰.

Some primary care interface services operate solely as triage services (ARMA 2009; Blackburn et al, 2009) and thus appropriate selection of patients for referral to specialist services (such as surgery) is the primary objective of these services. These services are based on the model of a Clinical Assessment Service (CAS) (Davies and Elwyn 2006). For such services there is difficulty in determining and publishing markers of quality such as patient reported outcome measures as they provide no specific treatment only triage and referral. Thus for these services, the measurement of referral appropriateness is one of the few outcome measures which demonstrates whether they are providing efficient health care delivery, quality for patients and value for money.

Individual studies have described their interface service and the role of their ESPs. The number of interface services in primary care is not currently known but they appear to have grown significantly despite the lack of literature supporting the clinical effectiveness (Kersten et al, 2007). The number of ESPs in the primary care environment also appears to have grown significantly in the past decade as expected in line with service growth. Following a review of MSK services ARMA (2009) found that 79% of Primary Care Trusts (PCTs) had implemented some type of interface service. Further support of the growth of ESPs within primary care can also be found from professional body membership. In 2011 the Chartered Society of Physiotherapy (CSP) ESP

¹⁰ The number of services providing 'see and treat' or primarily triage care is not known.

Professional Network recorded that approximately half of their membership worked in primary care, (403 ESP members, 200 of which identified that they worked in primary care) (Personal correspondence ESP Professional Network Administrator; January 2011). Weston-Simons et al, (2012) also surveyed UK ESPs through the professional network and identified that 39% worked in secondary care, 38% worked in primary care and 23% worked in both settings. Though the number of interface services in primary care cannot be identified the membership statistics and the results from Weston-Simons et al, (2012) imply that primary care ESPs are now a significant proportion of the ESP work force.

Following the publication of the Musculoskeletal Services Framework (DH 2006) the Arthritis and Musculoskeletal Alliance (ARMA) conducted a review of MSK services across England to determine whether the recommendations of the Musculoskeletal Services Framework (DH 2006) had been implemented (ARMA 2009). Despite many Primary Care Trusts (PCTs) reporting that they had some type of interface service ARMA (2009) concluded that the implementation of improved MSK services across England had been poor. They found that 21% of PCTs had still not introduced MSK interface services which they acknowledged were considered to be the 'keystone of the government's policy' (ARMA 2009:4). They concluded that patients were still experiencing delays in obtaining accurate diagnosis of long-term MSK conditions and experiencing delays in access to orthopaedic surgery.

Further evidence of poor quality care has also been shown by a Public Accounts Committee investigation into services for the MSK disorder rheumatoid arthritis (Public Accounts Committee 2010). The committee identified that people with this condition are not being diagnosed or treated quickly enough and reported that MSK services are still uncoordinated. The findings suggest that delays in access to good quality care continue to exist and data to demonstrate quality and efficiency is vital.

2.4 Assessment of Referral Appropriateness in MSK Interface Services

Despite the growing number of primary care interface services only three studies were found which have described and evaluated them, particularly with regard to the quality of care offered and the appropriateness of referrals. Hattam and Smeatham (1999) were the first to evaluate a Primary Care Orthopaedic Screening Service and found that 72.4% of patients referred to an orthopaedic consultant (via an interface service) could be managed successfully in primary care without seeing a consultant. The study was relatively small with analysis of 84 patients in total, (though the size of the study is consistent with the other early work in secondary care around this time). Patient screening was undertaken by two specialist physiotherapists. It is not known whether patients were satisfied with this service. The rate of re-presentation to the GP was low which assumes that patients were effectively managed (only 5.3% of patients returned to their GP after discharge with the same complaint, within the year of the study).

The suitability of secondary care referrals was not evaluated, and neither the conversion rate nor the level of clinical agreement was presented. Though the study is able to identify that the majority of patients were effectively managed in primary care, the ability of ESPs or specialist physiotherapists to make appropriate referral judgements in primary care was not evaluated and thus clinical robustness has not been evaluated.

Sephton et al, (2010) also undertook a prospective evaluation of primary care MSK services more recently with a larger study. Two hundred and seventeen patients were recruited into the study to determine the clinical effectiveness of a 'triage and treatment' MSK service. They found that patients were highly satisfied with the MSK care that they received (72% indicated total satisfaction with all aspects of care), and they showed that patients had a better quality of life score at 3 and 6 months (using EuroQuol and Short Form 36¹¹). This study

¹¹ EuroQuol and Short Form (SF) 36 are both 'Quality of Life' Outcome Measures

also found that low numbers of patients were referred to secondary care (11%) which supports the earlier findings of Hattam and Smeatham (1999) that large numbers of patients can be managed in primary care (i.e. 89% of patients were managed in primary care). Unfortunately, there was no analysis of those patients referred to secondary care and thus again the suitability of secondary care referrals and the diagnostic decisions made by primary care ESPs is unknown.

The third study by Maddison et al, (2004) has already been reviewed (section 2.3 page 39). This is the only study to have reported conversion rates for an interface service based, in part, within the community. The authors reported that there was a GP conversion rate of 37% (Table 2.1). After re-design into a multidisciplinary interface service with ESPs and GPs with a special interest (GPSIs), the conversion rate was reported to be unchanged. However there is no information describing how the conversion rate was calculated and raw data were not presented for further scrutiny. If the conversion rate was calculated by secondary care it is possible that it does not solely reflect the patients referred by the new community interface service. For example the results indicate that GP referrals routed through the newly designed MSK service resulted in a reduction of referrals to orthopaedics and reduced waiting lists. It is possible that other GPs from out of the area, began to refer to the Hospital to benefit from the reduced waiting times and increased capacity. These GPs may not have had interface services and thus it may have meant that when the Hospital calculated the overall conversion rate it was still unchanged. To determine the exact conversion rate for the newly designed service, the patients referred by that service, would have to have been analysed separately (i.e. in isolation to all the other referrals received by that hospital) and there is no evidence that this occurred. The lack of methodological detail regarding how the conversion rate was calculated means that it is not possible to be sure that the service changes introduced by Maddison et al, (2004) did not have an impact on the conversion rate. Thus a judgement regarding referral appropriateness of the ESPs within this primary care service cannot be made. Furthermore despite repeated searches, no other conversion rate data for ESP led primary care interface

services could be found. Therefore due to the lack of methodological detail in the Maddison et al, (2004) study and the lack of conversion rate studies pertaining to ESPs in primary care interface services, conclusions about the quality and appropriateness of referrals from primary care ESPs within interface services cannot be drawn.

2.5 Referral Appropriateness of Secondary Care ESPs

Though repeated searches did not reveal further evaluations of interface services, two studies have been found which investigated referral appropriateness and the conversion rates of ESPs working in a secondary care orthopaedic department (Pearse et al, 2006; Rabey et al, 2009). Both included the review of patient records or orthopaedic consultant letters.

The study by Pearse et al, (2006) was a prospective audit (n=150) of the numbers of GP referrals screened first by ESPs before being referred on to an orthopaedic surgeon. The study analysed referrals into sub-specialties including back, knee, shoulder and 'other' specialties. In this study GP referrals were deemed suitable for ESP assessment in line with the criteria outlined by Durrell (1996), which includes patients referred with non complex, benign¹² MSK conditions where immediate surgery is not indicated. Any patients triaged and seen by an ESP independently were analysed separately, and thus the conversion rates of those cases triaged by ESPs to see a consultant are a reflection of ESP rather than GP conversion rates as they had been screened by ESPs.

It is important to acknowledge that the inclusion criteria outlined by Durrell (1996) are open to considerable variation in interpretation. When referrals are assessed for their suitability for ESP clinics, they may well be much more complex than they appear on paper, particularly if the GP has not included

¹² In this context benign is used to denote a condition of MSK origin that is of no danger to health, not recurrent or progressive and not malignant. It would exclude patients referred with cauda equina syndrome, progressive radiculopathy (cervical or lumbar), patients with confirmed or suspected spinal infection and patients with confirmed or suspected malignancy.

significant parts of the patient history. This may mean that there are a number of unsuitable patients within the ESP clinic who should have been directly seen by the consultant. If these complex patients were therefore seen within the ESP clinic it could result in a lower ESP conversion rate. Some of these patients may require medical rather than surgical management and thus would not convert to surgery.

Analysis of the results from the study undertaken by Pearse et al, (2006) showed that the conversion rates for the knee speciality were 64%. This represented seventeen patients with knee pathology who were referred to the consultant, of these, eleven were listed for surgery. In the lumbar spine speciality seven patients were referred to the consultant and two were listed for surgery which is a conversion rate of 28%. The shoulder conversion rate was the lowest at 9%, with twenty two patients being referred and only two being listed for surgery.

Further analysis of the data shows that many shoulder patients underwent an injection which falls within the remit of many physiotherapists' skills, perhaps demonstrating that this conversion rate could have been higher if injection pathways had been in existence. Analysis of the cohort with spinal pathology shows that few patients were referred to the consultant, and only two patients received surgery. Though the conversion rate is low, the association between spinal pain and sinister pathology may mean that a percentage of these patients were referred for medical rather than surgical reasons. However the fact that all patients were supposed to have been screened prior to involvement in the study, in line with the guidelines from Durrell (1996) to exclude serious pathology suggests that this should not be the case. (In this context, sinister pathologies also called "red flags", are conditions which may be life threatening such as malignancy or aortic aneurism. They often mimic the symptoms of MSK back pain and must be medically managed without delay).

It is unfortunate that there was no gold standard conversion rate set before the audit was conducted. The moderate to high level conversion rate for knee pathologies in comparison to the low level conversion rate for shoulder

pathologies is an interesting finding and suggests that the shoulder pain pathway is the most inefficient or perhaps complex. The results from this study suggest that patients within the shoulder speciality may have the lowest quality care with respect to inappropriate referral and care delay. For example inappropriate referral of the type outlined by Pearse et al, (2006) could result in unnecessary appointments in secondary care which has resource implications for both the providers and the commissioners of care. There are also resource implications for patients who may have undertaken and incurred costs for unnecessary travel and some will have taken time from work for an appointment which may result in little benefit.

Referral to surgical services rather than for early specialist conservative treatment such as rehabilitation or injection may also lead to delays in access to care which result in increased pain, suffering and distress, loss of limb function and worsening patient outcomes for some patients. For example patients suffering from rotator cuff arthropathy, who are not suitable for surgery because the size of the tear is non-repairable, need access to early rehabilitation. Inappropriate referral to surgical services for these patients would create a time delay before starting conservative treatment. As the target waiting list for consultant led services has been set at 18 weeks (DH 2012) it is conceivable that these patients could wait 18 weeks to see a consultant before they are informed that there is no surgical option and they should have been sent for physiotherapy in the first instance. Reduced access to early conservative intervention for this group could cause significant difficulties with self-care, increased suffering and loss of independence. This is particularly important as rotator cuff tear pathology commonly affects the elderly (Lin et al, 2008) and thus reduced access to early care in this group may affect independence and ability to self care more significantly. Reduced access to early conservative therapy could also lead to poor clinical outcomes and difficulties regaining upper limb function.

An audit primarily conducted to identify the level of diagnostic agreement between orthopaedic consultants and physiotherapists in the shoulder specialty has also recorded the number of patients referred to consultants who eventually

received surgery (Oakes 2009). In this study there was high diagnostic agreement between consultant and therapist (90%) but it is not possible to calculate the conversion rate with the remaining information. In this audit 26 patients were referred by the ESPs to the shoulder consultant, and the article indicates that 13 of these were for a surgical review. Eleven patients (42%) were referred to the consultant for other reasons such as investigation, injection or second opinion which reinforces the view of Pearse et al, (2006) that the numbers of patients managed by ESPs, are not as high as predicted by Hockin and Bannister (1994), where estimates of the number of patients who could be managed independently by ESPs were recorded to be 85%. In the Oakes (2009) study the number of patients referred to a surgeon who are not referred for a surgical opinion is an interesting finding, particularly when diagnostic agreement was shown to be high. The finding raises a question regarding why patients are referred. Both Oakes (2009) and Pearse et al, (2006) highlighted that in the shoulder specialty some patients were referred for injection even though this is within the scope of physiotherapy practice. The provision of, or expertise required for, injection therapy appears to be limited in the shoulder specialty resulting in referral. This contrasts with the lower limb and spinal specialties, where injection does not appear to feature significantly as a reason for non-surgical patients being referred by ESPs to orthopaedic surgeons.

The other important consideration which has relevance for all ESPs is the issue of referring patients to surgeons for a second opinion even though no surgery is considered necessary. This recurring theme has been noted in GP referrals by West and McKibbin (1982), and Ross et al, (1983), and was further explored by Raymont et al, (2008) (see section 2.1 and 2.2 pages 32-34). The theme of patients being referred to secondary care by GPs or to surgeons by ESPs for a second opinion, even though no surgery is indicated, appears to highlight the need for more specialist input in the MSK field (DH 2006). Oakes (2009) noted that to improve the standard of ESP care continued development of clinical reasoning skills and knowledge of the indications for surgery would be beneficial.

With the increasing demands for improved health care delivery, clinical quality and the increased focus on the developing role of the ESP there will be increasing pressure to meet the highest possible efficiency targets. Therefore if ESP conversion rates in the upper limb specialty are much lower than those in the lower limb field it is important to identify this and address areas where efficiency or clinical care can be improved.

Rabey et al, (2009) carried out a prospective audit investigating the ESP conversion rate in lumbar spine and knee conditions as well as the number of investigations requested and the number of referrals made by ESPs to orthopaedics. For the conversion rate analysis 163 post-appointment patient letters were reviewed to determine if the patient had been listed for surgery. The process for selection of patient letters was not detailed in the article, however, 163 letters represents just under 10% of the total sample (n=1670 patients), which correlates with the number of referrals from ESP to the consultant (documented as 10%). It is assumed that there were no excluded patients and that the outcomes of all patients referred by ESPs were analysed. The results showed a conversion rate of 84% for ESP referrals to a knee specialist, however, the conversion rate analysis for the spinal referrals is less clear. Review of the spinal letters suggested that 89% were appropriate. Of these, 57% went on to have surgery and 32% were medically managed for conditions such as tuberculosis or ankylosing spondylitis. Further analysis to gain a true idea of the conversion rate as defined by Speed and Crisp (2005) by excluding these 'red flag' patients was not possible as not all the data was presented.

This evidence demonstrates that there is a variable range of conversion rate statistics from the ESP studies identified. The range varies from 9% for shoulder conditions (Pearse et al, 2006) to 84% for knee conditions (Rabey et al, 2009). The findings show variation across sub-specialties attached to secondary care units which may be a reflection of the complexity of the speciality or be connected with the clinical abilities of the individual ESPs. Alternatively the variation could be related to specific training issues at these sites or variation in consultant and patient decision-making.

2.6 Referral Appropriateness in the Context of MSK Interface Services

It is clear from the Musculoskeletal Services Framework (DH 2006) that referring patients to the appropriate service or clinician is a key objective for interface services. However the definition of an 'appropriate referral' will vary depending on the context and the specific factors which influence this context. There are also evidence based referral pathways in some specialities which help to shape whether a referral is considered appropriate such as the NICE Low Back Pain Early Management Pathway (2013).

For interface clinicians working within CAS or CAT services appropriate onward referral options may include secondary care surgical specialities and conservative treatment options such as physiotherapy, injection therapy and self-management (Bernstein 2011). Though the number of patients referred from interface services to secondary care orthopaedic services is only reported to be around 10% (Bernstein 2011; Sephton et al, 2010; Hattam and Smeatham 1999) it is important that these patients are referred appropriately (Kings Fund 2010; ARMA 2009; DH 2006).

Though there are care pathways where referral guidance exists there are many clinical areas where there is little information to guide referrers. Further complexity arises by virtue of the fact that referral appropriateness is multifaceted and dependent on political factors, staffing, available services, resources and clinical appropriateness. Figure 2.1 has been used to explain the notion of referral appropriateness within the context of MSK interface services.

Figure 2.1: Model of Referral Appropriateness



The interplay between clinically appropriate surgical referrals, the political climate, the influence of limited financial resources, the availability of commissioned services and the increasing demand for optimum health care delivery must be considered. In simple terms clinically appropriate referrals are those in which surgery is indicated. Although indications for surgery are broad and depend on the condition, there are general themes which emerge from the literature pertaining to orthopaedic and MSK surgery. These include the severity of the disease (Musila et al, 2011; Curtis et al, 2011), loss of function (Naylor and Williams 1996; Curtis et al, 2011), and specific disease or pathology factors (Quintana et al, 2000; Iannotti et al, 2010). Disease or pathological factors are condition-specific and within orthopaedic surgery examples may include the level of joint destruction, the occurrence of ligament or tendon rupture, fracture or bony mal-alignment. There are also specific technical factors that are thought to be pre-requisite for appropriate referral. For example for referral for hip arthroplasty to be considered as appropriate

Quintana et al, (2000)¹³ found that a specific level of bone quality¹⁴ was a key criterion.

As well as the clinical indication for a specific surgical procedure, appropriate orthopaedic surgery referrals are also seen within the context of whether a patient is fit for surgery (Mythen 2011). Fitness for surgery is based on age, existing co-morbidities and a range of factors such as smoking and obesity (Banz et al, 2011). Recent advances in MSK and orthopaedic surgery have shown improved patient outcomes in those cases where there has been a clear protocol for assessing fitness for surgery (NHS Institute for Innovation and Improvement 2008- Enhanced Recover Programme; Wainwright and Middleton 2010; Mythen 2011). There have been calls to accelerate the assessment of surgical fitness to a position within the care pathway before patients are even referred for a surgical consultation (Mythen 2011), to improve patient outcomes and to ensure that health care delivery is optimised. Thus a rationale to ensure patients are fit for surgery before they are referred is developing and contributes to the definition of referral appropriateness within the current political and financial health care context.

The influence of health care resource and political factors alongside clinical appropriateness can be seen clearly with a recent example from NHS North West London (2012). NHS North West London¹⁵ have published guidance to inform GPs and local surgical health care providers that they will no longer fund arthroscopic washout of knee joints for the management of osteoarthritis, or to aid diagnosis. Historically surgery to aid the symptomatic management of osteoarthritis was relatively common but now funding is no longer available there are anecdotal reports that referrals for and the incidence of such surgery have fallen significantly in North West London. These commissioning decisions are underpinned by clinical evidence such as NICE CG59 Osteoarthritis (2008)

¹³ Consensus on appropriateness was determined through a guideline development group.

¹⁴ Bone quality in this case was measured on X-ray using a classification outlined by Singh et al, (1970)

¹⁵ The commissioning group for North West London includes the boroughs of Brent, Ealing, Harrow, Hammersmith and Fulham, Hillingdon, Hounslow, Kensington and Chelsea, and Westminster.

and NICE IPG230 Interventional Procedure Guidance (2007). However the determination of what is considered to be appropriate has been shaped by those commissioning services rather than clinical factors alone.

As indicated in the Musculoskeletal Services Framework (DH 2006), within the context of MSK interface services, optimisation of the use of health care resources is becoming an increasing part of the consideration of an appropriate referral. A study undertaken to determine referral criteria for knee surgery showed that optimisation of health care resource was important to many of the clinicians involved in the study (Musila et al, 2011). Musila et al, (2011) conducted a consensus study to develop GP surgical referral guidelines for patients with osteoarthritis of the knee, as they highlighted that selection of appropriate patients for knee surgery in primary care was very difficult. The study used a guideline development group of 12 members which included patients, GPs, orthopaedic surgeons and other health care professionals. As well as obtaining consensus with regard to clinical factors they also found that the group gave priority to 'avoiding inefficient resource use in patients with mild symptoms' (Musila et al, 2011:68). This finding demonstrates the increasing importance of the optimum use of resources for patients and referring clinicians as well as those setting strategic policy.

The political climate is an equally important influence contributing to whether or not a referral is considered to be appropriate. In many ways the introduction of the 'interface service' (NHS Institute 2009; DH 2006) and the policies indicating that care should be shifted from secondary care out into the community (DH 2007; DH 2008; DH 2010c; DH 2011a) have set clearer guidance for the consideration of what is to be deemed as an appropriate referral within MSK care. There is growing support for outreach and 'office based' orthopaedic and MSK services in primary rather than secondary care services (Primary care Rheumatology Society (PCR) 2011). This changing function of hospital departments is likely to further influence the type and number of GP referrals.

Within this context, referral to secondary care would primarily be for surgical services rather than for advice on further management for example.

The availability and organisation of services also influences whether a referral is considered appropriate, particularly within the context of health care delivery and optimising the use of resources. For example referrals for basic services that are available in primary and secondary care, where there is no reduction in the quality of service received by the patient, should be delivered in primary care to avoid wasted resources (DH 2006) and to free up capacity in secondary care (NHS Institute 2009). An example of such a procedure could include a shoulder joint injection which would be considered more appropriate to be delivered in primary care due to reduced cost¹⁶. If however there are services that are currently only available in secondary care due to the level of specialism required to undertake the procedure and the need for radiological imaging such as cervical epidurals, then it would be considered appropriate to refer the patient to secondary care and inappropriate to refer to primary care where such services are unavailable.

This section has outlined the context of an appropriate or inappropriate referral within the current clinical, political and financial framework in the MSK interface specialty. In defining the context of 'appropriate' and 'inappropriate', alternative labels for this construct were considered such as the terms 'necessary' and 'unnecessary' referrals or 'directed' and 'misdirected' referrals. Due to the large body of existing literature that refers to the term 'appropriate referral', this labelling system has been retained. Where this term is used in the rest of the thesis it is used within the context discussed above. An appropriate referral in the context of an ESP within an interface service or a GP working in primary care is thus used to indicate a referral which is:

1. Clinically appropriate for the surgery for which the patient has been referred

¹⁶ For example national reference costs for shoulder injection in secondary care for 2012-2013 are £1680 for HRG code HB63Z and £2070 for HRG code HA63Z. In primary care (Hammersmith and Fulham CATS) shoulder injection costs are £189.

2. Is made with knowledge that the patient is fit for surgery
3. Optimises the use of resources and MSK pathways within the current NHS policy frameworks (e.g. does not refer for surgery no longer funded and does not refer for services in secondary care such as shoulder injection when the same service is available in primary care at a reduced cost).

The definition of an appropriate referral is based on evidence from Leung et al, (2012) and Cook et al,(2007) (see page 63-65) which provide empirical evidence that surgeons make decisions about which patients are appropriate for surgery based primarily on whether they are clinically appropriate. Secondly evidence from Wainwright and Middleton (2010) and Mythen (2011) has highlighted improved outcomes in patients who are fit for surgery and thus this parameter has gained importance in defining appropriateness. Thirdly local guidance from commissioners in North West London and empirical consensus studies (Musila et al, 2011) have also shown that patients do not want to see resources wasted on patients being referred for expensive treatments where inexpensive alternatives exist.

Inappropriate referrals are those which do not fall within the framework described above. There is less agreement within the literature regarding the term used for referrals that are not necessarily appropriate. The term 'misdirected' (Speed and Crisp 2005; 469) or the phrase 'variation in clinical practice' (Lowry et al, 1991; 354) have been used to describe this construct within the orthopaedic specialty. Where possible these phrases will be used to explain those referrals which do not fall into the framework described above.

2.7 Measuring Outcomes within Interface Services

One of the main recommendations of the Musculoskeletal Services Framework (DH 2006) focused on service redesign which would improve the quality and efficiency of MSK care. Redesign aimed to improve referral appropriateness which would in turn improve the delivery of health care by freeing up capacity.

Though there is no consensus on a definition of efficiency within clinical care (Academy Health 2006) it is generally seen to be divided into three main areas: health care delivery, clinical quality and patient satisfaction (Potash 2011; Laine et al, 2005). Examples of health care delivery may be the number of appointments, or the length of the waiting list. Examples of clinical quality could include improved health outcomes such as improved pain scores, adherence to best practice care pathways or appropriate referral to secondary care as measured by the conversion rate or against pre-determined standards. Health care delivery and clinical quality are often linked to patient satisfaction, and all of these markers are important with regard to delivering high quality, efficient care.

The term 'quality care' (Institute of Medicine, IOM 2012: no page: online) appears to be used more commonly than efficiency, though it reflects the same components of health care delivery and clinical quality. Quality care has been defined as, the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge (IOM 2012: no page: online).

There has been an increased focus on increasing the quality of health care over the last few years (Juran and Godfrey 1999; Batelden and Davidoff 2007; NHS Institute 2012). Many strategies have focused on increasing health care delivery such as the productive community series (NHS Institute 2012). Examples of strategies to improve clinical quality are more difficult to find and are lacking in the field of MSK interface services (Griffiths 2012) other than service redesign (DH 2006).

Methods to demonstrate quality such that it can be monitored are important (Crump and Adil 2009; IOM 2012). However for clinical quality and health care delivery to be measured and monitored they need to be clearly defined and linked to the purpose of the service under investigation. The most significant recommendation of the Musculoskeletal Services Framework (DH 2006) was to improve the quality of MSK services through the development of a new type of

service called the 'interface service'. The key objective for the interface service was to ensure patients were referred onward to the appropriate clinician (an aspect of clinical quality). In turn this would reduce referrals to secondary care and ensure shorter waits and fewer delays for orthopaedic patients specifically (an aspect of health care delivery).

Referral appropriateness as measured by the conversion rate is a measure of health care delivery and clinical quality. In simple terms it is a measure of health care delivery as it measures the percentage of patients referred by a health care professional and listed for surgery. However the referral of an appropriate patient is underpinned by measures of quality such as the reasoning and assessment skills of the ESP, their knowledge of the surgical and medical field, knowledge of surgical thresholds and application of this knowledge and skill to each individual patient. Without a skilled high quality assessment, knowledge of the appropriate surgical speciality, excellent communication skills to determine the beliefs and goals of the patient, and high level reasoning skills it is likely that the number of patients converting to surgery will not be particularly high. Thus the two components of health care delivery and clinical quality are interlinked with a very strong emphasis on reasoning, knowledge and communication. It is a direct measure of health care delivery underpinned by clinical quality.

Following a review of MSK services between 2008 and 2009, ARMA noted that 60% of PCTs had not audited outcomes for MSK patients (ARMA 2009). Of the 40% of PCTs that had audited MSK outcomes there was wide variation of data being collected. Though there is no published MSK quality outcomes framework (ARMA 2009) recommendations have been published to advise clinical commissioning groups¹⁷ (CCGs) on how to commission MSK services and guidance regarding a range of outcome measures to be used has been issued (PCR Society 2011). These include a range of health care delivery outcomes such as MSK waiting times and the number of orthopaedic referrals made. They also include measures of quality such as the appropriateness of

¹⁷ CCGs have replaced Primary Care Trusts (PCTs).

orthopaedic referrals by measures such as the conversion rate or the percentage of appropriate imaging referrals (PCR Society 2011; NHS Institute 2009). Other quality measures may include patient reported outcome measures for those interface services providing a triage and treatment function as well as other metrics such as quality of life, patient satisfaction or incident reporting. The measurement of outcomes within a specific interface services needs to reflect the aims of the service (Griffiths 2012). The range of outcome measures which may be used will now be discussed in detail in the following section.

2.7.1 Measures of Referral Appropriateness in MSK

For triage-type interface services specifically, outcome measures pertaining to referral appropriateness could be used which determine the number of appropriate patients referred for surgery (NHS Institute 2009; PCR Society 2011). It is also possible that appropriateness could be measured by reviewing referrals against a pre-determined standard (PCR Society 2011; Griffiths 2012), or by determining adherence to clinical pathways (Griffiths 2012). The surgical conversion rate may also be used as a measure of referral appropriateness (NHS Institute 2009; PCR Society 2011) so long as it is acknowledged that it measures a range of factors, some of which are out of the control of the referrer, and that it is likely to change with the changing political and financial climate. For triage-type services the 'physiotherapy conversion rate'¹⁸ may also be a useful measure to demonstrate appropriate physiotherapy referrals. This is particularly useful for interface services with multidisciplinary professionals who may not be aware of the key criteria which underpin appropriate physiotherapy referral. However, it is important to acknowledge that the physiotherapy conversion rate is subject to the same influences as the surgical conversion rate (such as variations in the decisions made by patients and clinicians, and the influence of political or financial factors). These influences

¹⁸ Anecdotally this measure has recently been trialled in Hammersmith and Fulham MSK service and is a measure of the number of referrals from the triage service which were judged as clinically appropriate for the physiotherapy service.

have also been identified by Clemence and Seamark (2003) in a qualitative study of the appropriateness of GP referrals to physiotherapy.

One alternative measure of the appropriateness of onward referrals within triage-type services has been demonstrated by Blackburn et al, (2009). In their study of a physiotherapy-led triage service, referral appropriateness was investigated through a GP opinion survey of appropriateness of care (Blackburn et al, 2009). Surveys of consultant opinion could also be used, though like the conversion rate, GP and consultant opinion of appropriateness is also affected by political and financial factors.

Analysis of the number of appropriate investigations requested by primary care ESPs¹⁹ (NHS Institute 2009) could also be used to demonstrate the quality of care provided by those working within interface services. Studies investigating the appropriateness of imaging referrals have not been found relating to interface services or secondary care ESPs²⁰. One area which has been explored is the area of diagnostic agreement (see section 2.8 page 68). The diagnostic accuracy of ESPs in secondary care and the level of agreement between ESPs and orthopaedic consultants (or radiological markers such as MRI) have been undertaken and provide evidence of clinical quality and appropriateness of care. However studies of diagnostic agreement undertaken in primary care have not been identified within the literature.

2.7.2 The Surgical Conversion Rate

Although the conversion rate has been used as a simple measure of referral appropriateness it is a complex outcome with 'limitations in that it may be dependent on or influenced by a range of economic, political, and personal factors such as commissioning barriers, waiting lists, and the personal preferences of clinical staff' (Griffiths 2012:85). It is also influenced by whether the referral is clinically appropriate, whether the patient is fit for surgery, as well

¹⁹ Appropriateness could be judged by comparing referral requests to the Royal College of Radiologists Guidelines (2007)

²⁰ Investigation of referral rates for radiological tests have been completed (Rabey et al, 2009), however studies of the appropriateness of radiological investigation have not been found.

as a range of complex factors which influence the decision-making of the surgeon undertaking the surgery and the decision-making and choices of the patient. Figure 2.2 illustrates these influences.

Figure 2.2: Factors Influencing the Surgical Conversion Rate



It is important to acknowledge that all of the factors outlined in Figure 2.2 may influence whether surgery takes place, and may thus influence the conversion rate. The conversion rate must therefore be acknowledged as measuring whether the referral is clinically appropriate within the current political and financial context, as well as measuring aspects of surgeon and patient decision-making. Clinically appropriate referrals and those made with the knowledge that the patient is fit for surgery have already been discussed (section 2.6, page 51). However even if clinically appropriate referrals are made, there is a range of factors which influence the decisions made by the patient and the surgeon which means that the referral may not convert to surgery even if it is clinically appropriate. These factors are explored below.

As well as the reliance of whether patients are referred appropriately with regard to clinical indications and fitness for surgery, the surgical conversion rate also depends on whether the patient takes up surgery once offered. There are a number of patients who decide not to take up surgery once they see the consultant even when there are clear clinical indications (Ghandi et al, 2013). There are only a few studies which have investigated this topic (Ghandi et al, 2013). For some patients the condition may have resolved by the time they see the consultant (Ross et al, 1983), for others they may have developed other co-morbidities which render them unfit for surgery. The patient's perception of the risks, clinical indication, clinical outcomes and trust in the surgeon also appear to be important (Ashman 2012; Ghandi et al, 2013). A recent study has found that optimizing a patient's willingness to undergo surgery, even when it was clinically indicated, entailed a process of patient education and shared decision-making between the patient and the surgeon (Ghandi et al, 2013). This shows the importance of such factors on the ultimate outcome of referral, even in the presence of an appropriate clinical referral.

Ghandi et al, (2013) undertook a questionnaire study of 1946 consecutive patients referred to an orthopaedic clinic (traumatic conditions were excluded). The questionnaire was completed prior to the surgical consultation to provide an understanding of patient perceptions before the influence of the surgical consultation. All responses were self-reported. Patients were asked about their willingness to undergo surgery and their perception of the risk of the surgery and its likely outcome. The results showed that 20.1% were unwilling or unsure about whether to proceed with surgery if it was offered to them. Those who reported that they were unwilling or unsure more often reported perceiving surgery as unsuccessful and risky for their condition. Of the 1946 patients involved in the study 23% had back or neck pain, 39% had hip or knee pain, 20% had shoulder or elbow pain and 18% had foot and ankle pain. Initially the back and neck pain group showed a higher percentage of patients who were unwilling to undertake surgery if it was offered. However after adjustment for risk perception the results were attenuated and differences between the condition specific groups became statistically non-significant.

Although the study shows that whether patients take up surgery, and ultimately convert to surgery, is partly dependent on patient decision-making and their perceptions of indication, risk and success, it is important to acknowledge that ESP competency documentation indicates that ESPs would be expected to have explored these issues with the patients they refer for surgery to improve adherence and compliance (Syme et al, 2013). The conversion rate could never be expected to be 100% as there will always be patients who decide not to undertake surgery even if there are clear clinical indications and they have been referred with an understanding of the risk and likely outcomes. However with scarce resources and a demand for efficient health care delivery, ESPs are expected to have attempted to determine whether patients would undergo surgery if it were offered to them prior to referral which may explain why some clinicians are currently able to report high conversion rates (Rabey et al, 2009). It is accepted however that despite this preparation, not all patients will proceed with surgery even when these issues have been discussed by ESPs with advanced communication and reframing skills, and those ESPs competent to list for surgery (NHS Institute 2009). The audit conducted by Oakes (2009) has an example of this scenario. In this small study 26 cases seen by an ESP in an orthopaedic shoulder clinic in secondary care were reviewed retrospectively to compare diagnostic agreement between ESP and consultant. Analysis shows that of the 26 patients referred by the ESP to the consultant 2 declined surgery as they 'had changed their mind about treatment' (Oakes 2009:129). Though this is a factor that may influence the conversion rate anecdotal reports are consistent with data reported by Oakes (2009) that these patients are a relatively small proportion of those referred.

By the same consideration even if referrals to surgery by GPs or ESPs were clinically appropriate and patients wanted to proceed, it is important to acknowledge that there is a range of reasons which may also influence the surgeon's decision to operate. Surgical decision-making has not been widely explored within orthopaedics however a number of studies have investigated these influences in other surgical disciplines (Leung et al, 2012; Cook et al, 2007) which can be applied to orthopaedics. Leung et al, (2012) investigated

39 academic surgeons' perceptions of surgical decision-making in a range of specialities including orthopaedics and neurosurgery using semi-structured interviews. They identified a useful model which shows that there are 3 key influences on surgical decision-making which they classified as 'avowed' (e.g. in the patient's best interest) (Leung et al, 2012:1368), 'unavowed' (e.g. teaching pressures), (Leung et al, 2012: 1368) and 'disavowed' (e.g. reputation or other factors considered to be in the surgeon's best interest) (Leung et al, 2012:1368). Their study suggested that clinical appropriateness is a key influence on whether surgeons decide to operate on a specific patient. However they suggested that other factors are also important such as teaching pressures or time pressures from surgeon family members, as well as factors rarely admitted such as reputation and fear of loss of operating time. Some of these factors may influence the surgeon's decision to choose whether to operate more such as fear of loss of operating time, whereas other factors such as reputation may have an effect either way. By their nature disavowed or unavowed factors are particularly difficult to investigate explicitly through empirical research or even less formally through mentoring, clinical observation or personal discussion.

In a qualitative semi-structured interview study of 6 plastic surgeons Cook et al, (2007) also found some similarities with the research undertaken by Leung et al, (2012). For example, they found that surgeons considered a range of factors when deciding whether to operate which included inherently clinical judgments such as the risks versus the benefits and the likelihood of a satisfactory outcome. In their study they also questioned surgeons on topics 'that would not conventionally be regarded as clinical' such as economic, psychological and value judgments (Cook et al, 2007:313).

They found that economic judgments in favour of surgery were based, for example, on scenarios where the procedure was considered to be inexpensive and of low risk to the patient's health, whereas requests for more complex surgical intervention often required more complex evaluation of the risk-cost benefit. Pain and dysfunction often influenced surgeons toward surgery where a surgical solution existed. Extreme abnormality, even in the absence of pain

and dysfunction could also 'justify surgery', as well as the patient's subjective accounts of the effect of the condition on their quality of life. Surgeons were unclear about how reports of a patient's quality of life influenced their decision-making, with some surgeons indicating that reduced quality of life increased the likelihood of surgery and others indicating that it would reduce the chance of offering surgery.

Although much of the information is taken from surgeons practising in non-orthopaedic specialties both studies show that a range of factors may influence a surgeon's decision to operate (Leung et al, 2012; Cook et al, 2007). It must be acknowledged that these factors mean that it is difficult for the interface ESP to be able to predict the range of factors which may influence the final surgical decision, which limits the value of the conversion rate statistic.

Despite the limitations of the conversion rate, ESPs in secondary care services have reported high levels of conversion to surgery within the knee specialty particularly (Rabey et al, 2009) (as explained in section 2.5 page 46-50). It is thus possible that some ESPs are able to maximise the clinically appropriate aspects of care which result in high conversion rates, and perhaps even components of surgeon and patient decision-making.

It is possible that some consultant factors stay relatively static such that ESPs working within interface services or secondary care orthopaedic departments are able to assess the impact of some of these factors on the decision-making processes of those to whom they refer regularly. This may account for the reports of high conversion rates. However during times of political or strategic change, particularly, for example, where jobs, power, position or status may be under threat, there may be times when surgical decisions are less predictable even if patients are referred with the same clinical indications.

Though the conversion rate has limitations ESPs may be able to record high conversion rates through optimising clinically appropriate referrals, even if they are not able to influence patient and surgeon decision-making factors. Measuring their performance against an agreed set of standards or referral

criteria as well as the conversion rate would go some way to enabling ESPs to demonstrate their quality and value.

2.7.3 Measurement of Treatment Outcomes

For those primary care interface services which provide a conservative treatment function (Clinical Assessment and Treatment (CAT) Services), there are other quality outcomes which could be measured. For example the outcomes of physiotherapy care or specialist treatment such as injection therapy could be used to demonstrate quality. As discussed earlier (section 2.4 page 44) Sephton et al, (2010) investigated the clinical effectiveness of their primary care interface service using quality of life (EuroQuol and SF 36) and patient satisfaction outcomes.

Studies of functional outcomes in patients managed conservatively by ESPs could also be undertaken. Studies are scarce (Stanhope et al, 2012), but a recent study of the clinical and cost effectiveness of ESPs within emergency departments has measured functional outcomes using the Disability of the Arm Shoulder and Hand Score and the Lower Extremity Function Scale to demonstrate that ESPs deliver comparative care to emergency department doctors and nurses (McClellan et al, 2012). Analysis of treatment outcomes along the whole MSK pathway, before and after surgery as was undertaken by Gardiner and Turner (2002) have rarely been studied but could also help to show the impact of the ESP role on patient care (Griffiths 2012). (See section 2.8 page 68 for further discussion of Gardiner and Turner 2002).

2.7.4 Measurement of Health Care Delivery Outcomes

It has been recommended that interface services record a range of health care delivery outcomes including: non attendance rates, the number of new and follow-up attendances, onward referral rates to secondary care, capacity and demand monitoring, turn-around time for diagnostics and 18 week waiting time data (NHS Institute 2009). There are examples of interface services which have published this data including Maddison et al, (2004) and Sephton et al, (2010).

2.7.5 Measurement of Safety and Incident Reporting

In general terms quality within interface services may also be shown by the number of serious untoward incidents reported or by the number and nature of complaints. Though historically physiotherapeutic and conservative MSK services have not tended to report high levels of serious untoward incidents there is a growing risk within this field. For example, as referrals shift from secondary to primary care there will inevitably be some patients referred inappropriately to primary care interface services. The assessment, treatment and appropriate referral of patients with complex, sinister or serious pathology must be dealt with efficiently by interface clinicians. The investigation, reporting and measurement of poorly managed patients through mechanisms such as incident reporting could also promote quality within these services. Studies which have audited these areas have not been found, however this area may become increasingly monitored as primary care services continue to develop and form an increasing part of the MSK workforce.

2.7.6 Commissioning Pressure for Outcomes of Appropriateness

Providing and demonstrating quality and improved service delivery is now a key priority within the NHS (DH 2010a; Crump and Adil 2009) though currently few interface services have published quality markers with respect to specialist referral. It is likely that there will be increasing pressure from commissioners and GP leads for ESPs to demonstrate their worth and effectiveness.

Despite its limitations, it has been recommended that commissioners assess the surgical conversion rate alongside other measures of health care delivery to determine whether care is optimal (PCR Society 2011). It is likely that this measure will continue to be used as a benchmark of performance as has been done recently by NHS Scotland (2012) in setting out their rationale for MSK service redesign in Scotland. The reliance on the conversion rate may relate to its simplicity from a commissioning perspective and may be favoured because commissioners are able to collect the data independently (through secondary care contract monitoring) unlike many other types of data such as patient reported outcomes.

It is highly possible that it may continue to be used at least until there is an agreed outcome framework for MSK interface services (ARMA 2009; PCR Society 2011) to enable commissioners to compare services more readily. A range of outcome measures such as those described would be useful to supplement the conversion rate and provide further evidence of clinical quality.

2.8 Diagnostic Agreement as a Measure of Appropriateness

Though only two studies were found which published ESP conversion rates a range of small pilot studies and audits have shown a high level of diagnostic agreement between ESPs and orthopaedic surgeons. The studies show a high level of clinical competence when compared to surgeons (Gardiner and Turner 2002; Dickens et al, 2003; Moore et al, 2005; Aiken and McColl 2008) and suggest that ESPs and specialist physiotherapists in MSK should be able to demonstrate high conversion rates. Though all the studies have design limitations (as shown below) they do demonstrate positive findings for physiotherapists for the accuracy of diagnosis in peripheral joints, specifically the orthopaedic knee speciality.

In one small prospective pilot study comparing the level of agreement for the diagnosis of knee and shoulder conditions between two orthopaedic surgeons and one physiotherapist there was clinical agreement on 21 out of 24 of the cases under investigation (Aiken and McColl 2008). The results showed a high level of agreement (90% diagnostic agreement) but it must be acknowledged however that the clinicians only had three broad category options from which to choose a diagnosis, and thus did not have to make matching clinical diagnoses. When diagnosing the pathology exactly and matching it to the results of a scan or surgery the clinical agreement across all clinicians reduced to 75%. Though this seems high, this component of the study was conducted with only eight patients which reduces the power of the results.

It could be argued that there was also inherent bias in that the physiotherapist had worked with the consultants for 4 months prior to the start of the study. The working arrangement would mean that the ESP had experienced the consultants' preferences and diagnostic behaviour. This may indicate that the

experience gained working alongside a specialist may help to enable clinicians to make similar judgements, and therefore the level of agreement may only reach these high levels if the working environment is similar, with clinicians having worked with their specialist for a similar time frame. Thus this level of agreement may not be consistently reproducible if ESPs worked in primary care for example or in a situation where the ESP was to stand in, or cover for absence.

Dickens et al, (2003) also carried out a prospective study to determine the diagnostic accuracy of experienced physiotherapists assessing knee complaints and to determine their ability to recognise when a patient required an arthroscopy. Fifty new patients attending one consultant's outpatient knee clinic were recruited and assessed by the consultant in addition to two physiotherapists. The physiotherapists had a special interest in knee injuries and an average of 5 years experience as a senior orthopaedic physiotherapist. All assessments were performed in similar time limits (5-10 minutes) following which an independent diagnosis was made. For the 33 participants who received an arthroscopy the consultant's diagnosis was correct in 92% of cases, physiotherapist 1 and 2 were correct in 84% and 80% of cases respectively. No analysis with regard to statistical significance between the three participant groups was presented. The authors concluded that an experienced physiotherapist is able to make accurate diagnoses when compared with an orthopaedic surgeon. However this finding could have been strengthened by using the statistical analysis of the level of agreement statistics such as Cohen's kappa (Sim and Wright 2000).

Moore et al, (2005) carried out a retrospective comparison of the diagnostic accuracy of MSK injuries by MSK trained physiotherapists (n=5), orthopaedic surgeons (n=3) and non-orthopaedic providers (for example, GP, podiatrist, emergency physician) (n=15) practicing in an army community hospital. Clinical diagnostic accuracy was based on the agreement between the provider's clinical diagnosis and the Magnetic Resonance Imaging (MRI) findings. The results showed that physiotherapists made an accurate diagnosis for 74.5% of cases, with orthopaedic surgeons at 80.8% and non-orthopaedic providers at

35.4%. Physiotherapists were significantly more accurate than the non-orthopaedic providers and there was no significant difference between physiotherapist and orthopaedic surgeon accuracy. The sample size was very small and not randomised and therefore could have been biased due to the retrospective nature of the study. However in contrast to other studies diagnosis was made by comparison to an independently reported MRI scan, which could be considered as more objective than previous comparisons which used the surgeon's decision as the gold standard.

Gardiner and Turner (2002) undertook a retrospective audit of patients referred for knee arthroscopy to determine whether an ESP working in an orthopaedic outpatient clinic was making reasonable decisions when compared with their medical colleagues. They assessed patients without prior screening of the referral letter by the consultant. The audit was undertaken over a 5 month period in 1998 and included all patients listed for arthroscopy. A total of 128 sets of notes were examined of which the ESP had seen 18% (n=23). The ESP had achieved 52% correct clinical diagnoses compared to only 37% by the doctors within the orthopaedic team. Though the findings support the hypothesis that physiotherapy decision-making is of a higher standard than other doctors within the orthopaedic clinic, it is important to note that findings relate to only one ESP, when assessing a small number of cases. Thus the findings cannot be widely generalized and should be interpreted with caution.

The diagnostic agreement studies above provide limited evidence (mainly through audits with a small sample size and retrospective studies) that secondary care ESPs can make comparative diagnostic judgements with their consultant orthopaedic colleagues. However the use of independent diagnostic measures is limited and all studies have used a small number of participants. None of the studies appear to have randomised the cases seen and thus it is not clear if the cases were representative of the majority of patients seen by ESPs or specifically selected. The studies provide some evidence to support the possibility that ESPs can effectively assess and diagnose patients referred for orthopaedic opinion, particularly in the knee sub-specialities, but the evidence is weak.

It could be, and possibly has been, assumed that the ESP conversion rate and studies of diagnostic accuracy measure the same construct. However the ESP studies which demonstrated high levels of diagnostic agreement do not necessarily indicate that the appropriate patients are selected for surgery. Disparity between the relatively high levels of diagnostic accuracy and the low conversion rates reported in some specialities may be connected with the size and quality of the studies undertaken. Disparity could also be related to other factors such as ESP knowledge of surgical thresholds, the stage of the condition and the patient's cardiovascular or respiratory fitness. Thus the concept of appropriate referral as measured by the conversion rate is a marker of a wide range of factors, not just the number of patients referred with the correct diagnosis.

2.9 Barriers to Appropriate Referral

The reasons for referral difficulties have not been explored extensively, particularly with regard to ESPs. A small number of studies have investigated referral barriers experienced by GPs when referring to a range of specialities (Madhok and Green 1994; Elwyn and Stott 1994; Augestad et al, 2008; Musila et al, 2011; Elliott et al, 2011). The key barriers identified for GPs were lack of referral criteria or consensus (Lowry et al, 1991; Madhok and Green 1994; Speed and Crisp 2005; NHS Institute 2009; Elliott et al, 2011; Musila et al, 2011), lack of knowledge or skills (Elwyn and Stott 1994; Morgan et al, 2007), and poor communication (Elwyn and Stott 1994; Augestad et al, 2008).

In addition there may be an array of non-clinical, political and economic barriers. These could include geographical isolation, waiting lists, government policy, (such as 18 week targets, or the patient choice agenda), financial incentives or economic pressures (such as 'payment by results' or the introduction of 'Foundation Trust Status'), patient pressure groups and public opinion. The influence of non-clinical factors on referral appropriateness or surgical activity has rarely been investigated in any professional group. One study has analysed surgical behaviour under different waiting lists (Appleby et al, 2005). They found no specific patterns to demonstrate that surgeons increase or

decrease their surgical activity when waiting lists reduce. Other studies investigating the impact of the political or financial landscape on surgical behaviour for example have not been found.

To date there are no studies that have explored ESP barriers to onward referral in primary or secondary care. However it is important to note that the primary care working environment may result in different challenges (for example lack of access to clinical support or communication difficulties). The barriers faced by GPs in primary care may specifically illuminate the difficulties experienced by primary care ESPs when compared to those working in secondary care. Understanding referral barriers may help to improve appropriate referrals in primary care ESPs and may improve the quality of care they provide. The key referral barriers identified in the literature will now be explored in more detail and the impact on referral appropriateness will be evaluated.

2.9.1 Knowledge and Skills

To meet the aims of the interface service staff must have the clinical expertise to assess patients who may present at any part of the MSK pathway. Patients may range from those suffering from simple MSK problems to those suffering from complex conditions requiring surgery. To ensure staff have the range of assessment and decision-making skills required for work within an interface service they need to have expertise in both conservative and surgical management. Traditionally, ESPs worked alongside consultants in secondary care clinics (Byles and Ling 1989; Hourigan and Weatherley 1994; Weale and Bannister 1995), in a supported environment where they had access to surgical knowledge. From the mid 1990's ESPs also began to work in primary care, which is generally an environment with limited access to surgeons (Weston-Simons et al, 2012).

The knowledge and skills of ESPs working within orthopaedics has been investigated by Weston-Simons et al, (2012). They found that there was a lack of formal training for orthopaedic ESPs in primary and secondary care in addition to the variation in postgraduate training and entry level qualification. Following this survey they recommended standardised training for ESPs

particularly with regard to x-ray interpretation and injection therapy. The relationship between referral appropriateness and lack of knowledge was not investigated in this study. However this has been investigated in a qualitative interview study of GP's referral behaviour for headache (Morgan et al, 2007). Eighteen GPs in South East London participated. All GPs had referred patients for headache in the previous twelve months and a variable referral rate had been shown. The results showed that there were differences in the levels of clinical confidence when making an appropriate diagnosis, and differing levels of uncertainty with regard to the GPs perception of the therapeutic value of referral.

When assessing the appropriateness of GP referrals generally, Elwyn and Stott (1994) also identified that there was a relationship between clinical knowledge and referral appropriateness. In this study seven out of the thirty two inappropriate referrals (22%) were attributed to lack of knowledge or skills, and two were attributed to the GP's interpersonal skills (i.e. failure of the GP to explore the patient's beliefs). These results highlight that there may be a relationship between the knowledge or skill of a referrer and their referral behaviour. Further studies in this field, particularly with regard to ESP referral behaviour are needed to explore this issue in more detail. However these findings do support the calls for standardised referral criteria particularly to facilitate appropriate referral in unusual or lesser seen conditions.

2.9.2 Clinical Support

Whilst reporting on the long term outcomes of employing a physiotherapist as an orthopaedic assistant in a back pain clinic, Hourigan and Weatherley (1995) highlighted the importance of experienced clinical support. Clinical support is a term they used to mean discussion of clinical cases to facilitate clinical reasoning, clinical decision making and diagnosis. Weatherley and Hourigan (1998) re-emphasized the importance of clinical support following a postal survey to 43 centres in the UK where ESPs were conducting spinal triage. The response rate was 91%, however the number of therapists was not identified. Their aim was to explore the clinical organisation, the ESP case mix, ESP access to further investigations and clinical support (in the form of ability to

discuss new or problem patients). Though many of the findings are not relevant to this study they did find that the ESPs surveyed experienced varying levels of clinical support and supervision.

Generally ESPs had access to clinical support with 82% seeing their consultant at least once a week. Despite this, 23% felt that they might miss a diagnosis because of a lack of medical knowledge. General comments from the survey indicate the 'need for a good relationship between the doctor and the physiotherapist' (Weatherley and Hourigan 1998:378).

Lack of clinical support could obviously impact on the quality of referrals to secondary care particularly where ESPs are unsupervised, lacking guidance or support, and are unclear about the diagnosis and their level of accountability. Weatherley and Hourigan (1998) did not explore these issues in further detail, and explicit questions about referral difficulties or conversion rates were not asked.

The authors concluded with a cautionary note concerning the levels of stress and isolation that were experienced by 74% of the ESPs surveyed. Hourigan and Weatherley (1994) had initially published a paper explaining what they felt was an appropriate workload for an ESP (this included discussion of all cases with the consultant after the initial assessment and ensuring all radiographic images were seen by the consultant). However in their follow up survey, Weatherley and Hourigan (1998) found that there was potential for ESPs to be isolated, seeing complex patients with significant medical problems where radiographic imaging was not being checked by an appropriate medical consultant. They identified that the responsibility was being borne by the ESP alone.

Dawson and Ghazi (2004) also investigated ESP experiences with a qualitative semi-structured interview study in orthopaedic outpatient (secondary care) clinics. They found that most ESPs felt that a good relationship with the medical team, who provided adequate ongoing training and support, was important to minimise many of the clinical difficulties encountered by ESPs.

These studies demonstrate the importance of access to knowledge, training and clinical support, however in their recent ESP survey Weston-Simons et al, (2012) found that as many as 79% of primary care ESPs worked independently to the consultant. They did not investigate whether this led to poor clinical care or inappropriate referrals however the findings contrast sharply with the levels of consultant support for secondary care ESPs where only 32% of ESPs worked without consultant support. Though ESP referral behaviour and clinical support have not been investigated explicitly the studies suggest that clinical support is important and that ESPs in primary care may be particularly vulnerable working in isolated primary care environments where there is no access to orthopaedic consultant support.

2.9.3 Communication

Communication has been identified as a possible barrier to appropriate referral. Whilst investigating the benefits of an electronic booking system between primary and secondary care services, communication was identified as an important factor to improve appropriate GP referrals (Augestad et al, 2008). They identified that poor communication between primary and secondary care often resulted in inefficiencies and unsatisfactory patient outcomes. As well as identifying the importance of clinical skills Morgan et al, (2007) also identified that communication was a factor which influenced referral behaviour and referral appropriateness.

Elwyn and Stott (1994) identified several instances of poor communication which had affected referral appropriateness. In this study a GP (the author) and an independent assessor reviewed a selection of GP referrals made to secondary care. They found that 34% of referrals were considered to be avoidable. On further investigation it was shown that ten of the avoidable referrals were due to inadequate hospital information about earlier contacts with the patient. They concluded that this practice is potentially costly. They did highlight that it could be argued that the referring doctor should have spent more time requesting this information. However the GP writing the study felt that in reality, in a busy practice, it is not practical to spend time in pursuit of missing information when other priorities are pressing. They concluded that it is

quicker to write a referral letter, particularly if the doctor thinks that the referral may be necessary anyway. Interestingly, the quality of patient care, particularly with regard to the time wasted by the patient in repeat referrals, was not discussed.

These studies suggest that the primary care environment alone may lead to referral difficulties particularly with regard to access to previous clinical information. It is important to determine whether primary care ESPs also experience these difficulties, and if this influences their ability to refer appropriately.

2.9.4 Surgical Referral Criteria

The lack of referral criteria has been highlighted as a significant barrier to appropriate referrals by GPs in a range of specialities (Lowry et al, 1991; Speed and Crisp 2005; Morgan et al, 2007).

Lowry et al, (1991) who were the first authors to identify and publish orthopaedic conversion rates, concluded that misdirected referrals were connected with a lack of consensus concerning the surgical management of orthopaedic conditions, though this was the authors' view and was not derived from empirical research. The study had not set out to determine whether there was consensus regarding the surgical management of specific conditions, and the GPs referring to the service were not asked whether they found referral difficult due to a lack of consensus about surgical management.

Speed and Crisp (2005), also advocated that some form of criteria would be useful to guide referrers. Indeed, when Speed and Crisp (2005) were trying to determine which referrals were appropriate for orthopaedics they identified that there were no published orthopaedic criteria available to guide their analysis. This resulted in the development of local criteria which were included in the publication. After their analysis of orthopaedic referrals, Speed and Crisp (2005) concluded that many referrals to hospital-based MSK services were likely to be misdirected. They recommended that integrated referral and care pathways are required for efficient and optimal care of patients with MSK

diseases. They also suggested that the development of such pathways would require significant support, education and training for GPs.

Despite the calls for the development of surgical referral criteria only three studies could be found which have attempted to develop robust surgical referral criteria. The areas were hip arthroplasty (Naylor and Williams 1996; Quintana et al, 2000) and knee arthroplasty for osteoarthritis; (Naylor and Williams 1996; Musila et al, 2011).

Naylor and Williams (1996) undertook a Delphi study to develop referral criteria for hip and knee arthroplasty. A panel chosen by the research team included four orthopaedic surgeons, two rheumatologists, two GPs, a general physician with health care research interest, an epidemiologist, and a physiotherapist. They developed and then rated 120 knee and hip osteoarthritis case scenarios for the appropriateness for referral to surgery and 42 scenarios for waiting list priority. Scenarios included details of the patient's age, their level of pain and their functional limitation. A nine point scale was used to determine whether clinical cases were appropriate for surgery and a four point scale was used for rating urgency. Three clinical descriptions of appropriate surgical cases based on the patient's age, their pain, the likely level of functional improvement and expected prosthesis survival rate (based on age and activity levels) were developed. It was expected that these descriptors would be useful in clinical practice to determine whether referrals were appropriate for hip and knee arthroplasty surgery.

Quintana et al, (2000) also developed explicit referral criteria for hip arthroplasty which were to be used to determine whether patients were appropriately referred for total hip replacement. A Delphi study was used with methodology similar to that described by Naylor and Williams (1996) including 216 scenarios and a nine point scale to rate appropriateness. Each scenario was deemed appropriate if the panel's median rating was between 7 and 9 (on the nine point scale) without disagreement. The panel consisted of nine orthopaedic surgeons, one rheumatologist, one rehabilitation medical specialist and one family physician. The resulting criteria for total hip replacement were based on

the level of pain reported, functional limitation, bone quality, surgical risk and previous surgery.

Musila et al, (2011) conducted a consensus study to develop GP surgical referral guidelines for patients with osteoarthritis of the knee, as they highlighted that selection of appropriate patients for knee surgery in primary care was very difficult. The study used a guideline development group of 12 members which included patients, GPs, orthopaedic surgeons and other health care professionals. They rated the appropriateness of referral (using a Likert Scale) for 108 case scenarios describing patients according to symptom severity, age, body mass index, co-morbidity and referral preference. Their findings resulted in 'referral recommendations' with ratings of referral appropriateness being strongly influenced by symptom severity and patients' referral preferences. Apart from symptom severity, the influence of other patient characteristics to guide appropriate referrals was small and the results showed that the group was not able to develop a range of objective criteria for appropriate referrals to secondary care. One consideration of this study was that the expert group was primarily non-specialist, which may account for the lack of consensus achieved. This highlights the inherent difficulties in identifying appropriate patients for surgery for those who do not have specialist surgical knowledge. A more specialist group may have achieved greater consensus for appropriate referrals for surgery. The limited nature of the findings suggest that it may be very difficult to develop criteria to identify appropriate cases for surgery and these results may help to explain why conversion rate statistics in some orthopaedic specialties are very low.

The use and importance of clinical referral criteria has also been emphasised by several authors undertaking ESP research. When reviewing the pilot study which had pioneered the role of the ESP working in a spinal clinic, Byles and Ling (1989) advocated that in order for ESPs to work independently, surgical criteria and a range of care pathways were necessary to assist the ESP in cases of indecision or emergency. Similarly in a study analysing the effectiveness of an ESP within a paediatric orthopaedic clinic, Belthur et al,

(2003) attributed their significant success and cost effectiveness to a well defined protocol for the assessment and management of patients using the service. In the study that investigated clinical agreement, Gardiner and Turner (2002) indicated that the development of surgical referral criteria was required to improve the appropriateness and selection of patients referred for knee arthroscopy by the orthopaedic surgery team. The NHS Institute (2009) have also recommended that they consider best practice within interface services to include the development of local MSK care pathways/criteria between interface services and orthopaedic surgical departments.

2.9.5 Summary of Section 2.9

There may be a wide range of referral barriers faced by primary care ESPs. The lack of support and the lack of access to communication with consultants may mean that their referrals are less appropriate than their secondary care colleagues. Referral criteria appear to be recognized in both primary and secondary care as an important component of clinical care. They have been used in ESP studies and have been recommended to improve referral appropriateness between GPs and secondary care orthopaedic departments. However orthopaedic surgical referral criteria are scarce and have only been found in relation to hip and knee arthroplasty surgery. Where they have been developed they appear to be of limited use, lacking in objective detail with a focus on pain. Thus further study is worthy of investigation.

Chapter 3: Developing Surgical Referral Criteria

The appropriateness of referrals in the shoulder specialty and the possible reasons for the high numbers of misdirected referrals are a focus for this study. Rotator cuff pathology is a common condition seen within the shoulder specialty. However there is lack of agreement surrounding the management of rotator cuff tear pathology and a lack of surgical referral criteria for repair of rotator cuff tears.

3.1 Appropriateness of Referrals in the Shoulder Specialty

The area where surgical referrals to specialist care by ESPs are considered to be most misdirected is in the shoulder speciality (Pearse et al, 2006). Although studies are limited to those undertaken in secondary care they have shown that ESPs have the lowest conversion rate in this speciality (Pearse et al, 2006). It is important to acknowledge that the component of the study relating to shoulder referrals was small, however the results showed a conversion rate of only 9% which is much lower than in other subspecialties, for example: 28%-57% for spinal conditions and 64%-89% for lower limb conditions (Pearse et al, 2006; Rabey et al, 2009). These findings and those from Oakes (2009) reviewed in section 2.5 page 46, may suggest that a large percentage of referrals may be misdirected. Alternatively there may be specific difficulties or referral barriers within the upper limb speciality. No studies have been found which have investigated referral appropriateness in the shoulder speciality from primary care ESPs or other health professionals such as GPs.

3.2 Surgical Referral Criteria in the Shoulder

The comparatively high number of misdirected ESP referrals in the shoulder subspeciality may reflect the lack of surgical referral criteria, the lack of standardised guidelines (Robb et al, 2009), and a lack of agreement between surgeons with regard to the management of some shoulder pathologies.

A small number of guidelines exist to provide basic detail about the management of shoulder conditions generally but do not contain referral criteria particularly with regard to common conditions such as rotator cuff pathology or

impingement syndrome (Accident Compensation Corporation (ACC), New Zealand Guidelines Group 2004).

In the field of rotator cuff pathology there is significant variation in clinical decision-making and a lack of clinical agreement regarding the surgical management of rotator cuff pathology (Dunn et al, 2005; Iannotti et al, 2010). Dunn et al, (2005) surveyed 1100 orthopaedic surgeons regarding the indications for rotator cuff surgery after acknowledgement that there was significant variation in the rates of rotator cuff surgery performed in the USA. They randomly selected orthopaedic surgeons listed in the American Academy of Orthopaedic Surgeons directory who had treated patients for a rotator cuff tear, or had referred patients for such treatment, within the previous year. They found significant variation in surgical decision-making and a lack of clinical agreement among orthopaedic surgeons about rotator cuff surgery.

Iannotti et al, (2010) also investigated the consistency of surgical decision-making in four experienced shoulder surgeons when assessing patients with rotator cuff pathology. The study measured the inter-rater agreement of surgical decision using 37 shoulders of patients who had significant rotator cuff tears where the tear was too large or the tissue quality too poor to be repaired. Surgeons had access to the patient's presenting signs and symptoms (including x-ray images). Iannotti et al, (2010) identified that the inter-rater reliability was only 'fair' when making decisions about surgery even when using radiographic and clinical data combined ($k=0.31$). When using radiographic data alone agreement was slightly higher ($k=0.34$).

The low conversion rates in the shoulder speciality and the lack of agreement among shoulder surgeons when selecting appropriate patients for rotator cuff surgery strengthens the case for the need to develop surgical referral criteria in this field. It is possible that the level of variation in decision-making is a barrier to the development of criteria. So far detailed consensus studies attempting to identify areas of agreement do not appear to have been undertaken. However it is possible that consensus on which referrals are most appropriate for surgery may become clearer as further studies on referral thresholds and referral criteria

are undertaken. The prevalence, aetiology and surgical management of rotator cuff disorders will now be explored in more detail.

3.3 Prevalence of Shoulder Pain and Rotator Cuff Pathology

Musculoskeletal disorders of the shoulder are extremely common (Lin et al, 2008; Kuijpers et al, 2006). Patients with cervical and shoulder problems have been reported to visit their GP at twice the annual average rate for patients visiting the health centres (Rekola et al, 1997), showing that the demand on GPs' time is significant. It has also been estimated that rotator cuff disease accounts for 10% of all referrals to physiotherapy (Peters et al, 1994).

Reports of shoulder pain prevalence defined as 'a figure for a factor at a single point in time' (Jekel et al, 2001) vary widely. One review estimates that one in three patients experience shoulder pain at some stage of their lives, which may increase to approximately half the population experiencing at least one episode of shoulder pain annually (Lewis 2009a). The elderly appear to be most afflicted with shoulder pain and the prevalence in the elderly population has been estimated to range from 21% to 27% (Lin et al, 2008). Luime et al, (2004) conducted a systematic review to investigate the prevalence of shoulder complaints and found a much more variable prevalence rate ranging from 6.7% to 66.7% in the general population for the lifetime prevalence of shoulder pain. Though the rate is variable, the most conservative estimate (i.e. 6.7%), indicates that shoulder pain is relatively common and is a significant health burden worthy of investigation.

Pathology of the soft tissues of the shoulder, including the musculotendinous rotator cuff and subacromial bursa, is a principal cause of pain and suffering (Lewis 2009b). Rotator cuff disease is the most common cause of shoulder pain seen in primary care practices (Lin et al, 2008; Gomoll et al, 2004; Murrell and Walton 2001), particularly in the elderly population (Kim et al, 2009). The clinical manifestations of rotator cuff dysfunction can translate into significant morbidity and disabilities for the elderly population, interfering with ability to self care and functional independence (Lin et al, 2008). In addition to the high incidence and impact on disability, it has been shown that symptoms are often

persistent and recurrent, with 54% of sufferers reporting ongoing symptoms after 3 years (Lewis 2009b).

Murrell and Walton (2001) reported that rotator cuff tears account for almost 50% of major shoulder injuries. However the finding that the conversion to surgery rate for shoulder conditions is very low (Pearse et al, 2006) suggests that the clinical management of rotator cuff disease is poor with high numbers being misdirected onto a surgical pathway. The prevalence of rotator cuff tears and the impact of rotator cuff disease on symptoms and disability suggest that efficient management of the disease could lead to significant improvement in patient care. Surgical referral criteria or evidence based guidelines could be beneficial to improve the quality of care.

3.3.1 Aetiology of Rotator Cuff Tears

The aetiology of rotator cuff disease is considered to be multifactorial, including both extrinsic and intrinsic factors (Maffulli and Furia 2012) as shown in Table 3.1.

Table 3.1: Summary of Intrinsic and Extrinsic Risk Factors for Rotator Cuff Tear

Intrinsic	Aging/ Degenerative Changes
	Degenerative Tendinopathy
	Avascularity
Extrinsic	Trauma
	Bony Impingement e.g. hypertrophic Acromio-clavicular joint
	Hooked Acromion
	Spur Formation
	Overuse Impingement

Rotator cuff dysfunction ranges across several pathological changes, from impingement syndrome, rotator cuff ‘tendinitis’ or tendinopathy and rotator cuff tendon tear (Neer 1972). Though the pathology varies the presenting symptoms are usually similar such as pain on abduction and a painful arc during movement. Impingement syndrome is a condition in which the subacromial bursa and the rotator cuff tendons impinge on the acromion as the arm moves into abduction. The impingement causes inflammation of the subacromial bursa and in some cases a tendinitis of the rotator cuff tendons as they insert onto the greater tuberosity (Mauffulli and Furia 2012). In some cases there are no inflammatory markers but the patient may suffer from tendinopathy. This is characterised by histological changes within the tendon and pain, but the mechanism of pain and the cause of the pathology is still unclear (Moulinoux et al, 2007).

Figure 3.1: Diagrammatic representation of subacromial impingement and supraspinatus tendon inflammation prior to tendon tear



(Permission to use image granted by Long Island Orthopaedic Association)

In older patients it is thought that the patients with rotator cuff dysfunction suffer from degenerative tears within the tendons of the rotator cuff rather than inflammatory bursitis around the tendon (Beaudreuil et al, 2010). Intrinsic

factors such as aging, degeneration and avascularity are thought to contribute to the pathophysiology (Maffulli and Furia 2012). A correlation between a torn rotator cuff (principally supraspinatus) and the presence of inflammatory and histological markers in torn rotator cuff (supraspinatus) tendons has been shown in 40 patients who were awaiting repair when comparing them to four normal uninjured subscapularis tendons²² (Matthews et al, 2006). The findings help to explain why patients experience inflammatory type pain irrespective of whether they have bursitis or a rotator cuff tear.

There is debate concerning whether the incidence of tears increases with increasing age in the normal population. Kim et al, (2009) completed a normative study investigating the presence of rotator cuff tears in normal volunteers. Of the 237 volunteers, forty-one were found to have a torn rotator cuff in at least one shoulder which equates to 17% of the volunteer study population, with prevalence rate increasing with increasing age in each decade (0% for subjects between 40-49 years old; 10% between 50-59 years old; 20% between 60-69 years old; and 40.7% for those 70 years or older). Hijioka et al, (1993) conducted a cadaver study in 160 shoulders to determine the effects of friction and rubbing in the development of rotator cuff tear. There were 80 cadavers, the age at death ranged between 43-93 years, and the mean age was 69.3 years. They found that the number of tendons with degenerative tears increased from the fifth to sixth decade of life, and that tear size increased with age. However, in contrast to Kim et al, (2009), there was no sustained increase in the prevalence from the age of 60 to 90 years. The percentage with degenerative changes of the cuff remained at approximately 60% in each decade from 50 years onwards. Linsell et al, (2006) found similar results to Hijioka et al, (1993) with an increase in tears up to the age of 50 years but no significant rise in rotator cuff tears in those aged 50 years and above.

Hijioka et al, (1993) showed that mechanical friction correlated with the development of a rotator cuff tear, suggesting a friction mechanism to the

²² The reason for comparison with the subscapularis tendon is not noted. Comparison with subscapularis may have been undertaken because it is more accessible than infraspinatus or possibly because a convenience sample was used.

development of cuff tears. Hijioka et al, (1993) also examined the surface of the cuff and the undersurface of the acromion in eight shoulders of fresh cadavers with electron microscopy. There was a significant correlation between the severity of the changes in the rotator cuff and the subacromial surface. The authors concluded that degenerative change of the rotator cuff tendon is aggravated by a friction and rubbing mechanism with the undersurface of the acromion which leads to development of a complete tear. They also found that 61% of degenerative changes were found in the supraspinatus tendon (as opposed to the other cuff tendons – subscapularis and infraspinatus).

In a retrospective review of 1067 patients undergoing surgery for rotator cuff tear Feng et al, (2003) analysed a wide range of pre-operative, intra-operative and peri-operative factors (including age, weakness, pain, muscle atrophy, tear size, tear type, degeneration, retraction, surgical technique and function) to determine the relationship to post operative success. They considered increased patient age to be the single most important contributing factor in the pathogenesis of rotator cuff tears. In addition, they concluded that degenerative tendinopathy appeared to be the primary pathology in rotator cuff tear, preceding hypertrophic spur formation. They also concluded that rotator cuff tears were unlikely to be initiated by impingement and suggested that they were more likely to develop as an intrinsic degenerative tendinopathy.

With the exception of traumatic tears there is still some debate with regard to the exact cause of rotator cuff tears. Intrinsic factors such as aging and degeneration have been suggested (Feng et al, 2003; Maffulli and Furia 2012) as well as spur formation and bony impingement (Neer 1972), and overuse impingement that may occur in the overhead athlete (Walch et al, 1992).

3.3.2 Management Options for Rotator Cuff Tears

The treatment of rotator cuff tears can focus both on the conservative and the non-conservative management. Conservative management may include exercise to increase or maintain shoulder function and steroid injection to reduce pain. Surgical options include subacromial decompression to reduce compressive forces on the tendon or direct repair of the tendon itself. Surgical

repair of the rotator cuff has become main stream with both open and closed (i.e. arthroscopic) surgical approaches. However conclusions regarding the superiority of specific treatment approaches have not yet been reached (Coghlan et al, 2009).

Coghlan et al, (2009) undertook a systematic review comparing the effectiveness of a range of treatment options for rotator cuff injury. After excluding poor quality or heterogenous studies they reviewed 14 randomised controlled trials (RCTs) investigating the management of rotator cuff tear (surgical and non surgical). The authors were unable to draw firm conclusions about the effectiveness or safety of surgery for rotator cuff disease due to methodological issues such as bias and heterogenous sampling. None of the studies reviewed met all the methodological quality criteria recommended by Cochrane, therefore they were only able to draw 'silver' level conclusions from the review, (Cochrane Collaboration 2011)²³. The authors concluded that there were no significant differences in outcome between open or arthroscopic subacromial decompression, and no difference between these surgical treatments and active non-operative treatment for subacromial impingement.

The success rates for rotator cuff repair are said to vary depending on a number of factors such as the skill of the surgeon (i.e. surgeon skill/training, familiarity with arthroscopic equipment) or the size of the cuff tear (Iannotti et al, 1997). However, there is no conclusive evidence to indicate when patients should be referred for a subacromial decompression, a rotator cuff repair or both.

Ide et al, (2007) and Hanusch et al, (2009) have investigated the integrity of rotator cuff repairs after surgery, and both of these studies indicate that there is a relatively high prevalence of cuff tendon re-tear (17-35%). Hanusch et al, (2009) conducted a small prospective study with 24 patients with symptomatic large and massive rotator cuff tears²⁴. They used diagnostic ultrasound (US) to

²³ See Appendix 3 for definition of silver level conclusions.

²⁴ Small tears <1cm; medium tears 1-3; large tears between 3-5cm; massive tears are defined as tears over 5cm (Pill et al, 2012; Ozaki et al, 1988; Cofield 1982).

evaluate the integrity of the tear and found that 17% of those undergoing the procedure (mini open repair) had a re-tear.

Ide et al, (2007) conducted a similar sample sized prospective study to evaluate rotator cuff repair but used arthroscopic repair. The patients, seventeen men and three women (twenty shoulders), with a mean age of 61.7 years, were followed for an average of 36 months, (all patients were followed up for at least two years). Results showed that seven of the twenty patients (35%) had recurrent tears after the surgery. A limitation of this study is that all patients had traumatic tears. This is particularly unusual because the main pathologies underpinning rotator cuff repair are considered to be degenerative or connected with overuse and thus the results from this study may not necessarily be broadly generalized. In spite of this the treatment of traumatic as opposed to degenerative cuff tears is generally considered to be more successful because the quality of the tissue is usually good and thus repairs remain intact. One would have expected the re-tear rate to be lower in the traumatic tear sample than the degenerative tear group. It is possible that the small sample size used in both of these studies has reduced the reliability of the findings.

Further analysis of the study by Ide et al, (2007) showed that of the seven patients in the re-tear group, one had an excellent outcome; five, a good outcome; and one, a fair outcome, bringing the importance of the surgery into question if outcomes were still acceptable despite re-tear.

Though the outcome in the re-tear group was reported to be 'good'²⁵ using the University of California at Los Angeles (UCLA) shoulder score, evaluations of the score have indicated that it has a limited ability to discriminate between pain and function (Roddey et al, 2000). Other measures to assess function showed significantly poorer functional outcomes for the majority of patients. For example the average score of post operative function, as shown by the Japanese Orthopaedic Association (JOA) shoulder score²⁶, was significantly lower for the

²⁵ There are four outcomes for the UCLA score (very good, good, not very good, and poor). A 'good' outcome equates to 28-33/35 points

²⁶ The JOA score is a validated tool which measures shoulder function (Hirota et al, 2003).

patients with a failed repair than it was for those with an intact repair ($p = 0.0034$). Thus, the study suggests that the level of pain may reduce despite re-tear, but functional outcomes are poor.

One study has been found which reported much lower re-tear rates. In a review of complications after rotator cuff surgery, Mansat et al, (1997) quoted re-tear rates of as low as 6% which seems particularly low. Despite occasional reported references to low re-tear rates most studies found have re-tear rates over 17%. Two are comparable with Ide et al, (2007) such as Moulinoux et al, (2007) whose re-rates were reported to be 32% and Zumstein et al, (2008) who reported re-tear rates of 37% in a group of patients with massive tears.

The lack of evidence supporting successful clinical outcomes in rotator cuff tear surgery, even when compared to conservative treatment, and the occurrence of re-tear in 6-37% of patients, undermines the validity of the surgical procedure. Despite this rotator cuff surgery has become a main stream procedure. The reasons for this are unclear but may be connected with the significant pain and dysfunction from which patients with rotator cuff disease suffer.

There is a lack of clarity with regard to the optimum patient selection for surgical and conservative treatment. Further guidance on selecting the most appropriate rotator cuff tear patients for surgical repair could significantly improve patient care.

3.3.3 Shoulder Surgery

There is a paucity of evidence detailing the numbers of patients referred for shoulder surgery and the types of surgery for which they are referred. One study by Linsell et al, (2006) found that 22.4% (study cohort $n=9215$) of shoulder pain patients seen within primary care over a 3 year period in the UK, were referred to secondary care for consideration of surgery. The methodology was not detailed enough to identify what types of conditions were referred and thus it is unclear how many patients were specifically referred for rotator cuff surgery or subacromial decompression. Surgical activity data, like referral data are also scarce. The NHS orthopaedic surgery and outpatient data are crude and tend to rely on data submitted into three main categories. The categories

are 'major, intermediate and minor shoulder/upper arm procedures for non trauma'. The 2009-2010 Department of Health reference cost data for the NHS (DH 2011c) (which receives returns from all secondary care and primary care trusts) indicated that approximately 117 million pounds was spent during 2009-2010 on elective (non trauma) shoulder procedures. This cost relates to 73,470 separate shoulder procedures from minor to major interventions. Data is not coded by procedure name or condition type and therefore the percentage of procedures attributed to specific conditions is not known. It is not clear how much of this cost relates to procedures performed in outpatients such as shoulder injections and how much activity relates to major procedures such as rotator cuff repair surgery or joint replacement. Therefore the number of and cost of rotator cuff repair surgery in England cannot be estimated.

The lack of information concerning the number of patients referred or the amount of surgical activity undertaken for rotator cuff repair/injury means that the number of patients in England who may be affected by the development of referral criteria for rotator cuff tear is unknown. The number of ESPs providing care (assessment, treatment and referral) for patients with rotator cuff problems is also unknown. In France, Beaudreuil et al, (2010) estimated that in 2005, 45,000 patients underwent some type of rotator cuff surgery²⁷, indicating that rotator cuff surgery is a significant area worthy of investigation.

3.3.4 Justification for the development of referral criteria for rotator cuff tears

The high level of misdirected referrals in the shoulder specialty (Pearse et al, 2006), the high prevalence of rotator cuff tears (Murrell and Walton 2001), the impact of rotator cuff tear on patients' pain and disability (Lin et al, 2008), the lack of agreement between surgeons about when to operate (Dunn et al, 2005; Iannotti et al, 2010) and the lack of evidence supporting surgical intervention in rotator cuff disease (Coghlan et al, 2009) indicate that there is a strong case for trying to develop surgical referral criteria in this field.

²⁷ Types of rotator cuff surgery may include rotator cuff repair surgery (open, mini open or arthroscopic) and/or debridement.

3.4 Existing Evidence to Underpin Surgical Referral Criteria

There is a limited amount of evidence which could be used to develop referral criteria for the surgical management of rotator cuff tears. It is generally of limited quality, often derived from uncontrolled case studies with conflicting findings. Three papers have been published which have included surgical inclusion criteria. The inclusion criteria used in all three papers are significantly different and thus do not represent a clear consensus. Moulinoux et al, (2007) outlined very specific inclusion and exclusion criteria to select patients for a study which investigated the outcome of arthroscopic rotator cuff repairs. However these criteria were not derived from either consensus studies or systematic review. The authors outlined three key surgical indications and a list of contra-indications for arthroscopic surgical repair of the rotator cuff. They recommended that surgery was indicated when patients had:

- An isolated full-substance rupture of the supraspinatus
- A full-substance tear of the supraspinatus and the superior part of the infraspinatus
- Incomplete tears affecting the superior part of the subscapularis, either isolated or associated with rupture of the supraspinatus.

They also recommended that patients presenting with symptoms from the following list were contra-indicated for a surgical repair:

- Fatty infiltration of infraspinatus and subscapularis of stage 3 and 4
- Frozen shoulder in the active phase
- Narrowing of the subacromial space (< 7 mm)
- Complete tear of the subscapularis
- Complete tear of the postero-superior cuff reaching the teres minor
- Patients older than or equal to 65 years of age (Moulinoux et al, 2007: 231).

An earlier study by Warner et al, (1997) identified pre-operative selection criteria for rotator cuff repair based on:

- Refractory pain in the setting of good range of motion and strength (after a positive impingement test)
- Absence of radiographic superior humeral head translation
- MRI evidence of minimally retracted tear without rotator cuff muscle atrophy.

They used these criteria in a prospective study of 24 patients out of 376 referrals for rotator cuff repair and found that using these criteria, alongside intra-operative criteria, enabled the authors to select suitable patients for arthroscopic and open rotator cuff repairs. Their outcomes showed that fourteen out of the fifteen patients available for follow up believed that their surgical outcome was excellent. The numbers of patients in this study are low, and thus the findings must be interpreted cautiously. There was no information about sample selection, except that patients met the inclusion criteria. Despite these weaknesses the study provides limited empirical evidence that patient selection using surgical criteria may provide better outcomes.

A recent systematic review, by Beaudreuil et al, (2010) provides a guide to the surgical management of patients requiring rotator cuff repair. This study aimed to determine the optimum surgical management options rather than determine consensus regarding referral. The study reviewed randomized controlled trials and case series evidence but did not provide details regarding the research quality or methodology of the studies included in the review. They made a number of recommendations concerned with the management of rotator cuff tears. They also listed broad referral criteria, though it is not clear how these recommendations were made as the review was not intended to define referral criteria.

Their recommendations concluded that:

- Conservative treatment (oral medication, injections, physiotherapy) is always the first option in the management of degenerative tears of rotator cuff tendons
- Surgery is a later option²⁸ that depends on clinical and morphological factors, and patient characteristics
- Surgery can be considered for the purpose of functional recovery in cases of a painful, weak or a disabling shoulder refractory to medical treatment²⁹
- Arthroscopy is indicated for non-reconstructive surgery or debridement, and for partial tear debridement or repair
- Open surgery, mini-open surgery or arthroscopy can be used for a full-thickness tear accessible to direct repair by suture
- A humeral prosthesis or total reversed prosthesis is indicated for cuff tear arthropathy (Beaudreuil et al, 2010:175).

When combining all components (inclusion and exclusion) of the three studies, the key areas that have been suggested as important to underpin referral for surgery are:

- Age
- Tear site and dimensions
- Fatty infiltration or Tendon Quality
- Bony morphology/position
- Absence of frozen shoulder
- Muscle weakness

²⁸ The reference to 'a later option' was not defined by the authors.

²⁹ Medical treatment was not defined but is assumed to represent medication or injection.

- Refractory pain
- MRI evidence of a tear
- Previous conservative treatment

In addition to the studies which have listed referral criteria, there are a number of studies which have investigated the outcomes of rotator cuff repair surgery in patients with different characteristics such as different age, or varying levels of weakness. The two areas which have been studied most extensively are: tear size (specifically large tears) and fat atrophy. These studies help to demonstrate which patients may be most suitable for surgery, and thus could help to define referral criteria.

Many of the studies investigating the outcomes of rotator cuff repair surgery are small, uncontrolled and non-randomized. They often consist of the analysis of a single surgeon's caseload and thus there is a significant element of bias in many of these studies. The results are often conflicting, such that drawing conclusions regarding optimal surgical outcomes or ideal candidates is difficult. However these studies do help to demonstrate the characteristics that surgeons have investigated and that appear to be important in surgical decision-making. Table 3.2 shows the influence of each parameter on decision-making. Some parameters are useful as they help the surgeon to determine whether the patient's symptoms are consistent with a rotator cuff tear and are thus useful diagnostically. Other parameters influence decision-making because they are an indicator of surgical outcome.

Table 3.2 Influence of criteria parameters on surgical decision-making

Parameters	Parameter useful as an indicator of surgical outcome	Parameter useful to assist diagnosis of a rotator cuff tear
Age	Yes	-
Tear site and dimensions	Yes	-
Fatty infiltration	Yes	Yes
Bony Morphology	Yes	Yes (as cause has been linked to bony impingement)
Absence of Frozen Shoulder	Yes	-
Muscle Weakness	Possibly	Yes
Refractory pain	Yes	Possibly but unreliable
MRI evidence of a tear	Possibly	Yes
Previous conservative treatment	Possibly depending on the type and extent of treatment	Yes

The studies which have investigated the outcomes of rotator cuff tear surgery are now discussed in more detail using the headings compiled from the three criteria studies. Other characteristics which may impact on the outcomes of cuff repair surgery but not identified in the three criteria studies have also been reviewed and are presented at the end of this section. These include functional limitation and repair delay. A quick reference summary of the quality of studies used to evaluate the effect of specific patient characteristics on surgical outcomes is presented in the Appendix 4.

3.4.1 Age

A number of studies of varying quality have investigated whether the age of the patient affects the surgical outcomes. Generally the studies are case series,

with a small number demonstrating statistical analysis. Interestingly, all studies found that older age was correlated with poor outcome. Harryman et al, (1991) investigated functional outcomes after rotator cuff surgery with regard to age and tear size with a prospective case series in eighty-nine patients (105 repairs). They followed patients up to five years postoperatively and compared the functional outcome with the integrity of the cuff using ultrasound. They found that in older patients and those in whom a larger tear had been repaired there were an increased number of recurrent tears.

Oh et al, (2010) undertook a prospective study of 177 patients with a rotator cuff tear to determine the effect of the patient's age on function (as measured by the validated Constant score) and integrity of surgical repair (measured by computed tomography arthrography). They looked at a range of other possible confounding factors such as tear retraction and tear size. When analysing groups with an intact repair and those who experienced re-tear, they found that older age was higher in the group with poor postoperative tendon integrity ($p < 0.001$). The mean ages in the re-tear and intact groups were 63.7 +/- 7.5 and 58.4 +/- 8.7 years, respectively. They also found that the Constant score exhibited a positive correlation with older age, showing worse functional outcomes after surgery were correlated with older age ($p = 0.009$), an increment of 0.313 points could be expected according to each additional year of age.

Kowalsky and Keener (2011) investigated the effect of patient age on surgical outcome in 29 patients with rotator cuff tear, though data was only available for 19 patients at an average follow up of 33 months. They measured tendon integrity with ultrasound and found that patient age had a significant effect on the post operative tendon repair integrity ($p < 0.05$), (i.e. re-tear was related to increased age).

Björnsson et al, (2011) investigated the effect of age in acute rotator cuff tears in a prospective case series of 42 patients with traumatic full thickness rotator cuff tears and no previous history of shoulder symptoms. They were followed

up for an average of 39 months after surgery and results showed that those patients with a re-tear were significantly older than those with intact tendons.

Ide et al, (2007) found an association between increased age and those experiencing re-tear after rotator cuff repair, which implies a possible correlation between age and poor surgical outcome. In their study the patients with a failed repair had a significantly higher mean age (68.4 years compared with 58.1 years for those with an intact repair; $p= 0.014$). Similarly Moulinoux et al, (2007), undertook a case series of 50 patients who had received arthroscopic fixation of a rotator cuff tear. At follow up (average 24 months) they found that 34 patients had “watertight repairs” (68%) and 16 patients experienced a complete re-tear or leakage (32%). Six of the 16 patients with a re-tear had advanced fatty infiltration, 6 were over 60 years old and four had had their tear for more than 24 months. These findings lead the authors to conclude that poorer outcomes were associated with those over 65 years, however these findings relate to small numbers and no statistical analysis was undertaken to demonstrate that these findings were significant.

Maman et al, (2009) undertook a retrospective review of the MRI scans of patients who had sustained a rotator cuff tear (diagnosed by MRI scan 6 months earlier) but who had not undergone surgery. They found that rotator cuff repairs in those patients over 60 years had progressed, and that tear progression was associated with age and follow-up time. The study was relatively small investigating 59 shoulders in 54 patients (mean age 58.8 years), and suggests a possible link between age and cuff tear progression.

Though there are a number of studies indicating that poor outcomes are associated with patient age, it is important to acknowledge that the quality of these studies is low. Non randomized samples, relatively small sample sizes and case series studies were primarily undertaken. The finding that there is a higher rate of cuff repair failure, and an association between worse function after surgery in the older age group does however correspond to the normative studies which indicate that cuff degeneration and the number of tears increases from the age of 50 years. It appears that the lack of consensus regarding

surgery in older patients is reflected by the lack of larger scale studies demonstrating that patient age correlates to poor outcomes. There would be significant value in seeking expert opinion to determine the influence of patient age on surgical decision-making, particularly for those referring to surgery so that appropriate referrals could be made.

3.4.2 Tear Dimensions

Though tear dimensions and the site of the tear have been identified by Moulinoux et al, (2007) as factors which should be considered in surgical inclusion criteria, other studies have been less clear. Several studies have identified that large tears are associated with poor surgical outcomes (Cofield et al, 2001; Ide et al, 2007; Green 2003), but few have taken the step to identify that these outcomes should be used to determine surgical criteria³⁰. Cofield et al, (2001) undertook a prospective long-term study to investigate rotator cuff repairs in 105 shoulders with a chronic rotator cuff tear between 1975 and 1983. Patients underwent open surgical repair and acromioplasty, and were followed for an average of 13.4 years (range, 2-22 years). There were 16 small tears, 40 medium tears, 38 large tears, and 11 massive tears. They showed that satisfactory pain relief was obtained in 96 shoulders ($p < 0.0001$) and significant improvement in active abduction ($p < 0.001$) and external rotation ($p < 0.007$) as well as improvements in strength in these directions of movement ($p < 0.03$ and $p < 0.002$, respectively). They showed that tear size was the most important determinant of outcome with regard to active motion, strength, patient satisfaction, and need for a re-operation (with larger tears leading to poorer outcomes in these areas). They also showed that a large tear size was associated with older age, less pre-operative active motion and pre-operative weakness. However they did not attempt to develop criteria with this information, or suggest which tear sizes should not be considered for surgery.

³⁰ Note tear size classification is as follows: small tears <1cm; medium tears 1-3cm; large tears 3-5cm; massive tears over 5cm (Pill et al, 2012; Ozaki et al, 1988; Cofield 1982).

Ide et al, (2007) found similar results and support the relationship between larger tears and poorer outcomes, but again this information has not been used to recommend inclusion or exclusion criteria. In their prospective case series of 20 patients undergoing repair for full thickness rotator cuff tear, the prevalence of recurrent tears was significantly higher in the patients with severe tendon retraction compared with those with minimal or moderate tendon retraction³¹ ($p = 0.0191$). An earlier study by Harryman et al, (1991) which retrospectively reviewed 89 patients (105 shoulders) in an uncontrolled case series also found a correlation between large tears and the number of re-tears after repair. A review paper by Green (2003) claims that poor surgical outcomes are associated with massive tears but no empirical evidence is provided for the claim.

In a study investigating healing rates in full thickness supraspinatus tears of varying size, Matthews et al, (2006) also supports the claims that large tears are associated with poor surgical outcome. Their biopsy study showed that the tissue from large and massive tears was of a degenerative nature in comparison to biopsies from tendons with a small tear. They concluded that the reparative and inflammatory changes diminished as the size of the rotator cuff tear increased making healing improbable in this group, increasing the risk of re-rupture after surgical repair (Mathews et al, 2006).

In contrast there are two studies which have suggested that tear size is not important with regard to surgical decision for rotator cuff repair. Both studies suggest that good results are obtained irrespective of tear size. Zumstein et al, (2008) investigated the long term outcomes of open rotator cuff repair in 23 patients with massive tears. The initial operative sample had consisted of 27 patients however only 23 returned for follow up. They found that 22 out of 23 patients remained satisfied with the results of surgery 9.9 years after the operation which suggests that tear size may not be a significant determinant of outcome. The results at 3 year follow up showed a typical re-tear rate of 37%.

³¹ Tendon retraction is a descriptor used to represent tear size and is used to denote the distance between the 2 torn ends of the tendon; it represents the distance that must be overcome to stitch the tendon ends back together.

At 10 year follow up the re-tear rate had increased to 57% however the difference was reported to be non significant ($p=0.168$). It is interesting to note that though patients with a re-tear were satisfied with the surgical outcome those with an intact repair had statistically better strength ($p=0.007$) and an overall better outcome as measured by the Constant Shoulder Score ($p=0.002$). Thus it is possible that in high functioning patients, who demand greater post operative strength, the size of the tear is more important.

Burkhart et al, (2001) reported no differences with regard to post operative recovery or post operative function when analysing tear size and concluded that tear size and surgical technique do not influence outcome and thus are not particularly important when determining the referral criteria. They investigated the long-term functional results of arthroscopic rotator cuff repair (average 3.5 years), and analyzed the results by tear size and repair technique with a case series. Sixty two patients were included in the case study, and 59 patients (59 shoulders) were available for follow-up. Pre-operative and post-operative outcomes were assessed by means of a modified University of California at Los Angeles (UCLA) scoring system. Tears were categorized according to size (greatest diameter, number of tendons involved, and pattern of tear specifically crescent shape versus U-shape). Good and excellent results were achieved in 95% of the cases, regardless of tear size. (On the UCLA scoring system 'good' relates to 28 to 33/35; 'excellent' relates to 34-35/35). It is important to note that the UCLA scoring system is considered useful as a measure of overall outcome but is considered to be limited with regard to differentiating between pain and function, (Roddey et al, 2000). This limits the application of these findings and the use of a modified UCLA scoring system which has not been shown to be valid reduces the value of these findings even further.

Within the case studies that have been published it is important to acknowledge that conflict regarding the relevance of tear size exists, however more evidence tends to support the finding that tear size is related to poor surgical outcome. Seeking expert opinion with regard to the influence of tear size would be valuable to determine whether this parameter influences surgical decision-making in the UK.

3.4.3 Tear Site

At present it is unclear whether the site of a tear within a particular tendon influences the outcome of surgery and thus whether this influences surgical decision-making. Kim et al, (2010) undertook a study to determine the most common location of degenerative rotator cuff tears and to examine tear location patterns associated with various tear sizes. Ultrasonograms of 360 shoulders with either a full-thickness (272) or a partial-thickness (88) rotator cuff tear were obtained to measure the width and length of the tear and the distance from the biceps tendon to the anterior margin of the tear. Tears were grouped on the basis of their size (anteroposterior width) and extent (partial or full-thickness). The mean age of the 233 subjects (360 shoulders) was 64.7 +/- 10.2 years. The mean width and length of the tears were 16.3 +/- 12.1 mm and 17.0 +/- 13.0 mm, respectively. After analysis of all tear sites the authors concluded that degenerative rotator cuff tears most commonly involve a posterior location, near the junction of the supraspinatus and infraspinatus muscle. The patterns of tear location across multiple tear sizes suggest that degenerative cuff tears initiate in a region 13 to 17 mm posterior to the biceps tendon.

Tear site appears to be gaining importance with regard to the cause of the tear and it is regularly noted on ultrasound reports confirming diagnosis. No studies could be found which have investigated the outcomes of cuff repair surgery based on different tear sites and there is a gap in the knowledge base with regards to whether this information guides surgical decision-making.

3.4.4 Tear Type

The importance of tear type on the outcome of rotator cuff surgery is also unknown. Only two studies (Feng et al, 2003; Sallay et al, 2007) which consider the influence of tear type have been identified. A study of prognostic indicators for rotator cuff surgery (Feng et al, 2003) has significant limitations. They retrospectively reviewed the records of 1067 patients (1120 shoulders) with rotator cuff tears who were treated by surgery and found that the condition of the tendon and the tear type directly influenced the operative outcome. However, this study appears to have used an unvalidated scoring system

developed by the researchers at the hospital where the research took place and published in conference proceedings only (Nobuhara et al, 1999). The scoring system does not appear to have been published in the research literature and validity and reliability studies cannot be determined.

One other study has also investigated the types of cuff tear and their influence on reparability. In a prospective study of rotator cuff tear type, using intra-articular observation of 193 full thickness rotator cuff tears, transverse tears were the smallest and most common tear type reported (Sallay et al 2007). Transverse tears were found to be easier to repair than U-shaped (tongue shaped) tears. U-shaped tears were found to have less mobility, more retraction and were associated with poorer tissue quality. In this study 38% of U-shaped tears could not be repaired (Sallay et al, 2007).

Overall there is little evidence in this area particularly with regard to selection of appropriate patients for surgery. It appears that outcomes may be better in patients with transverse tears, but these findings are primarily from one surgeon's practice and thus application to the wider population is limited. This is an area that would benefit from further research to determine the impact of tear type on surgical decision-making.

3.4.5 Fatty Atrophy and Infiltration

Surgical Outcomes

The quality of the tendon, the amount of fatty infiltration and the amount of muscle atrophy has been extensively studied and associated with failure after rotator cuff repair surgery (Yamaguchi et al, 2012, Melis et al, 2010; Gerber et al, 2007; Moulinoux et al, 2007; Ide et al, 2007; Feng et al, 2003; Post et al, 1983).

The degree of muscle atrophy or fatty infiltration has been reported to increase with the size of the tear and the duration of time since the injury or tendon rupture (Björkenheim 1989; Tomanek and Cooper 1972). These observations triggered a number of studies to be undertaken to observe the correlation between fatty muscle atrophy and surgical outcome. Studies showed that muscle atrophy and fatty muscle infiltration correlate with poor overall

outcome³³ after surgical repair of rotator cuff tendons as well as correlating with poor function (Goutallier et al, 1994; Goutallier et al, 1999; Harryman et al, 1991). Goutallier et al, (1999) investigated the significance of fat atrophy on the outcomes of rotator cuff surgery in a prospective case series of 74 patients. Patients had a range of tear sizes in different rotator cuff muscles. They found that the stage of fatty degeneration, particularly of the infraspinatus, had an influence on the final range of motion, particularly in external rotation, and on the final strength. Using post operative arthrography they also noted the number of re-tears. They found that re-tears only occurred in the presence of fatty degeneration and concluded that fat atrophy was correlated with re-tear after surgery, (though correlation statistical analysis was not presented). Nakagaki et al, (1995) undertook dissection of 76 shoulders (in 38 cadavers) to investigate changes in the supraspinatus muscle with and without a supraspinatus tear. Anatomical changes indicative of fat atrophy were found at dissection which were different in both tear and non tear groups. Statistical analysis of the differences was not presented and so cannot be clarified further.

Melis et al, (2010) retrospectively reviewed 1688 patients with supraspinatus tears recording the level of fatty infiltration using MRI or Computerised Axial Tomography (CT) scan, the level of muscle atrophy (using the tangent sign), the number of tendons torn and the time between onset of condition and diagnosis. They found that moderate supraspinatus fatty infiltration appeared at an average of 3 years after injury. Though they did not investigate surgical outcomes, they suggested that repair should occur before fat atrophy progressed especially when the tear involves multiple tendons.

Fat atrophy has also been shown to get progressively worse in patients who experience cuff re-tear after surgery, when compared to those who do not (Yamaguchi et al, 2012; Gerber et al, 2007). Yamaguchi et al, (2012) investigated the change in fat atrophy (measured by MRI scan) before and after

³³ Overall outcome is often measured by a validated tool which is made up of a combination of outcomes such as pain, function, range of movement and overall satisfaction. A number of tools are used, see Appendix 1 for further details.

rotator cuff repair in a case series of 24 patients with massive rotator cuff tear. They noted improvement in about half of the patients with a good repair, but in those with a re-tear they noted that fat atrophy became worse. Gerber et al, (2007) undertook a small prospective case study to quantify the development of fat atrophy in 13 patients. The measurement of fat atrophy took place before and after rotator cuff repair with an MRI scan using Goutallier's (1994) grading system³⁴. The results showed that even in successful repair, fat atrophy did not recover well (n=8), and that in those with a failed repair (n=5) the fat atrophy had progressed significantly. They concluded that even very strong muscles were at risk of repair failure because of the presence of fat atrophy. Research from animal studies has also shown that these changes are poorly reversed even after repair of the tendon (Gerber et al, 2004).

A number of case studies have indicated that fat atrophy leads to poor surgical outcomes (Goutallier et al, 1999; Harryman et al, 1991) and that fat atrophy has been shown to progress and deteriorate in those with re-tear (Yamaguchi et al, 2012; Gerber et al, 2007). The number of studies which have investigated fat atrophy suggest that this continues to be an important area for those involved in rotator cuff surgery. The recommendations by Moulinoux et al, (2007) that patients with fat atrophy should be excluded from surgery suggest that this is a key area where referral criteria could be useful to guide practice. However issues related to identification of fat atrophy complicate the picture and will be considered in the next section.

Identification of Fat Atrophy

A range of methods to determine the quality of the tendon–muscle tissue have been developed including observation of fatty infiltration of the muscle with CT (Goutallier et al, 1994) and MRI (Gerber et al, 2007); measurement of muscle volumes with MRI or CT (Tingart et al, 2003); and the measurement of

³⁴ Fat Atrophy Scale: Stage 0= Normal; Stage 1= Fatty streaks; Stage 2= Significant fat, but muscle bulk greater than fat; Stage 3 = Muscle bulk equal to fat; Stage 4= Fat greater than muscle bulk (Goutallier et al, 1994)

supraspinatus muscle atrophy, by measurement of the cross sectional area with MRI (Thomazeau et al, 1996) or ultrasound (Kavanagh et al, 2008; Khoury et al, 2008; Sofka et al, 2004). MRI measurements of cross sectional area are commonly referred to in the literature as the 'occupation ratio' (Thomazeau et al, 1996), 'scapula ratio' (Thomazeau et al, 1996) or the 'tangent sign' (Zanetti et al, 1998). The measurement of muscle volume has been validated (Tingart et al, 2003) but has been identified as impractical for use by clinicians (Morag et al, 2006). Reliability and validity studies for the other methods such as the observational grading systems are scarce and no gold standard method for detection of tendon quality or muscle atrophy has been identified.

The commonest method in use appears to be an observational grading system developed by Goutallier et al, (1994). This grading system was originally developed with CT scan but more recently MRI has been used to observe the changes within the muscle/tendon (Gerber et al, 2007). The original grading system aims to identify the different levels of fat atrophy within the muscle and is shown below:

Stage Appearance

Stage 0= Normal

Stage 1= Fatty streaks

Stage 2= Significant fat, but muscle bulk greater than fat

Stage 3 = Muscle bulk equal to fat

Stage 4= Fat greater than muscle bulk.

Goutallier et al, (1994) showed that in ruptured rotator cuff tendons, fatty degeneration of the muscles was correlated with both the age of the rupture and the age of the patient. Their study assessed fatty degeneration within the rotator cuff muscles of 63 patients scheduled for a rotator cuff repair using the grading structure with CT scans preoperatively and then 17.7 months after repair. Using the grading structure they found that at stage 3 and stage 4, fatty degeneration of the cuff muscles was often irreversible even after surgical

repair of the cuff. They concluded that that fatty degeneration of stage 3 and 4 was associated with a poorer clinical outcome.

Thomazeau et al, (1996) undertook a study to determine whether it was possible to quantify supraspinatus muscle atrophy with MRI scan firstly in five cadavers, and then in 55 patients with a rotator cuff tear, respectively. They proposed that they were able to measure the area between the surface of the muscle belly and the suprascapular fossa (occupation ratio) in a control group, in patients with a degenerative cuff before surgery and in post operatively repaired cuff tears. The findings suggest that this measurement method could be applied in clinical practice, or at least applied within radiology departments. As explained earlier research findings suggest that fatty infiltration and fat atrophy is associated with poor surgical outcome, therefore evaluation of these parameters should be important when selecting appropriate patients for surgery. However, reliability studies for these advanced measurement techniques are rare and the use of these measurements does not seem to be a feature of the day to day assessment procedures used in standard orthopaedic departments.

Two studies have evaluated orthopaedic surgeons' ability to reliably assess the level of fat infiltration or fat atrophy and the findings showed that these methods were not reliable in practice. Spencer et al, (2008) examined the inter-observer reliability of ten fellowship trained experienced orthopaedic shoulder surgeons when assessing a range tendon characteristics with MRI. They showed that the level of agreement between surgeons when observing the quantity of the supraspinatus muscle (such as volume/area), or the appearance of fat atrophy with Goutallier's grading structure was very poor. The Kappa statistic for level of agreement was $k=0.25$ and $k=0.1$ respectively, where $k=1.0$ is perfect agreement and $k=0$ is no agreement (Landis and Koch 1977). Similarly, poor levels of agreement have been shown by Lippe et al, (2012). Their study examined inter-observer agreement with three shoulder surgeons using MRI to determine fat atrophy using Goutallier's classification. The level of agreement among surgeons on this occasion was moderate ($k=0.53$).

It appears that fat atrophy is a key factor associated with poor surgical outcome and that identification prior to surgery would be useful so that the most appropriate patients for surgery can be selected. However there is a lack of clarity within the literature with regard to gold standard measurements and reliability of the assessment tools. The standard orthopaedic medicine examination does not include these measurement techniques (Magee 2007), nor does the advanced examination procedure recommended for shoulder surgeons (Maffulli and Furia 2012).

It is clear that the impact of fat atrophy on surgical outcomes has received much attention from surgeons within this field as there are a number of published case studies. Despite the lack of robust evidence it appears as though fat atrophy is considered important with regard to the prognosis of rotator cuff repair. The lack of a gold standard for reporting fat atrophy and the lack of reliability with regard to detection of fat atrophy by clinicians adds complication, as the prognostic value remains unclear. There is a need to determine the influence of fat atrophy on surgical decision-making so that patient care can be optimised and appropriate patients can be referred.

3.4.6 Bony Morphology

Moulinoux et al, (2007) and Warner et al, (1997) have both included the presence of specific morphological bony changes (acromial and humeral) in their exclusion criteria. Moulinoux et al, (2007) highlighted that subacromial narrowing (of less than 7mm) should be included as part of the exclusion criteria for cuff repairs, where as Warner et al, (1997) indicated that humeral head migration should be an exclusion (both bony changes result in similar problems). Beaudreuil et al, (2010) recommended that the outcome of surgery depends on morphological factors but were not specific about the type of bony morphology associated with poor outcome.

Historically textbook information on this matter includes changes such as subacromial spurs, subacromial narrowing or humeral head migration (Magee 2007). Interestingly, despite many common orthopaedic texts indicating that

bony spurs and humeral migration are associated with the development of cuff tears (Magee 2007; Maffulli and Furia 2012), the empirical evidence supporting this assertion is very limited and only one study could be found to support this theory. Keener et al, (2009) showed that proximal humeral head migration was greater in shoulders with a symptomatic tear ($P=0.03$), when compared to those with an asymptomatic tear, i.e. migration correlates with symptoms. However more substantial evidence indicating that morphological changes actually correlate with the deterioration of cuff tears could not be found. Though these findings directly support the use of 'humeral migration as a predictor of symptoms, there is no existing empirical evidence to demonstrate that bony change, such as humeral head migration is significantly correlated with poor surgical outcome.

3.4.7 Loss of Range and Frozen Shoulder

Moulinoux et al, (2007) indicated that one exclusion criterion for rotator cuff repair is acute phase frozen shoulder. Candiotta et al, (2002) has also found that reduced range of movement is associated with poorer post operative outcomes which indicates that this may be a useful determinant within a surgical criteria. They retrospectively evaluated 134 patients with chronic subacromial impingement syndrome (81 female and 53 male, with a mean age of 56.4 years). After a mean follow-up of 1.3 years (range 8 months - 2 years), good or excellent results were obtained in 87% of the patients with rotator cuff tears without loss of active motion, and in 75% of the cases with loss of active motion. Data was presented descriptively and detailed statistical analysis was not carried out. Therefore it is difficult to conclude whether this difference is statistically significant.

Even though reduced range of movement has been associated with poorer surgical outcome it is important to acknowledge that patients may have reduced range for several reasons. Reduced range is commonly associated with frozen shoulder but may also occur as a result of chronic, ongoing pain or inflammation. Thus exclusion based on this parameter may be unreasonable

as the tear itself may be responsible for reduced active range as well as the frozen shoulder. Ko and Wang (2011) have also acknowledged that stiffness may be present in rotator cuff tear patients due to the role of the subacromial bursa. They suggest that in patients with rotator cuff lesions and frozen shoulder an approach of manipulation, lysis, acromioplasty and rotator cuff repair may be useful in patients who do not improve after 3 months of aggressive conservative rehabilitation. There is lack of evidence available in this field such that conclusions regarding the impact of shoulder stiffness or frozen shoulder on surgical decision-making in cuff tears are difficult to draw. Further evidence in this field would be useful.

3.4.8 Muscle Weakness

Weakness and Surgical Outcomes

Beaudreuil et al, (2010) listed shoulder muscle weakness within their referral criteria as a reason to proceed with rotator cuff repair, along with pain and a disabling shoulder condition which does not respond to treatment. However, in contrast, Warner et al, (1997) suggested that an association between weakness and friable tendon tissue in chronic rotator cuff tears led them to exclude patients with muscle weakness from their study investigating arthroscopic rotator cuff repairs, though it is not clear how weakness or chronicity were evaluated.

Empirical studies investigating the association between a specific level of weakness, for example 3/5 using the Oxford Scale, and poor surgical outcomes are scarce. When investigating the impact of fat atrophy, a small study (n=13) by Gerber et al, (2007) showed that poor outcomes were related to weakness, but primarily in the presence of fat atrophy and fatty infiltration. Gerber et al, (2007) investigated the relationship between strength and muscle atrophy in 13 patients with rotator cuff tear, by measuring intra-operative muscle strength with muscle stimulation whilst patients were anaesthetized. They showed that weakness at the time of the repair was correlated with fat atrophy ($P < 0.003$), and that this weakness persisted post operatively in some patients, particularly

if the repair failed (n=4). Further studies with regard to the surgical outcomes of patients with weakness are needed to show conclusive evidence in this area. This evidence would help to guide referrers with regard to whether patients with rotator cuff tear and weakness were suitable for surgery or more suitable for conservative management.

Muscle Weakness and Rotator Cuff Tear Diagnosis

Muscle weakness (in the range of abduction and lateral rotation) has been associated with rotator cuff tear in both asymptomatic and symptomatic rotator cuff tears (Yamamoto et al, 2011; Meyer et al, 2011a; Kim et al, 2009; Feng et al, 2003; Wolfgang 1974). This suggests that weakness may be an important factor in confirming rotator cuff tear prior to referral and that it may be important in surgical decision-making.

In a fairly large prospective normative study (n=237) Kim et al, (2009) found that those with asymptomatic large or massive rotator cuff tear had significantly reduced abduction strength in the affected limb. They found that in those patients with a tear, their lateral rotation strength was not reduced in the same proportion, suggesting that abduction strength was a much more valuable indicator of rotator cuff tear. They found that in the shoulders with a large-to-massive full-thickness rotator cuff tear, abduction strength was significantly decreased ($p = 0.007$). Additionally, the ratio of abduction strength to external rotation strength was significantly decreased in the shoulders with a large-to-massive full-thickness tear compared with the shoulders with an intact rotator cuff ($p < 0.001$) (Kim et al, 2009).

In a prospective medical screening programme Yamamoto et al, (2011) also observed the characteristics of symptomatic and asymptomatic rotator cuff tears within the normal population (n=283 shoulders). They found that in the symptomatic group, weakness of lateral rotation was a significant finding rather than weakness of abduction. They also demonstrated that in the group with asymptomatic rotator cuff tears (65.4%), normal levels of abduction and lateral rotation strength were present which demonstrates the importance of weakness as an indicator of symptomatic rotator cuff pathology.

Thus on assessment the finding of weakness may demonstrate the presence of a symptomatic cuff tear and its presence may be important diagnostically, but it is not necessarily an indicator of good or poor outcome. The correlation between weakness and symptomatic rotator cuff tears, does suggest that weakness is important in screening prior to surgery to enable those with referred pain from other areas or those with other undiagnosed pathologies to be excluded from the group referred for cuff repair.

When reviewing the literature with regard to screening for muscle weakness the studies which have investigated the diagnostic accuracy of muscle strength tests tend to be retrospective case series and therefore must be considered with some caution. A study by Itoi et al, (2006) retrospectively reviewed the case notes of 149 patients with rotator cuff tears or rotator cuff tendinitis (n=160 shoulders). The diagnostic accuracy of manual resistance tests for supraspinatus and infraspinatus muscle weakness were evaluated along with the active 'lift off' test for subscapularis muscle weakness. They found that the supraspinatus test was an accurate indicator of rotator cuff tear when weakness was evident on manual muscle strength testing at less than grade 5 on the Oxford Scale. The external rotation strength test was most accurate with weakness evident on testing at less than grade 4+ on the Oxford scale and the lift off test was most accurate with a threshold less than grade 3 on the Oxford scale.

A review by Diehr et al, (2006) came to similar conclusions with regard to the diagnostic selection of patients with shoulder pain with possible rotator cuff tears. They identified that (for those under 60 years of age) three clinical tests were highly predictive of rotator cuff tear diagnosis when found to be positive. The tests were supraspinatus strength, infraspinatus strength, and impingement testing. For those over 60 years of age only two of these tests need to be positive to be highly predictive of rotator cuff tear. In each case (both under and over 60) there was a 98% chance of having a rotator cuff tear, no further statistical information was given to support these findings.

In a retrospective study of 301 patients with arthrographically proven rotator cuff tear Litaker et al, (2000) found similar results to Diehr et al, (2006). Litaker et al, (2000) investigated the diagnostic accuracy of a range of diagnostic tests including strength of the supraspinatus and infraspinatus muscles, impingement tests, night pain, age and active shoulder movements. Using linear regression they found that weakness of external rotation, age greater or equal to 65 years, and night pain, were strong predictors of the presence of a rotator cuff tear. The adjusted odds ratio (AOR) for weakness with external rotation was 6.96 (3.09, 13.03). AOR for age greater than or equal to 65 was 4.05 (2.47, 16.07). AOR for night pain was 2.61 (1.004, 7.39).

Though the influence of the level muscle strength or the duration and chronicity of muscle weakness on surgical outcome is unknown, there are a growing number of studies (ranging in quality) which indicate that identification of muscle weakness is important in the clinical diagnosis of symptomatic rotator cuff tears. External rotation and abduction strength appear to be important, and weakness below grade 5 for abduction and below grade 4+ for lateral rotation on the oxford scale for manual resistance testing have been shown to be diagnostically valuable.

As with measurement of muscle atrophy, reliable quantification of muscle strength is considered to be poor (Longo et al, 2011) which adds further confusion as to whether muscle strength should be used within criteria for surgery. The lack of evidence regarding the outcomes of surgery in patients with weakness demonstrates the need for more research in this area. Muscle weakness is a key component of the standard orthopaedic and physiotherapeutic examination and it is important that the relevance of this parameter on surgical decision-making is evaluated.

3.4.9 Refractory Pain

Refractory pain is included in the surgical inclusion criteria outlined by both Warner et al, (1997) and the broad guidelines outlined by Beaudreuil et al, (2010). Refractory pain is defined as that which is persistent or chronic in

nature (Taylor 2006), Smith et al (2012) suggest a time period of one year. Refractory pain also features in the inclusion criteria developed by consensus for hip and knee arthroplasty surgery (Naylor and Williams 1996; Quintana et al, 2000; Musila et al, 2011). However this is perhaps the most contentious parameter to be used to select appropriate patients for surgery due to the subjective nature of pain symptoms. Neither Quintana et al, (2000) nor Musila et al, (2011) evaluated the problems of including a subjective component which is so affected by emotional, psychological or social issues, despite the fact that it is firmly acknowledged that pain is a complex construct involving psychosocial and emotional factors (Jeffery et al, 2011; Gatchel et al, 2007; Orbell et al, 1998). Naylor and Williams (1996) however did note the difficulty of using a subjective parameter within the criteria.

Cofield et al, (2001) evaluated clinical outcomes after rotator cuff surgery in 81 patients and found 90% of patients reported satisfactory long term pain relief (13 years) in comparison to pre-operative levels. These findings show that rotator cuff repair has a positive impact on pain relief, even in the long term. However studies showing surgical outcomes in patients with a range of different pain characteristics or pain states (i.e. severe night pain versus pain on overhead activity) have not been conducted. Thus it is not possible to say that pain is a good indicator of patients who should be referred for surgery. It is possible that severe levels of pain could be seen by many surgeons as an important pre-requisite for surgery, or an indicator of need, rather than a parameter associated with good outcomes.

The available research evidence suggests that chronic pain and biopsychosocial factors may impact on the outcome of orthopaedic surgery (Koljonen et al, 2009; Gatchel 2001; Mayer et al, 1998; Orbell et al, 1998). A qualitative study undertaken by Jeffery et al, (2011) found that patients with ongoing chronic pain and distress after total knee replacement surgery did not result purely from pain intensity, but were related to an individual's illness beliefs and their perceptions of their condition in a social context, which is in line with other similar studies in chronic pain patients (Lopez-Martinez et al, 2008; Harris et al, 2003). There is also experimental evidence to demonstrate that

health clinicians who consider psychosocial factors in the patient assessment as opposed to assessment with a purely biomedical approach have shown improvement in patients' beliefs and attitudes towards recovery (Domenech et al, 2011). Patients' beliefs and the beliefs of health professionals are thus shown to be important factors in patients with ongoing pain and distress and are likely to influence the outcome of surgery.

No research within the rotator cuff field has identified that surgeon's decisions are influenced by the patient's pain or the findings of the psychosocial assessment. The studies reviewed in this thesis suggest that psychosocial issues can influence surgical outcome, and thus could influence surgical decision-making. It is unclear however whether the severity of pain affects the surgical outcome or influences surgeon behaviour in a different way. The research by Jeffery et al, (2011) adds weight to the importance of finding surgeons' views about the impact of psychosocial issues on surgical decision-making as well as pain severity.

3.4.10 MRI Evidence and imaging

One area which has been widely studied is that of appropriate investigations for rotator cuff tears. As indicated by Warner et al, (1997) patients must have an appropriate investigation completed before surgery which indicates that a tear exists. They recommended MRI, as well as a radiograph to exclude humeral head migration. No other studies have listed which investigations they consider necessary before surgery is undertaken, but studies have investigated the sensitivity and specificity of MRI and ultrasound when diagnosing cuff tears (Teefey et al, 2004; Vlychou et al, 2009).

Vlychou et al, (2009) investigated the sensitivity and specificity of ultrasound and MRI in the detection of rotator cuff tears comparing the imaging results to open or arthroscopic findings. Fifty-six patients (17 men, 39 women; mean age 53.7 years) were included in the study, with symptomatic impingement syndrome of the shoulder after having failed to respond to conservative treatment. All patients underwent ultrasound and MRI scans prior to surgical intervention. Arthroscopy or mini-open surgery revealed 53 cases with partial

tears of the rotator cuff and three with extensive tendinopathy. Both imaging modalities successfully detected 44 cases of partial tears of the supraspinatus tendon. Ultrasound imaging yielded a sensitivity of 95.6%, a specificity of 70%, an accuracy of 91%, and a positive predictive accuracy of 93.6%. The corresponding values for MRI were 97.7%, 63.6%, 91%, and 91.7%, respectively. The authors concluded that ultrasound imaging can be considered almost equally as effective as MRI when detecting partial tears of the rotator cuff, particularly those located in the area of the supraspinatus tendon. They recommended that MRI could be reserved for doubtful or complex cases, in which delineation of adjacent structures is mandatory prior to surgical intervention.

Teefey et al, (2004) found comparable results when they prospectively studied 124 patients with shoulder pain. They compared the MRI and ultrasound findings with the results following arthroscopy. They concluded that the decision regarding which test to perform for rotator cuff assessment does not need to be based on accuracy concerns as both had comparable levels of accuracy. The choice can be based on other factors, such as the importance of ancillary clinical information (regarding lesions of the glenoid labrum, joint capsule, or surrounding muscle or bone), the presence of an implanted device, patient tolerance, and cost. As discussed above, the practice of imaging with either MRI or ultrasonography, to demonstrate the presence of a rotator cuff tear is well established and supported by research evidence. Where the evidence is more limited is whether to investigate for bony morphological changes such as subacromial narrowing, humeral migration and subacromial spurs.

3.4.11 Previous Conservative Treatment

Beaudreuil et al, (2010), recommended that a period of conservative treatment should take place before surgery. Recent review studies have highlighted that high quality studies investigating the outcomes of conservative versus surgical treatment for rotator cuff repair are scarce (Lambers Heerspink et al, 2011; Longo et al, 2012). The view put forward by Beaudreuil et al, (2010), was supported by a recent review by Chaudhury et al, (2010) which outlined

management options for patients with shoulder pain. They concluded that regardless of cause, shoulder pain can be effectively treated conservatively with rest, physiotherapy and steroid injections, and this should be attempted for up to 6 months.

3.4.12 Repair Delay

Burkhart et al, (2001) investigated whether outcomes varied in those with varying levels of delay before surgery and concluded that delay between injury and surgery, even of several years, did not adversely affect the surgical outcome. The healing rate study discussed earlier by Matthews et al, (2006) (section 3.4.2 page 98) also found that there was no association between increased duration of symptoms and poor healing rate. Both studies concluded that increased time between injury and repair was not considered as a contraindication to rotator cuff repair.

In contrast, Petersen and Murphy (2011) recently conducted a prospective study of 42 consecutive traumatic rotator cuff tear patients and found that massive tears which were repaired after 4 months had the worst outcomes. They recruited a small non randomized sample (n=42) which reduces the applicability of the findings to a wider patient population. They also investigated traumatic rather than degenerative tears which means that the results do not necessarily apply to the majority of cuff tears seen³⁵. Patients suffering from traumatic rather than degenerative tears are likely to respond better to surgery as the quality of tendon tissue is generally better (Pill et al, 2012). Therefore it is possible that delay between injury and repair may be even more significant in the degenerative tendon group.

Another study investigating the point at which fat atrophy develops in supraspinatus tears suggested that rotator cuff repair should be performed before the appearance of fatty infiltration (Stage 2) and muscle atrophy (tangent

³⁵ Note the aetiology of rotator cuff tears is primarily degenerative rather than traumatic.

sign³⁶), especially when the tear involves multiple tendons (Melis et al, 2010). They retrospectively reviewed the clinical details of 1688 patients with rotator cuff tear recording the level of fatty infiltration using MRI or CT scan, the level of muscle atrophy (using the tangent sign), the number of tendons torn and the time between onset of condition and diagnosis. They found moderate supraspinatus fatty infiltration appeared at an average of 3 years after onset of symptoms and severe fatty infiltration at an average of 5 years after the onset of symptoms. A positive tangent sign appeared at an average of 4.5 years after the onset of symptoms. Thus this study suggests that the duration of time between injury and repair is important.

The studies discussed earlier in the section on tear size also demonstrated that large, chronic tears are associated with poor outcomes (Cofield et al, 2001; Ide et al, 2007; Zumstein et al, 2008). In an animal model, Meyer et al, (2011a) identified that chronic tendon tears are associated with retraction, fatty infiltration, atrophy and loss of muscle strength. A human study by Meyer et al, (2011b) also adds further weight to the argument that delay between injury and repair is important. In their study, quantitative evaluation of the retracted ends of the tendon demonstrated that in chronic tears both the tendon stumps and the muscle unit were retracted. Though they could not identify the exact stages of shortening for each part of the muscle-tendon unit, they consider it likely that the tendon shortens in the early stages of the injury, and then muscle shortening increases with chronicity and with the presence of fat atrophy. The finding of increasing shortening suggests that repair will become more difficult over time, and though it is acknowledged that repair failure is not always associated with a poor outcome (Jost et al, 2000; Gerber et al, 2000), the risk of repair failure is likely to increase (Meyer et al, 2011b).

³⁶ A normal supraspinatus muscle should cross superior to a line drawn through the superior borders of the scapular spine and the superior margin of the coracoid process. When below this marker it is called a positive tangent sign and is an indicator of advanced fatty infiltration Williams et al, (2009).

3.4.13 Functional Limitation

Functional limitation has not been identified as a factor which should be considered as part of surgical criteria for rotator cuff tear, however it is a parameter, like pain, which tends to be interpreted as an indicator of severity and perhaps surgical need or priority³⁷. No studies have identified that a specific level of pre-operative function results in a better outcome, but it is possible that severe functional impairment could be seen by some as an important pre-requisite for rotator cuff surgery. Equally, as is the case in muscle strength testing (Warner et al, 1997), severe functional loss could be seen as an indicator that rotator cuff repair surgery is not appropriate and that other surgical options may be preferable. For example it is possible that in the presence of severe functional limitation a reverse shoulder arthroplasty³⁸ rather than a rotator cuff repair would be more appropriate. Therefore it is important to clarify whether functional limitation is a parameter that influences surgical decision-making.

Gazielly et al, (1994) investigated the anatomic condition of the rotator cuff and the impact of occupational use after surgery, in a homogeneous series of 100 full thickness cuff tears in 98 patients (average patient follow up of 4 years). In a regression analysis they found that there were three predictors of re-tear, which were size of the tear (accounting for 57% of re-tears), age of the patient (accounting for 25% of re-tears), and the degree of occupational use (accounting for 18% of re-tears). Though the likelihood of re-tear is correlated more strongly with the size of the tear and the age of the patient, this is one of the few studies that identified that the occupation and hobbies of the patient may have an impact on the success of the surgery, and thus may influence surgical decision-making.

³⁷ Functional limitation is defined as “any health problem that prevents a person from completing a range of tasks, whether simple or complex” (Jonas 2005).

³⁸ A reverse shoulder arthroplasty is a partial shoulder replacement which tends to be undertaken in severe cuff tears which involve bony damage.

There is very limited evidence to support the use of function as a parameter which influences surgical decision-making in rotator cuff tear. Gazielly et al, (1994) suggests that the degree of occupational use may correlate with re-tear which may influence patient selection. However it is also possible that surgeons only use function as a measure of surgical need as may occur in the pain dimension. Currently the value of function within the decision-making process for rotator cuff repairs is unknown.

3.4.14 Summary of Section 3.4

In summary there are no current evidence based referral criteria for patients with rotator cuff tear. Three studies (two case studies and one review) have attempted to highlight basic referral criteria for rotator cuff repair and a range of parameters to identify appropriate patients for surgery have been suggested (Warner et al, 1997; Moulinoux et al, 2007; Beaudreuil et al, 2010). There are also differences between the recommendations indicating a lack of consensus.

Studies that have been published to demonstrate patient outcomes after rotator cuff surgery help to show the factors which may influence surgical decision-making. However the results from these studies generally show a high level of variance in agreement for a range of parameters. The studies are case studies or case control studies with a high risk of confounding bias or chance (Scottish Intercollegiate Guidelines Network 2002). Such studies are considered to be low in the hierarchy of evidence to support the development of guidelines (Scottish Intercollegiate Guidelines Network 2002). A detailed comparison of the type of study, listed by author, grouped by parameter can be found in Appendix 4, which enables the quality of evidence which supports each parameter to be seen.

The key parameters identified from the three main published studies which could form the basis of inclusion and exclusion criteria are: patient age, the site/dimensions of the tear, tendon quality, bony morphological factors, range of movement, muscle weakness, refractory pain and the presence of radiological evidence such as MRI (Warner et al, 1997; Moulinoux et al, 2007; Beaudreuil et

al, 2010). Other studies have also identified that a delay between injury and repair (Petersen and Murphy 2011) and level of function (Gazielly et al, 1994) may also influence surgical outcomes.

The lack of agreement with regard to surgical referral criteria impacts on the ability of ESPs to make appropriate referrals to secondary care. The conflicting research findings help to explain why conversion rates are so low in the shoulder specialty. In the absence of high quality studies with conclusive outcomes, there is a need to develop referral criteria through consensus to improve the consistency and efficiency of ESP referrals and most importantly to improve the quality of patient care.

3.5 Implementing Evidence in Practice

The introduction of referral criteria has been reported to be necessary to improve efficiency within orthopaedic services (Lowry et al, 1991; Speed and Crisp 2005). However the effects of introducing referral guidelines or criteria on clinician behaviour are not clearly understood (Hakkennes and Dodd 2008). The last section of the literature review will consider factors associated with implementing new referral criteria into practice, the effect on referral behaviour and the possible effects on clinical care.

3.5.1 Evidence Based Guidelines

Evidence Based Medicine (EBM) was defined by Sackett et al, (1996) as “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.” Though consensus through expert opinion is not considered to be the best evidence, judged for example against the hierarchy of evidence used by Sackett et al, (1996), in the absence of high quality research evidence it may be the only evidence available. Within health care, EBM is considered to be desirable to ensure that public money is spent wisely on interventions which have been shown to be effective. Some areas within the MSK and orthopaedic field have been investigated with regard to the development of consensus based referral criteria for knee and hip arthroplasty (Musila et al, 2011; Quintana et al, 2000), but their findings are limited. In other areas such as back pain or osteoarthritis, evidence based

guidelines for optimum management have been published (NICE CG59 Osteoarthritis 2008; NICE CG88 Low back pain 2009).

Those in favour of EBM present a view that it is a path from scientific research to developments in clinical practice (Armstrong 2007). However it has been identified that dissemination of information via national publications (such as NICE guidelines) and books is largely ineffective (Evans et al, 2005; Van Tulder et al, 2002; Cabana et al, 1999; Kallmes 1998). Consideration of the factors influencing the implementation of referral criteria are important if changes in clinical practice are to be made. Currently the lack of evidence-based referral criteria for rotator cuff tear pathology means that it is very difficult for ESPs to refer these patients appropriately for surgery. However even if guidelines were available it is important to consider whether they would have an impact on ESP referral behaviour.

3.5.2 Changing Referral Behaviour

Within the management of rotator cuff pathology a number of factors are likely to influence referral behaviour. Barriers to referral in general for ESPs and other professionals working in primary care have already been considered. Through a combination of studies investigating GP and ESP behaviour it was suggested that referrals made by ESPs could be adversely affected by the primary care environment through poor communication and isolation (Dawson and Ghazi 2004; Augestad et al, 2008); by the lack of surgical criteria or consensus (Byles and Ling 1989; Lowry et al, 1991; Madok and Green 1994; Gardiner and Turner 2002; Speed and Crisp 2005; Musila et al, 2011; Belthur et al, 2003; NHS Institute 2009), or lack of clinical support and supervision (Weatherley and Hourigan 1998; Elliot et al, 2011).

As well as acknowledging the existence of current referral barriers, it is also important to consider how referral behaviour might be influenced by the introduction of referral criteria. In a review of studies which have attempted to change referral behaviour between primary and secondary care, Faulkner et al, (2003) noted that professional interventions (i.e. education, training or guidelines) generally had an impact on referral rates consistent with the

intended change in clinician behaviour. Similarly, specialist 'outreach' or other primary care-based specialist provider schemes had at least a small effect upon referral rates to secondary care with the direction of effect being that intended.

The review initially identified 139 studies, 44 of which met their inclusion criteria. They considered the change in referral behaviour and reviewed the strategies which had been used to change referral behaviour. They were unable to draw conclusions about successful methods which had changed referral rates between primary and secondary care because the studies identified were extremely diverse in methodology, clinical speciality, organisational structure, and the quality of evidence.

Grimshaw et al, (2004) undertook a systematic review of the effectiveness and costs of different guideline development, dissemination and implementation strategies within the UK. In total 235 studies met the inclusion criteria and in these studies the majority of interventions observed modest to moderate improvements in care. Overall they found that there was a limited evidence base to support decisions about which guideline dissemination and implementation strategies are likely to be most effective or efficient. They suggested that further research was required before optimum health professional and organisational behaviour to effectively implement change in health care could be determined.

Hakkennes and Dodd (2008) reviewed the literature pertaining to the effectiveness of the guideline dissemination and implementation strategies used within the research of allied health care professionals. A number of studies were reviewed: 14 met their inclusion criteria and of these 10 focused on educational interventions. Six of the 14 used a single intervention, seven used a multifaceted strategy and one compared the two strategies. As with Grimshaw et al, (2004) they found that there was no evidence to support a specific guideline implementation strategy for allied health care professionals. They found no difference between multifaceted and single approach strategies and recommended that it was important to first identify specific barriers to change and then to develop strategies that deal with these barriers.

When considering possible barriers which may impact on the use of referral guidelines by ESPs, the study undertaken by Michie et al, (2005) provides details of the number and type of dimensions which could affect behaviour when trying to implement guidelines. They undertook a consensus review using three groups of experts including a psychology theory group, a health psychology group and a health services research group. Following consensus, several domains important for successful behaviour change with regard to guidelines were identified which included; knowledge and skills, beliefs, decision processes (i.e. motivation, goals, memory), and the environmental context.

The findings of Michie et al, (2005) are similar to earlier work in behavioural change in the field of smoking cessation. The transtheoretical model of change proposed by Prochaska and DiClemente (1983) also highlights that the decision- making abilities of the individual, their self efficacy and self belief are key components of successful behaviour change.

While the exact barriers to implementing guidelines within primary care ESPs are unknown, they are likely to stem from a number of the dimensions listed by Michie et al, (2005). Barriers including access to existing knowledge and training, clinical reasoning, organisational factors and beliefs are explored in the following sections.

3.5.3 Knowledge and Clinical Reasoning Among ESPs

Clinical skill and judgement is required to identify, interpret and apply evidence and knowledge to practice (Bonisteel 2009). Although patient preference is recognized in evidence based medicine, the nature of guidelines and criteria mean that there is a tendency to emphasize routine and standardized approaches to treatment (Donald 2001) rather than offering individualised care, through the interpretation and subsequent application to each individual. It is acknowledged that in practice, for EBM to be useful it must use an interpretive approach. It must bridge a gap between research knowledge, knowledge derived from the patient experience (Whitley et al, 2011) and knowledge or experience derived from the clinician. Ensuring that emphasis is placed on the

interpretive dimensions of EBP may help clinicians to guard against a one-size-fits-all approach to referral criteria and clinical interventions (Whitley et al, 2011).

When considering ESP knowledge acquisition it is important to consider how ESPs currently practicing at the interface between primary and secondary care acquire and develop their knowledge, clinical reasoning and judgement skills. Currently there is no formal or accredited training in place for ESPs (Weston-Simons 2012). The lack of structured training may mean that it is very difficult for ESPs to develop into this role, particularly as it encompasses knowledge and skills which are not presently within the physiotherapy undergraduate curriculum such as radiological image interpretation and analysis of pathological tests (Ruston 2008; CSP 2002). These skills were previously confined to the role of doctors (Ruston 2008), however now physiotherapists have taken on the roles previously attributed to medics, training in these skills needs to be addressed. The outcomes of radiological, pathological or other advanced tests may impact on referral decisions and thus how and when ESPs obtain and develop these skills is important. As well as knowledge acquisition an ESP's ability to clinically reason and apply knowledge is also important.

Clinical reasoning within the practice of MSK ESPs is based on a primarily biomedical approach (Daykin and Richardson 2004; Frost et al, 2004; Jorgensen 2000). The biomedical model of clinical practice is characterized by a set of positivist assumptions (e.g. knowledge is objective and measurable) (Higgs and Titchen 2000) and uses a particular form of reasoning or problem solving known as hypothetico-deductive reasoning. The hypothetico-deductive model of clinical reasoning remains the most appropriate and relevant means of identifying and assessing physical impairment within physiotherapy (Edwards and Richardson 2008; Elstein et al, 1990). No studies have investigated ESP clinical reasoning models directly, but as the role is an amalgam of physiotherapy and medicine, it is reasonable to assume that the reasoning frameworks are the same.

In the hypothetico-deductive method, clinicians attend to initial information from or about the patient. From this information, tentative hypotheses are generated. For example during the diagnostic process ESPs use objective tests such as measurement of muscle strength, ligament integrity, joint range of movement, radiological images and blood counts which are compared for deviations from 'normal values' and analysed with the underlying knowledge of the course of the disease process (Carpenter 1996; Higgs and Titchen 2000). The generation of hypotheses is followed by ongoing analysis and interpretation of patient information and clinical data. Continued hypothesis creation and evaluation take place with ongoing assessment and treatment allowing the various hypotheses to be confirmed or negated (Hastie 2001; Elstein et al, 1990). To achieve the required levels of decision-making significant cognitive demands on clinician memory are required along with demands on attention (Michie et al, 2005).

Though there are no studies that have investigated the skills and clinical decision-making of ESPs, it has been acknowledged that clinical decision-making is a fundamental component of standard physiotherapy clinical practice (Smith et al, 2008). High levels of accountability in decision-making are expected in physiotherapists and evidence based practice guidelines are being increasingly promoted to guide practitioners in their clinical decision making (Beattie and Nelson 2006). Though investigated primarily in the physiotherapy role this expectation also applies to ESPs, and along with the diagnostic components of clinical reasoning, ESPs are required to make referral decisions in partnership with their patients. Research that pertains to extended scope nursing practice has shown that the practice of advanced nurse practitioners (a role similar to that of ESPs) is characterized by responsibility and competence in making autonomous judgments based on expanded clinical competence. This expanded competence includes advanced skills for assessing and meeting the needs of patients and the creation of safe and trustful relationships with patients (Nieminen et al, 2011).

As there are no dedicated formal courses that lead to ESP competency generally or within the sub-specialist field of shoulder or upper limb care, ESPs may have to rely on a varied and unstructured approach to gaining competence and advanced skills. Research evaluating the ESP role demonstrates that ESPs have to rely heavily on mentoring and relationships with consultants (Hourigan and Weatherley 1995). This is particularly difficult in the primary care environment as access to specialists is limited due to geographical location and lack of relationships /communication. Thus clinical referral criteria and guidelines could be very important to assist ESP decision-making, particularly in primary care.

Clinical reasoning skills are assumed to be at a high level in both primary and secondary care although these skills have only been tested in secondary care ESPs where clinical agreement between consultant and ESP in lower limb and spinal specialities has been shown (Hourigan and Weatherley 1994; Harrison et al, 2001; Gardiner and Turner 2002; Dickens et al, 2003; Aiken and McColl 2008; Moore et al, 2005). However ESPs in both working environments have similar autonomy and similar scope with the ability to request investigations or alternative opinions. The ability of ESPs in primary care to take on, interpret and apply new knowledge is crucial if referral behaviour is to change.

3.5.4 ESP Beliefs

While it seems as though consensus referral criteria might provide much needed support to ESPs working in the upper limb speciality, it is important to acknowledge that not all clinicians feel that evidence based guidelines are valuable. The literature suggests that some clinicians have resisted EBM because it provides them with limited answers to the complex situations faced in everyday clinical care (Dopson et al, 2003). Whereas others have commented that it ignores the interests and biases that influence the production, interpretation, and application of knowledge (Mykhalovskiy and Weir 2004).

These differences in beliefs and opinions demonstrate that even the production of referral guidelines, in an area where knowledge is lacking, may not be considered helpful. Furthermore criteria may even be resisted, particularly if

they lack the detail required to make clinical judgements (Levin 1998) or appear to lack validity (Shekelle et al, 1999).

Though ESP beliefs have not been studied the importance of physician beliefs on the outcomes of patient care have been shown. A qualitative study of the beliefs of medical prescribers with regard to restricted antibiotic prescribing was undertaken with 20 hospital physicians (Björkman et al, 2010). Physicians specialised in internal medicine, surgery or urology and were interviewed with regard to antibiotic resistance, variations in prescribing and restricted prescribing. The results showed that some physicians did not consider antibiotic resistance because of a dominating focus on the care of the patient, a lack of focus on restrictive antibiotic use, uncertainty of how to manage infectious diseases or the pressure from the health care organisation. This work echoes the views of Dopson et al, (2003) and Levin (1998) with regard to the difficulties clinicians face in practice with the implementation of guidelines. It is important to note that though this work is in an entirely different field the beliefs of ESPs when introducing referral guidelines may be similarly affected by a focus on patient care. For example they may not want to restrict the referral of a patient to a specialist because it may be seen to deny the patient access to care due to uncertainty about how the patient would be otherwise managed if they were not referred.

The quality of a guideline has also been noted to have influence on whether it is accepted by clinicians. Vague or non specific guidelines have been reported to be a major source of rejection by GPs (Grol et al, 1998). There is little information about guideline quality within the literature although the need to ensure guidelines are clear and externally validated has been noted by Kainberger et al, (2002) which supports the claim by Grol et al, (1998) regarding quality. Evidence based guidelines have been criticised for not paying enough attention to clinical experience and clinical reasoning (Levin 1998). Concerns over 'freedom of choice' with regard to medical decisions when using guidelines (Evans et al, 1995) also indicate that clinical reasoning in partnership with evidence based medicine is important to improve patient care (Sackett et al, 2000). It appears that guidelines need to be of good quality, be clear and

externally validated whilst also communicating the context in which they operate, providing adequate information to allow clinicians to use their own expertise and reach their own judgement.

3.5.5 Environmental and Organisational Context

Michie et al, (2005) identified that implementation of guidelines may be affected by the environmental context. There are no studies which have considered the environmental or organisational impact on the behaviour change in ESPs when implementing new guidelines. It is possible that a number of environmental and organisational factors may apply to primary care ESPs, however there are two key areas that seem particularly worth highlighting.

Firstly, primary care ESPs have to interface with secondary care trusts when they refer patients for specialist care which suggests that their behaviour may be influenced by two organisational structures. The strategic and organisational priorities of secondary care trusts may be different from those in primary care. For example, clinicians may attempt to implement the referral criteria but if local thresholds for surgery change due to rationing resulting in rejected referrals despite following the referral criteria, the implementation and ultimate success will be affected.

Studies which have investigated the impact of organisational factors on the implementation of referral guidelines showed that priorities for implementing strategies to change patient behaviour were different in different organisations. Byrne and Campbell (2003) compared the implementation of guidelines to change patient behaviour between areas with different organisational structures (Ireland and Scotland) and indicated that the organisational environment influenced how guidelines were implemented.

Secondly, the study discussed earlier by Björkman et al, (2010) highlighted the importance of organisational pressure on referral decisions made by physicians with regard to antibiotic prescribing. As the main role of the ESP within primary care clinical assessment and interface services is to reduce the number of misdirected referrals to secondary care (DH 2006; NHS Institute 2009), ESPs may be put under pressure to manage patients in an overly conservative way,

and focus primarily on conservative management. The increased focus may result in guidelines not being applied to patients appropriately to ensure that referral numbers to secondary care are maintained within the typical target referral rate of 10% of total referrals received into the service (Bernstein 2011).

The possible impact of the primary care environment on the appropriateness of ESP referrals was discussed in section 2.9. The lack of access to communication and feedback, and the environmental isolation which may affect GP referral behaviour (Dawson and Ghazi 2004; Augestad et al, 2008) may also be environmental factors which impact on the implementation of guidelines and the development of practice (McSherry 2004). The lack of access to communication and environmental isolation may make behaviour change slow and difficult. The environmental factors such as lack of communication, lack of formal feedback and lack of formal audit mechanisms between primary and secondary care is likely to be a significant problem to the development of knowledge, skills and clinical reasoning (McCormack and Garbett 2003).

3.5.6 Summary of Section 3.5

The evidence underpinning the difficulties in engaging clinicians to implement guidelines and change practice has been explored. Firstly it has been shown that there is no consensus or evidence to indicate the optimum strategy to implement evidence based guidelines. Six dimensions which are thought to be important when implementing evidence and practice change have been highlighted including knowledge, skills, reasoning, clinician beliefs and environmental and organisational factors. The literature shows that it is important to determine whether referral criteria can be implemented to improve the quality of care.

3.6 Overall Summary and Project Aims

The high waiting lists, high non-attendance rates, reduced capacity, over reliance on hospital care and poor conversion rates contributed to the view that MSK services were of poor quality and needed to change. Interface services primarily staffed by ESPs were developed to address these issues, and there is evidence to demonstrate that they have improved aspects of health care

delivery such as reduced waiting times. However the ability of ESPs working in primary care interface services to deliver high quality care with regard to referring patients appropriately to secondary care has not been demonstrated. Where secondary care ESP conversion rates have been published and shown to be poor, there has been little investigation of the underlying reasons.

A gap in knowledge exists regarding the demonstration of appropriate referrals made by ESPs working in primary care interface services which is a key marker of clinical quality. There has been little analysis of the referral barriers they face which may impact on referring appropriate patients to secondary care. Thus there is a need for further investigation in this field to identify the conversion rates of those working in primary care interface services and provide benchmark data of performance.

This is an important next step in the development of primary care ESPs. Providing and demonstrating clinical quality is a key priority particularly in light of the new drive to improve quality and service delivery within the NHS (DH 2010a; Crump and Adil 2009). It is likely that there will be increasing pressure from commissioners and GP leads for ESPs to demonstrate their worth and effectiveness through the publication of outcomes such as the surgical conversion rate.

Studies have reported that conversion to surgery rates from secondary care ESPs to shoulder specialists are low. This suggests that the quality of referrals in this pathway is poor. This pattern may be repeated in primary care, or indeed it may be worse as there appears to be little sub-specialism identified in primary care interface services³⁹ (Personal Correspondence CSP ESP Professional Network 2012).

The high prevalence of rotator cuff disease, its impact on pain and disability, the lack of agreement between surgeons about when to operate and the lack of

³⁹ The CSP ESP Professional Network has a very limited amount of data on specialist ESPs in primary care.

evidence supporting surgical intervention indicate that there is a strong case to develop surgical referral criteria in this field.

Despite the prevalence of rotator cuff tears the evidence demonstrating outcomes of surgery in patients with different characteristics has been shown to be conflicting. The lack of consistent evidence regarding surgical outcomes means that ensuring appropriate referral for patients with rotator cuff tear is difficult. The lack of agreement with regard to the optimum surgical candidates has been shown and the need to determine referral criteria for rotator cuff tear has been identified.

A clear strategy for effective implementation of referral guidelines into practice for allied health professionals or ESPs was not found in the available literature. A number of factors may be important such as knowledge, skills, clinical reasoning, clinician beliefs and environmental context. The lack of clear strategy for implementation suggests that piloting the criteria to determine its impact on ESP referral behaviour would be beneficial.

Study Aims

Stage 1

To determine whether MSK ESPs working in primary care record their ability to refer appropriate patients to secondary care (as measured by the conversion rate)

To determine whether MSK ESPs working in primary care experience specific barriers to onward referral which may ultimately affect their ability to refer appropriately.

Stage 2

To develop referral criteria to enable primary care ESPs to refer the most appropriate patients for rotator cuff repair surgery.

Stage 3

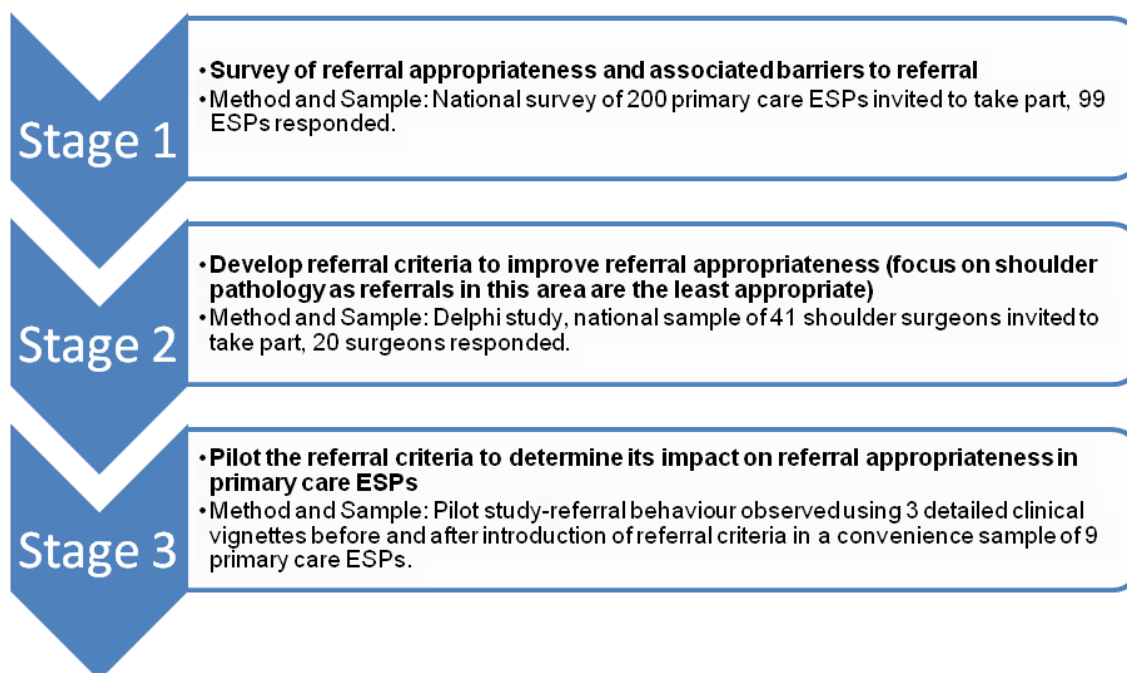
To determine whether referral criteria change ESP referral behaviour when assessing patients with rotator cuff tear.

Chapter 4: Method

Overview of the Methodology

Three interlinked studies were undertaken to achieve the aims of the thesis. The first stage was to investigate referral appropriateness and the barriers to referral in a national survey of 200 primary care ESPs. Ninety-nine responses were received. The second stage focused on one of the barriers to appropriate referral, specifically referral criteria and a Delphi study was offered to 41 shoulder surgeons to develop referral criteria, 20 responses were received. The criteria were then piloted with a sample of 9 primary care ESPs to determine whether the criteria improved referral appropriateness. Figure 4.1 shows the link between each stage from surveying referral appropriateness, developing criteria to improve appropriate referrals and finally testing the criteria to determine the impact on referral appropriateness.

Figure 4.1: Overview of Methodology at Each Stage



A primarily quantitative approach was used in this study. Qualitative approaches were used alongside the quantitative approach in stage one and stage two to help to explain and interpret the findings of the quantitative data (Bryman 2006). This approach facilitated the opportunity to explore the quantitative findings in more detail through the use of associated qualitative information (Ivankova et al, 2006). The qualitative information gained also helped to elucidate the reasons for unexpected results (Morse 1991). In stage one and two the quantitative and qualitative data were collected and analysed concurrently. A qualitative approach was also used when designing the Delphi questionnaire with a small number of interviews. Throughout the whole study three different methodologies were used including a questionnaire survey, a Delphi study and a vignette study. The exact methods utilised for each stage were dependent on the four research questions and will be explained respectively in sections 4.1, page 136; 4.2, page 144 and 4.3, page 164.

It has been identified that this type of multiple method approach is useful to address different but complementary research questions within a study (Bryman 2006; Robson 2011; Cresswell 2013). In this study the three methods were used to address three interlinked questions. In stage one a primarily quantitative questionnaire was used to determine details about ESP conversion rates and barriers to referral. Qualitative data was also obtained and used to help to explain the quantitative findings (Bryman 2006). In stage two the Delphi study was undertaken and a small amount of qualitative data was also gathered which helped to provide further clarification around consensus. In the Delphi study, the key areas which had been highlighted in the literature were further developed with a series of pilot interviews. Once the key areas which were considered important for rotator cuff surgery were determined from the interviews the Delphi study was undertaken to test these parameters. In stage three, referral behaviour was assessed with a vignette study resulting in nominal quantitative data.

Primarily quantitative data collection was most suitable for all three stages of the study. This was particularly relevant for the items relating to ESP specialism in the first stage of the study and the frequency data concerning

conversion rates and barriers to referral. Quantitative data collection was also important in the second stage of the research when undertaking the Delphi study with the Likert scale. However in both stage one and stage two it was also important for participants to explain their perceptions and views.

In stage three of the study the data collected was of a nominal nature. The main aim of the third stage was to determine whether the referral criteria changed ESP referral behaviour. Referral behaviour of each individual ESP could have been explored in a more qualitative way through description for example. However as the aim of the study was to determine whether the criteria changed the referral patterns of ESPs, quantitative data was considered more suited to analysis of change than qualitative data. It may have been difficult to compare the complex descriptive data in a 'before and after' manner if qualitative data had been used. Multiple methods investigation with a series of primarily quantitative studies to answer the varying research questions was considered the most appropriate methodology for the research questions identified.

A traditional mixed methods approach as highlighted by Creswell (2013) could have been used to reduce reliance on the primarily quantitative approach and to reduce vulnerability to the measurement error which may occur with a mono-method approach (Bryman 2006). Mixed methods are also used by some researchers because they have been viewed as useful in neutralizing the weaknesses of both quantitative and qualitative research (Creswell 2013). In this study a mixed method approach could have included a selection of ESP or consultant interviews in the first and second stage of the study to determine further information about the type of referral barriers encountered by ESPs or the reasons why consultants decide when to operate. In the third stage of the study it is possible that mixed methods could also have been useful to determine the reasons for specific referral choices.

Though it is possible that further evaluation of the research questions through ESP or consultant interviews may have added further quality and reliability to the findings, it would have added significant extra time to duration of the study

(both data collection and analysis) and would have increased the duration of the study for the participants involved (Ivankova et al, 2006). It was considered that the qualitative sections included in both stage one and two were more appropriate than a traditional mixed methods approach, and would still provide increased quality of the quantitative data obtained without unduly overloading the participants involved. Therefore a multiple method approach to answer the research questions was chosen. The justification for the method for each stage is discussed in detail in sections 4.1, 4.2 and 4.3.

Ethical approval for all three stages of the study was granted by Manchester Metropolitan University and King's College Hospital Research Ethics Committee (Appendix 5).

4.1 Stage 1: Survey of Referral Appropriateness and Referral Barriers

The first stage was to determine the conversion rates of ESPs working in primary care and to explore whether primary care ESPs working in the field of MSK medicine experienced referral difficulties which may impact on their referrals to radiology and secondary care. The development and use of referral criteria within their practice was also explored. Very little is known about whether primary care ESPs are primarily organised generically or whether they form subspecialist disciplines similar to those ESPs in secondary care. Also little is known about the number of primary care ESPs that may be practising within each specialty and whether differences exist between specialty groups regarding conversion rates or referral barriers. Primary care ESPs from all MSK specialties were therefore surveyed to determine the number of ESPs reporting a specialty and to determine whether differences between subspecialties could be identified if they existed. It was expected that there would be some ESPs working in a subspecialist way and that the specialties reported would include traditional orthopaedic specialties such as upper limb, lower limb and spinal services, as well as pain management, neurosurgical and rheumatology specialties.

4.1.1 Justification of Methodology

For the first stage of the study a self administered questionnaire was selected to determine accurate information about conversion rates and referral barriers in primary care ESPs. It has been identified that questionnaires are useful to separate fact from opinion, to obtain unbiased information and to identify opportunities for growth, change and improvement (Jackson and Furnham 2000). All these objectives were key to this study and thus a questionnaire was considered suitable. A questionnaire was deemed to be most appropriate for the type of data required which concerned ESP's conversion rates, their banding and specialism, and identification of whether they faced referral barriers and if they did what referral barriers they faced. A questionnaire was also considered to be the most suitable medium to survey a large number of therapists working in the UK in a standardised way (Sim and Wright 2000).

The questionnaire format is also familiar to most respondents and when using closed questions particularly, questionnaires are simple and quick to complete such that they do not overly burden the participants. When answering open questions participants also have time to think about their answers rather than being expected to answer immediately as in an interview which may encourage reflection (Sim and Wright 2000).

Questionnaires can also be useful when participants are being questioned about sensitive topics. Though the subject matter in the first stage of the study may not initially appear to be sensitive, it is possible that the topic of referral appropriateness and personal conversion rates is considered a sensitive area by some clinicians. Individual interviews may be too exposing for some individuals (Marks and Yardley 2004). Therefore a self administered questionnaire was selected over interview.

4.1.2 Inclusion Criteria

Clinicians in primary care with any associated MSK speciality (orthopaedic, rheumatology, neurosurgical or pain management) were specifically targeted. The organisation of primary care ESPs within the NHS has not been clearly

identified. It is assumed that some subspecialism exists but it is not known whether interface services are fully organised along traditional orthopaedic subspecialties. Anecdotally some ESPs within primary care interface services, particularly those staffed by small numbers of ESPs, appear to operate generically and without specific specialism. To compound this lack of information the ESP Professional Network did not hold membership data to the level of subspecialty⁴⁰ and thus it was not possible to target a subspecialist group (i.e. upper limb or lower limb) in isolation prior to the study. It was therefore necessary to study all primary care ESPs who recorded working within an associated MSK field to collect subspecialist information within the course of the survey.

Although subspecialist conversion rate data has been published regarding secondary care ESPs it is not known whether conversion rates vary between secondary care ESPs and those working in primary care within a subspecialty. As the study by Pearse et al, (2006) had identified that the conversion rate of secondary care ESPs in the upper limb specialty was the lowest, the upper limb subspecialist group in primary care was of particular interest. However it was considered important to compare findings (both conversion rates and barriers) from primary care ESPs with an upper limb specialty to those in other subspecialties to determine whether there were differences between subspecialist groups in primary care and differences between primary care and secondary care ESPs.

As there is a lack of information concerning the type, frequency and specialism of primary care ESPs, as well as a lack of information regarding the variation of conversion rates in different subspecialist groups, it was considered important to compare the findings of all primary care ESPs within the key associated MSK fields. Participants were asked to identify if they worked in the key orthopaedic specialties of lower limb, upper limb, or spinal. Other associated MSK

⁴⁰ The ESP Professional Network segregates membership data into groups of primary or secondary care ESPs, and main specialties such as orthopaedics but does not hold subspecialism data.

specialities of pain management, rheumatology and neurosurgery were included so that the full extent of the range of specialties in primary care could be analysed. The 'other' option was also available to determine whether there were other specialty arrangements in primary care which were not reflective of the standard orthopaedic, pain management, neurosurgical or rheumatology organisation found in secondary care.

4.1.3 Development of the Referral Appropriateness Questionnaire

A self-administered questionnaire was constructed consisting of 10 items. The content of the questionnaire was driven by the aims of the study and included requests to provide the type of conversion rate data available (team or individual data). Participants were asked to identify their specialism to determine whether ESPs in primary care are organised into subspecialist groups in a similar way to those working in secondary care. It was important to determine whether subspecialist groups in primary care, such as those specialising in the upper limb, reported different conversion rates to those in other specialities as has been reported in secondary care. It was also important to determine whether these groups reported specific referral barriers such as limited access to support or lack of referral criteria.

Participants were also asked to provide information on their use of referral criteria with regard to referrals to radiology and specialist secondary care services. ESPs were asked to identify their place of work and grading to provide further background information on the sample. A mixture of open and closed questions was used. Open-ended questions were included to ensure that ESPs had the opportunity to comment on referral barriers and there was opportunity to provide additional information at the end of each section (Sim and Wright 2000) (see Appendix 6 for Questionnaire). The open ended questions provided further information, helping to explain the context and nature of the barriers faced by ESPs in primary care.

4.1.4 Referral Appropriateness Questionnaire Pilot

The questionnaire was piloted on 10 specialist MSK ESPs (Band 8A)⁴¹ working in NHS interface services within primary care in 2010. A convenience sample was used. This sample consisted of 6 males and 4 females. These clinicians were selected as they were representative of the target respondents who were later surveyed in the principal study. They were recruited from a pool of ESPs attending an ESP training session in North West London. All ten ESPs at the training session were offered the chance to take part and all agreed. The questionnaire was sent to the participants via email. The questionnaire was in the form of a word document. Participants were given the opportunity to feed back via email, via the telephone, in hard copy via the post or given the option of meeting in person.

The ESPs were asked whether they understood the questionnaire as recommended by Robson (2011) to try to ensure that the wording was appropriate, and that respondents would interpret/comprehend the question as it was designed. They were encouraged to give their feedback on the questionnaire including whether they felt any of the questions were ambiguous or incorrectly formatted (Williams 2003). They were also asked for feedback about ease of use, readability and repetition.

No ESPs requested a meeting in person. Two ESPs returned their feedback in the post and eight returned the questionnaire via email. The responses from the pilot study were encouraging. Following the return of the pilot questionnaires the 6 ESPs who had made comments were contacted via email to ask if they would be willing to be contacted via telephone so that further clarification with regard to feedback could be determined. All 6 ESPs agreed and were contacted by telephone to gain further understanding and clarification with regard to comments made. They were questioned to determine their

⁴¹ ESPs at band 8A are specialists in their field. They are required to have advanced interpersonal skills, extended diagnostic and clinical skills. The role usually encompasses audit and/or teaching. Usually they are expected to hold a post-graduate qualification in MSK care (such as a Diploma in Manipulative Therapy, specialist ESP training or an MSc).

understanding of each question. This paper testing and the discussion of the meaning of questions with six ESPs showed that the meaning of the questions was clear to, and understood by, the sample ESP group.

Clarification regarding other aspects of the feedback was also undertaken. No issues around the meaning of the questions were found. Feedback mainly consisted of comments regarding structural difficulties with the questionnaire (3 ESPs). As well as positive comments of ease of use, there was a range of comments which included information on the time taken to fill in the questionnaire (too long), the length of the questionnaire (too long), dislike of the font type and font size used (preference for arial as this was easier to read). There were also comments suggesting that tick boxes and comments sections could be filled in more easily electronically. There was one ESP who expressed a preference for "SurveyMonkey" (www.surveymonkey.com) rather than a Microsoft Word attachment. Three ESPs also expressed confusion over the conversion rate question. They needed clarification with regard to where to put each conversion rate figure and whether referrals for conditions such as epidurals should be included in conversion rate analysis.

After feedback, the questionnaire was re-designed in a more accessible electronic format, using arial font. Text could be added electronically and the boxes enabled the insertion of a cross to indicate the chosen answer. The conversion rate question was re-structured so that it was split into two questions. The first asked whether the conversion rate was collected and the second asked ESPs to add their conversion rate if they had answered 'yes' to the previous question. To enable further understanding additional clarification about what constitutes conversion rate in practical terms was provided. The definition used in this study was 'the number of patients who undergo surgery or other significant orthopaedic intervention (such as biopsy or injection) following a referral to a surgeon or a surgical department'.

4.1.5 Questionnaire Sample Recruitment

A sample of 200 ESPs was recruited through the Chartered Society of Physiotherapy (CSP) ESP Professional Network. The researcher was asked to apply in writing and submit a copy of the ethics information to gain access to this support. The membership administrator of the ESP Professional Network filtered the membership data for all ESPs working within primary care who also noted orthopaedics as an associated specialty on their membership application. No further subspecialism filter was possible.

At the time the study was undertaken (January 2011), when the filter was applied to the membership data base by the administrator, the number of ESPs to meet the inclusion criteria (primary care ESPs with an associated orthopaedic speciality as outlined) resulted in the sample of 200 ESPs. The administrator sent the questionnaire to each of the 200 ESPs with an invitation email written by the researcher. Confirmation that the email had been sent was then sent to the researcher. At the time of the study the total number of ESPs registered on the membership data base was 403 (personal correspondence Professional Network Administrator January 2011).

4.1.6 Questionnaire Data Collection

The CSP ESP Professional Network sent the questionnaire electronically by email for data protection reasons. Individuals were asked to return the questionnaire by email or post, (the postal option was given in case individuals wanted to keep their place of work strictly anonymous due to the sensitive nature of the conversion rate data). The Professional Network sent a reminder of the questionnaire 8 weeks after the initial mailing. The use of multiple mailing was warranted in order to provide a further opportunity for non-respondents to report their experiences, and to optimise the response rate (Robson 2011). Sixty-five participants responded to the initial request and 34 responded to a follow-up request. In total 18 participants returned questionnaires via the post.

4.1.7 Questionnaire Data Analysis

The closed questions were analysed using descriptive statistics, with frequency analysis on all items of the questions. Initially responses from the open questions (7, 9 and 10) were evaluated by content analysis (Bauer 2000; Knight et al, 2010). Content analysis was used because it offered a model of systematic qualitative analysis with a clear procedure for checking the quality of the analysis (Marks and Yardley 2004).

Thematic analysis was considered, particularly as content analysis has been criticised for generating simplistic results (Silverman 2011). However as the qualitative data obtained from this study was relatively brief (in comparison to that obtained from interviews for example), and relatively simple (in comparison to studies regarding emotions or feelings), content analysis was considered to be the most suitable.

Initially responses were analysed by a consensus approach with a small sample. A sample of ten questionnaire responses was reviewed and themes which appeared in the qualitative sections were identified by the author using content analysis (Bauer 2000; Knight et al, 2010). The common themes were listed and examples from each questionnaire were matched to each theme (Knight et al, 2010). Manifest themes (those which were directly observable) were primarily used (Marks and Yardley 2004). However latent themes (those to which the participants implicitly referred) were occasionally used (Marks and Yardley 2004) to ensure participant responses were fully reported. The frequency data and qualitative information were thus used to explain the majority of the data (Dey 1993; Marks and Yardley 2004).

A colleague, who had not taken part in the research, was then asked to review the themes independently with the associated supporting examples from the ten sample questionnaire responses. The colleague was a manager within a neighbouring ESP service. All data was anonymized before it was seen by the independent reviewer. The reviewer did not have any specific research interests in this field but was familiar with the working practices of ESPs and the

barriers they face. No specific conflict of interest or bias which may have impacted on the interpretation of the data was noted. Themes were discussed and consensus with regard to matching the questionnaire responses to the appropriate theme was reached. Initial discussions led to small changes in the form of an increased number of themes. Once agreed these themes then became the categories by which the rest of the data were analysed (Marks and Yardley 2004).

The responses were allocated into the most appropriate category and the number of responses in each was calculated (Robson 2011). The coding framework changed slightly throughout the data analysis when responses were received for which there was no existing appropriate theme or category. This occurred for some of the rarer findings such as the report of 'pressure not to refer' identified by one ESP when responding to the question about referral barriers. Multiple themes identified in a single response were allocated to several categories (Silverman 2011; Marks and Yardley 2004; Sim and Wright 2000). For example if participants indicated that there were both commissioning and professional barriers to referring appropriately, the information was allocated to both themes.

A random selection of ten participant responses was also used to check reliability one month after the initial analysis had taken place. The content analysis was performed again and the results were cross checked with the initial data analysis to determine whether there were any changes to the categorization of the responses. None was found.

4.2 Stage 2: Developing Referral Criteria for Degenerative Rotator Cuff Tear

The purpose of the second stage was to develop referral criteria through consensus methodology which could then be used to improve the appropriateness of referrals made by primary care ESPs. The aim was to develop surgical referral criteria for a shoulder condition as the shoulder speciality has been shown to be the area where referrals are least appropriate.

The high prevalence of rotator cuff disease, its impact on pain and disability, the lack of agreement between surgeons about when to operate and the lack of evidence supporting surgical intervention indicated that there was a strong case for the development of surgical referral criteria for rotator cuff tear pathology.

4.2.1 Justification of Methodology

The literature review showed that at present there is no consensus with regard to which patients should be referred for degenerative rotator cuff repair. No randomized controlled trials, investigating the outcomes of cuff surgery in different rotator cuff tear subgroups to determine which patients respond best to surgery, could be found. In an ideal world clinical guidelines or referral criteria would be based on evidence derived from rigorously conducted empirical studies (Black et al, 2001). However in the field of degenerative rotator cuff repairs, as in many other areas of clinical or surgical practice, sufficient research based evidence to support guideline/criteria development does not exist (Chassin 1989; Dubinsky and Ferguson 1990). In the absence of published evidence Mann (1996) recommends that the development of guidelines has to be based partly or largely on the opinions and experience of clinicians or others with knowledge of the subject. Consensus methodology has been widely used in the behavioural science and health disciplines (Black et al, 2001). It has been used specifically to develop referral criteria in a range of MSK fields such as osteoarthritis (OA) of the knee and hip (Naylor and Williams 1996; Quintana et al, 2000; Musila et al, 2011). It has also been used to form guidelines such as the Diagnosis and Management of Shoulder Injuries and Related Disorders Guidelines (ACC 2004) and guidelines in other fields such as in the management of hip and knee OA (Zhang and Doherty 2006) and in the physiotherapeutic management of back pain (McCarthy et al, 2006). In the absence of robust empirical evidence to help support practice decision-making, an expert opinion consensus study was considered (Mann 1996).

A range of methodological options to determine consensus were contemplated including a Delphi questionnaire survey, a focus group (such as the Nominal Group Technique -NGT), and consultant interviews. A Delphi questionnaire study was considered as it has been highlighted that this method is useful to

gain consensus to facilitate clinical reasoning (Black et al, 2001; Keeney et al, 2006), to consolidate collegial knowledge and facilitate inter-professional communication (Powell 2003). Thus the Delphi method was considered ideal as the development of criteria to improve reasoning, knowledge and thus appropriate referrals were the primary objectives of the study.

The Nominal Group Technique (NGT) is also a type of consensus methodology which primarily encompasses a face-to-face meeting between the participants (Murphy et al, 1998) along the lines of a focus group, rather than a Delphi questionnaire study where participants do not meet. The Nominal Group Technique may be thought to have some advantage over the Delphi questionnaire type study as the interaction which occurs between experts in the group during a face-to-face, focus group-style meeting may encourage outliers or those with extreme views to be drawn into the group which would of course be beneficial to gaining consensus (Black et al, 2001). However it was considered important to reach consensus, if possible, by surgeons identifying an independent opinion rather than some surgeons appearing to agree due to the pressure of the focus group, or due to strong personalities within the group (Jairath and Weinstein 1994; Black et al, 2001). It was felt that without this level of independence, there would be the appearance of consensus that actually differed from the views of consultants in practice, making it difficult to use consensus criteria in future practice. This consideration has been supported by Hutchings et al, (2006) who compared the reliability of consensus study findings with a group of 213 GPs. The study compared the nominal group technique with the Delphi approach and found that when GPs were asked privately for their views after the study the nominal group technique was less reliable than the Delphi study (Hutchings et al, 2006).

Bringing many surgeons together to take part in a Nominal Group Technique was also considered to be difficult for many surgeons because of work pressures and time constraints. Usually there are only one or two shoulder surgeons employed within most large hospitals, thus bringing surgeons together for a group meeting would involve significant travel and expense for many. It was also considered that there was low motivation for consultants to share their

knowledge with others, particularly as the information may be politically or financially sensitive, therefore it was felt that consultants would not readily attend a focus group some distance from their place of work, and may not share information honestly when trusts were competing with each other for orthopaedic business. Therefore the NGT methodology was rejected as it was not considered feasible that a large number of expert consultants would be motivated or able to attend a group session, particularly as no funding was available.

Interviews were considered as an alternative to the Delphi type survey but were rejected as a method of gaining consensus. The level of technical detail required to gain information was considered to be more suited to a closed questionnaire format. It was felt that comparisons on a range of technical issues may be very difficult to draw if the information was obtained via interview. Interviews were not considered to be suitable to gain consensus particularly when using a process of repeated iterations, where information from others is sent back to participants with regard to topics where consensus had not been achieved. However, interviews were used to develop the Delphi Questionnaire (see section 4.2.6 and 4.2.7).

A questionnaire using a Delphi approach, seeking consensus among orthopaedic shoulder surgeons was finally selected as the most appropriate method for the second stage.

4.2.2 Limitations of the Delphi Approach

It is important to acknowledge that consensus methods are used for the purpose of making policy decisions or clinical decisions, making the best use of available knowledge or data and are not for the purpose of creating new knowledge. Thus one of the limitations of this type of methodology is that 'it is vulnerable to the possibility of capturing collective ignorance' (Black et al, 2001: 427). It was hoped that a large sample will help to guard against a large number of uninformed views.

Another weakness of the Delphi method concerns the lack of agreement with regard to the acceptable threshold which defines when consensus has been achieved. This area will be discussed in more depth in section 4.2.15.

4.2.3 Justification of 'Experts'

Setting the inclusion criteria is important for the validity of a consensus study (Beech 2001; Sackman 1975). There has been controversy about what constitutes a participant or 'expert' (Baker et al, 2006). It is acknowledged that as consensus study findings are the opinions of those involved in the study the credibility of the study depends to some degree on those who take part (Robson 2011).

Participants for the Delphi approach may be defined in a number of ways such as their position in a hierarchy, through public acknowledgement, through their experience and their ability to influence policy (Keeney et al, 2001; Kennedy 2004), as a representative of their professional group with sufficient expertise to be acknowledged by peers (Fink et al, 1984) or as a representative of the sample group or population (Mead and Moseley 2001). It is difficult to ensure that the sample participants are representative of the group or representative of the 'experts' representing this group, and thus Mead and Moseley (2001) argue that the sample is more likely to be a convenience sample. Ideally the experts or participants should not be known to the researcher personally (Murphy et al, 1998).

4.2.4 Justification of Inclusion Criteria

The inclusion criteria were formulated in consideration of the factors discussed above in conjunction with the aim of this stage of the study. As the aim was to determine surgical referral criteria, the participants needed to be practising surgeons, holding specific upper limb or shoulder clinics, who practice rotator cuff repair surgery. The expert group was drawn from a national pool of consultants publishing their details on the British Orthopaedic Association website (<http://www.boa.ac.uk>). This organisation was used to ensure that the sample was representative of the expert group (Duncan et al, 2004). A specialist Shoulder and Elbow Surgical Society also exists, but when contacted

they would not allow access to their membership database for data protection reasons, nor would they send information to their members.

Drawing from a local sample of surgeons was considered because the Musculoskeletal Services Framework (DH 2006) indicates that local (rather than national) level care pathways should be developed. The reasons for this recommendation may be underpinned by the fact that across the country there is variation in population type and surgical skill. Thus there is a need for local criteria, brought about by those working clinically, rather than enforced by NHS managers and politicians (Darzi 2008).

However it was considered that using a national sample would not impact negatively on the development of local pathways, indeed it was considered that agreement from a larger survey may help to positively influence local pathways where less specialism exists or where significant difference of opinion exists.

4.2.5 Justification of Sample Size

Historically Delphi studies have been conducted with a small number of 'experts' (Keeney et al, 2001; Kennedy 2004) (typically around 7-10). The first modern Delphi study is attributed to Dalkey and Helmer (1963), where a panel of 7 experts were used. However there is no agreement with regards to the optimum sample size (Keeney et al, 2001; Green et al, 1999).

In this study it was anticipated that inviting the views of a larger number of experts, would carry more weight than a small group, provide more credibility for the study and be more representative of the population of shoulder surgeons in the UK. Therefore a larger group of specialists than has historically been used in Delphi studies was recruited for this study. It was hoped that this would enable the criteria to be used in practice more widely.

The number of shoulder surgeons who are able to undertake degenerative rotator cuff repair has not been published but the aim was to identify as many specialist shoulder surgeons as possible who met the inclusion criteria described.

4.2.6 Formulation of Delphi Questions

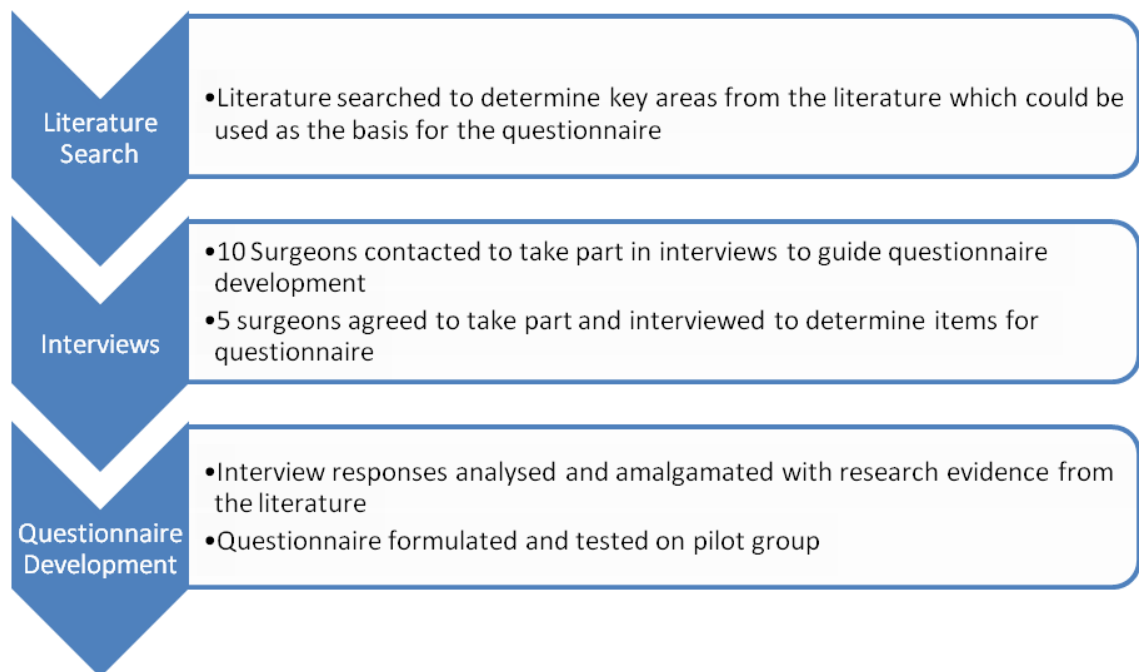
Figure 4.2 shows how the Delphi questions were developed including reviewing the literature, interviewing consultants to generate further ideas (n=10), analysing the responses, formatting the questionnaire and piloting the questionnaire (n=10).

Literature Search

The first stage was to complete a literature search to gather all existing evidence with regards to surgical criteria for rotator cuff disease similar to that undertaken by Quintana et al, (2000) in their study to determine criteria for total hip replacement surgery. Key areas which emerged from the literature as influential with regards to the outcomes of rotator cuff surgery (Warner et al, 1997; Moulinoux et al, 2007; Beaudreuil et al, 2010) were used to form topics for semi structured interview questions.

After searching the literature one other question regarding the importance of biopsychosocial issues was included. These issues are a significant feature of many MSK disorders (Jeffery et al, 2011; Gatchel et al, 2007). Pain severity and biopsychosocial factors such as depression and dependence on benefits have been correlated in patients suffering from chronic upper limb pain (Henderson et al, 2005). Biopsychosocial factors may have an impact on the outcome of surgery (Mayer et al, 1998; Gatchel 2001) and therefore it was considered important to determine whether these symptoms carry significant weight within the surgical community. The next step was to interview a sample of surgeons to generate further ideas for questionnaire development. Ten were contacted and five agreed to take part.

Figure 4.2: Formulation of Delphi Questions



4.2.7 Interviews

The use of interviewing at the start of a Delphi study to generate ideas has become more popular recently and is recommended by McKenna (1994). Interviews were considered most suitable because they are a flexible and adaptable way of finding information without limiting the participant's answers to a fixed format as in a questionnaire (Robson 2011). Many Delphi studies use a focus group for question formulation however the use of a focus group was rejected on the grounds of lack of consultant motivation, travel time for consultants and expense (Jackson and Furnham 2000). It was anticipated that the information provided would build on the existing research evidence, and provide context with regard to information not yet published or other information which had not been considered.

4.2.8 Interview Sample Recruitment

Ten shoulder consultants were contacted to take part. Initial contact was made via email asking surgeons if they would be prepared to be interviewed. Contact details were found from the publically available British Orthopaedic Association website (<http://www.boa.ac.uk>). Surgeons were selected from 8 trusts in the Greater London Strategic Health Authority and randomly selected from 2 trusts

outside London. There were only eight surgeons with active contact details practising in London. A further six surgeons practising in London could be identified but it was not possible to locate current contact details. All eight surgeons were contacted. All consultants identified as working in London were asked to take part in the interview study partly for convenience and resource reasons (travel costs, time taken from work to undertake interviews).

Two consultants outside London were also asked to take part in the interviews to try to ensure that the data obtained was not too locally focussed. For those surgeons practising outside London randomisation was undertaken using a simple randomisation process (Kang et al, 2008). A 'drawing lots' (Schulz and Grimes 2002: 517) randomisation process was considered most suitable because it was simple and could be undertaken by an independent assistant with minimal training. Thus a 'lucky dip' system was used. Labels were created, marked with the surgeon's name, folded and collected into a jar. Two surgeons were drawn from the jar by an independent assistant. Neither surgeon from outside London agreed to take part in the study. Five surgeons from the 8 London Trusts agreed to take part in the initial interview study.

Semi-structured interviews were thus undertaken with five specialist upper limb consultants to determine their views about the key issues/content required for the development of surgical criteria for degenerative rotator cuff repair. All five consultants who agreed to take part were interviewed in a face-to-face setting. A balance of open and closed questions was used. Broad open, non leading questions were used to ensure that a wide range of views was obtained (Jackson and Furnham 2000). Other questions were specifically related to the existing research evidence. The main topic areas for the semi-structured interview questions were: factors influencing the decision to operate, characteristics and dimensions of the tear, multiple tears, fat atrophy and tendon quality, specialist investigations, and other contributing factors. Written notes were taken during the interview with a voice recording device used as a back up to ensure that no data was missed. The topics did not change over

time. The data gained from the surgeon interviews was brief and lacking in detail. (See Appendix 7 for interview data).

4.2.9 Delphi Questionnaire Development

Once the interview data were analysed and interpreted the questionnaire was developed, in conjunction with the previous information from the literature review (Warner et al, 1997; Moulinoux et al, 2007; Beaudreuil et al, 2010). The pilot interviews demonstrated that there were some areas of agreement about the management of rotator cuff tear. Few surgeons were clear on the factors which influenced their decision to operate. The interviews confirmed the need for the consensus study and responses impacted on the questionnaire design by confirming that the key topics such as the characteristics and the quality of the tear/tissue were appropriate. They confirmed that there was much agreement in the literature and within practice concerning the need for rotator cuff imaging before surgery. Thus this topic was not included in the final questionnaire.

4.2.10 Structure of the Questionnaire

The questionnaire was designed in three sub-domains. The first section contained key subjective information (i.e. patient age, patient symptoms, refractory pain). The second section contained key objective information such as the presence of functional limitation, range of movement and muscle weakness. The third section contained questions regarding the characteristics of the tear such as tear site, tear dimensions, thickness of the tear, tendon quality, the presence of fat atrophy and the presence of specific bony morphological factors.

Sectioning the questions into sub-domains provided a more structured framework for those completing the questionnaire. It was hoped that this would improve recall about clinical decision-making (Black et al, 2001; Foddy 2001). Black et al, (2001) have identified that participants within a Delphi panel need to be guided by cues to enable them to answer questions appropriately. This is re-enforced by much of the survey design literature which indicates that setting the context is important for facilitating reliable answers from those completing

surveys (Strack and Martin 1987; Foddy 2001). It was hoped that this led to better consistency from respondents and improved the validity and reliability of the questionnaire. During the pilot phase consultants were asked about the cues used. Feedback indicated that the consultants felt they were appropriate (see section 4.2.11, page 154).

A Likert scale is often used in Delphi studies and participants are usually asked to 'agree or disagree' with regard to the statement in question. A five point Likert scale was used in this study. One question did not use a Likert scale, it was a closed question with a Yes or No option. Two Delphi studies from similar areas of practice have both used Likert scales. McCarthy et al, (2006) investigating the important components of the clinical examination of back pain, used a 5 point Likert scale. Ferguson et al, (2008) also used a five point Likert scale when using a Delphi study to investigate consensus among expert physiotherapists in relation to the management of low back pain.

No clear advantages have been highlighted for the use of a 5 point scale over the 3 or 9 point scales. It would appear logical to estimate that a 9 point scale may offer slightly more choice to individuals trying to express their position on each statement. However the use of a 9 point scale may also be longer and unwieldy, perhaps even presenting barriers for some individuals to select the most appropriate answer. The use of a 3 point scale was considered, however it was felt that it may limit the choice of expression for some individuals and therefore it was decided that a 5 point Likert scale would be used in this study.

The questionnaire included an opportunity at every stage for individuals to add comments about their criteria or their views. It was anticipated that the open-ended questions would reflect a wide range of practices which could help to clarify specific answers to enable interpretation.

4.2.11 Delphi Questionnaire Pilot

The questionnaire was then piloted on a random sample of ten consultants working within the UK drawn from a pool of 56 shoulder surgeons on the British

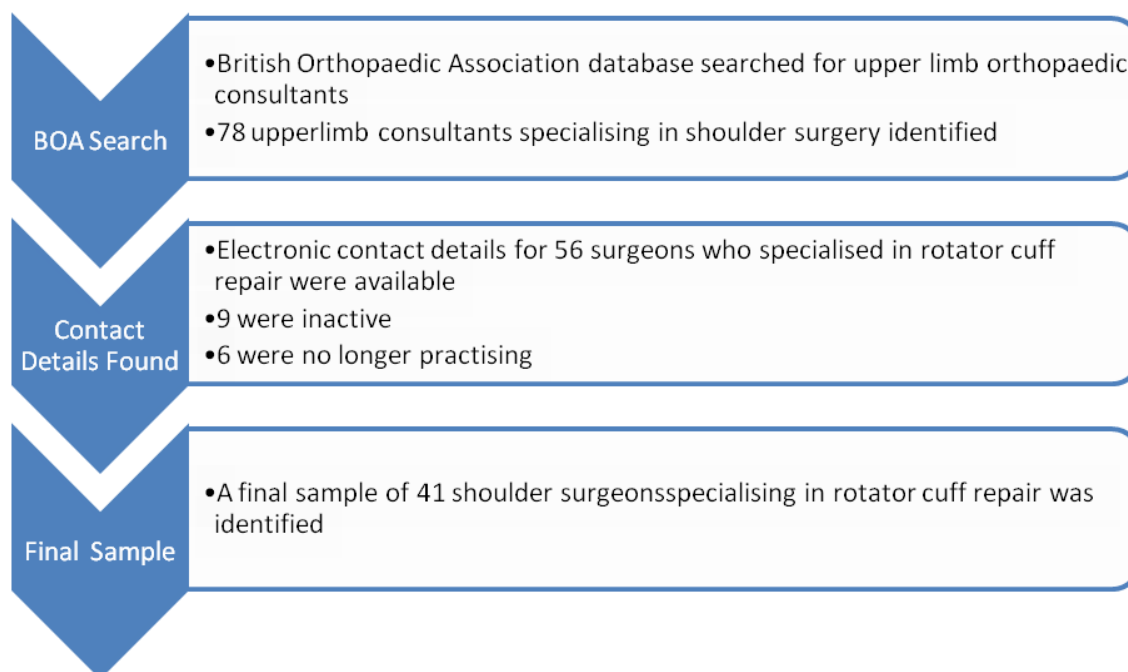
Orthopaedic Association website who identified that they undertook rotator cuff surgery. Initially the search revealed 78 shoulder surgeons who undertook shoulder surgery. From this group further analysis was undertaken to identify those who included rotator cuff surgery within their specialism. Those who did not identify rotator cuff surgery as one of their speciality procedures were excluded, as well as those who identified multiple specialities such as shoulder and foot surgery. Thus the initial sample of 78 was reduced to 56 shoulder surgeons. Of these 56, nine no longer had an active email address and could not be contacted and 6 were not available to take part which resulted in a sample of 41 surgeons. From this sample a simple randomisation process was undertaken using the previous system for interviewing consultants (Schulz and Grimes 2002; Kang et al, 2008). The randomisation resulted in consultants from across the UK from the following regions, Scotland (2), Southwest England(1), Northwest England (1), London (2), West Midlands (2), Herefordshire (1) and Wales (1) being surveyed. Consultants were emailed and asked to take part in the pilot. Out of the ten requests to take part four consultants responded; one email address was no longer available. The other five participants did not respond. Of the responders one consultant was from Southwest England, one from Northwest England, and two were from London.

They were requested to give their feedback on the questionnaire including whether they felt any of the questions were ambiguous or incorrectly formatted, and to report on the meaning of the questions (Robson 2011; Williams 2003). They were also asked for feedback about ease of use, readability, repetition and the use of specific cues to set the questionnaire context. Four consultants returned comments. One surgeon commented on the need for clarity with regard to the meaning of question 1.2 concerning the impact of the patient's occupation on decision-making. No other specific difficulties were reported and overall comments were positive and encouraging.

4.2.12 Delphi Study Sample Recruitment

The publically available British Orthopaedic Association website was used to identify specialist shoulder surgeons for inclusion in the study (see figure 4.3 for process).

Figure 4.3: Delphi Study Sample Recruitment Process



It was searched for all consultant surgeons who listed shoulder surgery as a speciality. In total 78 shoulder surgeons were identified from the list. From this group further analysis was undertaken to identify those who included rotator cuff surgery within their specialism. Those who did not identify rotator cuff surgery as one of their speciality procedures were excluded, as well as those who identified multiple specialities such as shoulder and foot surgery. This was because rotator cuff surgery is a relatively specialised procedure and it is unlikely that general orthopaedic surgeons have developed the shoulder arthroscopic skills to perform cuff repairs. From this group 56 shoulder surgeons were identified, and of these nine no longer had an active email address and could not be contacted. A further six were not included as they

were not available⁴² for a variety of reasons including retirement, serving overseas, not currently practising. The final sample was 41 shoulder specialists.

4.2.13 Delphi Study Data Collection

The statements or scenarios in a Delphi study are usually sent to the participants in the form of a questionnaire. Two rounds of questionnaire testing are common, though more may be required if adequate consensus has not been reached (Mead and Moseley 2001). Figure 4.4 shows a brief summary of the data collection process.

The questionnaire and participant information leaflet⁴³ were emailed to the 41 surgeons with a return date of 10 days. Email addresses were obtained from the British Orthopaedic Association website. A second questionnaire was sent if the questionnaire had not been returned after 5 weeks, with a follow up email to remind participants to take part (see Appendix 8 for first round questionnaire). The use of multiple mailing was warranted in order to provide a further opportunity for non-respondents to record their views on referral criteria, and to optimise the response rate (Robson 2011). The data were analysed as explained below and then a second phase of refined questions was sent to the group. The second questionnaire consisted of 10 questions where consensus had not been gained. This second questionnaire was re-sent by email if participants had not responded within 4 weeks (see Appendix 9 for second round questionnaire).

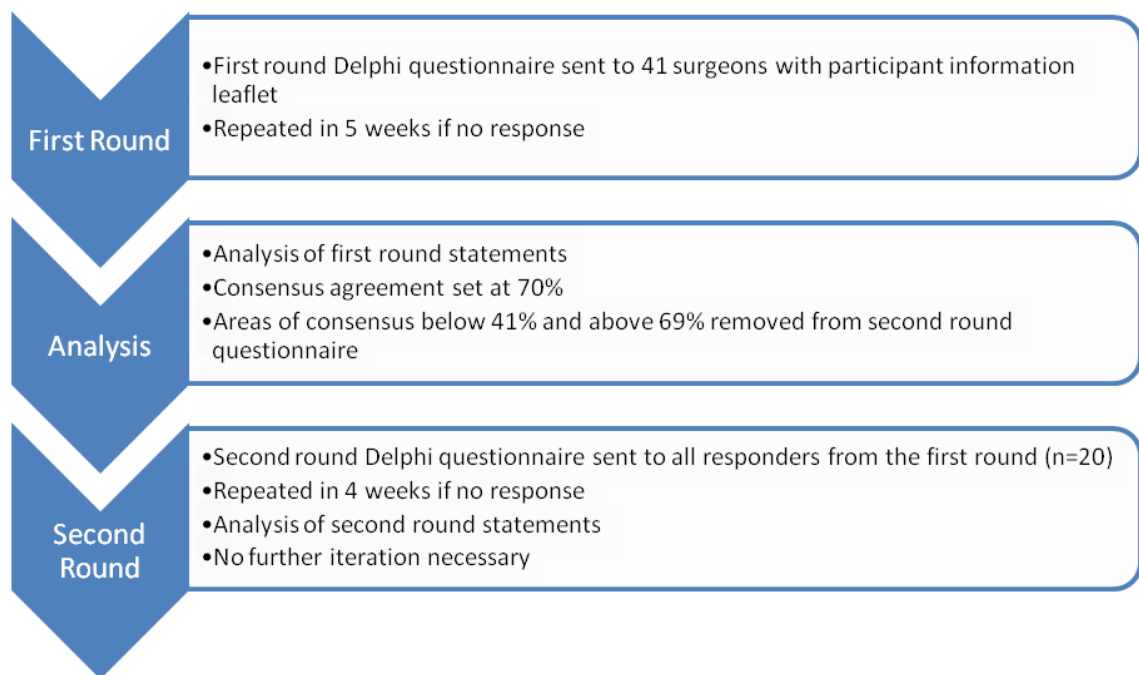
After analysis of the second round responses a further round was considered unnecessary and thus no further questionnaires were sent out. The results show that only three parameters were appropriate for a third round as the other

⁴² These individuals had active email accounts but they had messages which were automatically returned outlining various reasons for their absence and indicating that they would not be using the account.

⁴³ Formal consent forms were not required by the ethics committee for this stage of the study. Consent forms were only required for the consultant interviews.

seven had either high or very low consensus, such that a third attempt at consensus agreement was not considered appropriate (Mead and Moseley 2001). There was also an indication of questionnaire fatigue following consultant feedback from the second round, such that sending out another questionnaire for three questions was thought likely to result in a poor response rate (Keeney et al, 2001; Richardson 1972).

Figure 4.4: Summary of Data Collection



4.2.14 Delphi Study Data Analysis

For the closed questions (Likert scales and the Yes/No option question) the collected data were analysed using descriptive statistics. The responses from each participant were pooled and analysed, resulting in percentages of agreement or disagreement for each question/statement. Responses to open questions that directly related to the parameters which make up the referral criteria and other responses to open questions were evaluated and themes were identified using content analysis (Robson 2011). During the data analysis stage it was important to reduce the data collected to a simple form so that it could be formulated into table form for the referral criteria. This simple form was required so that the ESPs could use the criteria alongside the

vignettes. It was felt that the 5 point scale would lead to more uncertainty in decision-making for the ESPs. Therefore even though it had been important for the consultants to have the opportunity to choose between agree/disagree and strongly agree/strongly disagree, the requirements of the referral criteria meant that the 5 point scale was reduced to a 3 point scale for data analysis. This enabled the ESPs to see at a glance which areas had reached agreement and the strength of this agreement.

4.2.15 Consensus Threshold

There is no agreement in the literature as to what constitutes satisfactory consensus. Hicks (1999) indicates that consensus agreement is variable with rates quoted between 50% and 80%. Previous studies within the physiotherapy discipline have used 75% as an acceptable agreement cut off score (McCarthy et al, 2006; Carnes et al, 2010; Jackson et al, 2009), whereas in other areas Behrens et al, (2006) rated consensus agreement as two thirds of the group (66%), and Armon et al, (2001) have rated it as high as 83%. Mead and Moseley (2001) explain that in their view the level of agreement for consensus must be determined for each individual study and that it is a matter of research judgement. They indicate that it should be based on the nature of the study, emphasising that there are no ground rules. There has been little justification for the thresholds set in previous studies within the literature.

In this study it was decided that the threshold for consensus agreement would be 70%. The decision to use a threshold of 70% was based on the need for the level of agreement to be high enough to be accepted by the majority of those sampled and by those who would use the criteria in the future. Evidence from previous studies has shown that current practice is underpinned by a much lower level of agreement. For example Iannotti et al, (2010) showed that in a sample of 4 specialist shoulder surgeons the overall inter-rater agreement when making decisions about when to proceed with rotator cuff surgery was at best

fair ($K=0.34$)⁴⁴. It was judged that agreement of 70% would represent significant consensus when compared to these current levels.

A higher threshold was also considered, however it was important to ensure that the threshold was not set too high. When surveying a large number of surgeons ($n=1100$, response rate 49%, total sample 539) with regard to the indications for rotator cuff surgery Dunn et al, (2005) had previously used a consensus threshold of 80%. However at this level there was agreement on only four of the nine clinical questions and none of the four questions about the hypothetical vignettes. In light of these findings from Dunn et al, (2005), for this study specifically, an agreement level of 70% or above was judged to be the most suitable.

The responses demonstrated that two consultants expressed difficulty and reluctance when answering questions which would exclude patients from surgery. Therefore to ensure that the results were reflective of the views expressed it was decided that in those areas where scoring fell between 70% and 75% agreement would only be considered to have reached consensus if the outcome did not exclude patients from surgery.

It was hoped that by increasing the threshold to 75% for those patients for whom the criteria would exclude from surgery would also result in a wider acceptance of the criteria in practice. The 75% threshold was also considered to be an important safety consideration within this group ensuring that a higher percentage had to agree before patients were excluded from surgery.

Therefore after analysis any items with a high level of agreement (70% or more) were considered to have reached consensus and thus were removed from the second iteration. Any items which achieved a low level of agreement (40% or less) were also removed from the second iteration as recommended by Mead and Moseley (2001). It was considered that these items were less likely to reach consensus in the second iteration. It was felt that as views were so

⁴⁴ Landis and Koch (1977) define kappa agreement as fair if $k=0.21-0.41$. Substantial agreement is defined as $0.61-0.80$, and moderate agreement is $0.41-0.60$.

widely spread a significant shift would be required to reach consensus. For example even a moderately large shift from 40% to 60% would still not reach consensus for inclusion in the criteria. The decision to use a 40% lower cut off and to include agreement of 41% and above for the second round was made on a pragmatic basis. The cut off could have been higher at 45% or lower at 35% and both of these were considered. The threshold of 40% and below rather than below 39% excluded one further question. This question was not considered central to the consensus questionnaire and it was felt that it was likely that this would not reach consensus if it was sent out again in the second questionnaire. Therefore the threshold was set at 41% or above. It was decided that the second iteration would focus on areas where there had been a stronger agreement, with a greater chance of achieving consensus (Mead and Moseley 2001). Therefore items which had scored agreement between 41%-69% were transferred into a second questionnaire and fed back to the group.

4.2.16 Formulation of Referral Criteria

The consensus information was summarised into one coherent table (Table 4.1). Summary information for all areas where 70% agreement or above had been gained was formulated into referral criteria. The referral criteria were reviewed by two independent reviewers for clarity and readability. Following critique from the two reviewers, where possible, the information that could be summarised in sections was merged so that large amounts of information could be reduced into one table for ESPs to read and evaluate. This also facilitated the criteria to be reduced to a format which facilitated clinical reasoning and application to practice. Formulation of the criteria resulted in the amalgamation of some of the Delphi statements. This resulted in 12 rather than 14 statements

Three statements were combined which were:

- 3.2 The shape of the tear (75%)
- 3.9 Surgery for multiple partial thickness tears (70%)
- 3.10 Surgery for multiple full thickness tears (75%)

This information became: The number of tears (70%-75%) or the shapes of a tear within a tendon (75%) does not influence a surgeon's decision to operate. (note 75% of surgeons agree that they would operate on multiple full thickness tears; 70% of surgeons agree that they would operate on multiple partial thickness tears).

The statement in the criteria 'The site of the tear does not influence the surgeon's decision to operate' was based on question 3.8 'I would operate on a patient with a degenerative tear in any of the rotator cuff tendon'.

Table 4.1: Final Referral Criteria Summary

Criteria: Consensus has been achieved on the following parameters	Agreement
Patients with a high or severe level of pain influences the surgeon's decision to operate	(95% agree)
Patients with significant limitation of normal activities of daily living influences the decision to operate	(85% agree)
Patients with significant limitation of advanced functional activities (hobbies/sports) influences the decision to operate	(81% agree)
Patients with significant fat atrophy are less suitable for rotator cuff repair. Study recommendation: Liaise with surgeon to define local threshold.	(80% agree)
When referring patients for repair of a degenerative rotator cuff it is important that the referrer includes information about the presence of psychosocial issues (e.g. treatment compliance, passivity, acceptance, beliefs about cure, family issues, litigation)	(80% agree).
Patients with frozen shoulder are generally not suitable for repair whilst the disease is in the active/acute phase	(75% agree)

Criteria: Consensus has been achieved on the following parameters	Agreement
A course of conservative therapy should be attempted and the results included in the referral	(75% agree)
The number of tears or the shapes of a tear within a tendon does not influence a surgeon's decision to operate	(75%)
A delay between injury and repair (even of several years) does not influence the decision to operate. Study recommendations: Even long standing cuff tears may be suitable for surgery, liaison with surgeon to determine local thresholds.	(73% agree)
The patient's occupation or hobbies are a determining factor with regard to the success of cuff repair surgery (but surgeons would counsel their patients on the likely outcomes rather than exclude patients from surgery)	73% agree
The age of the patient does influence a surgeon's decision to operate. Age does not appear to be used in isolation and is linked to other factors such as tissue quality. Study recommendations: Liaise with surgeon to define local threshold.	(70% agree)
The site of the tear does not influence the surgeon's decision to operate.	(70% agree)
No consensus has been reached on the following parameters	
There was no agreement regarding whether patients being referred for a rotator cuff repair must have pain on resisted muscle testing of the affected tendon (only 36% agreed that it was), nor is it mandatory to have weakness on resisted muscle tests in the affected tendon (only 64% agreed that it was).	

No consensus has been reached on the following parameters
There is no consensus regarding the need to undertake investigations for subacromial narrowing or subacromial spurs.
There was no agreement regarding whether the dimensions of rotator cuff tears influence the decision to repair a degenerative rotator cuff in either full thickness or partial thickness tears.

4.3 Stage 3: Testing the Referral Criteria

The third stage was to determine whether the referral criteria developed from the consensus study could influence referral decisions in a group of primary care ESPs. This stage was particularly important to determine whether changes in clinical practice could be made. A range of methodological approaches was considered including retrospective and prospective analysis of conversion rates for rotator cuff repair, analysis of case notes and records, role play or real patient scenarios and vignettes.

4.3.1 Justification of Vignette Methodology

Vignettes are hypothetical clinical presentations of patients intended to elicit from practitioners an underlying practice pattern or 'medical signature' (Wennberg et al, 1997). Vignettes have been found to be a useful tool to observe attitudes, beliefs and views in a range of situations (Robson 2011; Hughes and Huby 2002; Sim and Wright 2000; Denk et al, 1997; Gould 1996).

Some investigators have raised concern as to the value and validity of vignettes as an outcome measure in assessing practitioner behaviour (Morrell and Roland 1990; Jones et al, 1990) suggesting that practitioners report what should be done rather than what they actually do. Jones et al, (1990) undertook a review of studies which had used clinical vignettes and found that very few (11 out of 74) had undertaken validity testing. Of the 11 studies that had demonstrated assessment of validity, few had demonstrated how well the responses to the vignettes performed as a measure of behaviour.

Morrell and Roland (1990) attempted to measure GP referral behaviour using vignettes in 20 GPs. The results showed no significant correlation between actual referral rates and the responses to the vignettes. The authors reported that the 'repeatability of the vignette tool was disappointing' (Morrell and Roland 1990:182) despite some validity monitoring using feedback from doctors who indicated that the vignettes were realistic. The reliability statistics are difficult to interpret and report from this study as it appears that a correlation statistical analysis was performed rather than statistical analysis for the level of agreement which is recommended to demonstrate reliability (Sim and Wright 2000). From the descriptions and language used (i.e. language such as 'disappointing') it would appear that the reliability was considered to be poor, even though this was not clearly shown.

However, further analysis of the study by Morrell and Roland (1990) has also shown that the vignettes used within the study were very brief, recorded at between 15 and 50 words. These small statements may have been too brief for GPs to establish confident clinical decision-making and it does appear as though this type of vignette would not engender consistent decision-making, as a number of clinical variables are likely to have been missing. The methodology also explains that clinicians were given small statements in a particular order and asked to determine whether they would refer to hospital at several points as more information was released. The other criticism which was in part highlighted by the study authors was that the research process used in this study only allowed GPs to answer whether they would 'refer to hospital or not.' No options for other actions were given. The authors identified that although some GPs said that they found the vignettes realistic the response options did not allow them to follow action that they would have taken and thus the results appear to have been skewed in some cases.

In contrast to these two studies other research has demonstrated that clinical vignettes are reliable, stable and valid measures of practitioner behaviour, as well as being more accurate than patient case notes (chart abstraction), which are often used as a measure of practitioner behaviour (Peabody et al, 2000). In

an outpatient setting Peabody et al, (2000) undertook a study to determine whether vignettes were a valid measure of physician behaviour. They used a random sample of 20 from a pool of 98 physicians, over 3 different sites. They compared structured reports by standardized patients, (trained actors who presented unannounced to physicians' clinics) considered to be the gold standard; the details of the medical case notes for the standardized patient visits; and the physicians' responses to clinical vignettes that exactly corresponded to the standardised patient presentations. A care quality scoring system was used to measure consistency in physician behaviour and the results showed that the care given in the vignette group was comparable to that given in the standard patient group indicating that GP behaviour was comparable in both groups and no significant differences were shown (quality care score was 71.0% for the vignette group and 76.2% for the standard patient group).

In a comprehensive study comparing the quality of practice Peabody et al, (2004) used a similar model to validate the quality of care offered by physicians. A similar methodology to that described above was used (outpatient setting, multisite, vignettes compared to standardised patients and case notes), except that in this study a larger sample of 116 out of 144 physicians was used. Again they found that the vignette model was valid as a means to measure the quality of care.

It has been identified that vignettes are suited to testing specialist areas (Sim and Wright 2000) and thus they were considered suitable for this study as rotator cuff pathology is a relatively specialist condition. They also allow signs and symptoms to be manipulated to test out complex attitudes or reasoning (Gould 1996) and thus they were considered particularly useful to test referral behaviour change before and after the introduction of the referral criteria. Monitoring prospective referral behaviour across a team of ESPs with regard to their working case load was considered. However aside from lack of standardisation, the time required to monitor referral behaviour in some clinicians who see shoulder patients less frequently, was considered prohibitive

for the study. For example within a six month period some ESPs may only receive referrals for a small number of patients with shoulder pathology. Even though rotator cuff tears are common amongst patients with shoulder pathology, it is possible that some ESPs would not have the number of suitable patients required within the time frame of the study.

Conversion Rates or Analysis of Records

The collection of conversion rates as a measure of clinical behaviour change was considered as a possible methodological option, but rejected due to the length of time it takes to obtain conversion rate information (which is often around one year depending on secondary care surgical waiting times). The use of actual conversion rate statistics was also rejected because it would be dependent on accessing the data bases and hospital systems of a large number of hospital trusts. It is unlikely that a large number of hospitals would allow access to their patient data base and surgical waiting list systems for data protection and commercial reasons. Therefore there would be a high dependency on the co-operation of secretarial and administrative staff employed by other trusts to manually search through a large number of records. It was considered likely that there would be low motivation for a large number of secretarial staff to take part in this activity and therefore this approach was rejected.

Standardisation of the conditions seen would also have been very difficult in a non-controlled environment and thus this method was considered suboptimal for the purposes of this study. Records analysis could also have been used, however as vignettes have been shown to be superior to chart abstraction (Peabody et al, 2000), analysis of case records was excluded from the methodological options.

Real Patients or Role Play

For a condition such as a degenerative rotator cuff prospective referral behaviour of real or fictive patients could not be easily monitored in primary care because all ESPs were geographically located across different sites. Using a real case was considered, but the difficulties of subjecting a patient to numerous subjective and objective physical examinations presented an unacceptable burden on participants, especially as rotator cuff disease primarily affects the elderly population (Lin et al, 2008). Role play with fictive patients may have been appropriate. However this was likely to be time consuming and it was possible that the same actor would not be available before and after the consensus information was developed. There was a considerable level of detail in the vignettes, particularly with regard to the loss of range and strength. It would have been very difficult for an actor to memorise this level of detail, therefore this method was discounted.

Clinical case scenarios, comparable with vignettes, were also used in previous studies of referral appropriateness in orthopaedics (Naylor and Williams 1996; Quintana et al, 2000; Musila et al, 2011) to observe medical decision-making and reach consensus. They appear to have been well received; neither study commented that the methodology had weaknesses or seemed inappropriate.

Vignettes have been shown to be valid tools to measure clinician behaviour under certain conditions provided that they are detailed enough to reflect a clinical case and allow clinicians to select realistic choices. They were therefore chosen in this study to assess practitioners' decisions about referral. They were considered to suit the primary care setting most appropriately and fulfilled the need to standardise the patient details within the experiment. They were thought to be the best way of exploring whether the consensus referral recommendations changed referral behaviour in a group of primary care ESPs. It was planned to use real patient vignettes and compare the referral decisions before and after consensus information.

4.3.2 Vignette Development

The vignettes were designed to assess practitioner referral behaviour with regard to a range of options which included injection, physiotherapy, orthopaedics, and referral back to the GP which are the primary options available to ESPs. All cases selected were based on real patients that had been referred from GPs to the specialist upper limb interface service (a community based service designed to screen patients that the GPs feel may need surgery⁴⁵). None of the patients selected had been seen by the ESPs who were to take part in the study, nor the pilot group used to test the vignettes.

Real clinical cases were used so that the vignettes were as valid and credible as possible (Barter and Renold 1999; Ludwick and Zeller 2001). The vignettes consisted of the clinical histories of 3 patients with rotator cuff tears complaining of a complex set of signs and symptoms. The information contained within the vignette was very detailed with an average of 430 words per vignette (actual words 271; 550; 467). The detail was considered important to ensure that the cases were not over simplified and so that 'the complex nature of reality was not lost' (Ludwick and Zeller 2001: 578). A range of vignettes were chosen to tease out different components of the reasoning and decision-making process as used by Rainville et al, (2000).

Patients were selected from three different clinical areas. Three separate and challenging cases were chosen to represent the range of patients that ESPs may assess. The patient's symptoms ranged from moderately severe, to very severe. Vignettes 1 and 2 were chosen from a small group of patients who were undergoing treatment at the time of the study. One was at the stage where conservative treatment had failed and the other whose treatment had just started. The third patient was chosen from a group of patients who had already been referred to surgery. Thus the selection represented an undecided case, a case in whom conservative care appeared to be the most appropriate option and a case who had already been referred to surgery. The vignettes were

⁴⁵ The service receives approximately 6000 referrals per year of which 1200 (20%) are patients complaining of upper limb pathology.

written to ensure that patients could not be identified from the information and were totally anonymous. No identifying demographic data was included such as NHS number or date of birth. Sensitive past medical history or personal information was not included.

Vignette 1 was based on a patient in significant pain who was complaining of a large rotator cuff tear. The patient had not received recent physiotherapy treatment and thus when cross referencing the vignette with the referral criteria the patient was suitable for conservative management. The conservative treatment options could have been physiotherapy or injection, but as the pain level was high and the patient's sleep was disturbed, early injection and then physiotherapy rehabilitation was a preferable choice of treatment.

Vignette 2 was based on a patient who had a complex condition with some psychosocial issues that might be barriers to recovery. Cross referencing the patient symptoms with the referral criteria indicated that the patient was suitable for conservative management in the first instance as the vignette indicated that the patient had not yet received recent physiotherapy.

Vignette 3 was chosen from a pool of 5 patients who had already been through the service and had been referred to a specialist shoulder surgeon between January 2011 and June 2011. Referral to surgery at that time was based on the current practice of the ESPs working within the shoulder speciality. There was no gold standard or informal criteria in place or available. However it is important to note that this patient had been listed for surgery and thus the target decision for this patient was orthopaedic referral based on the fact that this patient was already listed for surgery. Cross referencing the patient's symptoms with the referral criteria also indicated that this patient was suitable for a surgical opinion.

All vignette information included radiological findings to remove this variable from decision-making, as the majority of ESPs will use scans to assist their referral decisions in line with the Royal Society of Radiology Guidelines (2007).

It was also important to develop vignettes where all patients were reported to have radiologically confirmed rotator cuff tears, as without this finding there would not be a need for surgical referral. It is important to note that some ESPs may not be aware of this fact or may not be clear on the importance of it. However, the aim of the study was to test ESPs on the new knowledge available from the consensus study, and therefore this parameter was standardised across all vignettes. Patients for the vignettes were selected with a differing degree of: pain referral, previous or current treatment, stage of recovery, treatment compliance, objective findings, drug history and social history. Patients also varied in age and gender and all cases varied with regard to pain severity and its impact on sleep disturbance and difficulties in activities of daily living.

4.3.3 Testing and Reliability of the Vignette

Once the vignettes were developed they were first tested on a group of eight advanced physiotherapists, all graded at band 7. All had a minimum of five years specialised MSK physiotherapy experience. These therapists did not take part in the main study and provided feedback with regard to the clarity of the language used within the vignettes, the detail provided, the readability and the referral options. After the pilot feedback, some of the detail in the vignettes was changed and re-worded to make each vignette clearer. More detailed information was provided to highlight the objective findings.

The reliability of the vignettes was tested on fifteen ESPs in the form the percentage agreement as undertaken by Rainville et al, (2000). ESPs were recruited from an ESP training day in Northwest London. The vignettes were given to the 15 ESPs who agreed to take part. A face-to-face group setting was used at two successive regular training days. ESPs returned the vignettes to the researcher once completed at the end of the face-to-face session.

ESPs completed the vignette with one month between each test and the percentage of identical responses was calculated. Test-retest periods for vignette reliability testing vary greatly from 3-21 days (median 5 days) (Bijlenga

et al, 2009), 19 days (van der Wulp et al, 2008), 2 months (Sellier et al, 2012), 3 months (Rainville et al, 2000), and 20 months (Todoric et al, 2012). However no justification for the time length chosen has been presented in any of the studies. Van der Wulp et al (2008) demonstrated high test-retest reliability with their study, (intra-class correlation coefficient of 0.75; 95% confidence interval 0.72 to 0.77). Therefore this study aimed to follow the time duration used by van der Wulp et al, 2008). However due to difficulties accessing the test sample the time period used was increased to one month. The vignettes were also tested on three of the fifteen ESPs with a six month period between each test. This was undertaken as a secondary checking mechanism to ensure that the duration of 1 month used in the first reliability test had not been too brief and to ensure that ESPs were not influenced by the memory of their previous choices as recommended by Carmines and Zeller (1994). For the 6-month reliability test the vignettes were sent via email and returned via email for the convenience of the ESPs participating.

During the testing phase ESPs were asked to select their referral or treatment option of choice (see section 4.3.5 for referral and treatment options). They were also asked to provide brief information about their first referral or treatment option to add further reliability information. The information was used to ensure that realistic and consistent referral or treatment options had been selected. As all ESPs provided appropriate information this was not analysed further. Table 4.2 shows the percentage and the number of identical responses for each vignette when tested at one and six months.

Table 4.2: Percentage and Number of Identical Responses for Each Vignette at 1 and 6 Months

	Vignette 1	Vignette 2	Vignette 3
Percentage of ESPs with identical responses -Test Period 1 month (n=15)	93%	93%	73%
Number of ESPs with identical responses -Test period 1 month (n=15)	14	14	11
Percentage of ESPs with identical responses -Test Period 6 months (n=3)	100%	100%	100%
Number of ESPs with identical responses -Test Period 6 months (n=3)	3	3	3

4.3.4 Vignette Sample Recruitment

A convenience sample of ten ESPs working across two primary care interface services was recruited for the pilot as used in the vignette study conducted by Todoric et al, (2012). ESPs for this study were also recruited from an ESP training day in Northwest London. The ESPs were contacted by email with participant information leaflets. The vignettes were given to the ESPs who agreed to take part in a face-to-face setting at two successive regular training days.

All ESPs were representative of the sample of primary care ESPs surveyed in the first stage as recommended by Sim and Wright (2000). All ESPs worked at band 8A level, had access to radiological investigations and blood tests and had the ability to refer to secondary care. The sample was also considered to be representative of primary care ESPs as it contained ESPs that undertook

primarily triage assessment only and ESPs who undertook treatment⁴⁶. Three ESPs worked in a primarily triage environment and seven provided specialist MSK screening and treatment.

There were no clear recommendations with regard to adequate sample size for vignette studies. The vignette scenario study used by Quintana et al, (2000) consisted of nine surgeons. Similarly Peabody et al, (2000) compared two groups of 10 physicians using the same methodology.

4.3.5 Vignette Data Collection

Once the vignettes had been amended and tested for consistency, the vignettes were used to compare referral behaviour before and after receiving the consensus information. The study was conducted in two phases. In phase one each ESP was given three vignettes all of which contained detailed clinical information about patients with various stages of degenerative rotator cuff disease (ranging from moderately severe to severe). The information was given to ESPs in a group format for ease of collection and to try to ensure that the conditions were the same for all those taking part in the study. Group sessions allowed for ESPs to gain clarification about the process and also enabled the researcher to see how the criteria were received and interpreted by a relatively large number of participants.

As explained, all vignettes were based on real patients (see Appendix 10-12). At the end of each vignette ESPs were asked to choose from a range of five treatment or referral options.

⁴⁶ Primary care ESPs are made up of two groups. One group conducts primarily triage assessments only, referring patients on to others to perform physiotherapeutic or surgical treatment. The second group provides triage and physiotherapeutic treatment.

These were:

1. Refer patient for injection
2. Refer patient for orthopaedic opinion
3. Refer to physiotherapy
4. Home exercise programme and discharge back to their GP
5. Other – please state

They were asked to provide further information about referral or treatment choices if they selected the 'other' option. This option was included to give ESPs the opportunity to comment on alternative treatment approaches not presented. Morrell and Roland (1990) found that the treatment options in their vignette study had limited the GPs to unrealistic treatment choices. Therefore this option was included to provide greater validity and to prevent ESPs having to choose an unrealistic referral or treatment option, though it was not used by any ESP. Once completed the ESPs returned the vignettes back to the researcher.

In phase two, the ESPs were given the same vignettes and asked to repeat the exercise with the referral criteria. For this phase of the data collection ESPs also attended a group session. For both testing periods (before and after using the criteria) ESPs were able to ask questions with regard to information contained in the vignettes or contained within the referral criteria to improve clarity but they were not given support with regard to clinical decision-making. This was particularly important as the interaction facilitated clarification with regard to whether the referral criteria were clear and understood by the ESPs. The consensus information had been summarised into a referral criteria in one coherent table. Summary information for all areas where 70% agreement or above had been gained was included in the criteria. This was done so that large amounts of information could be reduced into one table for ESPs to read, interpret, evaluate and apply to the test vignettes. Referral options were the same, and again ESPs were asked to outline their treatment of choice if they chose option 5.

The period between the first and the second test was six months. It has been noted that the stability of the entity being measured should be considered when conducting a test-retest scenario (Knapp et al, 1998). Referral behaviour was considered to be a relatively stable entity which is supported by the work of Tejwani and Immerman (2008). When surveying a large group of surgeons they showed that practice was based on a combination of knowledge gained during training and personal experience. Taking these factors into consideration it was judged unlikely that behaviour would change significantly within the test period. This time interval of six months was considered small enough to ensure that referral behaviour would not be influenced by other factors (such as training or new knowledge). During the test period the ESPs under investigation received no in-service training sessions on the management of shoulder pathology. There were no updates to the shoulder pathway and no discussion of the ongoing research. Six months was also considered to be a large enough duration to ensure that the measure was independent (Sim and Wright 2000) and not influenced by memory and subject recall (Carmines and Zeller 1994). The benefit of a local convenience sample was that it enabled the study environment to be controlled. The local training environment was controlled ensuring that there were no local rotator cuff pathology training sessions during the two phases of the study. The group criteria session was also controlled which meant that ESPs had access to exactly the same information and did not use colleagues or specialists to influence their referral or treatment decisions (Alexander and Becker 1978).

Clarification of the criteria was not sought by participants, and there was no evidence of misunderstanding. Clarification about the process was sought and some ESPs expressed difficulty in making a definitive decision. ESPs expressed interest and surprise about some of the information in the criteria, however further clarification regarding whether this information was new knowledge for those ESPs was not sought.

4.3.6 Vignette Data Analysis

Both sets of results for each vignette were analysed with frequency analysis and percentage similar to the study conducted by Rainville et al, (2000).

Referral behaviour for each ESP was compared before and after consensus information to determine the number and percentage of ESPs who changed their behaviour. The behaviour change towards the desired outcome and behaviour change towards other referral options was noted.

Statistical analysis of the behaviour change was analysed with the paired McNemar Test. This is a form of the chi square statistic that can be used to test the hypothesis of no change before and after an intervention (Sim and Wright 2000). It is a test for nominal data (Bland 2000) and thus was appropriate for the data obtained in this study. Using the referral criteria as the gold standard, statistical analysis of the agreement or disagreement for each ESP before and after the criteria were issued was undertaken. For vignette 1 the gold standard was injection therapy, for vignette 2 the gold standard was physiotherapy, and for vignette 3 the gold standard was orthopaedics. All analyses used the conventional two-sided 5% significance level. All summaries and analyses were produced using SPSS version 15.

4.4 Summary

This chapter has justified the methodology for each stage of the study and explained the protocol for each stage in detail. A national survey of ESPs in primary care was undertaken to determine whether they recorded their ability to appropriately refer MSK patients for surgical intervention. Alongside this survey a Delphi study was undertaken to develop surgical referral criteria for degenerative rotator cuff tear pathology as this is the area where referrals to surgery are least appropriate. Finally the referral criteria were piloted on a sample of primary care ESPs to determine whether the criteria changed their behaviour when considering whether to refer for rotator cuff repair surgery. The next chapter shows the results of each stage.

Chapter 5: Results

The results from this study provide detail and interpretation with the primary focus on four research questions:

1. Do MSK ESPs in working primary care record their ability to refer appropriate patients to secondary care (as measured by the conversion rate)?
2. Do MSK ESPs in working primary care experience barriers to referral?
3. Can surgical referral criteria for degenerative rotator cuff tears be developed?
4. Can these criteria improve the appropriateness of ESP referrals?

The results are reported in three sections to address each research question. The first two questions were addressed by the findings of the referral appropriateness questionnaire and the results are found in section 5.1. Surgical referral criteria were developed through a Delphi study, the results of which are found in section 5.2. The findings of the pilot study to test the referral criteria and its impact on ESP referral behaviour are found in section 5.3.

5.1 Stage 1: Referral Appropriateness and Referral Barriers

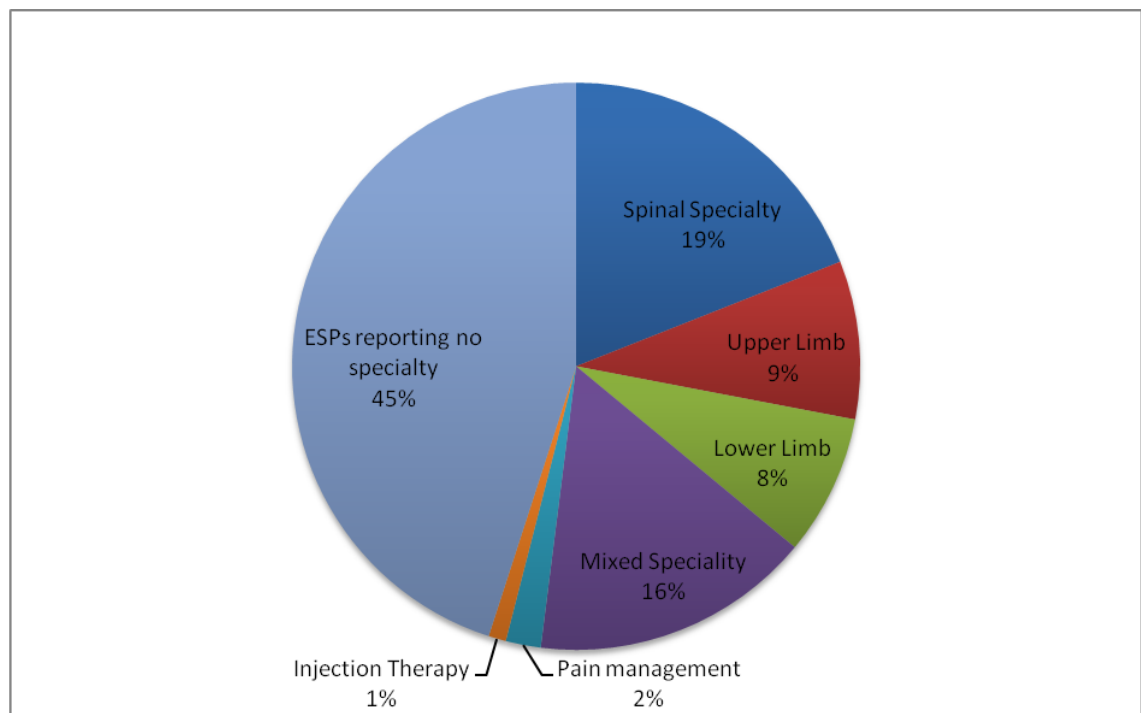
Two hundred questionnaires were sent out and 100 (50%) responses were received. One email response was inaccessible and thus the number of questionnaires for analysis was (n=99). Eighty-three (83/99; 83%) of the ESPs who responded worked in primary care, 6/99 (6%) worked in secondary care, 4/99 (4%) worked in both, and 6/99 (6%) worked in an integrated care organisation. With regard to the six ESPs who identified that they worked in secondary care, there was no clarity to indicate whether they worked in an isolated setting using the secondary care site as a clinic base, or whether they worked in a traditional setting alongside a consultant. Therefore, responses from these ESPs were included with regard to referral barriers, but data supplied by these participants was excluded from the conversion rate analysis. There were only two participants in the secondary care group that provided

conversion rate data, and two who provided information on referral barriers. (See Appendix 6 for Questionnaire).

5.1.1 Specialism

Fifty-four participants regarded themselves as having a specialism (Figure 5.1). Of those responding, 19/99 (19%) worked in the spinal speciality, 9/99 (9%) worked in the upper limb speciality, 8/99 (8%) worked in the lower limb speciality and 16/99 (16%) considered themselves to be mixed speciality ESPs. Those who identified that they worked in a mixed specialism commonly indicated that they worked in a combination such as: spinal and upper limb, spinal and lower limb, upper limb and lower limb, or upper limb and MSK ultrasound. The results show that there is some subspecialist organisation within interface services, however this organisation is not well developed with small numbers in each group. Forty-five participants (45/99; 45%) reported no speciality and a further 16/99 (16%) reported a mixed speciality which shows a more generic type role for the majority of participants who responded to the questionnaire.

Figure 5.1: Percentage of ESPs in each Specialty



5.1.2 Conversion Rate

Thirty three out of the 99 ESPs (33%) who responded to the questionnaire submitted their conversion rate data. Data were not provided by two-thirds of the participants. Six ESPs (6/99; 6%) recorded conversion rate data under more than one section so that the actual number of conversion rate statistics recorded was thirty nine.

Forty-seven of the 99 ESPs (47%) who responded to the questionnaire reported that they collect their conversion rate statistics but data were missing in 11 (11/47; 23%) of these respondents, and excluded in 3 (3/47; 6%) respondents. The excluded data were from 2 ESPs (2/47; 4%) who identified that they worked in secondary care along with data from one ESP who reported that their conversion rate data were calculated in conjunction with GP conversion rate data. Overall, the mean conversion rate for all participants was 74% (Table 5.1).

The questionnaire enabled ESPs to report the conversion rate data as representative of their team (specialist or mixed speciality team) or as a conversion rate for an individual (specialist or generalist). Of those who reported this data, most conversion rate calculations submitted represented a team of mixed speciality ESPs. Twenty two ESPs who responding to the questionnaire (22/99; 22%) reported a 'mixed team' conversion rate, the mean was 71% (Table 5.1). Seven respondents reported that the conversion rate was calculated for a single speciality team (7/99; 7%) (i.e. all ESPs working in a single speciality such as spinal care). In this sub-group analysis, the mean conversion rate was 76%. Two participants (2/99; 2%) identified their speciality and corresponding conversion rate. A conversion rate of 78% was reported for a team of spinal speciality ESPs and 79% for the knee speciality.

Six out of the specialist group of 54 ESPs (6/54; 11%) reported an individual conversion rate as a subspecialist ESP, the mean was 80% (Table 5.1). Of the nine ESPs highlighting an upper limb specialism, only one reported a conversion rate. The ESP reported that the conversion rate is usually around 90% but an accurate retrospective figure was not given. As only one sub-

specialist upper limb ESP reported conversion rate data it is not possible to draw conclusions regarding the quality of upper limb care within interface services. The lack of information submitted may suggest that analysis of personal or upper limb service conversion rates is not being undertaken. It could be a reflection of the organisation of primary care upper limb services or the level of specialism within this field. It is also possible that data was withheld due to low conversion rates. In both possible scenarios the lack of data submitted may indicate that quality may be lacking in the upper limb sub-specialty, however this is speculation.

Four ESPs from the total sample of ninety (4/99; 4%) (or 4/45; 9% of ESPs with no specialism) reported an individual conversion rate as a generic ESP with a mixed caseload (Table 5.1). The four scores were 30%, 85%, 87% and 95%, with a mean of 74%. Apart from the data reported from ESPs working in a team of mixed speciality ESPs, the number of ESPs reporting conversion rates from the other groups was low. Therefore it is not possible to identify whether the mean conversion rate is higher within a particular group or specialism such as subspecialist ESPs working within the upper or lower limb. Overall the mean conversion rate for all groups ranged from 71% (mixed speciality team ESPs) to 80% (individual subspecialist ESPs) showing little variation across the groups.

Table 5.1: Conversion Rate Statistics for Each Group

Team or Individual	Number of conversion rates reported	Mean Conversion Rate	Range
Overall Mean Conversion rate	39	74%	30-95%
Mixed Speciality Team	22	71%	30-95%
Single Speciality Team	7	76%	60-85%
Single speciality ESP	6	80%	65-90%
Generic ESP	4	74%	30-95%

(Note: Total number of ESPs =33, some ESPs reported more than 1 rate)

From the analysis of the open-ended questions one comment that ESPs frequently made with regard to the conversion rate data was that it was very difficult to collect. Sixteen ESPs (16/99; 16%) reported that they had difficulty collecting conversion rate data (see Appendix 13 for a selection of the open comments relating to conversion rate data collection). ESPs commented on the lack of feedback they received from secondary care trusts which made it very difficult to analyse their conversion rates accurately. ESPs noted that lack of formal feedback in the form of clinic letters and similar correspondence was one of the most significant barriers to calculating their personal conversion rates.

5.1.3 Barriers to Referral for Investigations

Ninety-eight respondents (98/99; 98%) reported that they were able to refer for radiological investigations with 74/98 ESPs (76%) indicating that they used radiological criteria. Twenty seven (27/98; 28%) used a locally developed imaging referral guide, and 15 (15/98; 15%) used the Royal College of Radiology (RCR) Guidelines. Six respondents (6/98; 6%) used Ionising Radiation (Medical Exposure) Regulations as a referral guide and 3 (3/98; 3%) indicated that they did not use any criteria but tried to follow guidance from clinical courses or research findings indicating the sensitivity and specificity of particular investigations. Thirty-six (36/98; 37%) respondents did not name the guidelines they used. Forty three (43/99; 43%) identified that they had experienced barriers when referring for radiological investigations. Of those who made comments with regard to referral barriers, commissioning barriers were a common theme, where referral pathways were too limited to allow patients adequate choice, or where pathways for certain investigations such as MRI or open MRI had not been negotiated. There were a small number of comments which indicated that access to radiology was only available through a consultant for specific investigations such as MRI. The reasons for these problems were cited as being associated with professional barriers, waiting lists or capacity considerations.

Of the 9 (9/99; 9%) ESPs identifying a specialism within the upper limb field 3 (3/9; 33%) reported experiencing barriers to radiological referral, which is a slightly smaller proportion when compared to the total group reporting barriers

(43/99; 43%). One ESP identified that barriers were associated with lack of access to MRI and one had no access to MRI and US. Due to the small numbers of upper limb ESPs it is difficult to draw conclusions with regard to whether these referral barriers specifically impact on the quality of care delivered by upper limb ESPs. However as there are fewer radiological barriers reported it would appear that this is not a factor in the quality of care delivered by upper limb ESPs in primary care.

5.1.4 Referral Barriers to Secondary Care

Thirty-eight (38/99; 38%) of the ESPs highlighted that they had difficulty referring patients to specialists. Ten main themes emerged from the open-ended questions regarding referral barriers. Some ESPs identified multiple difficulties and thus each barrier identified was coded into one of the ten themes. As with the previous section, the lack of fully commissioned pathways was the most common barrier to appropriate referral. Seventeen ESPs from the total sample of 99 (17%) identified commissioning barriers. Thus 45% (17/38) of those reporting barriers to referral experienced commissioning barriers. The second most common barrier was lack of knowledge/experience with regard to referral appropriateness, closely followed by difficulties identifying surgical referral criteria. Table 5.2 shows the numbers of ESPs citing each barrier.

Table 5.2: Number of ESPs Citing Specific Referral Barriers (n=38)

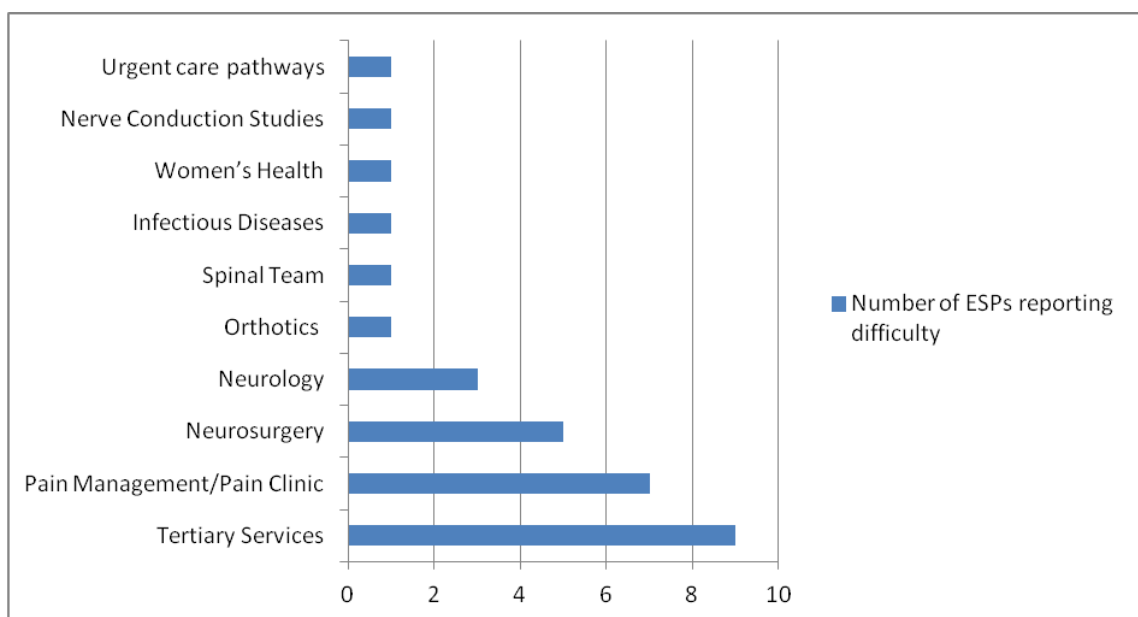
Main Themes from Open Questions	Number of ESPs
Lack of appropriately commissioned care pathways	17
Knowledge and Experience	8
Surgical Referral Criteria and Consensus	6
Waiting List Barriers	4
Administrative or Operational Issues	4
Communication	3
Pressure not to refer	1
Relationship with medical staff (GPs and consultants)	1
Lack of available choice for procedures	1
Triage Barriers	1

When commenting on the lack of appropriately commissioned pathways ESPs identified that referral pathways had not been developed for all conditions which led to difficulty particularly when referring rarer conditions, or where the condition was complex. Many ESPs identified that a number of referrals had to be countersigned by GPs, or were subject to other rationing procedures which impacted on their ability to refer. They commented that urgent-care pathways for suspected malignancy or cauda equina lesion were often incomplete. ESPs also found it particularly difficult to refer patients to tertiary centres and pain management services. Figure 5.2 shows the services to which the ESPs surveyed found most difficult in making referrals.

When commenting on consensus a small number of ESPs identified that there was a lack of consensus for many surgical procedures, even between

specialists in the same field and within the same hospital, which made it difficult to refer the most appropriate patients along a specific care pathway. Lack of formal feedback from consultants was frequently noted as a hindrance to appropriate referral, with several ESPs noting that consultants often informed the patient's GP about their assessment and treatment plan rather than informing the ESP directly.

Figure 5.2: Services to which ESPs Found Most Difficulty in Making Referrals (n=38)



Of the 9 ESPs (9/99; 9%) in the upper limb specialty, 4 (4/9; 44%) reported barriers when referring to consultants which is a slightly higher proportion than the barriers reported by the total group (38/99; 38%). One of these ESPs reported that barriers were specifically related to the nerve conduction studies pathway, a pre-requisite for carpal tunnel surgery. However due to the small number of responses from upper limb ESPs it is difficult to draw conclusions with regard to whether these referral barriers can be generalised to the majority of primary care ESPs working in the upper limb field.

5.1.5 Criteria for Referral

Fifty ESPs (50/99; 50%) reported that they used referral criteria when referring patients to secondary care. An open question was used to determine how these referral criteria were developed. The responses from the open section fall into nine themes as shown in Table 5.3. Collaboration between primary and secondary care was the most common method of developing ESP referral criteria, followed by use of national guidelines or the ESP's own knowledge or clinical reasoning. Some therapists identified that only general rather than condition specific referral criteria were in use. One therapist commented that the 'lack of condition specific criteria may be a reason why the conversion rates within their department were not higher'.

During data analysis the number of ESPs who had reported using referral criteria was cross checked with those who had reported a conversion rate statistic. However no conclusions could be made with this group due to the lack of data.

Table 5.3: Methods of Criteria Development used by ESPs/Interface Services (n=50)

Options for referral criteria development	Number of ESPs
Collaboration between primary and secondary care	38
National Guidelines, Clinical Reasoning	8
Informal Review by Consultant specialist	5
Policies or Pathways developed by Commissioners	5
Generic Criteria and Failed Conservative Management	3
Validated Outcome Measures (e.g. Oxford hip/knee score)	3
Peer Support	1

Options for referral criteria development	Number of ESPs
Patient Choice	1
Clinical Judgement	1

Three of the nine upper limb ESPs (3/9; 33%) reported using referral criteria. All criteria were identified as having been developed in partnership with secondary care. The results show that is a smaller proportion than the results from the total group (50/99; 50%), however the number of respondents is too small to make general conclusions with regard to whether this finding demonstrates reduced quality within the upper limb field.

When compared to the other subspecialist groups (spinal and lower limb), the number of upper limb primary care ESPs using criteria is also shown to be lower. In the lower limb group four out of seven ESPs (57%) reported using referral criteria and in the spinal group nine of the nineteen ESPs (47%) reported using referral criteria. Though these results are obtained from three small samples they add support to the hypothesis that there is a lack of referral criteria within the upper limb specialty.

5.2 Stage 2: Referral Criteria for Degenerative Rotator Cuff Repair

Twenty consultants (20/41) responded to the questionnaire, which was a response rate of 49% for the first round of consensus questionnaires. In the second round only those consultants that had responded to the first round were included. Of the twenty consultants contacted to take part in the second round, three consultants dropped out of the study because of work commitments which reduced the sample to seventeen. Of these seventeen consultants, eleven returned the questionnaire which is a response rate of 65% for the second round.

A summary of the results from the first and second round is presented first followed by detailed results from each section. The closed and open responses for each question are integrated and the general themes from the qualitative information with supporting examples are presented. The areas of consensus have been listed and referral criteria have been developed for use within clinical practice (Table 4.1 page 162).

5.2.1 First and Second Round Questionnaire

The percentage agreement for each question from the first round questionnaire can be seen in Table 5.4 ranked in order of highest to lowest agreement. The agreement for each question for each of the five response options can also be seen in the Appendix 14. After the first round there was agreement on 11/24 of the statements (46%), (one of these actually was strong disagreement). There was low agreement on 3/24 questions (13%) and moderate agreement for the remaining 10 questions (42%) (see Section 4.2.15 page 159 for consensus threshold clarification). Statements where consensus agreement or disagreement had been between 41%-69% were then sent out for further agreement with the previous scores identified under each question. Thus out of the original number of twenty four questions, fourteen questions were removed and ten questions sent out for the second round.

The results from the second round are shown in the Appendix 15. After the second round high agreement was reached on three further statements. Moderate agreement was reached in 4 statements and low agreement was reached in the remaining 3 questions. The statements with high agreement from both rounds were combined to show all statements where agreement was 70% or above (Table 5.5, page 196).

When analysing the first and second round results together, consensus was achieved in 14/24 statements (58%) (Table 5.5, page 196). Consensus was set at 70% agreement (see Section 4.2.15, page 159). No agreement could be reached on the remaining 10 statements (42%). Four areas where consensus could not be reached, which impact greatly on referral decisions were added to the referral criteria for ESP information purposes only and to demonstrate the

diversity of opinion amongst surgeons. These areas were pain and weakness on muscle testing, investigations for subacromial narrowing or spurs and the lack of agreement regarding the impact of the dimensions of a rotator cuff tear. The remaining statements where consensus could not be reached were not included in the referral criteria.

There were also a small number of responses to the open questions which fall into two themes (Table 5.5 page 196). Key responses to the open questions which relate to each area of the criteria have also been integrated into the analysis where they provide further clarification or explanation of the results.

Table 5.4: First Round Agreement and Disagreement percentages for all statements ranked in order of consensus agreement (n=20)

Con-sensus Ranking	Clinical Statement (note original questionnaire number is at the beginning of each statement)	% Agree	% Disagree	% Neither
1	1.3 When considering surgery for repair of a degenerative rotator cuff tear the severity of the pain symptoms are a determining factor.	95%	5%	0%
2	2.4 When considering surgery for repair of a degenerative rotator cuff tear, significant limitation of normal activities of daily living (for example eating, combing hair, dressing, driving) would make me inclined to operate.	85%	0%	15%
3	1.6 When considering surgery for repair of a degenerative rotator cuff tear it is important that the referrer includes information about the presence of psychosocial issues (for example treatment compliance, passivity, acceptance, beliefs about cure, family issues, litigation).	80%	5%	15%

Con-sensus Ranking	Clinical Statement (note original questionnaire number is at the beginning of each statement)	% Agree	% Disagree	% Neither
4	3.11 The presence of fat atrophy is a factor in whether I decide to operate on a patient with degenerative rotator cuff disease. (Grade 3 fat atrophy is the cut off for many but it is not an absolute)	80%	15%	5%
5	3.10 If the conditions were right, I would operate on a patient with multiple full thickness tears.	75%	5%	20%
6	3.1. The shape of the tear (e.g. transverse, crescent or U shaped) determines whether I decide to operate on the patient.	5%	75%	20%
7	2.3. I do not attempt to repair a degenerative rotator cuff if a patient presents with a painful/active phase frozen shoulder/adhesive capsulitis.	75%	10%	15%
8	1.4 When considering surgery for repair of a degenerative rotator cuff tear, the success with previous interventions (for example physiotherapy, injection, pain management programme) is a determining factor.	75%	10%	15%

Con-sensus Ranking	Clinical Statement (note original questionnaire number is at the beginning of each statement)	% Agree	% Disagree	% Neither
9	1.1 When considering surgery for a degenerative rotator cuff tear the age of the patient is a determining factor. (The mean cut off age was 70, for one it was 80 and for one it was 65)	70%	15%	15%
10	3.8 I would operate on a patient with a degenerative rotator cuff tear in any of the rotator cuff tendons.	70%	10%	20%
11	3.9 If the conditions were right, I would operate on a patient with multiple partial thickness tears.	70%	15%	15%
12	3.4 The extent of the retracted ends of the tear determine whether I operate on a full thickness tear.	65%	30%	20%
13	3.7 I do not operate on massive tears.	10%	65%	25%
14	2.5 When considering surgery for repair of a degenerative rotator cuff tear, significant limitation of advanced function (for example golf, tennis, squash, swimming, weightlifting) would make me inclined to operate.	60%	25%	15%

Con-sensus Ranking	Clinical Statement (note original questionnaire number is at the beginning of each statement)	% Agree	% Disagree	% Neither
15	3.5 In your experience, are specific tear dimensions associated with poor surgical outcomes?	60%	40%	0%
16	1.5 I would not operate on a patient who has had a delay of several years between injury of the rotator cuff and surgical repair.	20%	55%	25%
17	3.2 The size and dimensions of the tear determine whether I operate on a partial thickness tear.	55%	25%	20%
18	2.2 When considering surgery for repair of a degenerative rotator cuff tear the patient must have weakness on resisted muscle testing for the tendon being repaired.	50%	10%	35%
19	2.6 In patients who present with shoulder impingement symptoms, where a degenerative cuff tear is suspected, I prefer to investigate the extent of subacromial narrowing before I decide to operate.	50%	30%	20%

Con-sensus Ranking	Clinical Statement (note original questionnaire number is at the beginning of each statement)	% Agree	% Disagree	% Neither
20	1.2 When considering surgery for repair of a degenerative rotator cuff tear the patient's occupation/ hobbies are a determining factor (i.e. are outcomes are associated with specific jobs/hobbies?).	45%	20%	35%
21	2.1. When considering surgery for repair of a degenerative rotator cuff tear the patient must have pain on resisted muscle testing for the tendon being repaired.	45%	20%	35%
22	3.3 The size and dimensions of the tear determine whether I operate on a full thickness tear.	40%	40%	20%
23	2.7 In patients who present with shoulder impingement symptoms, where a degenerative cuff tear is suspected, I prefer to investigate for the presence of a subacromial spur before I decide to operate.	35%	40%	25%
24	3.6 The site of the tear within a specific tendon is important in determining whether to operate on a degenerative rotator cuff tear.	20%	35%	45%

Table 5.5: Final agreement showing statements from both rounds where percentage agreement was 70% or above.

	Clinical Statement	% Agreement
1	1.3 When considering surgery for repair of a degenerative rotator cuff tear the severity of the pain symptoms are a determining factor.	95%
2	2.4 When considering surgery for repair of a degenerative rotator cuff tear, significant limitation of normal activities of daily living (for example eating, combing hair, dressing, driving) would make me inclined to operate	85%
3	2.5 When considering surgery for repair of a degenerative rotator cuff tear, significant limitation of advanced function (for example golf, tennis, squash, swimming, weightlifting) would make me inclined to operate.	81%
4	1.6 When considering surgery for repair of a degenerative rotator cuff tear it is important that the referrer includes information about the presence of psychosocial issues (for example treatment compliance, passivity, acceptance, beliefs about cure, family issues, litigation).	80%
5	3.11 The presence of fat atrophy is a factor in whether I decide to operate on a patient with degenerative rotator cuff disease (Grade 3 fat atrophy is the cut off for many but it is not an absolute)	80%
6	3.10 If the conditions were right, I would operate on a patient with multiple full thickness tears	75%

	Clinical Statement	% Agreement
7	3.1 The shape of the tear (e.g. transverse, crescent or U shaped) does not determine whether I decide to operate on the patient.	75%
8	2.3. I do not attempt to repair a degenerative rotator cuff if a patient presents with a painful/active phase frozen shoulder/adhesive capsulitis.	75%
9	1.4 When considering surgery for repair of a degenerative rotator cuff tear, the success with previous interventions (for example physiotherapy, injection, pain management programme) is a determining factor.	75%
10	1.2 When considering surgery for repair of a degenerative rotator cuff tear the patient's occupation/hobbies are a determining factor (i.e. are outcomes associated with specific jobs/hobbies?)	73%
11	1.5 I would not operate on a patient who has had a delay of several years between injury of the rotator cuff and surgical repair.	73% disagree Thus a delay is not important
12	1.1 When considering surgery for a degenerative rotator cuff tear the age of the patient is a determining factor. (The mean decision point was 70 yrs, for one it was 80 yrs and for one it was 65 yrs)	70%
13	3.8 I would operate on a patient with a degenerative rotator cuff tear in any of the rotator cuff tendons	70%
14	3.9 If the conditions were right, I would operate on a patient with multiple partial thickness tears.	70%

(Note: After the second round 3 more statements were added. The original questionnaire number is at the beginning of each statement).

5.2.2 Analysis of Subjective Characteristics

Pain

Nineteen consultants (95%; 19/20) agreed after the first round that the severity of the pain was an influencing factor when deciding whether to operate on a patient with a degenerative rotator cuff tear. This was the area which achieved the highest consensus within the study. Pain of at least 6 months duration was identified by one surgeon as an appropriate threshold to consider surgery.

Patient Age

Fourteen consultants (70%; 14/20) agreed (at the end of the first round) that age was a determining factor when deciding whether to operate. However only four consultants documented the age they felt was an appropriate upper limit. For two consultants this was up to 70 years, for one it was up to 80 years and for the other one it was up to 65-70 years. Though it can be concluded that age does influence the surgeon's decision to operate, there is no consensus about the actual cut off age used by surgeons.

Psychosocial factors

Sixteen consultants (80%; 16/20) agreed that it was important that referrers include information about the presence of psychosocial factors such as litigation, fear avoidance behaviour, patient's beliefs and passive approaches to treatment. Consultants were not asked directly whether psychosocial factors influence their decision to operate because this area is complex and each construct would probably need to have been investigated separately and in detail (e.g. fear avoidance, health beliefs, ongoing litigation, passivity, depression, anxiety). However one consultant indicated that litigation was the main psychosocial factor that interested him/her.

Previous Interventions

Fifteen consultants (75%; 15/20) agreed that the success with previous treatment such as physiotherapy, pain management or injections is a determining factor when deciding to operate. The qualitative information which

accompanied this question was limited as only a small number of surgeons responded. However one surgeon indicated that he felt that in his experience patients do not have enough robust physiotherapy exercise before they are sent for an opinion. He commented that he felt that too many clinicians pay attention to the scan results rather than paying attention to the patient's symptoms (see Appendix 16).

Another surgeon commented that before referral, patients should have a trial of exercise based physiotherapy and should have a favourable response to injections (no more than 3 injections). In the pilot study interviews (Appendix 7) these views were echoed by another surgeon who indicated that before he operated he expected patients to have an extensive course of physiotherapy and if this had failed he expected the patient to have had two injections before being referred, one of these would preferably be an US guided injection. The success of the injections (expected outcome was short term pain relief) would then demonstrate whether or not the patient's pain was of an impingement type nature and suitable for surgery.

However in contrast to these views, one surgeon commented in the open section that physiotherapy and conservative interventions "were a waste of time and money which delayed the inevitable and probably made the result less successful" (see Appendix 16 for surgeon's comments). It is important to note however that this view was expressed by one surgeon only. The other comments expressed in various sections suggest that surgeons do expect patients to try a course of physiotherapy and possibly other courses of treatment such as injection before proceeding to a surgical opinion.

Delay between Injury and Repair

Initially there was no consensus regarding surgery in the circumstances of delay between injury and repair. However after the second round, eight consultants out of the eleven (73%; 8/11) disagreed with the statement 'I would not operate on a patient who has had a delay of several years between injury of the rotator

cuff and surgical repair', thus showing consensus that delay would not deter a surgeon from operating.

5.2.3 Analysis of Objective Characteristics

Function

After the first round questionnaire seventeen consultants (85%; 17/20) agreed that limitation of a patient's normal activities of daily living (ADL) was a factor influencing a surgeon's decision to proceed with a rotator cuff repair. After the first round limitation of advanced function did not meet consensus (60% agreement only) and thus consultants were asked again about this parameter. After the second round nine out of the eleven consultants (9/11; 81%) responding to the questionnaire agreed that limitation of advanced function does influence a surgeon's decision to operate. This is a shift from 60% to 81%. This was the highest agreement reached in the second round questions. After the second round, eight consultants (73%; 8/11) also agreed that the patient's hobbies or occupation were a determining factor when considering surgery, in the context that they influenced the outcome of surgery. The qualitative information that accompanied this statement from 3 consultants was generally consistent in that surgeons would not deny surgery to those with specific occupations or hobbies, but would counsel patients on the possible outcomes. For example consultants would advise patients that functional recovery after surgery may not be of a high enough level to resume previous activities.

Muscle Weakness and Pain on Muscle Testing

Perhaps one of the most significant findings concerns resisted tests for pain and muscle weakness. After the second round questionnaire only seven surgeons (64%; 7/11) agreed that 'patients must have weakness on resisted muscle testing for the tendon being repaired'. This was a shift from 50% agreement in the first round. This level of agreement does not signify consensus, though it could be seen as a trend towards higher agreement. Interestingly the percentage of consultants disagreeing also rose from 10% to 18% in the second

round which tends to show little overall gain in agreement. Three surgeons who agreed with this statement clarified that they felt that it was important to have weakness in comparison to the unaffected side. Two surgeons identified that they felt that weakness around grade 3 and 3-4 out of 5 on the Oxford Scale was relevant. One surgeon commented that the presence of a lag sign or significant external rotation weakness - particularly in infraspinatus tears was important. The same surgeon commented that lack of weakness should not be used to 'deny' surgery to patients.

Along the same lines, no agreement was reached on whether the patient 'must' have pain on resisted muscle testing for the tendon being repaired. Initially, after the first round the level of agreement was 45% (disagreement 20%). After the second round consensus agreement reduced to 35% agreement and disagreement increased showing no consensus in either round with regard to the importance of pain on resisted muscle testing for the tendon being repaired. Both of these results demonstrate that key areas of the objective examination are not considered to be significant markers which could help to ensure that patients are appropriately selected for surgery.

Acute/Active Phase Frozen Shoulder

Fifteen consultants (75%; 15/20) agreed that patients with painful/active phase frozen shoulder should not be referred for rotator cuff repair. One surgeon clarified with the comment that there may be a need to assist with the rehabilitation of a frozen shoulder by supporting with other treatments before repair.

Bony Morphology

Question 2.6 and 2.7 concerned x-ray investigations for subacromial narrowing and subacromial spurs. With regard to investigations of subacromial spurs, at the end of the first round questionnaire only 35% (7/20) agreed that it was important to investigate for a subacromial spur (40%; 8/20; disagreed). This question was therefore removed at this stage. With regard to subacromial narrowing, at the end of the first round there was no agreement on whether to

investigate for the presence of subacromial narrowing (agreement 50%; disagreement 30%). After the second round the percentage agreement decreased slightly from 50% to 45%, thus only 45% of consultants agreed that investigations of the subacromial space to assess for narrowing were necessary before decisions about surgery could be made. Two consultants commented that they did undertake x-rays sometimes but not with every patient.

The range of responses to the open question supports the consensus results accurately. One consultant commented that he investigated for subacromial spurs both radiologically and at arthroscopy. Two other consultants commented that they did not investigate for narrowing or spurs; one clarified that he looked for a cuff tear and accompanying bursitis with US or MRI. Another commented that he/she “just wanted to know the size of the tear and what the muscle behind looked like”.

Consultants were not questioned directly about whether they arranged MRI or US investigations prior to surgery as guidelines from the Royal College of Radiologists exist (Royal College of Radiologists Guidelines 2007). It was thus considered to be established clinical practice. Many open comments in different sections confirmed that consultants used MRI or US to confirm their suspicions about a tear, or clarify the extent of the tear. For example comments such as “I look for a tear and bursitis with MRI or ultrasound” and “I investigate fatty infiltration with MRI”.

However the responses to the open questions from three consultants indicated that they only assess the tear when they are at the surgery stage. This suggests that for a small number of consultants no qualitative information is gained from the scan and that they do not use the scan to determine the extent of the condition. Thus for some consultants the scan may be used only to indicate that a tear exists and no other information is gained at this stage.

There is no consensus about investigations for bony morphology. A small number of consultants indicated that they investigated for bony morphology in

some patients. A small number identified that they do not investigate at all and one identified that he/she does investigate the bony features with x-rays. The lack of consensus does not suggest that ESPs should routinely investigate for subacromial narrowing or spurs before referral.

5.2.4 Analysis of Tear Characteristics

Many factors associated with the dimensions of a tear do not appear to influence the surgeon when deciding to operate on a rotator cuff tear. The shape of the tear is not an influencing factor. Fifteen consultants (75%; 15/20) disagreed that the shape of the tear influenced their decision to operate. When asked about whether the site of the tear within a specific tendon is important in determining whether to operate on a degenerative rotator cuff tear only four (20%; 4/20) agreed that it was (35%; 7/20 disagreed and 45%; 9/20 answer neither). Thus there is no consensus to guide referrers to avoid referring tears within specific areas of the tendon, and no information to indicate that surgeons believe that specific tear sites respond better to surgery.

Full Thickness and Partial Thickness Tears

There was agreement that surgeons would operate on patients with multiple full thickness tears and multiple partial thickness tears; consensus agreement was 75% and 70% respectively. Thus multiple tears are not a barrier to referral. Consensus could not be reached in this area for whether the dimensions of a partial thickness or full thickness tear influence the surgeon's decision to operate. After the first round 40% (8/20) agreed that the size and dimensions of a full thickness tear influenced their decision to operate and 40% (8/20) disagreed, indicating a clear lack of consensus. After the first round there was a slightly greater level of agreement for whether the dimensions of partial thickness tears influenced their decision to operate, with 55%; 11/20 agreement and 25%; 5/20 disagreement. After the second round, there was a shift in agreement from 55% (11/20) to 27%; (3/11), and a matched increase in disagreement from 25% (5/20) to 64% (7/11) disagreement. This is the most significant change after the second round and appears to indicate that the feedback from the first round enabled surgeons to be clearer on their answers to this question. Though this level has not reached consensus the shift shows a

trend towards the suggestion that the dimensions of a partial thickness tear do not significantly influence the surgeon's decision to operate.

Tear Size and Surgical Outcomes

After the first round twelve surgeons (60%; 12/20) agreed that specific tear dimensions were associated with poor surgical outcomes, eight surgeons disagreed (40%; 8/20). Agreement increased to 64% (7/11) after the second round, with the number of surgeons who disagreed reducing from 40% (8/20) in the first round to 27% (3/11). Those expressing no preference increased to 9% (1/11) suggesting that overall disagreement had reduced a little. Despite this shift the findings were not considered to have reached adequate consensus.

Interestingly massive tears cannot be used as an indicator for those who should not be referred. When surgeons were asked to agree or disagree with the statement 'I do not operate on massive tears' there was an initial agreement of 65%; 13/20. However after the second round there was a significant change in consensus from 65% (13/20) to 36% (4/11) agreement (36% disagreed; 36% agreed; 28% neither). Though there is no agreement regarding surgery for massive tears the results must be seen in the context that 64% (7/11) of surgeons agreed that specific tear dimensions are associated with poor surgical outcomes. Although surgeons are aware of the outcomes, they do not use this parameter as a surgical threshold to select the most appropriate patients for surgery.

Surgeons were asked about tendon retraction as well as general tear dimensions. When the consultants were specifically asked whether the extent of the retracted ends determines whether they operate on a full thickness tear, 65% (13/20) initially agreed that the extent of retraction was an influencing factor. This decreased to 63% (7/11) after the second round. This was not high enough to reach consensus particularly as the number of surgeons disagreeing increased from 30% to 36% (4/11).

One surgeon commented that the mobility of the cuff and the quality of the tissues, at the time of surgery, is more important than the physical size of the tear as measured on a scan. Two other surgeons commented that no decisions about the tear size, dimensions and tissue quality would be made prior to the surgery, though this view was not echoed by the majority of surgeons. Surgeons were asked to indicate the tear size that they used as a general rule to guide their choice about surgery. Eight surgeons (40% of the initial sample size; 8/20) gave tear dimensions that they used as a surgical threshold. Three of these surgeons (3/20) gave a description of the tear dimensions they used (see Appendix 16). The responses from the others ranged from tear sizes of 3cm to 10cm. Thus no consensus regarding a tear size threshold or a level of retraction could be identified.

Tendon Quality and Fat Atrophy

Sixteen consultants (16/20; 80%) agreed that the presence of fat atrophy was a deciding factor when considering repair. Twelve of these 16 consultants commented on the grade of fat atrophy they considered to be the cut off for surgery and the remaining 4 did not provide a cut off grade. As with tear size, the responses and grades were very variable (see Table 5.6 for grades). Four consultants said that the cut off was grade 3 on the Goutallier et al, (1994) scale. Of these, two consultants clarified that in a patient with a significantly sized chronic tear they would be reluctant to operate in patients with fat atrophy of grade 3 or above.

Table 5.6: The Number of Consultants Selecting Each Fat Atrophy Grade

Grade of Fat Atrophy	Number of consultants selecting grade
2	1
Greater than 2	1
2-3	1
3	4
3+	1
3-4	3
4	1
No cut off	4

Two surgeons identified that fat atrophy of grade 3 or above was associated with poor outcome, but they indicated that they did not use this finding as a surgical decision point. In contrast one surgeon commented that fat atrophy of grade 2 was associated with poor outcome and thus reconstruction may be avoided in this group of patients.

5.2.5 Analysis of Responses to Open Questions

As well as clarifying statements and comments regarding specific questions, after analysis of the open responses, two other key themes emerged (see Table 5.7 page 207 for open comments associated with key themes). The two themes were;

1. Lack of appropriate conservative treatment before referral to surgery
2. Surgery Denial

Two surgeons expressed views that comprehensive conservative treatment needed to be undertaken before referral to surgery and one other surgeon highlighted their own criteria showing the progression through conservative options.

The theme regarding surgery denial was also expressed by two surgeons. They were concerned that criteria would lead to patients being denied access to surgery. One surgeon felt that all patients should have a discussion with the surgeon rather than patients being selected and referred based on the level of suitability. One surgeon found it difficult to answer definitively when the questions contained words like ‘must’, this may have reduced the level of consensus in question 2.1 and 2.2.

Table 5.7: Key Themes from the Open Questions with Supporting Statements

Key Themes from Open Questions
1. Lack of appropriate conservative treatment before referral to surgery
Comment 1 <i>‘My experience is that many patients are sent to me before they have had a trial of non operative management. Too much emphasis is placed on the results of MRI or ultrasound examination, and not enough on patient symptoms and examination’.</i>
Comment 2 <i>‘Before referral, patients should have a trial of exercise based physiotherapy and should have a favourable response to injections’</i>
One surgeon gave his/her own criteria as below <ul style="list-style-type: none"> • <i>‘More than 6 months of symptoms</i> • <i>A trial of exercise based physiotherapy</i> • <i>Response to injections – no more than 3</i> • <i>Pain bad enough to consider surgery</i> • <i>Patient fit for surgery, willing to undergo surgery, and prepared for long rehabilitation process’</i>

Key Themes from Open Questions
2. Surgery Denial
Comment 1
<i>'I think it depends on the patient,- clearly ADL is important for everyday but so is golf etc for some and if they want it, are prepared to go through the rehab, face the possibility/fact of failure of the cuff or the surgery not relieving the pain - then why not operate - I would not want a physio to deny someone a referral. I think the surgeon alone should have the conversation with the patient. There is not good enough strong evidence about cuff tears to deny surgery.'</i>
Comment 2
<i>'I would not deny surgery to patients with dominant shoulder pain in an overhead labourer' even though outcomes may be worse in patients with occupations of this type'.</i>

Another allied but separate theme was the finding that five participants also commented (both formally in the open section and informally via email) that they felt that the consensus questionnaire was a good idea. The reasons associated with the comments were variable and fell into three main themes which included awareness that there is very little research evidence to guide practice; a lack of certainty about what the current research indicated, and an uncertainty about their own optimum patient selection. Three surgeons asked for direct feedback of the results after the study was completed. One surgeon also commented on the different approaches of those trained in France and those trained in America and how these different approaches may affect the surgical management of rotator cuff tears. It was highlighted that though different approaches were evident, it was not clear which was superior and which may or may not have an adequate evidence base.

5.3 Stage 3: Referral Criteria and ESP Behaviour

Nine primary care ESPs were recruited into the vignette study. The results for each vignette can be seen in Table 5.8, page 210. Overall the largest behaviour change occurred with vignette 3. For vignette 3 there was a change in behaviour in four out of nine ESPs, (and all behaviour change resulted in a shift towards a less conservative approach). This represents a behaviour change of 44% through the introduction of the referral criteria. At phase 1, three of the nine ESPs had selected orthopaedic opinion and these ESPs repeated the same responses and selected surgery at phase 2. Three separate ESPs changed their referral option from physiotherapy to orthopaedic opinion at phase 2. Detailed analysis of the referral behaviour for each vignette is identified after Table 5.8.

For each vignette the gold standard was determined by applying the referral criteria developed in the second phase of the study to each case. For vignette 1 the gold standard was injection therapy, for vignette 2 the gold standard was physiotherapy, and for vignette 3 the gold standard was orthopaedic opinion.

Table 5.8: ESP referral choices before and after each vignette

ESP	Vignette 1		Vignette 2		Vignette 3	
	Before	After	Before	After	Before	After
1	Physio	Physio	Physio	Physio	Physio	Physio
2	Physio	Physio	Physio	Physio	Ortho	Ortho
3	Physio	Physio	Physio	Physio	Physio	Ortho
4	Injection	Injection	Ortho	Physio	Physio	Injection
5	Injection	Injection	Physio	Physio	Ortho	Ortho
6	Injection	Injection	Injection	Injection	Injection	Injection
7	Physio	Physio	Physio	Physio	Ortho	Ortho
8	Injection	Physio	Physio	Physio	Physio	Ortho
9	Physio	Ortho	Physio	Physio	Physio	Ortho
Total Physio	5/9	5/9	7/9	8/9	5/9	1/9
Total Injection	4/9	3/9	1/9	1/9	1/9	2/9
Total Ortho	0/9	1/9	1/9	0/9	3/9	6/9
Gold Standard	Injection		Physio		Ortho	
Total against the gold standard	4/9	3/9	7/9	8/9	3/9	6/9

Key: physio=physiotherapy; Ortho= orthopaedic opinion. The results highlighted in Table 5.8 in yellow show where ESPs changed their behaviour. The results in dark purple highlight those ESPs who had already chosen orthopaedic opinion at phase one. The total number of ESPs was nine so all totals are shown out of nine.

Vignette 1

Applying the gold standard to vignette 1 indicated that the most suitable option was physiotherapy in the first instance. Conservative treatment options could

have been physiotherapy or injection, but as the pain level was high and the patient's sleep was disturbed, early injection was a preferable choice of treatment. Initially all ESPs chose a conservative option (5 ESPs; 55% chose physiotherapy and 4 ESPs; 44% chose injection). After ESPs had been given the referral criteria, two out of nine ESPs (22%) altered their behaviour. One ESP changed their referral decision from physiotherapy to orthopaedic referral and the other changed from injection to physiotherapy. Against the gold standard this shows that initially 4/9 ESPs chose injection, but after the referral criteria only 3/9 ESPs chose injection showing a worsened position when using the criteria.

The patient's presenting signs and symptoms in vignette 1 and 3 were similar. However in vignette 3 the information explained that the patient had tried exercises recently, (both had previously received injection therapy which had failed). The fact that the patient in vignette 1 had been given an injection previously could have influenced some ESPs choose physiotherapy rather than injection. However the injection described in this case was not the most appropriate for this condition and therefore another injection would have been the optimum treatment. Though the criteria appeared to have little effect on the treatment choices for this patient, the finding that overall 78% of ESPs did not change their behaviour may suggest that most ESPs were able to apply the criteria correctly.

Vignette 2

Applying the gold standard to vignette 2 indicates that a course of physiotherapy would be suitable in the first instance. The vignette showed that the patient had not received physiotherapy and that she may have biopsychosocial barriers to recovery which further supports the need to trial a course of physiotherapy. At the first phase seven out of nine ESPs (78%) chose to try physiotherapy, one chose orthopaedic opinion and the other chose injection. At the second phase the ESP who had chosen orthopaedic opinion changed their referral decision away from orthopaedics towards physiotherapy, which does indicate that the criteria may have been useful in this case. Thus

against the gold standard 7/9 ESPs chose physiotherapy which increased to 8/9 ESPs after the referral criteria had been given.

Though the change only affects one ESP, the move from surgical referral to physiotherapy may have been influenced by the referral criteria (though this could also be a chance finding). The other point worthy of note is that none of the group of ESPs who had chosen physiotherapy initially changed their original decision. The criteria may have influenced ESP decision-making resulting in consistent and appropriate conservative management (though again this could be a chance finding). Overall the results from vignette 2 showed that there was consistency in decision-making both individually and across the team at phase one and at the end of the second phase all ESPs had chosen a conservative option with one ESP changing their behaviour following the use of the referral criteria.

Vignette 3

The results for vignette 3 are perhaps the most interesting as this is the patient that had already been referred to secondary care, and the gold standard indicated that this patient was suitable for an orthopaedic opinion. Initially at phase 1, three ESPs (33%) had already chosen to refer this patient to orthopaedics (this is the case with the highest number of ESPs who had chosen orthopaedics at phase 1). One ESP had chosen injection and five ESPs (55%) had chosen physiotherapy.

Interestingly, three out of the five ESPs who had chosen physiotherapy (33% of the total group) changed their referral behaviour from conservative management to orthopaedic opinion. One other ESP changed their referral decision from physiotherapy to injection, showing a progression to a more invasive treatment approach. Combining the referral behaviour shows a change in referral behaviour for four out of nine ESPs (44%). Overall, after introduction of the criteria, six out of nine ESPs (66%) chose to refer for an orthopaedic opinion, of those, 33% changed their initial referral option from physiotherapy in favour of an orthopaedic opinion. Comparison to the gold standard shows a greater change with vignette 3 than with the other two

vignettes. Against the gold standard there was a change from 3/9 ESPs to 6/9 ESPs choosing orthopaedic opinion when using the referral criteria, showing a more improved position.

Statistical analysis with the paired McNemar Test showed however that there were no statically significant changes for all three vignettes (for vignette 1 $P > 0.999$; for vignette 2 $P > 0.999$; for vignette 3 $P = 0.250$), though there is a trend of change observed in vignette 3⁴⁹. The lack of statistical significance may be due to the small sample size. See Appendix 17 for further detail.

5.4 Overall Results Summary

The survey of referral appropriateness showed that 33% of the ESPs surveyed record their conversion rates. The conversion rates reported are comparable with those recorded in secondary care. The survey also showed that 50% of ESPs currently use referral criteria, which adds support to the calls for the development of referral criteria to improve the quality of care. Surgical referral criteria for degenerative rotator cuff tears were developed and piloted on a small group of ESPs. Though the results are not significant the pilot suggests that these criteria may help improve the number of appropriate referrals in the management of rotator cuff pathology. The next chapter will discuss the findings for each part of the study in great detail.

⁴⁹ See section 3.3.6 for more information regarding statistical analysis. Using the referral criteria as the gold standard statistical analysis of the agreement (or disagreement) for each ESP before and after the criteria was undertaken. (Gold standard for vignette 1 was injection therapy, for vignette 2 it was physiotherapy, and for vignette 3 it was orthopaedic surgery).

Chapter 6: Discussion

6.1 Overview of Research

The main aims of the study were:

1. To determine whether MSK ESPs working in primary care record their ability to refer appropriate patients to secondary care (as measured by the conversion rate)
2. To determine whether MSK ESPs working in primary care experience specific barriers to onward referral which may ultimately affect their ability to refer appropriately.
3. To develop referral criteria to enable primary care ESPs to refer the most appropriate patients for rotator cuff repair surgery.
4. To determine whether referral criteria change ESP behaviour when referring patients for rotator cuff surgery.

Conversion rates and referral barriers were explored with a national survey of 200 ESPs working in primary care from all MSK subspecialties (upper limb, lower limb and spinal). Out of these 99 ESPs responded with usable data. The questionnaire investigated three key areas which included ESP conversion rates, perceived barriers to radiology and specialist referral and the use of specialist care referral criteria. The lack of published referral criteria for orthopaedic conditions is thought to contribute to inappropriate or misdirected specialist care referrals. Developing criteria within the hip and knee subspecialties has been attempted but criteria in the shoulder and upper limb subspecialties are scarce. As doubts have been raised about the appropriateness of ESP referrals to shoulder specialists, the upper limb subspecialty was considered appropriate for the development of referral criteria. Rotator cuff pathology was used because it is one of the most common conditions affecting patients with shoulder injury. A Delphi-type questionnaire was undertaken with a national sample of forty one shoulder surgeons to develop referral criteria for degenerative rotator cuff tear. Finally once the

consensus study was complete the referral criteria were piloted on a convenience sample of nine ESPs to determine whether the referral criteria improved appropriate referrals in clinical practice.

6.2 Summary of Key Findings

The main findings from the first stage show that although 47% of ESPs indicated that they record their conversion rate, only 33% of primary care ESPs provided their conversion rate data when surveyed. Of those supplying data, the mean conversion rate was 74%. The findings suggest that primary care ESPs can achieve conversion rates which are comparable to their secondary care colleagues and that they are referring appropriately.

A significant number of primary care ESPs (50%) reported that they used referral criteria when referring patients to secondary care and only 6% reported barriers associated with a lack of referral criteria. The high number of ESPs using referral criteria adds strength to the arguments made in the literature that referral criteria are beneficial and that they could facilitate more appropriate referrals to specialist care. Many ESPs documented that they had developed criteria in conjunction with consultants. This suggests that they may have been formulated to standardise and improve the quality and appropriateness of referrals.

As conversion rates in the shoulder specialty of secondary care ESPs had been shown to be the lowest of all subspecialties (Pearse et al, 2006) the results from ESPs working in the upper limb subspecialty were analysed separately to determine whether similar patterns existed. The results from this group were small (only one upper limb ESP reported conversion rate data), therefore conclusions about the quality of care within this subspecialty are difficult to draw. The small number of ESPs within this subspecialty and the lack of conversion rate data may indicate that ESPs in this area are not analysing their conversion rates. It is possible that upper limb ESPs need further support to investigate referral appropriateness. Further work to survey upper limb ESPs to determine whether they use other measures of referral appropriateness may be beneficial. Only 33% of upper limb ESPs in comparison to 50% of the total

group responding reported the use of referral criteria, which may support the development of consensus criteria. However as the size of this sample is small further conclusions are not considered.

The main findings from the Delphi questionnaire reveal that the severity of the patient's pain, their functional limitation and the identification of fat atrophy influence the surgeon's decision to operate. The dimensions of the rotator cuff tear appear to have little influence on surgical decision-making, though many consultants agreed that surgical outcomes are associated with tear size. There was consensus that a course of physiotherapy or conservative management should be attempted first and that consultants should be informed about psychosocial factors. There was agreement that a delay between injury and repair, even of several years, has little influence on the decision to proceed with rotator cuff tear surgery. Patient age on the other hand does influence the decision but there was no consensus regarding the age that consultants would use as a criterion. There are a number of areas, where the agreement was moderate; it is suggested that these areas may be useful to develop specific local criteria or referral pathways between primary and secondary care.

The pilot to test the impact of the referral criteria suggests that the criteria may be useful to improve the appropriateness of referrals for degenerative rotator cuff tears. The results showed that with the use of a clinical vignette (based on a patient who had been listed for surgery) one third of the ESPs changed their referral decisions appropriately after the introduction of the referral criteria. These findings must be interpreted cautiously however as statistical analysis showed that this trend for behaviour change was not significant. Overall despite the lack of significance the findings suggest that these criteria may have merit in providing valuable support to assist ESPs in the selection of appropriate patients for rotator cuff surgery. Implementation of the referral criteria with an active approach which includes a focus on clinical reasoning may result in greater behaviour change. Further research to test the criteria with an active rather than passive approach is recommended.

6.3 Referral Appropriateness in Primary Care ESPs

6.3.1 Conversion Rate

The survey has shown that 47% (47/99) of primary care ESPs record their conversion rate, however, of the 47 ESPs who identified that they collect this information, only thirty three (33/47; 70%) actually submitted conversion rate data when surveyed. Of the total sample of 99 ESPs, 33 (33%) submitted conversion rate data. Comments from the open-ended questions indicated that some ESPs did not collect this data regularly whilst for others their managers collected the data and this had not been shared with individuals.

The mean conversion rate across all ESPs was 74% (range 30% to 95%). This rate is higher than the GP conversion rates previously reported in the literature of around 18%-37% (Lowry et al, 1991; Maddison et al, 2004; Oldmeadow et al, 2007) (note that these studies were not specific to a single specialism and were generic in nature). The mean conversion rate of 74% was comparable with those reported by secondary care ESPs (Rabey et al, 2009). Caution is regarded in the interpretation of these findings, as two thirds of the participants did not submit conversion rate data.

The overall conversion rate statistic may be a useful bench mark for primary care ESPs. The specialism data shows that 45% work in a generic role, and specialist ESPs who work within a larger mixed team could use this statistic to report the performance of the whole team. A bench mark conversion rate could be a useful standard against which primary care ESPs could monitor their team performance. It could also act as an indicator to GPs and commissioners of the quality of care they provide. Although the conversion rate has limitations as a measure of clinical quality, it is one method which can be used to indicate referral appropriateness and the level of clinical agreement between ESP and surgeon. One clear limitation of the conversion rate statistic is that it measures ESP referral behaviour against the surgical decisions of the consultant which are assumed to be the gold standard. It is thus biased towards the decisions made by the surgeon as opposed to the decision-making of the therapist or multi-disciplinary team. This limitation highlights the importance of developing

consensus or standard referral criteria for use when referring patients between primary and secondary care. Such criteria, if they could be developed, could provide a standard against which referral appropriateness could be measured independently. This is particularly important in light of the finding that many ESPs acknowledged that it was very difficult to obtain accurate conversion rate data due to lack of formal feedback. Without feedback it is very difficult to monitor and improve the quality of care provided; an independent method of measuring referral appropriateness without reliance on consultant decision-making or feedback would be very useful.

6.3.2 Barriers to Referral

The main referral barriers experienced by ESPs were associated with poorly commissioned clinical pathways, lack of knowledge or experience, and lack of surgical criteria or consensus. Less common barriers included issues such as lack of communication and administrative barriers. Lack of knowledge or skills (Elwyn and Stott 1994), poor communication and feedback (Augestad et al, 2008), and lack of consensus (Lowry et al, 1991; Madhok and Green 1994; Speed and Crisp 2005; Musila et al, 2011) are barriers consistent with the findings previously identified in studies involving other disciplines. Interestingly ESPs did not indicate that the primary care environment or the level of isolation was a barrier to referral.

Importantly, the lack of appropriately commissioned MSK pathways has not been identified from previous studies, but it was a relatively common finding in this study (17 out of 99 ESPs identified commissioning barriers). It may be that this is specifically related to primary care, the relative newness of interface services or perhaps the complexities of improving referral pathways between two very different care providers. Therefore, further study is required.

Previous studies which have investigated the secondary care ESP model have identified that consultant support is vital to the ESP role (Hourigan and Weatherley 1995). However it is interesting to note that poor consultant support did not feature highly in this study's findings despite the relative isolation that primary care ESPs experience. This may be because ESPs in primary care do

have access to adequate consultant support or perhaps because clinicians in primary care have had no experience of this working environment and have had to seek alternative ways of gaining the information which would have historically been provided by consultants.

Lack of knowledge has been previously reported as a referral barrier for GPs (Elwyn and Stott 1994) but this has not previously been identified by secondary care ESP studies as a barrier to appropriate referral. Only a small number of ESPs (8%) in this survey identified that this was a barrier. This was cited particularly in conjunction with other barriers such as lack of consensus/criteria or lack of support.

The main implications from the barriers identified indicate that interface services could be more efficient and could deliver better patient care if they were commissioned more thoroughly. Those in positions to develop and improve interface services (both commissioners and providers of care) could be petitioned to provide better pathways of care. For example a thorough assessment of the diagnostic pathways required for interface services is of key importance if patients are to receive access to care. Upper limb services which accept referrals for carpal tunnel syndrome for example, should not be developed without access to nerve conduction studies.

Although lack of knowledge was not reported by many ESPs, the findings suggest that there is still a need for ESP training. Basic training provided locally or nationally and focussed around referral criteria, thresholds for surgery or review of existing consensus studies may support ESPs to refer optimally rather than many of the traditional physiotherapeutic courses on offer.

6.3.3 Referral Criteria

The results showed that 50% of ESPs were using referral criteria of some kind when referring patients to secondary care, which for most, had been developed after collaboration between primary and secondary care. The high number of ESPs using consensus type criteria may explain why only a small number of ESPs identified that lack of surgical criteria was a barrier to appropriate referral. Analysis of the free comments from the participants showed that some

therapists used informal criteria from studies or guidelines, and others used peer support from other ESPs or from consultant colleagues. Some therapists identified that only general referral criteria were in use, and one therapist suggested that the lack of condition specific criteria might be a reason why the conversion rates within their department were not higher. It could be argued that narrowing the referral criteria may exclude some borderline patients from being referred for a surgical opinion. This could lead to reduced access or inequity if referral criteria are not standardised between interface services and secondary care trusts. In addition, ESPs identified that inequity currently exists across different departments, which raises the broader issues of clinical quality and standardisation within orthopaedics.

Furthermore therapists had observed their commissioning teams and local public health departments taking a more central role in setting referral thresholds, thus providing an alternative influence to the development of MSK care pathways. Considering the current commissioning changes, and the development of GP commissioning consortia, it is possible that this type of influence may become greater. It may be appropriate for ESPs to think more widely about broadening their stakeholder groups when developing future care pathways and criteria.

6.4 Consensus Referral Criteria for Degenerative Rotator Cuff Repair

6.4.1 Key Areas of Consensus

The results from the consensus study have enabled the formation of referral criteria for use by ESPs when referring patients for degenerative rotator cuff tears, it is hoped that this information will engender more appropriate referrals between primary care ESPs and orthopaedic departments. The key areas of consensus were: severity of the patient's pain, functional limitation, the level of fat atrophy and completion of a course of conservative treatment before referral. There was also agreement that surgery would not be attempted in the presence of an active frozen shoulder, and that referrers should include information regarding biopsychosocial barriers to treatment. There was consensus that the

duration of time between injury and repair did not influence the decision to operate and that multiple tears and the shape of the tear did not influence surgery. However there was no consensus regarding the site of the tear, surgery for massive tears, tear dimensions or the extent of retraction. Interestingly, there was no consensus regarding investigations of bony morphology for subacromial narrowing or subacromial spurs, and consultants did not agree that patients must have muscle weakness or pain when testing the tendon for which surgery was to be considered.

As well as the areas where consensus has been achieved the results have identified areas where there is only moderate agreement. Though these areas cannot be used as part of the referral criteria they can be used by individuals as a basis for discussions between ESPs and consultants, or to provide general insight into the factors which affect surgical decision-making. The following sections highlight these findings and identify areas where the inclusion of enhanced referral information could improve patient care. The sections below also highlight where practice, as identified by the Delphi study, appears to differ from the referral recommendations identified by Warner et al, (1997), Moulinoux et al, (2007) and Beaudreuil et al, (2010).

6.4.2 Diagnostic Factors: Muscle Weakness and Pain on Muscle Testing

Perhaps the most relevant finding for ESPs screening patients with degenerative rotator cuff tears for their suitability for surgical referral concerns two key areas which are used to make a clinical diagnosis of rotator cuff tear. When testing for the presence of a rotator cuff tear the finding of pain and/or weakness when testing the tendon in question is thought to indicate the presence of pathology within the injured tissue (Magee 2007; Lewis 2009b). However in this study there was only moderate agreement (64%) that muscle weakness must be present when deciding whether to operate on a rotator cuff tear and there was much less agreement for the presence of pain. (It is worthy to note that only 36% of consultants agreed that pain on resisted muscle testing must be present before surgery would be considered). The finding that neither

the presence of pain nor weakness was considered a mandatory marker of diagnosis when making surgical decisions is surprising. Two possible explanations for this finding have been explored. Firstly it is conceivable that though these tests have been traditionally valued as useful diagnostic markers they have become less important in present day diagnosis or surgical decision-making. It is possible that for some consultants the diagnosis of a rotator cuff tear has been superseded by MRI or ultrasound scanning. This is however in contrast to the literature which showed that weakness is associated with symptomatic rotator cuff tear (Yamamoto et al, 2011; Kim et al, 2009; Wolfgang 1974).

Secondly, it is possible that weakness and pain are still important diagnostic markers for surgeons but that surgical decision-making may be influenced by a desire to undertake surgery before these features become significant. Warner et al, (1997) indicated that patients with chronic cuff tears should be excluded from surgery because of an association between weakness and friable tendon tissue. A small study (n=13) by Gerber et al, (2007) also showed that weakness was associated with chronicity and muscle/tendon wasting which supports the views of Warner et al, (1997). Therefore, it is possible that some surgeons hold the view that surgery should proceed before weakness is established, and in this scenario it would be rational to disagree with statement (2.2) as presented in the questionnaire.

This alternative view provides a different emphasis with regard to the identification of muscle weakness before proceeding with surgery. If a surgeon's views are focused towards operating on patients before weakness progresses, then the presence of weakness would not need to be a mandatory finding in all patients, and thus may have led to the lack of consensus seen. Indeed this view was partly expressed by one consultant who indicated that he/she did not feel that weakness 'must' be present. The lack of consensus agreement found in this study is in keeping with the different opinions within the literature. Both views were evident in the consultants surveyed. Future

empirical studies should focus on the evaluation of surgical outcomes in patients with varying levels of, and duration of, weakness.

It is interesting to note that these findings are similar to the findings of the study to develop referral guidelines for total knee replacement (Musila et al, 2011). They also found that objective markers from the orthopaedic assessment did not feature highly within the referral criteria. In this present rotator cuff study the presence of factors such as the severity of pain, failed conservative treatment and limitation of activities of daily living were considered more important than objective markers of weakness when guiding surgeons to repair degenerative rotator cuff tendons. These findings suggest that the formation of criteria based on more objective findings from the orthopaedic assessment will continue to be difficult. This may be one of the underlying reasons why the conversion rate may be as low as 9% for some ESPs within this discipline (Pearse et al, 2006).

6.4.3 The Reliance on Pain as a Guide to Surgery

The area where there was greatest consensus regarding signs or symptoms which influenced surgical decision-making was pain severity (95% agreement). This result is consistent with the findings of Naylor and Williams (1996) and Quintana et al, (2000) who developed orthopaedic referral criteria through Delphi consensus studies for hip arthroplasty. When developing referral criteria for knee arthroplasty, Musila et al, (2011) also showed similar results finding that the level of pain and patient choice were the only areas where consensus was achieved. The reliance on pain as an indicator for surgery is an interesting finding because of its subjective nature. The issue was also highlighted by Naylor and Williams (1996) when they considered the clinical implications of the hip arthroplasty referral criteria.

Perhaps even more interesting is the finding that the level of pain was considered as a key determinant of referral appropriateness without any accompanying objective markers such as rotator cuff muscle weakness. Though many ESPs and other clinicians with a conservative focus may also consider the patient's pain as an important contributor to decisions about referral, the subjective nature of pain symptoms makes it very difficult to use

pain as a guide to referral. Firstly, it is well known that the patient's pain and their underlying pathology are not necessarily highly correlated (Jeffery et al, 2011; Gatchel et al, 2007). Biopsychosocial issues are a significant feature of many MSK disorders (Carleton et al, 2009; Gallagher 2003). Pain severity and biopsychosocial factors such as depression and dependence on benefits have been correlated in patients suffering from chronic upper limb pain (Henderson et al, 2005), though one study suggests that the impact of biopsychosocial factors on shoulder pain pathologies may be less than in other conditions such as chronic low back pain (van der Windt et al, 2007). Studies from the general orthopaedic and psychological field suggest that biopsychosocial factors may impact on the outcome of surgery (Mayer et al, 1998; Gatchel 2001) which demonstrates the difficulties of using subjective markers such as pain within the referral criteria for rotator cuff surgery.

The complexity of pain and its association with biopsychosocial factors suggests that the severity of pain may not be a reliable marker on which to determine whether patients are appropriate for surgery. The pain experienced may not necessarily originate from the pathology of the presenting condition, (for example it may be related to an alternative condition such as referral from the cervical spine). Therefore without focus on objective signs, surgery may be undertaken unnecessarily.

The inclusion of unqualified symptoms of pain within the referral criteria means that the referrer is likely to find it very difficult to exclude any patient. In support of this conclusion some surgeons commented in the open sections that "patients should never be excluded from surgery if their pain persists". However a counter argument must be considered here. Using refractory pain as an isolated and unqualified criterion could mean that patients would receive surgery for painful cuff tears even if the outcome and success rates were likely to be very poor. Limited resources, which are currently under threat of being rationed in the NHS, would then be used to operate on those whose outcomes are likely to be very poor. This issue goes to the heart of the papers reviewed earlier such as Lowry et al, (1991). Without clear thresholds for surgery and without information which identifies which patients should not receive an offer of

surgery for a rotator cuff tear, many clinicians are likely to feel bound to refer all patients who have not recovered with conservative treatment, rather than patients who would benefit from surgery.

When questioned about psychosocial issues 80% of consultants did agree that it was important that the referrer included information about the presence of psychosocial factors. This demonstrates that surgeons are aware of the importance of these parameters. There is a lack of empirical studies which have investigated surgical outcomes in rotator cuff repair patients with psychological distress. This type of study may be required to further evaluate the relationship between pain, psychosocial factors and the outcome of surgery. It could also provide further guidance regarding the selection of appropriate surgical patients.

The finding that 80% of surgeons agreed that knowledge about psychosocial factors was important suggests that referral letters from ESPs to consultants should include information about the existence of psychosocial factors as standard. This information could enhance the quality of ESP referral letters ensuring that they contain adequate information. A Cochrane review undertaken by Akbari et al, (2008) found that the use of standard referral information was one of the few interventions which had been shown to improve referral rates between primary and secondary care. The impact of standardised high quality referral information on efficiency and patient care should not be underestimated. Therefore it is recommended that ESP consultant referral letters should contain biopsychosocial information routinely which could include details about the patient's beliefs, coping strategies and litigation.

6.4.4 Functional Limitation

There was no consensus that muscle weakness must be present before proceeding with rotator cuff surgery. However there was consensus that limitation of a patient's activities of daily living and limitation of advanced function was a factor which influenced a surgeon's decision to proceed with rotator cuff repair.

Previous studies which have developed orthopaedic surgery referral criteria through consensus have found similar findings (Naylor and Williams 1996; Quintana et al, 2000). However these studies relate to the development of criteria for hip or knee arthroplasty rather than shoulder surgery or soft tissue repair (possibly due to the comparatively high incidence of hip and knee surgery). For example Naylor and Williams (1996) and Quintana et al, (2000) achieved consensus regarding the limitation of function when developing referral criteria for total hip replacement surgery. Despite these conditions being different, it is interesting to note that there are similarities in decision-making regarding the selection of patients for orthopaedic type surgery which may be useful for ESPs in all specialties.

In this current study none of the surgeons clarified the way they use functional limitation within their decision-making. One of the surgeons identified that they used a different strategy for active patients; this involved more counselling regarding outcomes, but did not involve surgical selection based on function or due to participation in specific activities.

It is possible consultants use the severity of functional limitation as a guide to surgical need, similar to the way pain is used. The finding that surgeons identified that functional limitation was a more important factor than the presence of weakness in surgical decision-making supports this possibility. The findings suggest that surgeons could be less concerned with the diagnostic component of the assessment, giving priority to the patient's needs, pain and disability. A similar approach was undertaken by Naylor and Williams (1996) when trying to determine surgical referral criteria for hip and knee replacement surgery. In addition to developing referral criteria they also aimed to develop subsections of the criteria to facilitate ranking patients so that resources could be prioritized to those in most need. High pain severity and severe loss of function were the two main components which influenced surgical urgency (Naylor and Williams 1996).

6.4.5 Patient Age

The age of a patient as a determining factor for rotator cuff tear surgery reached 70% consensus after the second round questionnaire. These findings are consistent with the referral criteria suggested by Moulinoux et al, (2007). Only four consultants defined the age they felt was an appropriate decision point for surgery (range 65-80 years) and in all cases it was higher than that recommended by Moulinoux et al, (2007) who recommended 60 years of age. The findings suggest that current practice for many consultants may be consistent with the guidance issued by Moulinoux et al, (2007). However as only a small number of consultants gave the age they considered to be an acceptable cut off, a firm conclusion on this criterion cannot be drawn from this study. This is an area where direct communication between ESPs and those shoulder surgeons to whom they refer could lead to local agreement about surgical criteria. Further studies in this area are needed.

6.4.6 Success with Previous Interventions

Seventy five percent of consultants agreed that the success with previous treatment such as physiotherapy, pain management or injections was a determining factor when deciding to operate and comments were made suggesting that patients had not been given adequate trials of physiotherapy. Two of the surgeons commented that physiotherapy (with injection therapy) should be attempted for at least six months before referral which is supported by Chaudhury et al, (2010). Beaudreuil et al, (2010) also recommended that conservative treatment should always be undertaken before progression to surgery is made though no time frame was outlined.

The call for more physiotherapy and the comments that patients do not always receive an adequate course of conservative treatment may be a sign that there has been a gradual change in the number of sessions physiotherapists can provide. An audit of physiotherapy provision across the UK recently found that 57.4% of physiotherapy managers were already experiencing or expecting a reduction in spending on physiotherapy patient services (Chartered Society of Physiotherapy 2012).

It is an important point to consider for future patient outcomes, particularly in light of the recent commissioning changes (DH 2010a) and the recent financial pressures faced by NHS managers (Grant et al, 2012). As financial pressures increase there may be a temptation to reduce the amount of physiotherapy available. It is thus important for service leads to highlight conservative therapy options where possible to commissioners as they form part of the overall care pathway for the optimum management of patients with rotator cuff disease.

Other factors important with regard to the call for more physiotherapy treatment include the patient's attitude and beliefs to conservative versus surgical care (Jeffery et al, 2011; Darlow et al, 2012). This is particularly important for ESPs, as many patients are referred to specialist MSK and triage services with the knowledge that access to specialist treatment such as surgery is an available option. In this scenario even if there is no limit to the number of physiotherapy treatment sessions available, the patient's attitude and beliefs will impact on whether they comply with exercise, particularly if the condition is painful.

Negative exercise beliefs can also be inadvertently encouraged if their consultant feels that physiotherapy or other conservative treatment is unlikely to help, particularly if suggestions that they will ultimately need surgery have already been made (Darlow et al, 2012). Though the optimum levels of physiotherapy for rotator cuff rehabilitation are not known (Longo et al, 2012; Ainsworth and Lewis 2007), promotion of the conservative approach for a period of twelve weeks has been shown to be effective in reducing pain and improving shoulder function in patients with persistent subacromial impingement syndrome (Holmgren et al, 2012). The exercise strategy employed in their trial reduced the need for patients to progress to arthroscopic subacromial decompression, an alternative surgical technique used for patients with impingement or degenerative rotator cuff pathology. Thus in the absence of evidence identifying the optimum rehabilitation period required before patients should be referred for consideration of rotator cuff repair it would appear that a minimum of 12 weeks of rehabilitation may be a useful place to start. As the outcomes of rotator cuff surgery have not been found to be better than those for conservative treatment (Coghlan et al, 2009; Ejnisman et al, 2004), it seems

sensible to proceed with caution before surgery is attempted. Overall a full course of therapy has been shown to be beneficial in subacromial impingement (Holmgren et al, 2012), is recommended by the literature (Beaudreuil 2010; Chaudhury et al, 2010), and is echoed by the majority of consultants surveyed in this study.

6.4.7 Bony Morphology

The results from this study do not tend to correlate with the rotator cuff repair referral criteria recommendations from previous studies (Warner et al, 1997; Moulinoux et al, 2007; Beaudreuil et al, 2010). Moulinoux et al, (2007) recommended that repairs were contra-indicated in patients with subacromial narrowing of more than 7mm. Similarly Warner et al, (1997) recommended that humeral head migration should be an exclusion criterion for cuff repair surgery. In this study only 45% of consultants agreed that investigation of subacromial narrowing before deciding to operate was important which is not consistent with the findings from previous studies. It appears that there is no agreement that radiological investigations of bony morphology should be completed before surgeons decided whether to operate or not. The lack of consensus suggests that ESPs need to liaise with the surgeons to whom they refer to determine whether local agreements regarding investigations for subacromial narrowing or spurs should be made.

6.4.8 Characteristics of Rotator Cuff Tears

Overall there was little consensus regarding the use of tear characteristics to guide surgical decision-making or to define the most suitable patients for rotator cuff repair. There was agreement that the presence of multiple partial thickness and multiple full thickness tears did not exclude patients from surgery (70% and 75% agreement, respectively). There was also agreement that a cuff tear in any of the tendons would be suitable for surgery (70%), and that the shape of the tear does not influence surgery (75%). There was no consensus on whether the size of the tear, the degree of retraction or the number of tears influenced surgical decision-making.

It is interesting to note that after the second round the agreement with regard to the importance of tear size and its association with poor outcomes rose slightly from 60% to 64%, however this was still too low to reach consensus.

Interestingly, not even the question about massive tears reached consensus, even though 64% agreed that specific tear dimensions are associated with poor surgical outcomes. The finding that 40% of consultants who responded identified the tear sizes they used as a surgical decision point suggests that this is an area which could be used at a local level to define referral pathways between primary care interface services and local surgical departments to enhance appropriate referrals and improve conversion rates. The variability of tear sizes documented by consultants was very large and thus it is impossible to identify and provide a general guide from the responses.

These findings also suggest that there may be a divergence between the clinical practice of some clinicians and the evidence base around surgery for large tears. Though the evidence is generally weak, and primarily made up of case series', there is a growing body of literature which tends to support the finding that large tear sizes are related to poor surgical outcome (Ide et al, 2007; Matthews et al, 2006; Green 2003; Cofield et al, 2001). The lack of consensus gained in this study with regard to patient selection and tear size may suggest that surgeons are not necessarily motivated by the need to gain a successful outcome⁵⁰ and are motivated primarily by the patient's needs at assessment. It is also possible that they are also unconvinced by the poor quality evidence available and are not prepared to make decisions that exclude patients from the opportunity to try surgery until the evidence is more compelling.

Exploring the motivation and beliefs of surgeons in detail was beyond the scope of this study but there were comments made by a small number of surgeons which may engender further understanding with regard to the decision-making used by surgeons when contemplating surgery. This information could then be

⁵⁰ In this context 'outcome' is used to mean a combination of pain levels, range of movement, strength, power and overall satisfaction.

used to better understand components of surgical decision-making which fall outside of the technical and physical parameters which result from the orthopaedic assessment of the condition requiring surgery. For example two surgeons commented that they were specifically concerned that patients were not 'denied access to surgery' through the development of criteria or through the use of ESPs and clinical assessment services generally.

No surveys could be found which have previously investigated surgeons' attitudes to the development of referral criteria, or their attitude towards ESPs and their role in 'gate keeping' or triaging referrals to secondary care. However there is one study which has investigated surgeons' beliefs and attitudes with regard to the substantial variations in the rates of rotator cuff surgery per capita undertaken by shoulder surgeons in the USA. As well as investigating perceptions about the indications of rotator cuff surgery Dunn et al, (2005) explored surgeons' attitudes concerning medical decision-making about rotator cuff surgery. The researchers found that there was significant variation in surgical decision-making and a lack of clinical agreement among orthopaedic surgeons about rotator cuff surgery. There was a positive correlation between the number of procedures performed by the surgeon and the surgeon's perception of outcome, with surgeons who had a higher procedure volume being more enthusiastic about rotator cuff surgery than those who had a lower procedure volume.

Though this research does not explain the concerns that some consultants have with regard to service rationing and patient exclusion, it does identify that there are other factors that influence surgical decision-making such as the consultant's belief in the procedure, irrespective of the evidence. The importance of surgeon and ESP beliefs with regard to specific surgical procedures does not appear to have been widely researched. However its impact on surgical decision-making may be significant and further research in this field may help to clarify future criteria studies within orthopaedic surgery.

6.4.9 Fat Atrophy

In this study, the results showed that there was 80% agreement that the presence of fat atrophy was an influencing factor when consultants decided whether to operate on a degenerative rotator cuff tear. This finding is in agreement with a number of case studies published which identify that the presence of fat atrophy is linked to poor surgical outcomes (Goutallier et al, 1999; Harryman et al, 1991; Moulinoux et al, 2007; Gerber et al, 2007; Feng et al, 2003). Fat atrophy and poor surgical outcomes such as post-operative muscle weakness have also been associated with tear chronicity (Yamaguchi et al, 2012; Gerber et al, 2007; Melis et al, 2010; Meyer et al, 2011b). However the findings in this study showed that 73% of consultants disagreed that a delay (even of several years) between injury and repair would influence their decision to operate showing divergence away from the evidence. Comparison with the findings from health care settings in other countries may be useful.

Where consultants indicated the level of fat atrophy they used to guide surgical decisions in degenerative cuff tears, the level of fat atrophy was identified as ranging from grade 2 to grade 4 on the Goutallier et al, (1994) scale.

Comments made by five surgeons indicated that they felt that poor outcomes were associated with a high level of fat atrophy. However it was clear that fat atrophy was not used in isolation. The findings from this study were similar to the findings of Björkenheim (1989) and Tomanek and Cooper (1972) and showed that, in addition to fat atrophy, surgeons considered both the chronicity of the tear and the size of the tear when considering whether to proceed with surgery.

One interesting area raised by one of the consultants was the issue regarding the assessment of fat atrophy. The consultant commented that assessment of fat atrophy could only be made once surgery had started and thus it could not be used as a criterion to select appropriate patients for surgery. Though there is no gold standard for the measurement of fat atrophy and issues remain over the reliability of the measure, this comment is in contrast to the literature which indicates that fat atrophy can be assessed following observation of CT scan

(Goutallier et al, 1994); MRI scan (Gerber et al, 2007); or by calculation of the cross sectional area of the muscle on MRI scan (Thomazeau et al, 1996; Gerber et al, 2007). The open comments made by this surgeon, and the finding that only two consultants identified that they measure fat atrophy when considering surgery suggest that fat atrophy is not measured routinely by all consultants (see Appendix 16 Open Comments). This could be due to the complexity of the calculation or the radiological skill needed to accurately evaluate the amount of atrophy.

The possible benefits of detecting fat atrophy at an early stage could be significant to the management of rotator cuff injuries both at a conservative and surgical level. If this could be done before referral, patients could be given enhanced advice about success rates and perhaps appropriate patients could be selected early. The reliability of the detection of fat atrophy remains poor within the shoulder surgeon group, and studies with other specialists such as MSK radiologists have not been undertaken. Equally important is the finding that there is a dearth of studies involving the use of fat atrophy investigations by upper limb ESPs. It is possible that ESPs do not possess the level of knowledge and skill within this field to make these assessments reliably. This could be an area of development for ESPs in primary and secondary care which could impact on the conversion rate of shoulder conditions.

6.5 Referral Criteria and ESP Behaviour Change

Three vignettes based on real patients with a range of symptoms were used to observe referral behaviour before and after the introduction of the rotator cuff referral criteria. The first two vignettes were based on patients receiving conservative treatment and the third was based on a patient who had been listed for surgery. Independent application of the criteria to the vignettes confirmed that the outcome of assessment should be conservative treatment for vignette 1 and 2, and surgical referral for vignette 3. The results show that overall most referral behaviour change was observed for vignette 3.

For vignette 3, before introduction of the criteria, six of the nine ESPs had chosen conservative management and three had chosen surgical management. After the criteria three ESPs (33%) changed referral behaviour from conservative to surgical management (physiotherapy to surgery), and a fourth ESP changed from physiotherapy to injection. The behaviour change was consistent in that all ESPs changed behaviour from physiotherapy to a more interventionist option. Importantly none of the ESPs who had initially selected surgery changed their referral choice. The findings appear to show that the criteria may have had an impact on behaviour change for vignette 3 where surgical management was the desired referral option, though this trend was not statistically significant. It is important to note that this was a small pilot and the findings should be interpreted cautiously. For example other factors such as changes in clinical reasoning, training or personal development could have influenced these findings.

The behaviour change observed in the other two vignettes was small and the referral criteria did not appear to have a noticeable impact on behaviour change. For vignette 1 application of the referral criteria indicated that a conservative rather than a surgical option would be appropriate in the first instance. After the introduction of the referral criteria one of the ESPs changed referral behaviour from injection to physiotherapy. Offering physiotherapy rather than injection was an acceptable choice as the patient had not tried physiotherapy but had tried a previous injection unsuccessfully (though this was not the most appropriate injection).

The finding that one ESP chose to refer the patient to orthopaedics rather than manage the patient conservatively may be explained by the complexity of the case. This action was contrary to the referral criteria and inconsistent with the behaviour of the rest of the group, though Todoric et al, (2012) have identified that vignettes may identify variance in the performance of individuals.

It is unclear whether the referral behaviour of this ESP was connected with interpretation of the referral criteria. It is possible that the change occurred because of the emphasis surgeons placed on physiotherapy evident in the

criteria. However it could also be related to other factors such as the existing knowledge and beliefs of the therapist or a change in the reasoning which occurred between the first and second phase. Another interpretation is that the criteria actually made it more difficult for the ESP to determine the appropriate management for the case used in vignette 1, and had a detrimental effect on the decision making process.

Vignette 2 was a less complex case, seen earlier within the duration of the disease and primarily complicated by the existence of psychosocial barriers to recovery. The results for vignette 2 appear to reflect the fact that the case was more straightforward. There was consistency in decision-making at the first phase of the study with all but one ESP choosing a conservative treatment option. After the introduction of the criteria the ESP who had initially chosen surgery, changed their referral choice to a conservative option which may suggest that the criteria facilitated more appropriate management. However again, these changes could be related to other factors such as a change in the reasoning or knowledge of the therapist.

6.5.1 Lack of Behaviour Change

Though 33% (3/9) of the ESPs changed their referral behaviour with vignette 3 from conservative to surgical management (with one other ESP choosing injection), It is interesting to note that three ESPs (3/9) did not choose orthopaedic referral. One changed behaviour from physiotherapy to injection. The other two ESPs remained with their original choice one chose physiotherapy the other injection. These results are consistent with the findings from the literature which show that implementation of guidelines or criteria and the resultant behaviour change is not straightforward. The reasons why behaviour change did not occur in all ESPs may be associated with factors such as current knowledge and skills, reasoning and decision-making, clinician beliefs, environmental and organisational factors (Michie et al, 2005; Prochaska and DiClemente 1983). Two areas are particularly worthy of further discussion with regard to implementation, firstly the difficulties of integrating referral criteria into the clinical reasoning of ESPs within a short space of time and secondly the

method of referral criteria implementation. These areas will now be explored in more detail.

6.5.2 Developing the Clinical Reasoning of ESP Teams

Clinical reasoning and decision-making result in significant cognitive demands on clinician memory in addition to demands on attention (Michie et al, 2005). It is likely that referral criteria need to be integrated into the cognitive reasoning processes employed by ESPs to enable appropriate referral judgments. It is possible that some of the ESPs were able to embed the new knowledge and apply reasoning process to this information. However, it is possible that some ESPs were unable to undertake this process during the test period and thus a different outcome was achieved. The fact that ESPs may have differing levels of reasoning is not surprising as it has been acknowledged that the process of developing clinical reasoning is difficult (Askew et al, 2012). The findings from this aspect of the study suggest that those who clinically lead ESP services may need to pay attention to how clinical reasoning can be developed within the team if changes in referral behaviour and improvement in conversion rates are to be seen.

Audetat et al, (2012) undertook a qualitative focus group study to determine how educators managed clinical reasoning difficulties in their students and found that the processes to identify and remediate clinical reasoning difficulties were unstructured. Even knowledgeable supervisors did not implement systematic procedures to manage clinical reasoning difficulties. Audetat et al, (2012) recommended that structured processes are put in place to develop clinical reasoning and clinical judgement. Applying this recommendation to this study suggests that to embed referral criteria into the clinical reasoning processes employed by ESPs, may need a structured process. This may require in-service training on a regular basis to improve the skills or knowledge of ESPs. More structured processes in this study such as a detailed explanation of the key findings, followed by clinical examples, may have resulted in greater ESP behaviour change. For successful implementation of the referral criteria it may be important for those in clinical leadership roles to

consider structured processes to facilitate the integration of referral criteria into the reasoning framework used by ESP teams.

6.5.3 Guideline Communication

The other area worthy of further discussion was the method used to communicate and disseminate referral criteria to the group. In this study a relatively passive approach was taken which involved the ESPs being given a set of referral criteria and three vignettes. They were then asked to complete them without discussion with the other members of the team, though they were allowed to ask for clarification of the meaning of phrases or comments within the criteria. The passive approach to implementation may be one of the reasons that behaviour change towards the gold standard only occurred in 33% of the group. The lack of behaviour change following passive implementation (via national publications and books) is in keeping with the results of previous studies (Evans et al, 2005; Van Tulder et al, 2002; Cabana et al, 1999; Kallmes 1998).

A small number of studies have investigated whether active guideline dissemination processes are more successful than passive approaches in changing behaviour following the production of guidelines. Though conclusions with regard to the optimum strategies for implementation cannot be drawn from the available literature (Grimshaw et al, 2004; Hakkennes and Dodd 2008) two studies which used a more active approach to implementing guidelines have found positive results. In a randomized controlled trial Bekkering et al, (2005) found a statistically significant positive change in some of the targeted behaviours of Dutch physiotherapists using a multifaceted educational intervention, compared to passive dissemination of printed guidelines alone. The multifaceted intervention utilised education, discussion, role-playing, feedback and reminders. In another randomized controlled trial targeting Dutch GPs, Engers et al, (2005) found small changes in some of the behaviours exhibited by GPs. Again a multifaceted intervention programme was used which consisted of active and passive components, including the Dutch Low Back Pain Guideline for GPs, a 2-hour educational and clinical practice

workshop, 2 scientific articles on low back pain management, a tool for patient education and a tool for reaching agreement on low back pain care with physical, exercise, and manual therapists.

Though there are only a limited number of studies showing positive behaviour change after active guideline marketing, it is possible that a more active approach to dissemination of consensus information may be beneficial. The approaches used by Engers et al, (2005) and Bekkering et al, (2005) consisted of discussion, role play and clinical practice workshops which seem comparable to clinical reasoning strategies. It is possible that a more active dissemination involving clinical discussion, targeting clinical reasoning and judgement at the same time, may lead to a more significant change in behaviour. It is also possible that clinical discussion sessions could facilitate the opportunity for clinicians to explore their beliefs about their capabilities, or consider their professional position or role within the workplace to engender more effective implementation as suggested by Michie et al, (2005). Therefore these types of intervention strategies could be explored to determine whether active implementation of the referral criteria results in improved referral behaviour amongst ESPs.

6.6 Implications for Clinical Practice

The main findings from the ESP questionnaire show that though 47% of ESPs indicated that they record their conversion rate, only 33% of primary care ESPs provided their conversion rate data when surveyed. Of those supplying data, the mean conversion rate was 74%. Though these are self reported statistics, they suggest that primary care ESPs can deliver high conversion rates, which could, in future, be used as a benchmark to demonstrate high standards and clinical quality within primary care interface services.

The survey indicates that 50% of those who responded are using clinical criteria to assist with referral decisions. It may be important for newly developed services and those without clinical criteria to consider their use as some

clinicians have made a link between the use of criteria and the level of their conversion rate. The development of referral criteria are also important to ensure that the measurement of referral appropriateness can be performed independently without consultant bias. In future, it may be important to ensure that criteria can be agreed by all stakeholders including clinical and commissioning staff, allowing services to demonstrate their quality and effectiveness against widely agreed standard criteria. It is acknowledged that referral criteria may not result in improved conversion rates because many of the factors that influence the conversion rate are out of ESP control. However compliance with referral criteria may be able to replace conversion rates as a more robust method to audit the effectiveness of ESP interface services.

Poorly commissioned services and incomplete clinical pathways were the greatest barriers to referral that ESPs experienced. It is likely that the current commissioning and organisational changes in the NHS may see a shift in services from secondary to primary care, and therefore it is important to learn from these experiences. Greater engagement between clinical and commissioning staff may be one way to ensure comprehensive care pathways are robustly developed. As identified, several ESPs indicated that they had difficulty obtaining conversion rate data. Those who commission interface services may need to consider how this information can be obtained and fed back to those working within these services to facilitate performance monitoring and quality.

This is the first expert consensus study undertaken to determine referral criteria for degenerative rotator cuff tears. The study has resulted in the development of referral criteria which have been shown to change referral behaviour towards the gold standard (orthopaedic opinion) in 33% of a small sample of primary care ESPs (though this was not statistically significant). After applying the referral criteria to a clinical vignette three of the six ESPs who had originally chosen to manage the patient conservatively chose a surgical referral option. This suggests that the referral criteria have the potential to influence referral behaviour. This may also have the potential to affect the surgical conversion rates if agreement of the criteria between ESPs and consultants can be

reached. Further study in this area is required so that the referral criteria can be tested with a larger sample.

Though agreement was not reached in all areas, consensus, set at 70%, was reached on 14 out of 24 of the original questions including pain severity, functional limitation, fat atrophy, previous conservative management, age, presence of active frozen shoulder, duration of injury, tear shape and the number of tears. The consensus on referral criteria is greater than that achieved in previous studies attempting to develop referral criteria in other orthopaedic disciplines and includes a number of useful objective parameters to guide practice. As conversion rates have been reported to be low in the shoulder speciality it is hoped that the referral criteria developed in this study will be useful to many clinicians who are attempting to improve the quality of care they provide. There are also areas identified from the study that are useful to include within the clinical referral letters sent by ESPs to consultants, and areas which did not reach consensus but may be valuable in the formation of local referral criteria or as a basis for further discussion.

Implementation of the referral criteria remains a challenge. Following the results of this study it is suggested that further research could be undertaken to determine whether active dissemination with structured clinical reasoning improves referral behaviour beyond that which occurred with passive implementation.

In practice it was and is expected that patients referred for surgery would meet the all of the referral criteria, with the exception of the level of fat atrophy which needs to be decided at a local level. During the pilot testing it was expected that referral would be based on all of the criteria being met, however there were no requests for clarification about this during the testing and thus it is not clear if the ESPs used the criteria in this way. In the next phase of testing with a larger sample participants could be instructed that it is desirable that all items of the criteria are met before referral. Clarification relating to limitation of function could also be included to indicate that either limitation of advanced function or

activities of daily living should be evident as limitation of advanced function is likely to occur if activities of daily living are affected.

6.7 Study Limitations

6.7.1 Sample Size

With regard to the questionnaire of referral appropriateness it is important to note that the mean conversion rate identified was calculated from a small number of participants which indicates a need for empirical conversion rate studies from primary care ESPs. The overall response rate for the questionnaire of 50% may also mean that the study has some non response bias. Though there is no consensus with regard to an acceptable response rate (Jackson and Furnham 2000; Robson 2011), the results gained in this study may not be representative of all primary care ESPs. Therefore further studies are required.

With regard to the Delphi questionnaire it is important to note that if more participants had taken part in the study, it is possible that the results would more accurately represent the views of shoulder surgeons. The sample was taken from a national pool which means that the information can be applied to the UK, however a larger number of participants would have provided greater robustness. Typically a Delphi study is small, often consisting of around 7-10 experts. This study was not small by these standards, however it is possible that a larger sample could have provided greater consensus, particularly in the areas where only moderate agreement could be reached.

In the pilot study to test the criteria, the limitations focus primarily around the use of a small convenience sample (n=9). Recruitment of a random selection of ESPs may have meant that the results from this study would be more widely applicable to the body of ESPs working in primary care. However the use of the convenience sample meant that the training environment could be more tightly controlled. The reason for this was to limit external influences that may account for changes in ESP clinical reasoning, and thus facilitate a more controlled environment to test the criteria specifically.

This methodology also allowed for a thorough test of how the consensus information may be best presented before going out to a wider audience. Though a convenience sample was used it enabled the format of the consensus information and the implementation strategy to be tested. The findings obtained indicate that further research could be undertaken to test the effectiveness of the implementation strategy before recommendations about implementation can be made.

The sample used was representative of the sample of ESPs who responded to the questionnaire of referral appropriateness in that they worked in a specialised role in primary care. They also had a similar conversion rate to the mean conversion rate reported in the survey of referral appropriateness⁵². It may have been possible to access a larger sample of ESPs through the ESP professional network and this could be considered for future research. However the use of a larger sample would have been limited by the lack of a controlled training environment. It would not have been possible to ensure that ESPs were not using other sources or the support of other colleagues for example.

6.7.2 Access to the Sample Database

The questionnaire of referral appropriateness was limited by the inclusion criteria which selected those ESPs on the Professional Network database with an associated orthopaedic specialty. The specialism data shows that respondents did have a range of backgrounds as well as orthopaedics including pain management, MSK ultrasound and injection therapy. However the inclusion criteria and the use of the Professional Network potentially may have limited the sample, excluding those specialising in rheumatology or neurosurgery, and those ESPs not registered with the network. In the Delphi study there were also limitations regarding access to specialist shoulder surgeons. A register of shoulder surgeons specialising in rotator cuff repair was not available and therefore it is difficult to estimate the size of the sample as it

⁵² Post hoc assessment showed that the conversion rate of the pilot sample was 70%, and the average conversion rate from the referral appropriateness questionnaire was 74%.

compares with the number of shoulder surgeons currently practising rotator cuff repair.

6.7.3 Questionnaire Design and Interpretation

With regard to the questionnaire of referral appropriateness it is important to note that some ESPs may not have thought that lack of knowledge or lack of support was a barrier to referral even though the pilot stage was used to ensure that ESPs understood the meaning of each question. It may have been useful to have given a list of options from which ESPs could have selected referral barriers. Therefore, a range of items could have been introduced to those who have not previously considered these areas as barriers to referral.

In the Delphi questionnaire the two questions using the word 'must' gave one consultant some difficulty. The open section which accompanied these questions contained comments from one surgeon (repeated twice) indicating that he/she found it difficult to answer questions containing the word 'must'. The two questions (2.1 and 2.2) were purposely definitive as the parameters under investigation (pain and weakness) were considered to be key referral parameters. These parameters are currently used by many ESPs to screen patients for referral and were also supported by two of the referral criteria studies (Warner et al, 1997; Beaudreuil et al, 2010). Pilot testing did not identify any problems with regard to the use of the word 'must', however it may have been more appropriate to qualify these questions with similar information to that found in the questionnaire introduction, informing consultants that they could clarify areas where there may be exceptions.

This issue goes to the heart of the development and the use of referral criteria and clinical guidelines as many surgeons do not have a definitive cut off criteria for patients being referred for rotator cuff repair, and resist the idea of following a more technical approach. It is possible that more detail concerning how the information would be used could have provided more reassurance for some surgeons regarding surgical thresholds. However the consultant who found these questions difficult also commented that he/she wanted to ensure that 'no

one was excluded from surgery⁵³, rather than giving guidance with regard to which patients were most suitable. It may be the case that this belief system is generally incompatible with the development of criteria, and thus, further reassurance would have been of little value.

The open sections of the questionnaire were poorly completed compared with the closed questions and therefore, where open responses were required, it may have been beneficial to have also listed a set of responses. For example when questioned about the age cut off for rotator cuff surgery, 70% of surgeons said they used an age cut off. However when consultants were asked to document the age limit they used, only four consultants responded with the information. If these questions had listed a range of options there may have been greater compliance to complete the questionnaire and thus greater information could have been gained. It is also important to consider the work of Keeney et al, (2001) who explain that some participants may have a vested interest in manipulating the results or preventing the research from taking place. This view needs to be considered with respect to this research as it is important to acknowledge that some consultants may have answered in a certain way because the development of criteria may affect their work and their livelihood significantly if it resulted in a reduction in referrals. This is a speculation, therefore further studies would be required to determine this assertion.

6.7.4 Conversion Rate Self Report Findings

The conclusions drawn from the first study are limited by the reliability of the self-report conversion rate data. The data cannot be independently verified and therefore these results must be considered within this context. It is not clear whether all ESPs use a similar definition of 'conversion rate', nor is it clear whether methods for data collection are similar. Some data may be collected from secondary care systems whereas others may be collected following analysis of consultant letters, or after post-operative contact with the patient. A robust method of confirming the claim made in this study is worthy of

⁵³ Note two consultants commented about surgery denial but only one consultant commented on the use of the word must.

investigation for example using regionally or nationally agreed conversation rate definitions and criteria.

6.7.5 Limitations of Consensus Methodology

It has been acknowledged that where possible clinical guidelines or referral criteria should be based on evidence derived from rigorously conducted empirical studies (Black et al, 2001). However in the absence of these studies consensus methodology can be useful to guide practice (Mann 1996). One area of weakness in the field of consensus methodology, which is inherent in its approach, is the reliance on personal opinion. Though it is hoped that opinions are enlightened, knowledgeable and representative of current practice it is possible that consensus methodology may result in a number of less informed views (Black et al, 2001). A UK wide sample was used to mitigate against this.

Another weakness of consensus methodology is that repeated rounds of questioning may also lead to participant fatigue and reductions in sample size (Keeney et al, 2001). In this study repeated rounds led to reduced consultant involvement and therefore attempts to gain agreement with a smaller sample by using a third round were not considered. Though the sample used in this study was larger than that used in many traditional Delphi studies (Keeney et al, 2001), the sample size reduced from 41 to 20 consultants by the second round (this reduced to 17 after 3 consultants dropped out). It was felt that further reductions in sample size may have affected the reliability of the results (Mead and Moseley 2001; Richardson 1972).

6.7.6 Implementation of the Referral Criteria

One specific weakness of the study relates to the implementation of the referral criteria. All vignettes were given in the same order as opposed to randomly which means that ESPs may have improved their reasoning skills by the time they reached the third vignette.

The referral criteria were given in passive format as a written document rather than actively through role play or presentation for example. Several attempts were made to ensure that the document would fit onto one page, and much

consideration was given to the language and format used to ensure that ESPs did not have to wade through several pages to find the information needed to relate to each part of each case. During the process it was observed (due to the time taken to complete and the concentration required) that the cases and criteria were long and detailed. It was clear that the process of knowledge acquisition and reasoning made significant cognitive demands on most ESPs. If this was to be re-tested in future research it is proposed that a more active approach could be used as explained in section 6.5.3. A more active implementation may include for example a presentation to a group of ESPs to explain the key components of the referral criteria followed by a group discussion to promote understanding. Then each clinical vignette could be explained to the group and ESPs would have the opportunity to discuss the patient details, diagnosis and prognosis. Finally the referral criteria could be re-introduced and issues that arose from application to the vignette could be discussed in detail to aid reasoning and understanding.

6.8 Recommendations of the Consensus Criteria

There are a number of key recommendations from the consensus study with regard to which patients with rotator cuff tear are most appropriate to refer to surgery. These include referral to surgery for patients in severe pain, with significant limitation of the activities of daily living or significant limitation of advanced function, after the completion of a course of conservative treatment. There was also agreement that surgery would not be attempted in the presence of an active frozen shoulder, and that the referrers should include information regarding biopsychosocial barriers to treatment. The age of the patient and the level of fat atrophy were identified as important factors which influenced surgical decision-making. However consensus regarding the threshold age or the level of fat atrophy indicating that surgery was no longer appropriate was not reached. There was also consensus that the duration of time between injury and repair did not influence the decision to operate and that multiple tears and the shape of the tear did not influence whether to proceed with surgery.

6.8.1 Strengths of the Criteria

The strengths of the consensus criteria are that ESPs working in the upper limb field have a guide to referring patients for rotator cuff surgery. This may help some ESPs, particularly those working without orthopaedic support to refer patients appropriately, improve the clinical quality of care they provide and possibly improve their conversion rates (particularly through the improvement of clinically appropriate referrals). The criteria provide clarity regarding the importance of a range of clinical characteristics which influence surgeons when they make decisions regarding surgery. The criteria also provide valuable information about which tear characteristics are not relevant in surgical decision-making. This also facilitates more confident management of patients requiring conservative rather than surgical treatment.

In future the criteria could be used as a tool against which ESPs could independently benchmark their quality and performance. This could help ESPs to show the quality of their care more responsively than using traditional conversion rate analysis and reduce the risk of confounding factors such as changes in policy or increase in waiting lists.

6.8.2 Weaknesses of the Criteria

There are still a number of areas where consensus could not be reached such as whether surgery should be undertaken for massive tears, whether tear dimensions or the extent of retraction are important and whether the site of the tear influences the decision to operate. There were also some areas where consensus was reached but where further qualifying information was not clear such as the level of fat atrophy or the age of the patient. The lack of a definitive threshold for these two areas means that liaison with a local surgeon regarding their personal preferences will probably be required until further empirical research provides more guidance.

6.9 Summary of Findings

- Mean conversion rates for primary care ESPs are 74%. These are self reported findings from a small percentage of ESPs (33%). They lack

external validation, but they do provide the first bench mark of ESP performance in primary care.

- 38% of primary care ESPs experienced barriers when referring to secondary care. The main referral barriers were commissioning barriers, lack of knowledge or experience and lack of clinical criteria or consensus.
- Commissioning barriers have not been identified before within the literature, and in light of the changes facing the NHS, it is important for those developing new interface services to consider these findings.
- Referral criteria have been developed from the consensus information and key areas of agreement have been shown including severity of pain, limitation of function, presence of fat atrophy, the absence of frozen shoulder, the duration of injury and the importance of previous conservative treatment. Overall there is little consensus with regard to the influence of the dimensions of rotator cuff tears on surgical decision-making.
- Referral behaviour changed from conservative management to orthopaedic opinion (gold standard) in 33% of primary care ESPs with the use of referral criteria when piloted with a detailed vignette based on the real clinical history of a patient with a degenerative rotator cuff tear.
- Future research to test the effectiveness of the referral criteria could include active implementation, through case discussion sessions and workshops, which promote structured clinical reasoning. Until the optimum strategies for dissemination and implementation are identified dissemination of the guidelines through passive means such as journal publication is recommended.

Chapter 7: Conclusion

7.1 Summary of Research and Findings

This thesis investigated:

- The level of appropriate referrals made by primary care ESPs, their referral barriers and the use of referral criteria
- The development of surgical referral criteria for rotator cuff tears to facilitate improved referral appropriateness
- The impact of implementing rotator cuff referral criteria on ESP referral behaviour.

The study has shown that the mean self-reported conversion rate for primary care ESPs is 74%. These findings are from a relatively small number of ESPs and lack external validation, but they do provide the first bench mark of ESP performance in primary care and are comparable to those recorded in secondary care. The study also showed that half of the ESPs surveyed currently use referral criteria, which adds support to the recommendations from researchers and policy makers for the development of referral criteria to improve the quality of care.

The Delphi study resulted in agreement across a range of parameters which, in the absence of good quality evidence, were used to develop surgical referral criteria for degenerative rotator cuff tears. There was agreement on fourteen out of twenty four questions which will help ESPs to select appropriate patients for onward referral. Surgical referral criteria for degenerative rotator cuff tears were developed and piloted on a small group of ESPs. The pilot suggests that these criteria may help improve the number of appropriate referrals in the management of rotator cuff pathology, though further research to test the criteria actively with a larger sample may be considered.

7.2 Implications for Practice and Quality Care

Though the mean conversion rates of primary care ESPs have been shown to be comparable with those of secondary care ESPs, only a small number of ESPs appear to collect this data. This has implications for the body of ESPs particularly at this time as there is a growing demand to demonstrate quality and improved health care delivery. There have been calls from the Chartered Society of Physiotherapy (CSP) to encourage physiotherapists to collect outcome data to demonstrate the quality of care they deliver. This research demonstrates that the CSP and other professional leads need to continue to re-enforce the need for interface services to focus on demonstrating quality.

For those ESPs surveyed, lack of referral criteria did not appear to be a barrier to referral. It was also interesting to note that 50% of ESPs currently use referral criteria which may explain why lack of referral criteria was not highlighted as a specific barrier. The relatively high number of ESPs using criteria adds further support to the recommendations from the literature to develop and implement referral criteria.

Early pilot work suggests that the rotator cuff tear referral criteria developed within this study may influence ESP referral behaviour to improve appropriate surgical referrals. It is hoped that the referral criteria for rotator cuff tear will have a significant impact on the quality of patient care through their impact on the selection of the most appropriate patients for surgery. It is possible that the criteria could have an impact on the conversion rates in the shoulder speciality, but further work is needed in this area. It is hoped that the criteria will also facilitate the optimum management of patients who are unlikely to benefit from surgery ensuring that these patients have quicker access to the most appropriate conservative care, again further work in this area is needed.

In future these referral criteria could be used to provide a benchmark against which ESPs can independently demonstrate the quality of care they provide. These referral criteria could provide a more responsive and simple method for primary care ESPs to calculate referral appropriateness. It is hoped that this will influence more ESPs to collect data on referral appropriateness.

7.3 Contribution to Policy and the NHS

Primary care MSK interface services were recommended in the Musculoskeletal Services Framework publication (DH 2006) to improve the quality of MSK care in England. They had previously been shown to improve health care delivery through reduced referral rates and reduced waiting times, however clinical quality, demonstrated by a high level of appropriate referrals had not been shown. The results from the referral appropriateness survey conducted in the first stage of this study provide baseline information about the conversion rates for primary care ESPs. They suggest that in general primary care ESPs are able to refer the majority of patients to secondary care appropriately. Thus these findings support the previous recommendations from the Musculoskeletal Service Framework (DH 2006). They also support the current policy of shifting MSK services from secondary to primary care showing that in general ESPs working within interface services are capable of selecting appropriate patients for referral to secondary care.

The results from the referral appropriateness survey demonstrated that poorly commissioned pathways were the most significant barrier to appropriate referral. This finding had not been previously reported in the literature and this information provides new knowledge to enable commissioners and providers of interface services to improve the pathways of care for patients. These findings demonstrate the importance of engagement with commissioners during this time of change in the NHS.

7.4 Future Research

The key areas for further research are summarised below.

Empirical studies of ESP conversion rates are recommended to validate the self-reported findings. It is recommended that future conversion rate studies should use standard criteria similar to the kind developed in this study as opposed to comparisons between ESPs and one consultant's opinion. Conversion rate studies measured against such criteria should be relatively simple to complete and would mean that those ESPs who had difficulty

obtaining data could measure their performance against an independent standard. Such studies would enable ESPs to robustly demonstrate their performance and benchmark their quality. Once published the referral criteria developed in this study could also be used as a basis for standard empirical conversion rate studies. Future studies should also consider the efficacy of training opportunities for ESPs in primary care to improve their clinical practice in referring patients to secondary care.

Further research to determine whether the consensus criteria could be used to change ESP referral behaviour in a larger sample is recommended. Further research to determine the most successful strategy for the implementation of the referral criteria could also be considered. A comparison of active and passive implementation strategies to determine whether active implementation, with a more structured approach to reasoning, is superior to passive implementation could provide further information for those attempting to implement referral criteria and improve referral appropriateness. Until further evidence of the optimum implementation strategy is available publication of the criteria through journals, the Chartered Society of Physiotherapy and the ESP professional network is recommended.

High quality empirical studies which identify the outcome of rotator cuff surgery for patients with a range of clinical characteristics such as differing levels of weakness or different age groups are also required. Hopefully further high quality research in the field of rotator cuff tear management may help to develop evidence based rather than opinion and experienced based guidelines in future. However until then, the expert opinion referral criteria will assist ESPs working in the shoulder speciality to refer patients appropriately.

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Appendices

Appendix 1: Outcome Measures used in Shoulder Surgery and MSK

A range of outcomes are used when measuring the success of shoulder surgery. No measure has been shown to be superior (Oh et al, 2009).

Validated and reliable shoulder measures include the Disabilities of the Arm, Shoulder and Hand (DASH), the Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH), the Western Ontario Rotator Cuff index (WORC), the American Shoulder & Elbow Surgeons assessment form (ASES), the Constant shoulder score, the Japanese Orthopaedic Association Score (JOA) and the University of California, Los Angeles (UCLA) (Maffulli and Furia 2012; Bas de Witte et al, 2012; Oh et al, 2009; Bialocerkowski 2007; Bot et al, 2004; Hirotakka et al, 2003).

These measures rate functional improvements usually via the use of a questionnaire. Some also include sections for pain, strength and quality of life. Other measures may include pain rating scales such as the visual analogue scale or measures of isometric strength with the use of a dynamometer. Quality of life scores such as the EuroQuol (EQ5D/EQ5D5L) may also be used.

Outcome Measure	Parameters Measured
Constant Shoulder Score	Pain, function, range of motion and strength
UCLA	Pain, range of motion, strength satisfaction
DASH	Physical function and pain
ASES	Pain and function
WORC	Pain and physical symptoms, sport, work, lifestyle, emotional factors
JOA	Pain, range of movement, function, ADL

Patient satisfaction with surgery is known to be related to reduced post operative disability, expectations of improved pain, range of motion and strength (Ramzjou et al, 2011).

Outcome Measures used in other conditions:

Hospital Anxiety and Depression Scale (HADS): Measure of anxiety and depression

Short Form 36 (SF 36): Quality of life score

Oswestry Disability Index (ODI): Measures levels of functional limitation in back pain patients with regard to activities of daily living

Western Ontario and McMaster University Arthritis Index (WOMAC): Measures pain, stiffness and functional limitation. Has been used in rheumatoid arthritis, hip, knee and spinal conditions.

VAS: Visual analogue score (Level of Pain Score)

Appendix 2: Search Strategy: Keywords and Phrases

Musculoskeletal Service and Quality; Efficiency; Musculoskeletal care and quality, musculoskeletal care and efficiency, ESP, interface service, effectiveness and interface service; interface service and primary care;

Rotator cuff tear and surgical criteria; rotator cuff tear and surgical referral criteria; degenerative rotator cuff tear and repair; degenerative rotator cuff tear and outcomes; degenerative rotator cuff tear and fat atrophy; degenerative rotator cuff tear and tear size; degenerative rotator cuff tear and age; degenerative rotator cuff tear and surgical indications; reliability of surgical decisions and rotator cuff tear; rotator cuff tear retraction and surgical outcome; diagnosis of rotator cuff tear; pain and rotator cuff tear;

ESP and conversion rate; conversion rate; conversion rate and spinal; conversion rate and upper limb; conversion rate and lower limb; conversion rate and secondary care; conversion rate and primary care; conversion rate and GP;

Vignette reliability; vignette validity; evidence based guidelines and implementation; guidelines, implementation and health professionals; guidelines, implementation and change;

Appendix 3: Cochrane Musculoskeletal Grading System

Silver Ranking

Silver ranking would include evidence from at least one study of non-randomized cohorts who did and did not receive the therapy or evidence from at least one case-control study. A randomized trial with a “head-to-head” comparison of agents is considered Silver level ranking unless a reference is provided to a comparison of one of the agents to placebo showing at least a 20% relative difference

The Silver ranking is given to evidence from a randomized trial that does not meet the criteria outlined below for platinum or gold level evidence.

Platinum level: The Platinum ranking is given to evidence that meets the following criteria as reported is a published systematic review that has at least two individual controlled trials each satisfying the following:

Sample sizes are of at least 50 per group. If they do not find a statistically significant difference, they are adequately powered for a 20% relative difference in the relevant outcome. -Blinding of patients and assessors for outcomes
-Handling of withdrawals >80% follow up (imputations based on methods such as Last Observation Carried Forward (LOCF) acceptable -Concealment of treatment allocation).

Gold level: The Gold ranking is given to evidence if at least one randomized controlled trial meets all of the following criteria as reported:

Sample sizes are of at least 50 per group. If they do not find a statistically significant difference, they are adequately powered for a 20% relative difference in the relevant outcome. Blinding of patients and assessors for outcomes
-Handling of withdrawals >80% follow up (imputations based on methods such as Last Observation Carried Forward (LOCF) acceptable -Concealment of treatment allocation).

Appendix 4: Summary of Studies in Review of Criteria for Rotator Cuff Tear

Authors	Relates to specific section	Type of study	Prospective / Retrospective	Number of subjects
Beaudreuil et al, 2010	Criteria, bony morphology	Systematic Review	Review Article	-
Warner et al, 1997	Criteria, function	Non-randomised, uncontrolled case series	Prospective	24
Moulinoux et al, 2007	Criteria, age, tear dimensions	Uncontrolled case Series	Retrospective	50
Ide et al, 2007	Age, tear dimensions	Uncontrolled case series	Prospective	20
Maman et al, 2009	Age	Review of past case histories	Retrospective	54
Cofield et al, 2001	Tear dimension, pain	Uncontrolled case series	Prospective	105
Green 2003	Tear dimensions	Review article	Review Article	-
Matthews et al, 2006	Tear dimensions, repair delay	Human lab based biopsy study	Lab Study	-
Zumstein et al, 2008	Tear dimensions	Uncontrolled case series	Retrospective	59
Burkhart et al, 2001	Tear dimensions, repair delay	Uncontrolled case series	Prospective	59
Feng et al, 2003	Tear Type, muscle atrophy	Review of past case histories	Retrospective	1067
Sallay et al, 2007	Tear type	Uncontrolled case series	Prospective	193
Yamaguchi et al, 2012	Fat atrophy	Uncontrolled case series	Prospective	24
Gerber et al, 2007	Fat atrophy	Uncontrolled case series	Prospective	12
Goutallier et al, 1999;	Fat atrophy	Uncontrolled case series	Prospective	74
Nakagaki et al, 1995	Fat Atrophy	Dissection case series	Prospective	38 cadavers

Authors	Relates to specific section	Type of study	Prospective / Retrospective	Number of subjects
Harryman et al, 1991	Age, tear size, fat atrophy	Uncontrolled case series	Retrospective	89
Melis et al, 2010	Fat atrophy	Review of notes	Retrospective	1688
Keener et al, 2010	Bony morphology	Non-randomised controlled observation	Prospective	160
Candiotta et al, 2002	Loss of range	Uncontrolled case series	Retrospective	134
Yamamoto et al, 2011	Muscle weakness	Non-randomised normative observation study	Prospective	283
Kim et al, 2009	Muscle weakness	Non-randomised normative observation study	Prospective	237
Meyer et al, 2011a	Repair delay, muscle weakness	Controlled laboratory study	Prospective	20 sheep
Gazielly et al, (1994)	Function	Uncontrolled case series	Prospective	98

Appendix 5: Ethics Approval



National Research Ethics Service

King's College Hospital Research Ethics Committee

1st Floor Camberwell Building
King's College Hospital
94 Denmark Hill
London
SE5 9RS

Telephone: 020 7188 2259
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05 March 2010

Ms Stephanie Griffiths
Consultant Physiotherapist
Ealing PCT
1 Armstrong Way
Southall
Middlesex UB2 4SA

Dear Ms Griffiths

Study Title: A study to design surgical referral criteria for rotator cuff tears, and to determine referral difficulties faced by specialist musculoskeletal physiotherapists.
REC reference: 10/H0808/32
Protocol number: 1

The Proportionate Review Sub-committee of the King's College Hospital Research Ethics Committee Research Ethics Committee reviewed the above application at the meeting held on 03 March 2010.

Ethical opinion

Favourable Opinion with Additional Conditions

The researcher is to assure the committee that the statistical analysis of Study 3 will enable the appropriate comparison of levels of agreement.

1. Participant Information Sheets x 3

What is the purpose of the study? section:

- please add a new sentence to this paragraph as follows: This research project is also for educational purposes, as part of my degree in ... text as appropriate.

The researcher clarified the following queries presented by the committee:

Q1. A13 The Delphi process in Study 2 involves a questionnaire and subsequent refinements but how will this be translated into a consensus statement on referral criteria?
A. After the last iteration of the questionnaire a document listing agreed referral criteria will be produced and then circulated to the participating surgeons for final agreement.

Q2. Will the ESPs also see the results of study 2 ... otherwise how can they possibly change their views (study 3).

A. Yes, the consensus on referral criteria will be sent to all participating in Study 3.

This Research Ethics Committee is an advisory committee to London Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within
the National Patient Safety Agency and Research Ethics Committees in England

Q3. Is the study being carried out on behalf of a professional body (BOA or CSP). If not, what status will the consensus have?

A. No, this is an independent study but after consensus Ms Griffiths would make the results available to the CSP.

Q4. Not clear how the results of Study 3 will be analysed using kappa statistic ... what groups are being compared and how?

A. The within-group agreement is being determined (i.e. how much ESPs agree with each other, how much surgeons agree with each other etc). Ms Griffiths has consulted a statistician and can let us know what additional tests ... comparing kappas before and after the Delphi process).

Q5. A6-2 Why send the surgeons questionnaire to all 78 rather than just picking friendly surgeons or a random selection. This is unusual for a Delphi process and having so many subjects could make the results difficult to handle (although perhaps this is because it is expected that most won't reply).

A. The two peer-reviewers had different views: one suggested a small group (as usual in a Delphi process), one a large group. However, the anticipated participation rate will probably quite low, so a minimum of 6 would make the process worthwhile.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>. Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

With the Committee's best wishes for the success of this project

Yours sincerely



Dr Mike Philpot
Chair

Email: samantha.roper@gstt.nhs.uk

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

"After ethical review – guidance for researchers"

Copy to:

Sponsor Dr Abebaw Yohannes
Faculty of Health, Psychology & Social Care
Elizabeth Gaskell Campus
Oxford Road
Manchester M13 0JA

R&D Ms Sylvia Westrup
Welfrenac, Department of Primary Care
Room 334, 3rd Floor
Reynolds Building
St. Dunstan's Road
London W6 8RP

Appendix 6: Referral Difficulties Faced by Extended Scope Physiotherapists Questionnaire



Statement of confidentiality:

Any information that would permit identification of an individual will be strictly confidential.

I am writing to ask you to take part in a survey to determine the referral difficulties faced by musculoskeletal extended scope physiotherapists when referring patients to secondary care. This research project is also for educational purposes as part of a Professional Doctorate in Physiotherapy.

The study aims to survey extended scope physiotherapists (or specialist musculoskeletal physiotherapists who have responsibilities to refer patients to secondary care) in the UK, at Band 7 or above. You have been selected to take part because you are a member of the extended scope physiotherapist occupational interest group.

You are asked to complete the following questionnaire which asks you to answer questions about your work location and banding, referral difficulties and barriers to referral. Data concerning the referral rate and the number of patients converting to orthopaedic surgery is also requested.

After completing the questionnaire please return it by email to stephaniegriffiths@nhs.net or by post to:

Stephanie Griffiths

Consultant Physiotherapist

Ealing PCT

1 Armstrong Way

Middlesex

UB2 4SA.

All information will be entirely anonymous. Please note if you require further information you can telephone me on **0203 313 9619** or fax on 0208 758 9270.

Thank you very much for you co-operation in advance

Yours sincerely

Stephanie Griffiths MPhil. MSc. MCSP.

Consultant Physiotherapist

For office use

Please answer all questions from 1 to 10. Please choose the most appropriate answer(s) by clicking on the grey boxes. Where you are required to add comments please start your answers at the grey tab and add as much detail as you feel is necessary. Once complete please save your answers and return the form to me by email or post to the address on the first page.

Section A concerns your current extended scope physiotherapy role. If you have more than one post, please answer questions on your main extended scope role only.

1. Please mark the answer which relates most clearly to your current post. Do you work in a specialist interface service within:

- Primary care
- Secondary care
- Integrated care organisation
- Other (please give details)

2. What Agenda for Change band are you? Please mark the answer which relates most appropriately to your current post.

- a) 8a
- b) 7
- c) Other (please give details)

3. In your current post which services do you refer to? Mark as many options as appropriate.

- a) Orthopaedics
- b) Neurosurgery
- c) Pain Clinic
- d) Rheumatology
- e) Other (please give details)

4. Do you have a speciality in your current post?

Yes No

If yes, please indicate in which of the following areas you have specialised. Mark as many options as appropriate.

- a) Upper limb
- b) Lower Limb
- c) Spinal
- d) Rheumatology
- e) Pain management
- f) Other (please give details)

SECTION B relates to Orthopaedic or Neurosurgical conversion rates. For the purposes of this questionnaire, the definition of the 'conversion rate' is the number of patients who undergo surgery (or other significant orthopaedic intervention such as a biopsy or injection), following a referral to a surgeon or a surgical department. The rate is usually expressed as the number of patients undergoing surgery (biopsy or injection) divided by the total number of patients referred to surgical team/secondary care.

5. In the main service in which you work, do you, or does your manager/service lead calculate your conversion rate to orthopaedic surgery or neurosurgery? Please add extra clarification if required below.

Yes No

Comments:

6. If yes, please write the conversion rate below in the box next to the most appropriate option. If your service calculated more than one conversion rate please write against each relevant option.

*Note for the purpose of this question 'mixed specialty' means a team of individuals who work in more than one sub-specialty e.g. spinal and lower limb; 'single specialty' refers to ESPs working in one specialty such as spinal only.

Please write the conversion rate in the grey box below against the relevant option

a) Conversion rate for a team of mixed specialty

b) Conversion rate for a team working in a single specialty

c) Individual conversion rate for you working as a mixed speciality ESP

d) Individual conversion rate for you working as a single speciality ESP

e) Other conversion rate

SECTION C relates to referral barriers and referral practice.

7. Do you refer patients for radiological investigations such as x-ray, MRI or Ultrasound?

Yes No

If yes do you use a criteria or guideline to help you?

Yes No

If yes please write the title of the guideline you use:

8. Have you experienced difficulty referring patients for radiological investigations such as commissioning barriers associated with payment or professional barriers which only allow medical referrals for example?

Yes No

If yes, can you describe the barriers that you have faced?

9. Do you have any difficulty in referring your patients to particular departments such as orthopaedics, rheumatology, pain clinic or neurosurgery, tertiary centres, or specialist areas?

Yes No

If yes can you outline the key problems below and indicate in which speciality you experienced difficulties.

Comments:

10. Do you use a criteria when referring patients to secondary care?

Yes No

If yes can you outline below how it was designed (i.e. departmental, with input from a range of specialists, or enforced from surgeon/department)

Comments:

If you have other comments that are not included in the questionnaire, please list them below.

Comments:

Thank you very much for taking your time in completing this questionnaire.

Appendix 7: Interview Data

1	<p><u>Decision to Operate</u> Tell me about the things that influence your decision to operate on a patient with degenerative rotator cuff tear?</p>
	<ul style="list-style-type: none"> • <i>I don't really have a clear list of criteria that I can give you. After prompts.</i> • <i>The maximum age of the patient is probably around 70 years old, when I am repairing degenerative cuff tears with humeral head migration</i> • <i>Generally I think one of the cut off's I use is age. If the patient is aged over 65 I generally think they shouldn't be repaired.</i> • <i>Do I have a criteria- not really, can you give me an idea of what you mean? What would you say was a criteria?</i> • <i>I suppose I make some decisions on the patient's activity levels then I decide what to do. If the patient has an x-ray which shows crowding in the subacromial space. If I see a partial thickness tear then I operate early.</i> • <i>I don't tend to inject these, I'll like to operate before they become painful and stiff. I think the earlier I operate the better they recover. I do inject these patients if they decline surgery, and occasionally I try an injection to see what effect it has, if they have a good response to injection then there may be a good response to surgery. I hesitate about injecting next to a tear.</i> • <i>It's very difficult to decide on criteria as all patients are different. Rotator cuff conditions are the most difficult area to make a clear pathway. My criteria has probably got more conservative over time, I think you'll find me very conservative.</i> • <i>The amount of pain they are in, I mean the more severe the pain, the more likely I am to operate.</i> • <i>Patients who are young, who have had an acute injury. Those who have had a recent injury under 1 year. A tear that is not too big and not too small- following the oxford model. Those with an accessible tear, which can be operated upon with arthroscopic surgery.</i>

2	<p><u>Characteristics and dimensions of the tear</u> What aspects of the rotator cuff tear dimensions are the most important when making a decision to proceed with surgery for a degenerative rotator cuff tear?</p>
	<ul style="list-style-type: none"> • <i>If the patient presents with a partial thickness tear I will repair the tear if it is greater than 50% thickness of the tendon. If it is less than 50% thickness I aim to do a subacromial decompression.</i> • <i>Some surgeons would operate based on the size of the tear as shown on the US scan, others would go in first with an arthroscopy and then make the decision. The size of the tear is key- large massive tears are not very good/do not do well when repaired. I don't have an absolute cut off, it depends on many factors.</i> • <i>I don't make a surgical decision based on the size of the tear I am guided primarily by the patient's symptoms. I operate on small or large tears, even very large/massive tears if the tissue quality is good.</i> • <i>Using the tear size as a guide to surgery is difficult. One could follow the oxford model- namely large tears are not likely to recover so you exclude them and small tears are difficult to access. So moderate tears are probably the most likely to be selected if you are making a decision on tear size.</i> • <i>Large tears are considered to be 4cm or larger, they are probably not likely to stay intact if repaired.</i>
3	<p><u>Multiple Tears</u> What happens if you see a patient with multiple tears?</p>
	<ul style="list-style-type: none"> • <i>I operate on multiple tears, and tend to use an open approach. If subscapularis is involved I am much more likely to do an open approach.</i> • <i>We operate on these just like single tears, its dependent on age of patient and tear quality.</i> • <i>I operate on them just as I would do in a single tear if the tendon quality is good, even if they have two or 3 tears.</i> • <i>I do not exclude patients with multiple tears, I operate on them if they have good tendon quality. Often 1 tear progresses to another tear and then becomes a multiple tear so this is not an uncommon finding.</i> • <i>Less likely to repair partial tears, I am more likely to do a subacromial decompression in these instances. Then perhaps do a repair at a later date if necessary.</i>

4	<p><u>Fat Atrophy and Tendon Quality</u> What about fat atrophy and tendon quality?</p>
	<ul style="list-style-type: none"> • <i>I think age is related to tendon quality specifically, so I use tendon quality rather than age as a guide, but for older patients with humeral head migration, I generally don't operate if they are over 70.</i> • <i>You can look at the tendon quality with an Ultrasound scan before you do the surgery if the US is conducted by a MSK radiologist. If it's not done by an MSK radiologist and it is poor quality you can offer them an arthroscopy</i> • <i>I only make an assessment of tendon quality when I am in the joint doing the arthroscopy. I don't think that US is useful to make an assessment of tendon quality.</i> • <i>Tendon quality is probably the most important determinant for success in rotator cuff repair. But it is mainly checked when the patient is opened up, can't really check before hand.</i> • <i>I do look at the MRI if one is available before surgery in some patients, particularly when it's very difficult, and get a feel for the quality of the tendon. There is a classification identified by Goutallier which identifies how much fatty infiltration there is.</i>
5	<p><u>Specialist Investigations</u> What are your views on specialist investigations?</p>
	<ul style="list-style-type: none"> • <i>After the x-ray and ultrasound I tend to order an MRI to look at the cuff wasting and fat atrophy- I use Goutallier's definition of fat atrophy when I am looking at the MRI.</i> • <i>US and x-ray are the commonest investigations done in this clinic so that we can see if a SAD is needed too. We look for a bony spur so we can see if a subacromial decompression is needed too.</i> • <i>I always like a baseline x-ray for any shoulder referral, for a cuff tear I generally like patients to have had an US scan too.</i> • <i>US is the preferable specialist investigation rather than MRI. It is useful so that you can see what happens to the tendon in real time, for example what happens when the tendon moves – does it ruck up/crinckle under the acromion.</i> • <i>Yes. I think it's also useful to have an x-ray in most cases so that you have several views to help verify your findings.</i> • <i>The narrow subacromial space is very dependent on operator error, unless the x-ray demonstrates that the line of the axilla is broken. If this is the case it demonstrates that the humeral head is actually raised</i>

6	<p><u>Key Issues</u></p> <p>Of all the factors which may influence your decision to operate, which do you think are the key area which influence if and when you decide to proceed with a repair of a degenerative rotator cuff?</p>
	<ul style="list-style-type: none"> • <i>Age, humeral head migration, tendon quality, retraction of the tear and size of the tear.</i> • <i>Weakness is important, when a patient is examined I look for cuff weakness on testing rather than just pain.</i> • <i>Age is important.</i> • <i>I operate on any size good quality degenerative tendon tear. I have no upper age cut off limit.</i> • <i>Age, tendon quality, severity of pain, no success with physio, tried previous physio but not benefit, tried injections and no help, then consider surgery.</i>
7	<p><u>Other Contributing Factors</u></p> <p>What other factors do you think are important when you make the decision to operate on a patient with a degenerative cuff tear?</p>
	<ul style="list-style-type: none"> • <i>Consideration of Yellow flags is important particularly for example in compensation cases. They do influence my decision to operate because I am aware that they influence the outcome. Patients presenting with yellow flags make me more conservative and do make a difference in my decision to operate.</i> • <i>Yes I think all of these things influence me, politics, yellow flags etc all of it, they all influence when you operate.</i> • <i>Other factors such as yellow flags do influence my decision to operate. A patient may be claiming compensation for example but I still treat them accordingly. However if they don't respond to conservative treatment or other things like local anaesthetic injection, I explain that surgery may not help and thus try to avoid surgery for those patients with significant yellow flags.</i> • <i>I don't think there are any other factors I can think of.</i>

Appendix 8: Developing Surgical Referral Criteria for Rotator Cuff Tears Questionnaire



Ealing and Harrow Community Services

Invitation to take part

I am writing to ask you to take part in a questionnaire study to develop surgical referral criteria for degenerative rotator cuff tears.

Why are we doing this research?

The aim of the study is to gain consensus on the referral criteria/guidelines for degenerative rotator cuff tears for patients referred **from extended scope physiotherapists to shoulder surgeons**. Extended scope physiotherapists are highly trained musculoskeletal specialists, many of whom work in primary care or within 'interface' or clinical assessment services. Their role in screening musculoskeletal primary care referrals has increased since the publication of the Musculoskeletal Framework (2006). Many of these interface type services now form an integral part of the care pathway for patients with musculoskeletal disease, however selecting the most appropriate patients to refer to secondary care remains a challenge. Please note that this research is being conducted as part of a clinical doctorate programme.

Why have I been invited to take part?

The study aims to survey consultants all over the UK. You have been selected to take part because you have been identified as an expert in the surgical management of degenerative rotator cuff tears.

What will happen if I take part?

You will be asked to complete the following questionnaire which asks you to answer questions about a range of factors which influence your decision to operate on a patient with a degenerative rotator cuff tear. Once the questionnaire is completed you should return it by email to stephaniegriffiths@nhs.net or you can return it to:

Stephanie Griffiths

Consultant Physiotherapist

1 Armstrong Way

Southall

Middlesex

UB2 4SA.

The results will be collated and any questions in which there is a poor level of agreement will be added to another questionnaire which will be sent out again to determine where further agreement can be gained. **All information will be entirely anonymous once collected.** Please note if you require further information you can contact me on **0203 313 9619**.

Thank you for your co-operation

Stephanie Griffiths MPhil. MSc. MCSP.

Consultant Physiotherapist

INTRODUCTION TO THE QUESTIONNAIRE

Answer these questions as if they were concerned with patients referred to you with typical degenerative rotator cuff symptoms, from specialist extended scope physiotherapists. You should answer the questions with the assumption that extended scope physiotherapists would be trained to a high level, not necessarily in clinic with you but contactable should queries arise.

You should not answer the question as if the answers relate to every patient you may see, particularly atypical or complex patients. The aim is that your answers will help to guide extended scope physiotherapists when referring 'typical' degenerative rotator cuff patients so that they can improve their efficiency and reduce the number of inappropriate referrals.

The questionnaire is divided into 3 sections. All questions ask you to determine your level of agreement with a statement, out of 5 possible options, except question 3.5 which requires a Yes or No answer only. Click on the box next to the answer that most represents your views. You are asked to add more information at the end of some specific questions and you are invited to add extra detail to clarify your answers/views at the end of each section if you wish to. **Tick one box per question only.**

SECTION 1

Patient Subjective Information

This section is aimed at gaining information about the specific aspects of the patient's subjective or social history which influence your decision to proceed with surgery for a degenerative rotator cuff tear.

1.1 When considering surgery for a degenerative rotator cuff tear the age of the patient is a determining factor.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

If you agree what age would you consider to be an appropriate cut off for a degenerative cuff repair?

1.2 When considering surgery for repair of a degenerative rotator cuff tear the patient's occupation/ hobbies are a determining factor (i.e. are outcomes are associated with specific jobs/hobbies?).

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

If you agree with this statement which hobbies or occupational groups do you feel are associated with poor outcomes?

1.3 When considering surgery for repair of a degenerative rotator cuff tear the severity of the pain symptoms are a determining factor.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

1.4 When considering surgery for repair of a degenerative rotator cuff tear, the success with previous interventions (for example physiotherapy, injection, pain management programme) is a determining factor.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

1.5 I would not operate on a patient who has had a delay of several years between injury of the rotator cuff and surgical repair.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

1.6 When considering surgery for repair of a degenerative rotator cuff tear it is important that the referrer includes information about the presence of psychosocial issues (for example treatment compliance, passivity, acceptance, beliefs about cure, family issues, litigation).

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

Please add any extra information you would like to add here:

SECTION 2

Objective Assessment

The aim of this section is to determine which objective signs you think must be present before you will consider rotator cuff repair surgery for a 'typical' patient with a degenerative cuff tear.

2.1. When considering surgery for repair of a degenerative rotator cuff tear the patient must have pain on resisted muscle testing for the tendon being repaired.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

2.2. When considering surgery for repair of a degenerative rotator cuff tear the patient must have weakness on resisted muscle testing for the tendon being repaired.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

If you agree with the statement above do you have a specific criteria? (e.g. 2/5 on the oxford scale)

2.3. I do not attempt to repair a degenerative rotator cuff if a patient presents with a painful/active phase frozen shoulder/adhesive capsulitis.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

2.4 When considering surgery for repair of a degenerative rotator cuff tear, significant limitation of normal activities of daily living (for example eating, combing hair, dressing, driving) would make me inclined to operate.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

2.5 When considering surgery for repair of a degenerative rotator cuff tear, significant limitation of advanced function (for example golf, tennis, squash, swimming, weightlifting) would make me inclined to operate.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

2.6 In patients who present with shoulder impingement symptoms, where a degenerative cuff tear is suspected, I prefer to investigate the extent of subacromial narrowing before I decide to operate.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

2.7 In patients who present with shoulder impingement symptoms, where a degenerative cuff tear is suspected, I prefer to investigate for the presence of a subacromial spur before I decide to operate.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

Please add any extra information you would like to add here:

SECTION 3

Tear Characteristics and Tendon Quality

This section is aimed at gaining information about the tendon quality and tear characteristics which influence your decision to proceed with surgery for a degenerative rotator cuff tear.

3.1. The shape of the tear (e.g. transverse, crescent or U shaped) determines whether I decide to operate on the patient.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

3.2 The size and dimensions of the tear determine whether I operate on a partial thickness tear.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

3.3 The size and dimensions of the tear determine whether I operate on a full thickness tear.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

3.4 The extent of the retracted ends of the tear determine whether I operate on a full thickness tear.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

If you agree/strongly agree with the statements above concerning tear size please identify the tear dimensions that you use as a general rule to guide your choice about surgery

3.5 In your experience, are specific tear dimensions associated with poor surgical outcomes?

Yes No

If yes what tear size is associated with poor outcomes?

3.6 The site of the tear within a specific tendon is important in determining whether to operate on a degenerative rotator cuff tear.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

If you agree/strongly agree with the statement above, please explain which aspects of the tear site influence your surgical decision

3.7 I do not operate on massive tears.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

3.8 I would operate on a patient with a degenerative rotator cuff tear in any of the rotator cuff tendons

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

If you disagree/strongly disagree with the statement above explain why

3.9 If the conditions were right, I would operate on a patient with multiple partial thickness tears.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

3.10 If the conditions were right, I would operate on a patient with multiple full thickness tears.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

3.11 The presence of fat atrophy is a factor in whether I decide to operate on a patient with degenerative rotator cuff disease.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

If you agree/strongly agree with the statement above please identify what grade of fat atrophy you think is an important cut off for surgery, and whether this is consistent for all rotator cuff tendons

(NB: Fat Atrophy Grades according to Goutallier et al, (1994). (Grade 0 Normal; Grade 1 Fatty streaks, Grade 2 Significant fat, but muscle > fat; Grade 3 Muscle = fat; Grade 4 Fat > muscle).

If you have any other comments about the management of degenerative rotator disease please add them here

Thank you again for taking part.

Please send by email to stephaniegriffiths@nhs.net or by post to Stephanie Griffiths, Consultant Physiotherapist, 1 Armstrong Way, Southall, Middlesex. UB2 4SA.

Appendix 9: 2nd Round Developing Surgical Criteria for Rotator Cuff Tears Questionnaire



Ealing and Harrow Community Services

Thank you for taking part in the previous consensus questionnaire to determine agreement on referral criteria for degenerative rotator cuff repair.

Why have I been contacted again?

All those who responded to the previous questionnaire have been contacted again to see if further agreement can be reached.

A high level of agreement has been reached on 11 out of 24 of the previous questions (for your information the results can be seen on the final page of this attachment). 3 items had poor agreement and have been removed from the questionnaire. 10 items remain where there is moderate agreement falling between 45% and 65%. I have listed the remaining clinical statements with the levels of agreement/disagreement shown in bold below each statement (percentages of 'neither' are not shown).

What do I have to do now?

I would be very grateful if you could review the questions below where agreement has not been reached to see if you could reconsider your answers in light of the findings. As you will remember, the aim of the study is to gain consensus on the referral criteria/guidelines for degenerative rotator cuff tears for patients referred **from extended scope physiotherapists to shoulder surgeons**. Once the questionnaire is completed you should return it by email to stephaniegriffiths@nhs.net or you can return it to:

Stephanie Griffiths

Consultant Physiotherapist

1 Armstrong Way

Southall

Middlesex

UB2 4SA.

The results will again be collated and any statements that continue to have a low level of agreement (below 45%) will be removed from the questionnaire. It there are areas where there is moderate to good agreement (i.e. between 55-65%) you may be asked to review statements again to see if consensus between surgeons can be reached. As always all information will be **entirely anonymous** once collected. Please note if you require further information you can contact me on **0203 313 9619**.

Thank you for your co-operation

Stephanie Griffiths MPhil. MSc. MCSP.

Consultant Physiotherapist

Remember when answering the following questions mark the box which most represents your views. Mark one box only and add comments at the end if you wish to clarify your answers.

1. When considering surgery for repair of a degenerative rotator cuff tear the patient must have pain on resisted muscle testing for the tendon being repaired.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

(Agree 45%

Disagree 20%)

2. When considering surgery for repair of a degenerative rotator cuff tear the patient's occupation/ hobbies are a determining factor.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

(Agree 45% Disagree 20%)

3. When considering surgery for repair of a degenerative rotator cuff tear the patient must have weakness on resisted muscle testing for the tendon being repaired.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

(Agree 50% Disagree 10%)

4. In patients who present with shoulder impingement symptoms, where a degenerative cuff tear is suspected, I prefer to investigate the extent of subacromial narrowing before I decide to operate.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

(Agree 50% Disagree 30%)

5. I would not operate on a patient who has had a delay of several years between injury of the rotator cuff and surgical repair.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

(Agree 20% Disagree 55%)

6. The size and dimensions of the tear determine whether I operate on a partial thickness tear.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

(Agreement 55% Disagree 35%)

7. When considering surgery for repair of a degenerative rotator cuff tear, significant limitation of advanced function (for example golf, tennis, squash, swimming, weightlifting) would make me inclined to operate.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

(Agreement 60% Disagree 25%)

8. In your experience, are specific tear dimensions associated with poor surgical outcomes?

Yes No

(Yes 60% No 40%)

(Note previous surgeons who answered yes to this question indicated that poor outcomes were associated with tear sizes ranging from 3.5cm to 10 cm. The average tear size was 6cm and the median was 5cm).

9. The extent of the retracted ends of the tear determine whether I operate on a full thickness tear.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

(Agree 65% Disagree 30%)

10. I do not operate on massive degenerative rotator cuff tears.

Strongly Agree Agree Neither Agree/Disagree Disagree Strongly Disagree

(Agree 65% Disagree 10%)

If you have any other comments about the management of degenerative rotator disease please add them here

For your information only: Agreement Reached so far.

Clinical Statement/Question	Agreement
When considering surgery for repair of a degenerative rotator cuff tear the severity of the pain symptoms are a determining factor	95%
When considering surgery for repair of a degenerative rotator cuff tear, significant limitation of normal activities of daily living (for example eating, combing hair, dressing, driving) would make me inclined to operate.	85%
When considering surgery for repair of a degenerative rotator cuff tear it is important that the referrer includes information about the presence of psychosocial issues (for example treatment compliance, passivity, acceptance, beliefs about cure, family issues, litigation)	80%
The presence of fat atrophy is a factor in whether I decide to operate on a patient with degenerative rotator cuff disease	80%
If the conditions were right, I would operate on a patient with multiple full thickness tears	75%
The shape of the tear (e.g. transverse, crescent or U shaped) does not determine whether I decide to operate on the patient	75%
I do not attempt to repair a degenerative rotator cuff if a patient presents with a painful/active phase frozen shoulder/adhesive capsulitis	75%
When considering surgery for repair of a degenerative rotator cuff tear, the success with previous interventions (for example physiotherapy, injection, pain management programme) is a determining factor	75%
When considering surgery for a degenerative rotator cuff tear the age of the patient is a determining factor	70%
I would operate on a patient with a degenerative rotator cuff tear in any of the rotator cuff tendons	70%
If the conditions were right, I would operate on a patient with multiple partial thickness tears	70%

Appendix 10: Shoulder Vignette 1

Subjective Examination

Mr B is a 63 year old patient referred to you for physiotherapy. When he attends for assessment he reports a history of chronic bilateral shoulder pain which flared up 6 months ago particularly on the right side. His left shoulder is painful but much less than the right. He has had no recent physiotherapy and his wife is quite keen that he is referred on to see a consultant.

His right sided pain is mainly in the deltoid area and lateral aspect of the upper arm to the elbow. The pain is fairly constant and low grade in nature at rest but increases significantly when he uses his arm. He has tried an injection into the joint capsule which his GP administered. Unfortunately this did not have any effect on his pain/function/quality of life.

His pain is aggravated by movement, he is unable to lie on his side for long periods and is having some disturbed sleep.

PMH- He has a chronic lumbar spine condition which he has had treated previously with physiotherapy, exercise and facet joint injection. None of these treatments have helped him, however he is accepting of his spinal condition but is unable to work as a builder because of it.

SH: He lives with his wife and he would like to get back to some form of work before he has to retire. He knows he cannot return to building work but would like to try something lighter, perhaps in a warehouse.

Objective Examination

Posture fair, slight cervico-thoracic kyphosis consistent with age, generally holds/nurses arm close to body.

Cervical Range of Movement- full, end range limited in all directions but no pain

Shoulder Right Side: Forward flexion pain starts at 40 degrees continues to 140 degrees

Abduction Pain starts at 30 degrees of passive and active mvt, continues to end range- no limitation, pain throughout mvt but no clear painful arc. Patient demonstrates apprehension and fear avoidance to abduction, reluctant to move freely.

Passive Movements

Lat Rotation full passive mvt; Pain starts at $\frac{3}{4}$ range mvt

Medial Rotation full passive mvt. Pain starts at ¾ range active mvt

Adduction-NAD

Abduction -as above

Resisted Movements

All mvts tested with shoulder 10 degrees away from body

Abduction-painful and weak 3/5

Lateral rotation painful and weak 4/5

Med Rot -much less pain no significant weakness 5/5

Flexion – no pain, no weakness 5/5

Extension – moderate pain, no weakness 5/5

Ultrasound Report

The GP requested an ultrasound report a few weeks ago, the report has been attached to the referral. It reads: ‘ there is a massive cuff tear within the right side supraspinatus tendon’. There is evidence of subacromial inflammation and bilateral tendinopathy within both supraspinatus tendons. There is also moderate a full thickness tear on the left side measuring approximately 2.5cm.

Please select from the list below, in order of preference what treatment options you would choose for this patient.

- 1. Refer patient for an injection**
- 2. Refer patient for orthopaedic opinion**
- 3. Refer to Physiotherapy**
- 4. Give the patient a home exercise programme and discharge back to their GP**
- 5. Other- please state:**

.....
.....
.....
.....

If you choose option 1, 2, or 3, please indicate below what type of injection, surgery or physiotherapy you were hoping/expecting the patient to receive.

Comments:

Appendix 11: Shoulder Vignette 2

Mrs x is a 43 year old patient who has been referred to physiotherapy after a fall at work 6 months ago. She is complaining of pain in the lateral aspect of the deltoid with some referral down to the elbow.

Due to her lack of recovery, the GP referred her for an ultrasound scan which showed a 1cm partial thickness tear in the supraspinatus tendon. She has been off sick for 6 months now and has had a couple of sessions of private massage therapy but she feels no better. She has been back to her GP several times lately as her painkillers (Diclofenac) are not helping anymore. Her GP has not tried any other treatment or medication.

On objective examination she has a painful arc, pain on resisted abduction in neutral, pain on resisted abduction in internal rotation (empty can), slight discomfort on passive movements but no significant limitation. All other resisted movements appear to be pain free except resisted lateral rotation which evokes some pain. The scarf test is negative and all palpation around the joint is painful. Abduction and lateral rotation are weak.

Please select from the list below, in order of preference what treatment options you would choose for this patient.

- 1. Refer patient for an injection**
- 2. Refer patient for orthopaedic opinion**
- 3. Refer to physiotherapy**
- 4. Give the patient a home exercise programme and discharge back to their GP**
- 5. Other- please state:**

.....
.....

If you choose option 1, 2, or 3, please indicate below what type of injection, surgery or physiotherapy you were hoping/expecting the patient to receive.

Appendix 12: Shoulder Vignette 3

60 year old retired cleaner presents to the interface service with a 4/12 history of right shoulder pain. Insidious onset. Pain in the deltoid area referring to the right forearm. Pain is aggravated by all activities of daily living. Nothing eases the pain, taking paracetamol regularly but it has little effect.

24 hour; no pattern.

Sleep; She tends to lie on the right shoulder at night. Sleep not disturbed.

Previous treatment

Subacromial injection performed by GP 11/7/2011 - no change in symptoms at all. Has also tried exercises and rest - no improvement.

PMH

R thumb infection (required surgery and IV Antibiotics) in 2004. Admitted to hospital for ten days.

No other major illnesses/ops.

Thyroid and Diabetes; under lx.

No epilepsy

DH

Betamethasone, Paracetamol, Simvastatin, Nebivolol, Bendroflumethiazide

Aspirin

SQ; no weight loss, steroids

SH Retired. Lives with husband – he is elderly and not too supportive. Patient tends to do majority of domestic ADLs.

Obs:

Posture – normal limits, slight kyphosis – cervical movements clear.

Passive Movements

Full range of passive movement but very painful through abduction and forward flexion.

Active Movements very limited:

Flexion 30 degrees – painful++

Abduction 40 degrees – painful++

Lateral Rotation $\frac{3}{4}$ range – very little pain

Medial Rotation $\frac{3}{4}$ range – pain at end range pain++

Resisted Movements

Flexion – pain++ very weak power 2/5

Abduction – unable to lift due to pain, power 2/5

Lat rotation 3-4/5

Medial rotation 3/5

Extra tests

Scarf test positive

Painful on palpation

US Scan Report

Technical Findings:

The supraspinatus tendon fibres are not identified, appearances are consistent with a complete tear.

Fluid and synovial thickening identified within the subacromial-subdeltoid bursa.

The patient exhibits a limited range of arm movement.

Extensive degenerative changes identified

The subscapularis, infraspinatus and teres minor tendons appear intact.

The biceps tendon is identified within the biceps groove and appears intact, fluid is identified within the surrounding sheath.

The CA ligament appears normal.

No significant joint effusion identified.

The AC joint exhibits cortical degeneration and synovial thickening.

Conclusion:

The supraspinatus tendon fibres are not identified, appearances are consistent with a complete tear.

Fluid and synovial thickening identified within the subacromial-subdeltoid bursa.

The AC joint exhibits significant cortical degeneration, and synovial thickening.

Radiological Recommendations:

No diagnostic recommendations.

Please select from the list below, in order of preference what treatment options you would choose for this patient.

- 1. Refer patient for injection**
- 2. Refer patient for orthopaedic opinion**
- 3. Refer to physiotherapy**
- 4. Give the patient a home exercise programme and discharge back to their GP**
- 5. Other – please state:**

.....
.....
.....

If you chose option 1, 2 or 3, please indicate below what type of injection, surgery or physiotherapy you were hoping/expecting the patient to receive.

.....
.....
.....

Add other comments here:

Appendix 13: Difficulties Collecting Conversion Rate Data

A selection of open responses from the Referral Appropriateness Questionnaire. Subjects were asked whether they collected their conversion rates and then were invited to add comments. 16 subjects identified that they had difficulty collecting conversion rate data, a selection of the comments can be found below.

- *Unfortunately we have a patchy response from our secondary care surgical colleagues/opinion about whether we should exist. Feedback is very sparse*
- *These are the numbers that we all want, but I know within our service getting the details from secondary care has been near impossible.*
- *We have to chase up referrals to the local orthopaedic provider and check letters on the computerised hospital system to calculate conversion rates, or whether further investigations were required which we cannot authorise. Unfortunately patients who go elsewhere we are unable to get their conversion rates to surgery.*
- *We try to do so, but it's difficult to get accurate figures as often we don't get letters back from the consultants, particularly with orthopaedics.*
- *This [conversion rate] has been an informal audit by ourselves, relying on letters back from consultants. It is hoped to be more formalised, but it's difficult to get data from secondary care.*
- *This is because we work for primary care and we do not have access to records in secondary care. We have not been able to access their information and not all consultants send letters back to us with outcomes. We are in the process of trying to collect some data but it is difficult.*
- *There is poor feedback from secondary care in our area so this information is not available.*
- *Some of the patients we were refer are seen in secondary care outside the local area, this makes it difficult to ascertain our effectiveness in improving conversion rates.*

A selection of open responses from the Referral Appropriateness Questionnaire. Subjects were asked whether they collected their conversion rates and then were invited to add comments. 16 subjects identified that they had difficulty collecting conversion rate data, a selection of the comments can be found below.

- *Yes we try but do have difficulty with the secondary care providers separating our referrals from that of GPs. Currently no separate figures for our service but the local conversion rate is 30%*
- *It's difficult to calculate accurately because of the lack of feedback from secondary care letters. This has got worse lately perhaps secretarial staff are under more pressure.*
- *Not recently as it's very difficult to get all the letters back from consultants.*

Appendix 14: Complete Results of First Round Delphi study

Agreement and Disagreement values for all statements ranked in order of consensus agreement after the first round study

Consensus statement	% Strongly Agree	% Agree	% Disagree	% Strongly Disagree	Neither
1.1 When considering surgery for a degenerative rotator cuff tear the age of the patient is a determining factor. (The average cut off age was 70, for one it was 80 and for one it was 65)	15%	55%	15%	0%	15%
1.2 When considering surgery for repair of a degenerative rotator cuff tear the patient's occupation/hobbies are a determining factor (i.e. are outcomes associated with specific jobs/hobbies?)	10%	35%	20%	0%	35%
1.3 When considering surgery for repair of a degenerative rotator cuff tear the severity of the pain symptoms are a determining factor	55%	40%	0%	0%	5%
1.4 When considering surgery for repair of a degenerative rotator cuff tear, the success with previous interventions (for example physiotherapy, injection, pain management programme) is a determining factor.	15%	60%	5%	5%	15%
1.5 I would not operate on a patient who has had a delay of several years between injury of the rotator cuff and surgical repair.	5%	15%	45%	10%	25%

Consensus statement	% Strongly Agree	% Agree	% Disagree	% Strongly Disagree	Neither
1.6 When considering surgery for repair of a degenerative rotator cuff tear it is important that the referrer includes information about the presence of psychosocial issues (for example treatment compliance, passivity, acceptance, beliefs about cure, family issues, litigation).	20%	60%	5%	0%	15%
2.1. When considering surgery for repair of a degenerative rotator cuff tear the patient must have pain on resisted muscle testing for the tendon being repaired.	5%	45%	15%	5%	35%
2.2 When considering surgery for repair of a degenerative rotator cuff tear the patient must have weakness on resisted muscle testing for the tendon being repaired.	5%	45%	10%	0%	35%
2.3. I do not attempt to repair a degenerative rotator cuff if a patient presents with a painful/active phase frozen shoulder/adhesive capsulitis.	30%	45%	10%	0%	15%
2.4 When considering surgery for repair of a degenerative rotator cuff tear, significant limitation of normal activities of daily living (for example eating, combing hair, dressing, driving) would make me inclined to operate.	30%	55%	0%	0%	15%
2.5 When considering surgery for repair of a degenerative rotator cuff tear, significant limitation of advanced function (for example golf, tennis, squash, swimming, weightlifting) would make me inclined to operate.	15%	45%	25%	0%	15%

Consensus statement	% Strongly Agree	% Agree	% Disagree	% Strongly Disagree	Neither
2.6 In patients who present with shoulder impingement symptoms, where a degenerative cuff tear is suspected, I prefer to investigate the extent of subacromial narrowing before I decide to operate.	15%	25%	25%	5%	20%
2.7 In patients who present with shoulder impingement symptoms, where a degenerative cuff tear is suspected, I prefer to investigate for the presence of a sub acromial spur before I decide to operate.	5%	30%	35%	5%	25%
3.1. The shape of the tear (e.g. transverse, crescent or U shaped) determines whether I decide to operate on the patient. <i>i.e. The shape of the tear does not influence whether I will operate</i>	0%	5%	40%	35%	20%
3.2 The size and dimensions of the tear determine whether I operate on a partial thickness tear.	10%	45%	15%	10%	20%
3.3 The size and dimensions of the tear determine whether I operate on a full thickness tear.	10%	30%	20%	20%	20%
3.4 The extent of the retracted ends of the tear determine whether I operate on a full thickness tear.	15%	50%	15%	15%	20%
3.5 In your experience, are specific tear dimensions associated with poor surgical outcomes?	Yes=60%		No=40%		

Consensus statement	% Strongly Agree	% Agree	% Disagree	% Strongly Disagree	Neither
3.6 The site of the tear within a specific tendon is important in determining whether to operate on a degenerative rotator cuff tear.	0%	20%	20%	15%	45%
3.7 I do not operate on massive tears.	0%	10%	55%	10%	25%
3.8 I would operate on a patient with a degenerative rotator cuff tear in any of the rotator cuff tendons.	15%	55%	10%	0%	20%
3.9 If the conditions were right, I would operate on a patient with multiple partial thickness tears.	0%	70%	15%	0%	15%
3.10 If the conditions were right, I would operate on a patient with multiple full thickness tears.	10%	65%	5%	0%	20%
3.11 The presence of fat atrophy is a factor in whether I decide to operate on a patient with degenerative rotator cuff disease. (Grade 3 fat atrophy is the cut off for many but it is not an absolute)	20%	60%	10%	5%	5%

Appendix 15: Second Round Results/ First and Second Round Comparisons

	Consensus Statement	Strongly Agree	Agree	Disagree	Strongly Disagree	Neither
1	When considering surgery for repair of a degenerative rotator cuff tear, significant limitation of advanced function (for example golf, tennis, squash, swimming, weight lifting) would make me inclined to operate.	36%	45%	9%	0%	9%
2	When considering surgery for repair of a degenerative rotator cuff tear the patient's occupation/ hobbies are a determining factor (i.e. are outcomes associated with specific jobs/hobbies?)	45%	27%	18%	0%	9%
3	I would not operate on a patient who has had a delay of several years between injury of the rotator cuff and surgical repair.	18%	9%	73%	0%	0%
4	When considering surgery for repair of a degenerative rotator cuff tear the patient must have weakness on resisted muscle testing for the tendon being repaired (One unanswered)	0%	64%	18%	0%	9%
5	The size and dimensions of the tear determine whether I operate on a partial thickness tear.	0%	27%	55%	9%	9%
6	In your experience, are specific tear dimensions associated with poor surgical outcomes?	Yes= 64%		No=27%	No answer 9%	

	Consensus Statement	Strongly Agree	Agree	Disagree	Strongly Disagree	Neither
7	The extent of the retracted ends of the tear determine whether I operate on a full thickness tear.	18%	45%	27%	9%	9%
8	When considering surgery for repair of a degenerative rotator cuff tear the patient must have pain on resisted muscle testing for the tendon being repaired.	9%	27%	45%	0%	18%
9	In patients who present with shoulder impingement symptoms, where a degenerative cuff tear is suspected, I prefer to investigate the extent of subacromial narrowing before I decide to operate.	18%	18%	27%	0%	27%
10	I do not operate on massive tears (plus one no answer).	0%	36%	27%	9%	18%

Comparisons of first and second round Delphi Questionnaire

	Statement	Agreement from 1st round	Agreement from 2nd round
1	When considering surgery for repair of a degenerative rotator cuff tear, significant limitation of advanced function (for example golf, tennis, squash, swimming, weight lifting) would make me inclined to operate.	60% Agree 25% Disagree	81% Agree 9% Disagree
2	When considering surgery for repair of a degenerative rotator cuff tear the patient's occupation/ hobbies are a determining factor (i.e. are outcomes are associated with specific jobs/hobbies?)	45% Agree 20% Disagree	73% Agree 18% Disagree
3	I would not operate on a patient who has had a delay of several years between injury of the rotator cuff and surgical repair.	20% Agree 55% Disagree	27% Agree 73% Disagree
4	When considering surgery for repair of a degenerative rotator cuff tear the patient must have weakness on resisted muscle testing for the tendon being repaired.	50% Agree; 10% Disagree	64% Agree 18% Disagree
5	The size and dimensions of the tear determine whether I operate on a partial thickness tear.	55% agree; 25% disagree	27% agree 64% disagree
6	In your experience, are specific tear dimensions associated with poor surgical outcomes?	60% agree; 40% disagree	64% agree 27% disagree

	Statement	Agreement from 1st round	Agreement from 2nd round
7	The extent of the retracted ends of the tear determine whether I operate on a full thickness tear.	65% agree; 30% disagree	63% agree 36% disagree
8	When considering surgery for repair of a degenerative rotator cuff tear the patient must have pain on resisted muscle testing for the tendon being repaired.	45% agree; 20% disagree	36% Agree 45% Disagree
9	In patients who present with shoulder impingement symptoms, where a degenerative cuff tear is suspected, I prefer to investigate the extent of subacromial narrowing before I decide to operate.	50% agree; 30% disagree	45% agree 27% disagree
10	I do not operate on massive tears.	65% agree 10% disagree	36% agree 36% disagree

Appendix 16: Surgeons Comments from the Open Questions

Surgeon Comments from Open Questions
1.Success with Previous Interventions
Comment 1 <i>“My experience is that many patients are sent to me before they have had a trial of non operative management. Too much emphasis is placed on the results of MRI or ultrasound examination, and not enough on patient symptoms and examination”.</i>
Comment 2 <i>“My personal view in the under 70’s with a cuff tear is that they need a referral for surgery and that injections/physio/pain management programmes are a waste of time and money and all they do is delay the inevitable - and probably make the result less successful - probably because of muscle atrophy and the steroids weakening the cuff. This is even more true for the larger tears”.</i>
2.Function
Comment 1 <i>“I think it depends on the patient,- clearly ADL is important for everyday but so is golf etc for some and if they want it, are prepared to go through the rehab, face the possibility/fact of failure of the cuff or the surgery not relieving the pain - then why not operate - I would not want a physio to deny someone a referral, I think the surgeon alone should have the conversation with the patient, there is not good enough strong evidence about cuff tears to deny surgery”.</i>
Comment 2 <i>“I would not deny surgery to patients with dominant shoulder pain in an overhead labourer’ even though outcomes may be worse in patients with occupations of this type”.</i>
Comment 3 <i>“The occupation and sports are only relative determinants to discuss with the patient with regards to the possible outcome”.</i>

3.Active Frozen Shoulder
<i>"I would treat the frozen shoulder with an interval release and get the movement back and as soon as it was ok then repair the cuff – i.e. a two stage operation".</i>
4.Bony Morphology
Comment 1
<i>"I do not know about spurs and narrowing of the space, I just want to know the size of the tear and what the muscle behind looks like".</i>
Comment 2
<i>"I investigate to see if tear present, and if so, where, how big and characteristics and then add to clinical situation".</i>
5.Tear Size
Comment 1
<i>"over 3 cm particularly with muscle atrophy and fatty infiltration on MRI".</i>
Comment 2
<i>"3.5 x1 >3.5 cm retraction of > 6 months standing + muscle signal changes on MRI".</i>
Comment 3
<i>"A tear size retracted beyond the corocoid with fatty degeneration".</i>
Comment 4
<i>"the greater the degree of retraction and the more traction required to reduce the cuff to an anatomical position, the less likely I am to operate".</i>

6.Fat Atrophy

Comment 1

“Despite the decision to operate being made, the decision to repair the tendon tear is usually dependent upon tendon quality, being able to mobilise the tendon and reduce it satisfactorily. If the tissue quality is poor and if cannot be reduced it cannot be (sensibly) repaired”.

Comment 2

“If there is a massive retracted tear and I am assessing operability I would look for fat atrophy and if it is grade 3 or 4 it would be one factor against repair but I can't give a figure that says operable or not”.

Comment 3

“Multifactorial, but if significant chronic tear with grade 3 plus I would be reluctant to operate”.

6.General Comments:

One surgeon gave his/her own criteria as below

- *“More than 6 months of symptoms*
- *A trial of exercise based physiotherapy*
- *Response to injections – no more than 3!*
- *Pain bad enough to consider surgery*
- *Patient fit for surgery, willing to undergo surgery, and prepared for long rehabilitation process”.*

Appendix 17: Statistical Analysis

Vignette 1: Gold Standard Injection Therapy

Before	After		p-value
	Incorrect	Correct	
Incorrect	5 (55.6%)	0 (0.0%)	>0.999
Correct	1 (11.1%)	3 (33.3%)	
p-value from paired McNemar test (using Binomial distribution)			

Vignette 2: Gold Standard Physiotherapy

Before	After		p-value
	Incorrect	Correct	
Incorrect	1 (11.1%)	1 (11.1%)	>0.999
Correct	0 (0.0%)	7 (77.8%)	
p-value from paired McNemar test (using Binomial distribution)			

Vignette 3: Gold Standard Orthopaedics

Before	After		p-value
	Incorrect	Correct	
Incorrect	3 (33.3%)	3 (33.3%)	0.250
Correct	0 (0.0%)	3 (33.3%)	
p-value from paired McNemar test (using Binomial distribution)			

Appendix 18: Participant Information and Consent Leaflets



Study Title: Referral Difficulties Faced by Extended Scope Physiotherapists

Invitation

Thank you for considering to take part in this questionnaire study to determine the referral difficulties faced by extended scope physiotherapists. Please read the following information which describes the study and its aims and objectives.

What is the purpose of the study?

The study aims to survey extended scope physiotherapists (or specialist Msk physiotherapists who have responsibilities to refer patients to secondary care) all over the UK, at Band 7 or above.

Why have I been invited to take part?

You have been selected to take part because as a member of the extended scope physiotherapist special interest group you have been identified as a specialist physiotherapist who may work within an interface service with the responsibility to refer on to other specialist services. The study aims to determine difficulties that you may experience when referring patients to secondary care.

Do I have to take part?

It is up to you to decide to join the study. If you agree to take part all you have to do is return the questionnaire to the address at the end of this leaflet. You are free to withdraw at any time, without giving a reason.

What will I have to do?

You are asked to complete the attached questionnaire which asks you to answer questions about your work location and banding, referral difficulties and barriers to referral. Data concerning the referral rate and the number of patients converting to orthopaedic surgery is also requested.

Expenses and payments

There are no expenses paid for those taking part.

What are the possible benefits of taking part?

Information about referral difficulties and conversion rates will help those in the role of extended scope physiotherapist, within interface type services, to re-shape their services, hopefully helping them to become more efficient.

What if there is a problem or I want to make a complaint?

If you have a concern about any aspect of this study, you should firstly speak to the researcher, contact details are found at the end of the information leaflet. If you remain unhappy and wish to complain formally, you can do this by

contacting the complaints department at Ealing PCT. Any complaint about the way you have been dealt with during the study will be addressed.

Will my taking part in the study be kept confidential?

Yes, ethical and legal practice will be followed at all times. Please note you can submit all questionnaire information anonymously. All information which is collected during the course of the research will be kept strictly confidential. Please note that the questionnaire does not ask for personal details about you.

What will happen to the results of the research study?

The results of the study will be collated and published when the work is complete. If you wish to receive a copy of the results before this time please contact me on the address at the end of the form.

Who is organising and funding the research?

The study is sponsored by Ealing PCT, there is no associated funding. Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the King's College Hospital Proportionate Review Sub-Committee.

Further information and contact details.

For all information about taking part please contact:

Stephanie Griffiths
Consultant Physiotherapist
Ealing PCT, 1 Armstrong Way
Middlesex, UB2 4SA.

Telephone: 0203 313 9619

Fax: 0208 758 9270

Email address: stephaniegriffiths@nhs.net

Study Title: Developing Surgical Referral Criteria for Rotator Cuff (Interview Pilot)

Invitation

Thank you for considering to take part in the pilot phase of this research study. I would like to ask you to consider being interviewed about surgical referral criteria for rotator cuff tears so that I can use the information to design a questionnaire. The questionnaire will then be used in the main study to survey a large number of Consultants in the UK. Please read the following information which describes the study and its aims and objectives. Please note that this research is being conducted as part of a clinical doctorate programme.

What is the purpose of the study?

The aim of the main study is to gain consensus on the referral criteria/guidelines for degenerative rotator cuff tears for patients referred from extended scope physiotherapists to shoulder surgeons. Extended scope physiotherapists are highly trained musculoskeletal specialists, many of whom work in primary care or within 'interface' or clinical assessment services. Their role in screening musculoskeletal primary care referrals has increased since the publication of the Musculoskeletal Framework (2006). Many of these interface type services now form an integral part of the care pathway for patients with musculoskeletal disease, however selecting the most appropriate patients to refer to secondary care remains a challenge.

Why have I been invited to take part?

You have been selected to take part because you have been identified as an expert in the surgical management of degenerative rotator cuff tears. You will be asked to take part in an interview lasting approximately 1 hour to discuss the factors which influence your decision to operate on a patient with a degenerative cuff tear. The results will be used to help to develop a questionnaire to gain consensus for referral criteria.

Do I have to take part?

It is up to you to decide to join the study. If you agree to take part you will be contacted to arrange a convenient time for the interview to take place, this could include being interviewed by telephone if this is more convenient or I could arrange to meet you at a convenient location. You are free to withdraw at any time, without giving a reason.

What will I have to do?

You will be asked questions about a range of factors which influence your decision to operate on a patient with a degenerative rotator cuff tear. The answers will be analysed and the results will be used to support the development of a questionnaire, which will then be used to determine consensus.

Expenses and payments.

There are no expenses paid for those taking part.

What are the possible benefits of taking part?

Referral criteria will help those in the role of the extended scope physiotherapist, within interface type services, to refer the most appropriate patients for surgery. Hopefully the information can be used to re-shape their referral pathways helping them to become more efficient. Hopefully better referral pathways will enable surgeons to see a higher percentage of surgical candidates.

What if there is a problem or I want to make a complaint?

If you have a concern about any aspect of this study, you should firstly speak to the researcher, contact details are found at the end of the information leaflet. If you remain unhappy and wish to complain formally, you can do this by contacting the complaints department at Ealing and Harrow Community Services. Any complaint about the way you have been dealt with during the study will be addressed.

Will my taking part in the study be kept confidential?

Yes, ethical and legal practice will be followed at all times. All information which is collected during the course of the research will be kept strictly confidential. Please note that the interview does not ask for personal details about you.

What will happen to the results of the research study?

The results of the study will be collated and published when the work is complete. If you wish to receive a copy of the results before this time please contact me on the address at the end of the form.

Who is organising and funding the research?

The study is sponsored by Ealing and Harrow Community Services, there is no associated funding.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the King's College Hospital Proportionate Review Sub-Committee.

Further information and contact details.

For all information about taking part please contact:

Stephanie Griffiths
Consultant Physiotherapist
Ealing and Harrow Community Services
1 Armstrong Way, Middlesex, UB2 4SA.
Telephone: 0203 313 9619
Fax: 0208 758 9270
Email address: stephaniegriffiths@nhs.net

Study Title: Developing Surgical Referral Criteria for Rotator Cuff

Invitation

Thank you for considering to take part in this questionnaire study to develop referral criteria for degenerative rotator cuff repair. Please read the following information which describes the study and its aims and objectives.

What is the purpose of the study?

The aim of the study is to gain consensus on the referral criteria/guidelines for degenerative rotator cuff tears for patients referred from extended scope physiotherapists to shoulder surgeons. Extended scope physiotherapists are highly trained musculoskeletal specialists, many of whom work in primary care or within 'interface' or clinical assessment services. Their role in screening musculoskeletal primary care referrals has increased since the publication of the Musculoskeletal Framework (2006). Many of these interface type services now form an integral part of the care pathway for patients with musculoskeletal disease, however selecting the most appropriate patients to refer to secondary care remains a challenge.

Why have I been invited to take part?

The study aims to survey consultants all over the UK. You have been selected to take part because you have been identified as an expert in the surgical management of degenerative rotator cuff tears. You will be asked to complete the attached questionnaire which asks you to answer questions about a range of factors which influence your decision to operate on a patient with a degenerative rotator cuff tear.

Do I have to take part?

It is up to you to decide to join the study. If you agree to take part all you have to do is return the questionnaire to the address at the end of this leaflet. You are free to withdraw at any time, without giving a reason.

What will I have to do?

You are asked to complete the attached questionnaire which asks you to answer questions about a range of factors which influence your decision to operate on a patient with a degenerative rotator cuff tear. When the questionnaire is returned to me I will collate the answers and determine whether there is a high level of agreement among the surgeons within the study. Any statements which have a poor level of agreement will be sent to individuals again for further consideration.

Expenses and payments.

There are no expenses paid for those taking part.
What are the possible benefits of taking part?

Referral criteria will help those in the role of the extended scope physiotherapist, within interface type services, to refer the most appropriate patients for surgery. Hopefully the information can be used to re-shape their referral pathways helping them to become more efficient. Hopefully better referral pathways will enable surgeons to see a higher percentage of surgical candidates.

What if there is a problem or I want to make a complaint?

If you have a concern about any aspect of this study, you should firstly speak to the researcher, contact details are found at the end of the information leaflet. If you remain unhappy and wish to complain formally, you can do this by contacting the complaints department at Ealing and Harrow Community Service. Any complaint about the way you have been dealt with during the study will be addressed.

Will my taking part in the study be kept confidential?

Yes, ethical and legal practice will be followed at all times. Please note you can submit all questionnaire information anonymously. All information which is collected during the course of the research will be kept strictly confidential. Please note that the questionnaire does not ask for personal details about you.

What will happen to the results of the research study?

The results of the study will be collated and published when the work is complete. If you wish to receive a copy of the results before this time please contact me on the address at the end of the form.

Who is organising and funding the research?

The study is sponsored by Ealing and Harrow Community Services, there is no associated funding.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the King's College Hospital Proportionate Review Sub-Committee.

Further information and contact details.

For all information about taking part please contact:

Stephanie Griffiths
Consultant Physiotherapist
Ealing and Harrow Community Services
1 Armstrong Way, Middlesex, UB2 4SA.
Telephone: 0203 313 9619
Fax: 0208 758 9270
Email address: stephaniegriffiths@nhs.net

Study Title: Study to test the impact of referral criteria when managing degenerative rotator cuff tears

Invitation

Thank you for considering to take part in this study to determine the impact of referral criteria when referring patients with degenerative rotator cuff tears for repair. Please read the following information which describes the study and its aims and objectives.

What is the purpose of the study?

The study aims to measure the referral behaviour extended scope physiotherapists about who should be referred for rotator cuff repair by using 3 real life case scenarios.

Why have I been invited to take part?

You have been selected to take part because you have been identified as an extended scope physiotherapist working in primary care managing patients with upper limb conditions.

Do I have to take part?

It is up to you to decide to join the study. If you agree to take part all you have to do is return the scenarios to the address at the end of this leaflet. You are free to withdraw at any time, without giving a reason.

What will I have to do?

You are asked to read through a range of case scenarios and at the end of each scenario you are asked to choose the referral option which most represents your referral decision. You will then be asked to repeat the exercise using a referral criteria. Comparisons of referral decisions with and without the criteria will then be analysed.

Expenses and payments

There are no expenses paid for those taking part.

What are the possible benefits of taking part?

This study will enable the researcher to determine whether using a referral criteria is useful and effective in referring the most appropriate patients to a relevant specialist.

What if there is a problem or I want to make a complaint?

If you have a concern about any aspect of this study, you should firstly speak to the researcher, contact details are found at the end of the information leaflet. If you remain unhappy and wish to complain formally, you can do this by contacting the complaints department at Ealing and Harrow Community

Services. Any complaint about the way you have been dealt with during the study will be addressed.

Will my taking part in the study be kept confidential?

Yes, ethical and legal practice will be followed at all times. Please note you can submit all questionnaire information anonymously. All information which is collected during the course of the research will be kept strictly confidential.

What will happen to the results of the research study?

The results of the study will be collated and published when the work is complete. If you wish to receive a copy of the results before this time please contact me on the address at the end of the form.

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1 Armstrong Way, Middlesex, UB2 4SA.
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Fax: 0208 758 9270
Email address: stephaniegriffiths@nhs.net

Interview Consent Form



Ealing and Harrow Community Services

Centre: Community Musculoskeletal Service

Study Number:

Participant Identification Number:

Title of Project: Surgical Criteria for Degenerative Rotator Cuff Surgery:
Developing Consensus through a Delphi Study

Name of Researcher: Stephanie Griffiths

Please Initial Box

1. I confirm that I have read and understand the information sheet dated 1.10.10 (version1) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.

3. I agree to take part in the above study.

Name of Participant.....

SignatureDate.....

Name of Person taking consent

SignatureDate.....

When completed: 1 for participant; 1 for researcher site file

Appendix 19: Interview Questions



Ealing and Harrow Community Services

Interview Questions: Developing Surgical Referral Criteria for Rotator Cuff Tears

1. Decision to Operate

Tell me about the things that influence your decision to operate on a patient with degenerative rotator cuff tear?

Prompt: What information in the patient's objective history could influence your decision to proceed with surgery for a degenerative rotator cuff tear?

2. Characteristics and dimensions of the tear

What aspects of the rotator cuff tear dimensions are the most important when making a decision to proceed with surgery for a degenerative rotator cuff tear? For example is the size of the tear a key factor when deciding to operate, or is the thickness of the tear more important?

3. Multiple Tears

What happens if you see a patient with multiple tears?

4. Fat Atrophy and Tendon Quality

What about fat atrophy and tendon quality?

5. Specialist Investigations

What are your views on specialist investigations?

Prompt if necessary: What specialist tests or investigations help you to make the decision to operate?

Prompt in necessary: Do you think that it is helpful if these are done before patients attend their appointment with you?

6. Key Issues

Of all the factors which may influence your decision to operate, which do you think are the key area which influence if and when you decide to proceed with a repair of a degenerative rotator cuff?

7. Other Contributing Factors

What other factors do you think are important when you make the decision to operate on a patient with a degenerative cuff tear? For example have recent policy changes or financial pressures influenced your decision making?

Appendix 20: Permission to use image for literature review

Consultant Physiotherapist

Ealing Community Services
Clayponds Hospital
Sterling Place
South Ealing
London
W5 4RN
UK

28th August 2012

Orthopaedic Surgeons of Long Island Association
410 Lakeville Road
Suite 303
New Hyde Park,
NY 11042
USA

Dear Sir/Madam

I am writing to request permission to use an image available at www.google.co.uk/images which is attributed to your organisation. The image is entitled shoulder 2.jpg. I would like to include this image in my thesis which I am submitting as part of a Professional Doctorate in Physiotherapy. The image will not be used for any other purpose. If the use of your image is not acceptable please contact me on the address above.

Thank you

Yours faithfully

Stephanie Griffiths

Appendix 21: Questionnaire Validity Testing

Taken from Foddy (2001)

Were there any questions that you found difficult to understand?

What did you think question xxx meant?

Which questions were most difficult or awkward for you to read or complete?

Which questions were easy to understand?

Did any sections/parts drag?

Were any of the questions repetitive?

Were there any questions in which you felt you would have liked the opportunity to say more?

Were there any questions which made you feel uncomfortable?