# Delay to diagnosis and specialist consultation following anterior cruciate ligament injury.

A study investigating the nature of, and factors associated with, pathway delay.

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# Abstract

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Delay to diagnosis and specialist consultation following anterior cruciate ligament injury: A study investigating the nature of, and factors associated with, pathway delay.

Keywords: Anterior cruciate ligament; ACL; delayed diagnosis; delay to diagnosis; survey; questionnaire; direct observation; acute knee clinic.

*Background:*

Historically the identification of ACL injuries upon initial presentation is low and considerable diagnostic delays have been reported. However, specific evidence on the individual elements of, and factors which influence delay, is lacking.

*Aims:*

The overarching aim was to provide a comprehensive picture of delay to diagnosis and specialist consultation, including factors which influence delay. An additional aim was to determine whether the approach to examining acute knee injuries varied as a consequence of varying patient presentation or experience of the assessing clinician.

*Methods:*

Study 1: Cross -sectional survey.

Study 2: Non-participant direct observation methodology.

*Results:*

Data from 194 patients were analysed in the survey. Only 15.5% of patients were given a correct diagnosis of ACL rupture at the initial consultation. Median

delay to diagnosis was 67.5 days (IQR= 15 to 178 days) and specialist consultation 108 days (IQR= 38 to 292 days). The factors most influential on delay were whether a follow-up appointment was arranged after attending A&E, whether the site of attendance operated an acute knee clinic and whether MRI was performed.

The direct observation study showed wide variation in approach to injury assessment. Specialist clinicians performed the most comprehensive examination. A&E clinicians were more likely to assess for bony, neurovascular and gross tendon injuries as opposed to ligamentous or meniscal injury.

*Conclusions:*

The diagnostic rate of ACL injury at initial presentation remains low. Considerable delays to diagnosis and specialist consultation are apparent following ACL injury, the majority of which is attributable to health system delay.

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This thesis has been the result of over four years work and would not have been possible without the assistance of numerous people.

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# Dedication

For Zoe, Zac and Dylan.

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# List of abbreviations

| | |
|---|---|
| AAOS | American academy of orthopedic surgeons |
| A&E | Accident and emergency |
| ACL | Anterior cruciate ligament |
| AKC | Acute knee clinic |
| AMED | Allied and complementary medicine database |
| ANOVA | Analysis of variance |
| BOA | British orthopaedic association |
| CARE | Consultation and relational empathy |
| CI | Confidence interval |
| CINAHL | Cumulative index to nursing and allied health literature |
| CVI | Content validity index |
| CVR | Content validity ratio |
| EBSCO | Online research service |
| ENP | Emergency nurse practitioner |
| GP | General practitioner |
| IKDC | International knee documentation committee |
| IRAS | Integrated research application system |
| IQR | Interquartile range |
| KOOS | Knee injury and osteoarthritis outcome score |
| KOS-ADLS | Knee outcome survey- activities of daily living scale |
| LCL | Lateral collateral ligament |
| LEFS | Lower extremity functional scale |
| MCL | Medial collateral ligament |
| Medline | Medical literature and analysis and retrieval system (MEDLARS) online |
| MeSH | Medical subject headings |
| MIU | Minor injury unit |
| MRI | Magnetic resonance imaging |
| NHS | National health service |
| NICE | National institute for health and care excellence |
| NPV | Negative predictive value |
| NZGG | New Zealand guidelines group |
| OA | Osteoarthritis |
| PCL | Posterior cruciate ligament |
| PPV | Positive predictive value |

| | |
|---|---|
| PRISMA | Preferred reporting items for systematic reviews and meta-analyses |
| SD | Standard deviation |
| SPORTDiscus | Sports medicine database |
| UK | United Kingdom |
| USA | United States of America |
| VAS | Visual analogue scale |

## Glossary of terms

| | |
|---|---|
| Accuracy (relating to a clinical test) | The ability of clinical test (or combination of tests) to correctly identify both the presence and absence of a condition; the proportion of cases correctly classified. Calculated by: $Accuracy = \frac{True\ positives^* + True\ negatives^*}{Total\ study\ population}$ |
| Acute injury | An injury is defined as a single physical traumatic event of identifiable origin. An injury is considered acute up to 42 days following trauma (BMJ Best Practice, 2014). |
| Acute knee clinic (AKC) | A specialist (defined below) led service for streamlining patients with acute knee injuries. |
| Accident and emergency (A&E) clinician | A health professional based within the A&E department setting with a role including the clinical assessment acute knee injuries. |
| Assessment (clinical) | The action of assessing someone |
| Delay | A period of time by which something is late or postponed |
| Examination (clinical) | A detailed inspection or study |
| Follow-up | A further examination of a patient at a later date. |
| Negative predictive value (NPV) | The likelihood that a patient does not have the condition if the given clinical test is negative. Calculated by: $Negative\ predictive\ value = \frac{True\ negatives^*}{True\ negatives + False\ negatives^*}$ |
| Non-specialist | A medical professional working in an orthopaedic role assessing soft tissue knee injuries not fulfilling the criteria to be classified as a specialist (see specialist definition). |
| Positive predictive value (PPV) | The likelihood that a patient has the condition if the given clinical test is positive: Calculated by: $Positive\ predictive\ value = \frac{True\ positives^*}{True\ positives + False\ positives^*}$ |
| Sensitivity (relating to a clinical test) | The ability of a clinical test (or combination of tests) to determine patients without the condition. Calculated by: $Sensitivity = \frac{True\ positives^*}{True\ positives + False\ negatives^*}$ |
| Specialist | A medical professional working in an orthopaedic role highly trained in the assessment and management, including surgery, of soft tissue knee injuries (including ACL injuries). |
| Specificity (relating to a clinical test) | The ability of a clinical test (or combination of tests) to correctly determine patients who do not have the condition. Calculated by: $Specificity = \frac{True\ negatives^*}{True\ negatives + False\ positives^*}$ |

*_True positives:_ The patient has the condition and the clinical test is positive.
_False positive:_ The patient does not have the condition but is test positive.
_True negative:_ The patient does not have the condition and is test negative.
_False negative:_ The patient has the condition but is test negative.

# Chapter 1: General introduction

## 1.1 Background

The knee joint (comprising patellofemoral and tibiofemoral articulations) is the largest and one of the most complex joints in the body. It has little inherent bony stability and therefore is reliant on ligamentous structures to provide stability (Johnson and Pedowitz, 2007). Of the many ligaments surrounding the tibiofemoral joint four primary restraints are often identified; the anterior cruciate ligament (ACL), posterior cruciate ligament (PCL), medial collateral ligament (MCL) and the lateral collateral ligament (LCL) (see figure 1).

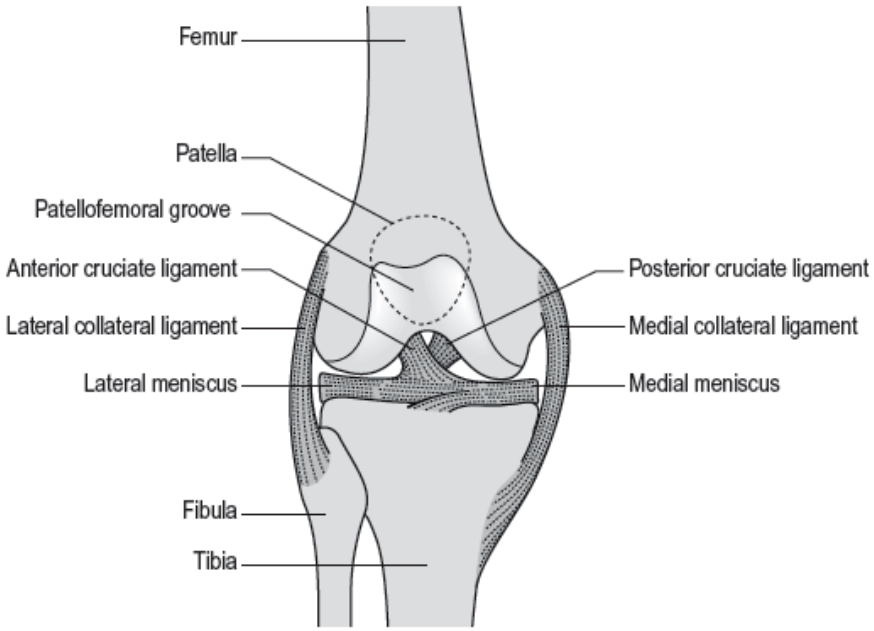


**Figure 1: Ligaments and menisci of the knee from anterior aspect (Hardy and Snaith, 2010 fig.4.13 p.238)**

### 1.1.1 The anterior cruciate ligament

The ACL is one of two 'cruciate' ligaments, so named as they cross each other in the knee and forms the main focus of this thesis. Along with other ligaments

and musculotendinous structures it contributes significantly to stability and normal kinematics at the tibiofemoral joint. The ACL arises from the medial aspect of the lateral femoral condyle and inserts within a depression on the anterior aspect of the intercondylar eminence of the tibia (Standring, 2008). Cadaveric studies have shown the length of the ACL varies between 31mm and 38mm with an overall diameter range of 10-12mm (Smith et al., 1993). The ACL has considerable strength with a reported mean ultimate load to failure of 1500-2160 N (Chandrashekar et al., 2006; Woo et al., 1991). Such loads are not encountered during normal functional activities (Taylor et al., 2012; Beynnon and Fleming, 1998) and therefore ACL rupture is associated with significant trauma. The ACL is an intra-articular structure (Duthon et al., 2006) and highly vascular, receiving the majority of its blood supply from the middle genicular artery (Toy et al., 1995). Consequently, rupture is often followed by marked bleeding with a reported 72% of knee haemarthroses being associated with ACL injury (Noyes et al., 1980a). ACL healing is acknowledged to be poor (Woo et al., 1997) and therefore once injured there is a subsequent loss of normal function and resulting sequelae including further injury and joint degeneration (Fu et al., 1999).

It is generally accepted that the ACL has two distinct bundles of fibres named according to their attachment onto the tibia; an anteromedial and a posterolateral band (Amis, 2012; Petersen and Zantop, 2007). The posterolateral band is taught in extension and is thought to play a greater role in resisting rotation whilst the anteromedial band is more taut in flexion and is the main restraint to anterior tibial drawer in relation to the femur (Amis, 2012; Petersen and Zantop, 2007; Amis and Dawkins, 1991). Limitation in the role of

the ACL once injured may therefore result in loss of joint stability and episodes of giving way (i.e. subluxation of the tibia relative to the femur).

In addition to its role in joint stability, the ACL plays a vital role in normal knee kinematics including the 'screw home' mechanism of the knee, where the tibia laterally rotates to lock the knee as it becomes taut near full extension (Moglo and Shirazi-Adl, 2005). In ACL deficient knees abnormal rotational kinematics have been found during walking, running and cutting manoeuvres (Gao and Zheng, 2010; Stergiou et al., 2007; Andriacchi and Dyrby, 2005; Waite et al., 2005; Tashman et al., 2004; Georgoulis et al., 2003), and in-vitro and in-vivo investigations have reported altered cartilage contact pressures (Imhauser et al., 2013; Van de Velde et al., 2009). The ACL has been described as the guardian of the meniscus (Reider, 2009) as deficiency of the ACL also increases force on the medial meniscus (Papageorgiou et al., 2001). It has been theorised that the alteration in joint kinematics and associated abnormal knee forces which occur following ACL rupture may predispose the knee to degenerative changes even in the absence of discrete giving way episodes (Stergiou et al., 2007; Andriacchi et al., 2006).

### 1.1.2 Incidence and costs of anterior cruciate ligament injury

ACL injuries are a global problem with an estimated one million occurring annually (Noyes and Barber-Westin, 2013) and the ACL is reportedly the most frequently injured ligament in athletic knee injuries (Majewski et al., 2006). Of all knee ligaments the ACL has been reported to be the most frequently totally ruptured (Beynnon et al., 2005) and accounts for more cases of pathologic knee motion than any other knee ligament injuries (Miyasaka et al., 1991).

In the United States of America (USA), previous estimates have suggested up to 250,000 ACL injuries occur annually (Griffin et al., 2006) resulting in between 100,000 and 200,000 ACL reconstructions (Buller et al., 2015; Noyes and Barber-Westin, 2013; Lyman et al., 2009). Silvers and Mandelbaum (2007) estimated a 33 per 100,000 chance that a member of the general population will sustain an ACL injury during the course of a year in the USA. A similar annual incidence of 30 per 100,000 has been reported for the United Kingdom (UK), based on an estimation of 20,000 new ACL injuries per year (Bollen, 2000). Other UK based studies (Jameson et al., 2012; Clayton and Court-Brown, 2008) reported lower annual incidences of ACL injury and surgery but as these estimates were based solely on National Health Service (NHS) patients they are likely to underestimate the true incidence.

Reported annual population based incidence rates of anterior cruciate ligament surgery in Australia, New Zealand, Denmark, Norway and Sweden have been estimated at between 32 and 50 per 100,000 population (Moses et al., 2012; Gianotti et al., 2009; Granan et al., 2009; Lind et al., 2009; Granan et al., 2008). The figures provided within these studies underestimate the overall population based incidence for ACL injury as they fail to account for patients who are managed conservatively. Further, these population based estimates of incidence belie the incidence of ACL injury in high risk groups.

In the high risk age group for suffering ACL injury (16-39 year age group) the annual incidence of ACL reconstruction in Norway increases to 85 per 100,000 (Granan et al., 2008) and in Denmark (15-39 year age group) to 91 per 100,000 (Lind et al., 2009). Incidence rates are also considerably higher in sporting

populations particularly amongst professional athletes with reported annual incidence of between 150 and 3700 per 100,000 (Moses et al., 2012).

Participation levels in high risk sports (e.g. soccer, rugby, basketball) are greater amongst males, resulting in a higher overall incidence of ACL injury when compared to females (Moses et al., 2012; Clayton and Court-Brown, 2008; Csintalan et al., 2008). However, a systematic review with meta-analysis confirmed that females participating in basketball and soccer have roughly three times greater incidence of ACL injury compared to male counterparts with an annual incidence of rupture amongst females participating in these sporting activities of 5% (Prodromos et al., 2007). Across all sports investigated the mean increased incidence was found to be 2.5 greater amongst females, in comparison to males, per unit of game time (Prodromos et al., 2007). With female participation in sports at an all-time high, escalating rates of ACL reconstruction have been reported among this group. In the USA between 1994 and 2006 a 177% increase in the sex-adjusted rate of women undergoing ACL reconstruction has been shown compared to a population-adjusted rate of increase of 37%, narrowing of the male to female ratio for undergoing ACL reconstruction (Buller et al., 2015).

In New Zealand the mean cost of treatment for each patient undergoing ACL surgery based on data from 2000 to 2006 was $11,157 (New Zealand Dollars). In the USA individual lifetime burden of ACL rupture has been estimated at $38,121 when treated with ACL reconstruction and $88,538 when treated with rehabilitation (Mather et al., 2013).

### 1.1.3 Mechanism of injury

ACL injuries typically occur as a result of a single incident where applied forces exceed the maximum tensile strength of the ligament. Whilst ACL injuries do occur within the home and work environment, they most frequently occur during sporting activity and accordingly, sporting injuries account for the majority (65% to 73%) of ACL injuries which result in surgical reconstruction (Janssen et al., 2012; Gianotti et al., 2009).

Injuries to the ACL are often classified as non-contact or contact injuries; the latter involving application of a direct force across the knee as a result of external contact at the time of injury. The majority of knee injuries are classified as non-contact with between 56% and 95% of injuries thought to involve no, or only minimal, contact with between sport variations accounting for the majority of observed differences (Waldén et al., 2015; Reider, 2009; Pasanen et al., 2008; Cochrane et al., 2007; Mountcastle et al., 2007; Silvers and Mandelbaum, 2007; Agel et al., 2005; Faude et al., 2005; Giza et al., 2005; Boden et al., 2000; Myklebust et al., 1998; Myklebust et al., 1997). Whilst contact at the time of ACL injury is absent in the majority of cases, perturbation, such as collisions or players being pushed, may be a significant factor for ACL injury in certain sports and has been shown to frequently occur just prior to injury in basketball (Krosshaug et al., 2007). Other mechanisms of injury can place abnormal forces across the knee in the absence of direct external contact, such as skiing when bindings fail to release and significant rotational forces are imparted on the knee (Bere et al., 2011).

Non-contact ACL injuries typically occur on a weight bearing limb. A study by Faunø and Jakobsen (2006) found that 104 of 105 subjects who suffered an ACL injury reported that the foot of the affected leg was in contact with the

ground at the time of injury. More specifically, non-contact ACL injuries frequently occur during activities requiring rapid deceleration such as changing direction (cutting or pivoting) or when landing from a jump (Waldén et al., 2015; Kimura et al., 2010; Shimokochi and Shultz, 2008; Griffin et al., 2006; Olsen et al., 2004; Boden et al., 2000; Myklebust et al., 1997; Bollen and Scott, 1996). Video analysis has shown that ligament rupture occurs between 17 and 50ms following initial contact with the ground during these typical injury mechanisms (Koga et al., 2010; Krosshaug et al., 2007).

ACL injuries generally occur when the knee is close to full extension, or in hyperextension, and are associated with multiplane knee loading (Shimokochi and Shultz, 2008). Initial ground contact, either flatfooted or with the hindfoot, as opposed to the forefoot, has also been identified as a risk factor for ACL rupture (Boden et al., 2009). ACL injury has been most frequently associated with valgus collapse of the lower limb (Koga et al., 2010; Olsen et al., 2004) although in a video analysis of 39 male soccer players undertaken by Waldén et al. (2015) this mechanism was only identified in a minority of subjects, suggesting that injury mechanisms may depend upon the sport undertaken at the time of injury (see figures 2 to 5). It has also been suggested that the dynamic valgus may be a consequence, rather than a cause, of ACL rupture (Meyer and Haut, 2008; Shimokochi and Shultz, 2008). It is thought that unopposed quadriceps forces, axial loading, knee valgus, internal and external rotation all potentially contribute to ACL rupture although it is not possible to definitively state which motions are most problematic (Shimokochi and Shultz, 2008). Notwithstanding this uncertainty, it appears that patients suffering non-contact ACL injury will, at least, recognise a notable episode of giving way at the knee.


Figure 2: Dynamic valgus collapse during 'cutting' manoeuvre (Olsen et al., 2004)


Figure 3: Dynamic valgus collapse during one-leg landing (Olsen et al., 2004)

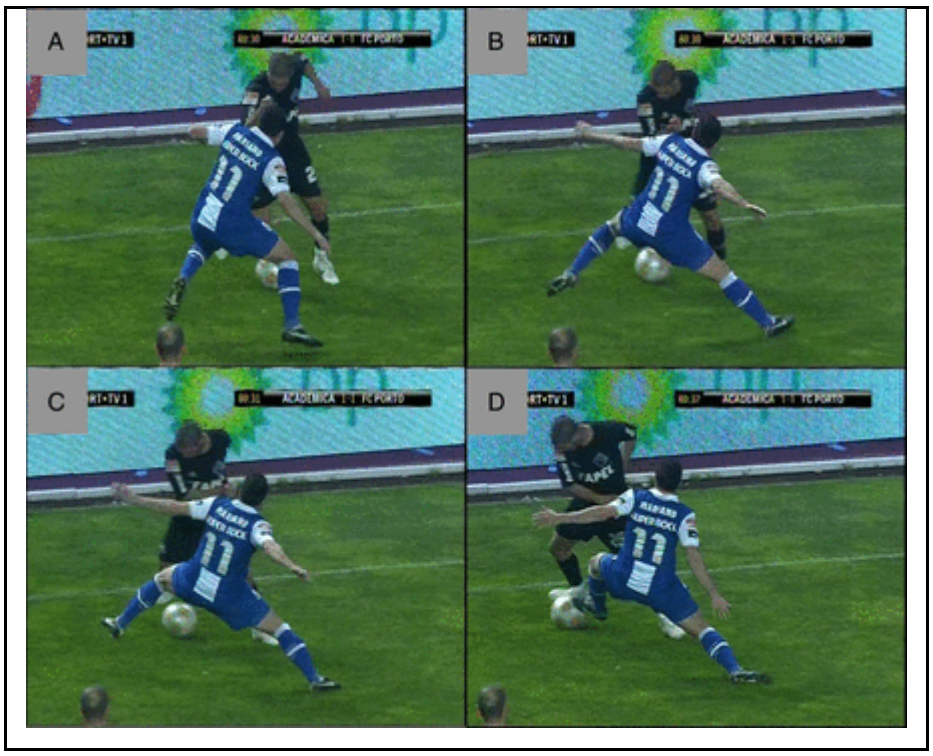


Figure 4: Non-contact valgus collapse injury right knee (Waldén et al., 2015)


Figure 5: Dynamic valgus collapse from direct contact (Waldén et al., 2015)

Whilst the mechanisms of injury identified as being associated with ACL injuries were initially established through retrospective interviews or questionnaires

which may be subject to recall bias, findings have been supported through observational studies using video analysis (Waldén et al., 2015; Boden et al., 2009; Cochrane et al., 2007; Olsen et al., 2004). A study by Olsen et al. (2004) on high level team handball players compared injury information obtained from a questionnaire with video analysis of the same injury and found 85% agreement between the two methods suggesting information on injury mechanism gained via an interview process is valid. Whilst the accuracy of simple visual inspection of recorded injury footage has also been questioned, findings have been corroborated using computer based model based image matching (Koga et al., 2011; Koga et al., 2010). Whilst there is some remaining doubt on the true underlying mechanism of ACL injury, the characteristic non-contact injury features identified and described above, suggest that suitable exploration of the history of injury as part of the clinical assessment process may be useful in alerting the clinician to the possibility of ACL injury (Bollen and Scott, 1996). However, it is also recognised that ACL injury can be associated with an atypical history, and it has been argued that almost any history of knee trauma could potentially result in an ACL injury (Prodromos et al., 2007). Consequently, whilst obtaining information on the mechanism of injury may be useful, in isolation it provides insufficient evidence to definitively determine whether or not an ACL injury may have been sustained.

## 1.2 Diagnosis of Anterior Cruciate Ligament injury

The diagnosis of ACL injury may be established in a number of ways; clinical examination (subjective and physical assessment), medical imaging or arthroscopy. Arthroscopy is generally accepted as the gold standard for determining ACL injury but it is an invasive procedure with associated surgical

risks (Salzler et al., 2014; Allum, 2002). Perhaps this explains why a survey of orthopaedic surgeons in the UK found that only the minority employ arthroscopy routinely in the diagnosis of ACL injuries (Kapoor et al., 2004), others relying on imaging and clinical assessment for diagnostic guidance. Further, the accuracy of diagnosis through arthroscopic investigation is dependent upon the skill of the surgeon. Bollen and Scott (1996) reported that 37 of 51 patients who had undergone diagnostic arthroscopy prior to being seen in a specialist knee injury clinic had not received a correct diagnosis of ACL injury, arguing that 'the value of arthroscopy is not in the investigation itself but in the surgeon using the tool' (Bollen and Scott, 1996 p.408).

The following subsections explore the alternative approaches used to diagnose an ACL injury including the subjective examination, physical examination, general clinical examination and medical imaging.

### 1.2.1 Subjective examination of Anterior Cruciate Ligament injury

Alongside the mechanism of injury there are a number of symptoms which have been associated with ACL injury which may help to identify the potential likelihood of ACL injury. These include both acute (experienced at the time of, or shortly following injury) and chronic symptoms.

Noyes et al. (1980b) investigated how frequently symptoms thought to be indicative of ACL injury were present at the time of, and shortly following, injury in knees surgically confirmed as ACL deficient (table 1).

**Table 1: Acute symptoms in ACL deficient knees**

| Clinical feature | Retrospective study (n= 103) Presence of feature (%) | Prospective study (n= 85) Presence of feature (%) |
|---|---|---|
| Giving way | 90 | 90 |
| Swelling within 6 hours | 90 | Not reported |
| Swelling within 12 hours | Not reported | 83 |
| Swelling within 24 hours | 100 | Not reported |
| Unable to continue playing | 88 | 85 |
| Heard pop or snap | 65 | 38 |
| Immediate knee pain | 85 | 67 |

Adapted from Noyes et al. (1980b)

The results of the prospective and retrospective studies by Noyes et al. (1980b) suggest that certain features are present in the majority of cases although hearing a pop or snap was less frequently reported. In support, a study undertaken by Wagemakers et al. (2010) on acute knee injuries within a primary care setting found that giving way, popping sensation, inability to continue activity and effusion were significantly associated with ACL injury. Other studies have reported that a 'typical' injury history can be obtained in the majority (73% to 91%) of cases (Davidson et al., 2014; Perera et al., 2013; Arastu and Twyman, 2012; Veysi and Bollen, 2008; Bollen and Scott, 1996) although definitions of a 'typical' history are inconsistent and in some cases not defined. Whilst these studies provide important evidence on the potential value of exploring injury history there are a number of shortcomings. The lack of agreement on what a 'typical' history entails makes it impossible to determine the most pertinent injury features. Incorporation bias was likely to occur to some degree in most of these studies as clinical assessment was used to establish the diagnosis which may inflate the true level of these symptoms. Furthermore, there is some evidence that the majority of patients do not report a 'typical' injury history. For example, Wagemakers et al. (2010) reported all three

features of effusion, popping sensation and giving way were only present in 18% of cases lending support to the view of Prodromos et al. (2007) that ACL injury should never be discounted based on the history alone. However, Wagemakers et al. (2010) did identify that sensitivity values were much higher (0.71) if at least 2 of these three features were present. The diagnostic reference standard of MRI used in this study may be criticised as being inferior to arthroscopic confirmation, however, it was applied to all patients regardless of the outcome of previous tests, thereby reducing the likelihood of verification bias. Whilst the study was performed in a primary care setting with limited external validity to a hospital setting, it still suggests that symptoms identified from the history may help guide the clinician to the possibility of ACL injury, although no symptom, whether in isolation or grouped, is pathognomonic.

A study by Geraets et al. (2015) reported a positive predictive value (PPV) of 0.65 and negative predictive value (NPV) of 0.81 for medical history assessment of ACL injuries by an orthopaedic consultant. For a primary care physician the PPV and NPV were similar at 0.69 and 0.72 respectively. Positively, this study had a suitable control group and made reasonable attempts to blind the examiners of the results of prior assessment limiting bias. Furthermore, all patients underwent the reference standard of arthroscopy. However, there were some acknowledged limitations, most notably that the study was relatively small (n= 60) and only included chronic cases, limiting the generalisability of results to the wider population. The inter-observer kappa value of 0.62 suggested borderline moderate to substantial inter-observer agreement between the professionals suggesting that information from the subjective examination appears to be interpreted similarly by clinicians with varying levels of experience.

Thus, whilst there is disagreement over whether a ‘typical’ series of symptoms exist, it does appear that history may be useful in playing a part in the assessment of ACL injury. Moreover, it appears that the subjective examination may be applied and interpreted in a consistent way by staff considered both expert and less experienced.

### 1.2.2 Physical examination of Anterior Cruciate Ligament injury

In addition to subjective examination, the clinical diagnosis of ACL injury is made through the application of physical examination tests which are used to identify instability indicative of ACL rupture. The three most commonly investigated tests are the Lachman, anterior drawer and pivot shift tests (see figures 6 to 8).

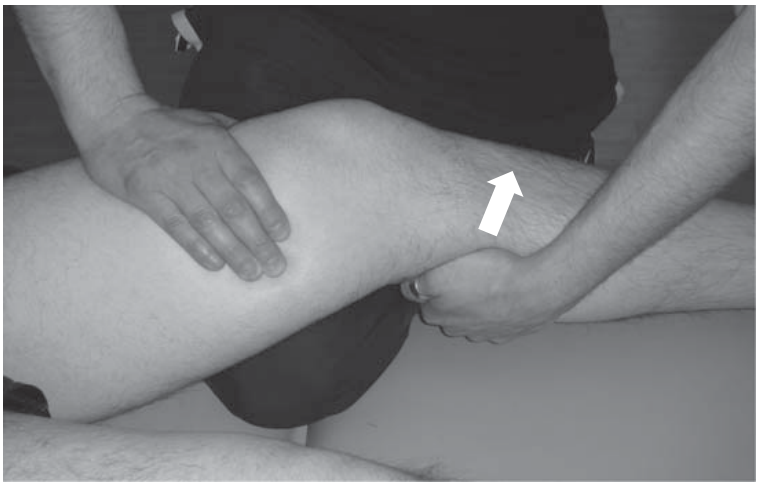

**Figure 6: Lachman test (Hardy and Snaith, 2010 fig. 14.9 p.244)**

With the leg relaxed, the knee is flexed to 20°-30°. One hand stabilises the femur whilst the other is placed on the posterior surface of the proximal tibia attempting to draw the tibia forwards. ACL injury is indicated by increased laxity. End feel should also be noted.

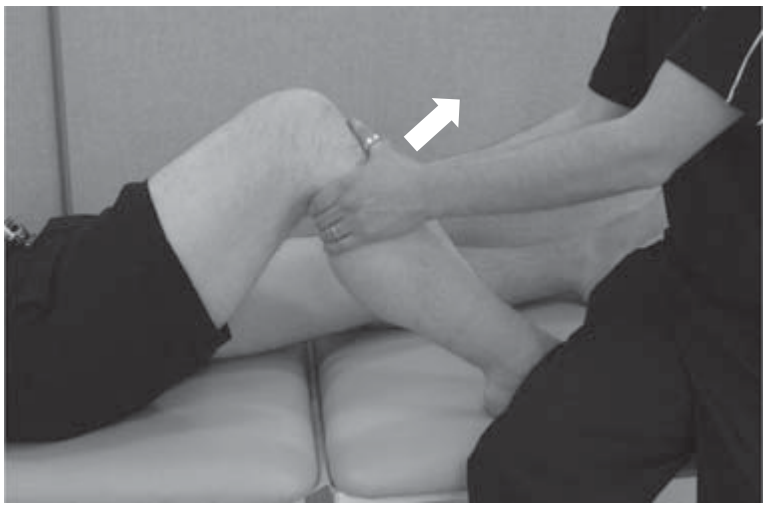

**Figure 7: Anterior drawer test (Hardy and Snaith, 2010 fig. 14.7 p.243)**

The knee should be flexed to 90° the foot flat on the examination couch. The hands encircle the proximal tibia and attempt to draw the tibia anteriorly relative to the femur. ACL injury is indicated by increased laxity. End feel should also be noted.

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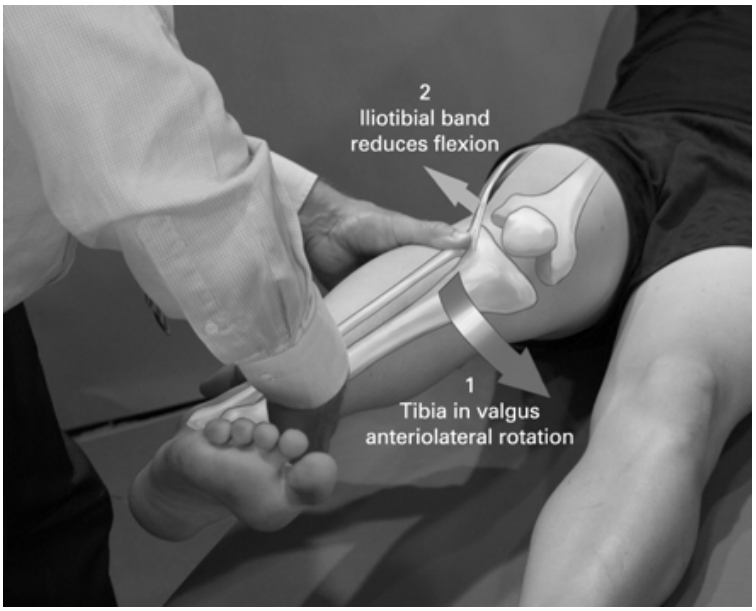


**Figure 8: Pivot shift test (Quatman and Hewett, 2009 fig.3 p.330)**

The hip is passively flexed to 30°. Knee fully extended in approximately 20° of internal rotation and a valgus force is applied to the tibia as it is slowly flexed. Subluxation at around 20°-30° of knee flexion indicates a non-functional ACL.

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Systematic reviews and meta-analyses have consistently reported the Lachman test to be the most sensitive and accurate test for diagnosing ACL rupture, although the pivot shift has been shown to have the highest levels of

specificity (van Eck et al., 2013; Benjaminse et al., 2006; Scholten et al., 2003; Solomon et al., 2001). The largest of these, a meta-analysis by Benjaminse et al. (2006), included 28 studies but acknowledged problems with heterogeneity with all possessing at least some possibility of bias due to the nature of study design. Pooled results from the study by Benjaminse et al. (2006) for the three tests under investigation are shown in table 2.

**Table 2: Pooled results for clinical tests used to asses anterior cruciate ligament rupture**

| Test | Sensitivity (%) (95% CI) | Specificity (%) (95% CI) | LR+ (95% CI) | LR- (95% CI) |
|---|---|---|---|---|
| Lachman | 85 (83 to 87) | 94 (92 to 95) | 10.2 (4.6 to 22.7) | 0.2 (0.1 to 0.3) |
| Anterior drawer | 55 (52 to 58) | 92 (90 to 94) | 7.3 (3.5 to 15.2) | 0.5 (0.4 to 0.6) |
| Pivot shift | 24 (21 to 27) | 98 (96 to 99) | 8.5 (4.7 to 15.5) | 0.9 (0.8 to 1.0) |

from Benjaminse et al. (2006)
CI= confidence interval; LR+ = Positive likelihood ratio LR- = Negative likelihood ratio

When interpreting the results from the meta-analysis by Benjaminse et al. (2006) it should be noted that there is remaining uncertainty over the true accuracy of each clinical test. The optimal design for assessing accuracy of diagnostic tests has been suggested as prospective, where both the clinical test and a suitable 'gold standard' reference are applied independently to a consecutive series of cases from a relevant population (Jaeschke et al., 1994). In reality this is difficult to achieve and it would be unethical to apply the currently accepted gold standard of arthroscopy to all patients within a study regardless of need, due to inherent surgical risks in cases where preliminary tests are negative. Methodological shortcomings (lack of blinding, not applying reference standard to all subjects and using healthy controls) have the potential to overestimate diagnostic accuracy (Rutjes et al., 2006; Whiting et al., 2003; Lijmer et al., 1999).

Geraets et al. (2015) attempted to overcome some of these methodological issues as discussed previously (see 1.2.1) but did suffer some additional

limitations in relation to the physical examination tests. As all of the patients used in the study had undergone arthroscopy, some many years previously, the cohort used is not typical of that where assessment would normally be applied, reducing the external validity of study findings. As all patients in the index group had chronic ACL deficiency and opted not to have reconstructive surgery, it is certainly possible if not likely, that the level of instability was lower than in other patients with persistent instability resulting in the need for reconstructive surgery. Further, in chronic ACL deficient knees with associated osteoarthritis the level of anteroposterior laxity has been shown to reduce with disease progression (Wada et al., 1996) which would potentially lower the accuracy levels of physical tests performed in this group. Despite this, Geraets et al. (2015) showed high levels of accuracy for the physical examination tests in the hands of an orthopaedic surgeon; in isolation the Lachman test was 83% accurate increasing to 87% when combined with the anterior drawer and pivot shift tests. However, the same tests were less accurate when performed by a primary care physician with isolated accuracy of Lachman test of 63% increasing to 70% when combined with the anterior drawer test.

van Eck et al. (2013) undertook a meta-analysis concentrating on physical examination tests in acute (<3 weeks) injuries. They reported that the Lachman test was the most sensitive at 81% when performed without anaesthesia, but in contrast to the findings of the review by Benjaminse et al. (2006), they noted that specificity levels were similar across the three tests reviewed.

Despite doubts over the ‘true’ level of diagnostic accuracy evidence suggests that the Lachman test, when performed by someone suitably skilled in its application and interpretation, can help to identify whether or not an ACL injury is present, even in acute knee injuries (van Eck et al., 2013; Benjaminse et al.,

2006; Katz and Fingeroth, 1986). Sensitivity (the proportion of true positives that are correctly identified by the test; Altman and Bland (1994)) is lower for the anterior drawer and pivot shift tests and therefore use of these in isolation may lead to false reassurances that the ACL has not been injured. Moreover, the sensitivity of the anterior drawer test is further reduced in acute knee injuries (van Eck et al., 2013; Katz and Fingeroth, 1986; Noyes et al., 1980a). The pivot shift test has the highest specificity and therefore, if positive, it is highly suggestive of ACL injury although it is difficult to perform, frequently not possible in acute injuries, and unfamiliar to the majority of primary care physicians (Wagemakers et al., 2010; Scholten et al., 2003). As no single test is superior to the others in all aspects it is suggested that a battery of tests are performed (BMJ Best Practice, 2014; Swain et al., 2014; NICE, 2011). Whilst there is conflicting evidence as to how much value is added when tests are applied by less experienced clinicians (Geraets et al., 2015; Wagemakers et al., 2010) it would appear that physical examination tests display moderately high levels of accuracy when applied by experienced clinicians even if applied in isolation.

The finding that the Lachman test is superior to the anterior drawer test in identifying ACL injury has been supported by best practice guidelines (AAOS, 2014; BMJ Best Practice, 2014; NICE, 2011). The guideline from the National Institute for health and Care Excellence (NICE, 2011) recognised the evidence for the Lachman test was based on studies at risk of bias and where orthopaedic surgeons were the examiners concluding that the test may be less accurate when performed by non-specialists.

### 1.2.3 General clinical examination of anterior cruciate ligament injuries

The accuracy of general clinical examination (incorporating both a subjective and physical examination), which most closely mimics assessment practices, has been investigated by a number of studies.

In a retrospective analysis of preoperative diagnosis compared to a gold standard of arthroscopy, Nickinson et al. (2010) found an overall accuracy of clinical examination for ACL injury of 97% with sensitivity (86%) and specificity (98%). In total 698 patients were analysed, 79 having an ACL injury, none of which had an MRI scan prior to the initial clinical diagnosis reducing the likelihood of diagnostic review bias. A particular strength of the study was that it included all patients who underwent arthroscopy, not just those with a given diagnosis, which reduces the possibility of spectrum and verification bias.

O'Shea et al. (1996) investigated the diagnostic accuracy of clinical examination incorporating history, physical examination and radiographs in the assessment of 156 consecutive patients with traumatic knee disorders. The study reported values for sensitivity (97%) and specificity (100%) for ACL ruptures. The study was undertaken in an Army hospital setting and therefore external validity is compromised but did include consecutive patients with blinding of the examination findings to the reference standard (arthroscopy) limiting diagnostic review bias.

A study with a low risk of bias undertaken on 50 consecutive patients comparing clinical diagnosis with a suitable reference standard of arthroscopy found high levels of accuracy (92%) for clinical diagnosis (sensitivity=91%; specificity= 92%) (Juyal et al., 2013).

Geraets et al. (2015) found that an orthopaedic surgeon was able to recognise 94% of participants with ACL rupture through a combination of positive medical history and physical examination. However, using a similar general clinical examination a primary care physician only recognised 62% of ACL injuries. Whilst it is not possible to generalise these results, the primary care physician in this study was highly skilled with 27 years of experience, a specialist interest in musculoskeletal conditions and was involved in the education of primary care physicians. It is therefore more likely that these results overestimate the average ability of primary care physicians and the 'true' difference in ability to recognise ACL injury may be more marked than reported.

Wagemakers et al. (2010) concluded that combining determinants from the history with the anterior drawer test gave the highest levels of accuracy in the primary care setting. However, sensitivity values were reduced from 71% to 63% with the addition of the anterior drawer test casting further doubt over the benefit of physical examination tests when performed by primary care physicians as the rate of false negatives increases. This will have the effect of providing false reassurances that the ACL has not been injured in a greater number of cases, potentially leading to missed and/or delayed diagnosis.

A systematic review reported pooled sensitivity and specificity values of 82% and 94% respectively (Solomon et al., 2001). This study included acute knee injuries which may account for the lower reported diagnostic accuracy rates.

A more recent systematic review noted that many studies assessing history and physical examination tests for the ACL have flawed methodology with resulting risk of bias (Swain et al., 2014). They concluded, based on analysis of high

quality evidence that individual test items are of little use in isolation but that combinations of tests may prove to be more useful.

A guidance document produced by the American Academy of Orthopaedic Surgeons (AAOS) also supports the use of general clinical examination finding 'strong' evidence that a relevant history and physical examination were effective tools for diagnosing ACL injury (AAOS, 2014).

### 1.2.4 Clinical diagnosis of acute Anterior Cruciate Ligament injuries

In theory, early diagnosis of ACL injuries should be possible as the majority patients present acutely following injury (Arastu et al., 2015; Parwaiz et al., 2015; Perera et al., 2013; Bollen and Scott, 1996). However, evidence suggests that only a minority of patients with ACL injuries are identified at initial presentation with the percentage identified by the original treating physician ranging from 6.8% to 28.2% (Arastu et al., 2015; Parwaiz et al., 2015; Perera et al., 2013; Guillodo et al., 2008; Veysi and Bollen, 2008; Hartnett and Tregonning, 2001; Bollen and Scott, 1996; Noyes et al., 1983).

This may be due to the lower accuracy of clinical tests in the acute phase (Simonsen et al., 1984) or inexperience of the attending clinician (Geraets et al., 2015; Jibuike et al., 2003). Non-specialist clinicians have been shown to misinterpret key clinical features such as instability, effusion, giving way (Guillodo et al., 2008), may fail to identify important features including haemarthrosis (Mitchell, 1999) and may misinterpret physical examination tests (Geraets et al., 2015; Guillodo et al., 2008). Based on the consistently low level of ACL injuries identified at initial presentation it would appear that further assessment and/or investigation is required at a later stage.

### 1.2.5 Medical imaging in the diagnosis of Anterior Cruciate Ligament injury

Whilst a number of radiographic features may suggest the possibility of ACL injury (e.g. Segond fracture, haemarthrosis, lipohaemarthrosis, avulsion of tibial or femoral ACL insertion, osteochondral fracture of lateral femoral condyle) the use of radiographs in the diagnosis of ACL lesions is of limited value as many of these features are not specific to ACL injury, with those that are more suggestive only present in a minority of cases (Ng et al., 2011; Hess et al., 1994). Magnetic resonance imaging (MRI) scanning is therefore considered the imaging modality of choice for identifying ACL injury (BMJ Best Practice, 2014; Sanders and Miller, 2005; NZGG, 2003).

A systematic review comparing MRI to arthroscopy comprising a total of 2040 patients with ACL injury found an overall accuracy rate for MRI of 93.4% with a sensitivity (86.5%), specificity (95.2%), positive predictive value (82.9%) and negative predictive value (96.4%) (Crawford et al., 2007). Interpretation of the figures warrants some caution as despite scoring the quality of studies using a modified Coleman scoring system the authors did not remove lower quality studies with a higher risk of bias from their analysis. An investigation of the differences in reported accuracy rates revealed that higher quality studies tended to report higher diagnostic accuracy rates. The presented results are therefore more likely to be conservative and potentially lower than the 'true' level of accuracy. The authors concluded that the high negative predictive value and specificity indicates that a negative MRI scan is helpful in ruling out ACL injury. A further concern was the fact that almost 20% of included studies (n=8/42) failed to give any detail on MRI sequences performed which may affect the diagnostic quality of examination.

Compared to the review by Crawford et al. (2007) similar levels of specificity (94.3%) but a higher sensitivity (94.4%) was noted in an earlier systematic review combined with meta-analysis undertaken by Oei et al. (2003). Funnel plot analysis within this study suggested publication bias was unlikely to be a significant feature making the results more robust.

The accuracy of MRI has been questioned when differentiating between complete and partial ruptures; Tsai et al. (2004) compared MRI to arthroscopy and found that 33% of patients who were diagnosed with a complete ACL rupture on MRI scan had only partial ACL tears confirmed arthroscopically suggesting inevitability of false-positive reporting. These findings were also noted by Behairy et al. (2009) who found lower levels of sensitivity for MRI in identifying complete ACL tears compared to any tear (partial or complete). Overall most studies report high levels of accuracy but there is acknowledgement that MRI is not a stand-alone investigation, especially due to the higher rate of false-positive results and therefore should be used in conjunction with the clinical examination (AAOS, 2014; Crawford et al., 2007).

### 1.2.6 Studies comparing clinical examination and Magnetic Resonance Imaging

A number of studies have compared results of a clinical examination and MRI scan and to a surgical reference test. There are some limitations to these studies with high likelihood of bias, however, results were fairly consistent with the majority reporting similar or marginally higher levels of overall accuracy for clinical examination (Navali et al., 2013; Rayan et al., 2009; Loo et al., 2008; Thomas et al., 2007; Kocabey et al., 2004; Rose and Gold, 1996; Liu et al.,

1995) although marginally lower levels of accuracy have also been reported (Boeree et al., 1991).

In contrast to other studies, Madhusudhan et al. (2008) showed significantly higher sensitivity and positive predictive values for clinical examination. Importantly, in this study, a negative MRI examination did not prevent arthroscopy reducing the likelihood of verification bias. In total 109 patients who had all three examinations were included in the study of which 31 had ACL injury. The sensitivity (54%) and positive predictive value (42.85%) of MRI scanning was considerably lower in this study which may be reflective of the cohort of patients many of which had arthritic knee conditions. However, there was a likelihood of bias with a lack of blinding as to prior test results and as patients were only included if they underwent all three investigations, the cohort is unlikely to be typical of the population of interest limiting both internal and external validity.

As a result of similar or marginally superior levels of accuracy of clinical examination, evidence suggests that correctly performed clinical examination is sufficient to determine likelihood of ACL injury and MRI is not warranted routinely (Navali et al., 2013; Rayan et al., 2009; Loo et al., 2008; Thomas et al., 2007). However, MRI should be used to assist diagnosis when clinical examination is equivocal.

### 1.2.7 Summary of diagnosis

Notwithstanding some caution on the true values for the accuracy of diagnostic tests, the evidence presented suggests that clinical examination, undertaken by an experienced clinician, is effective in identifying whether or not an ACL injury

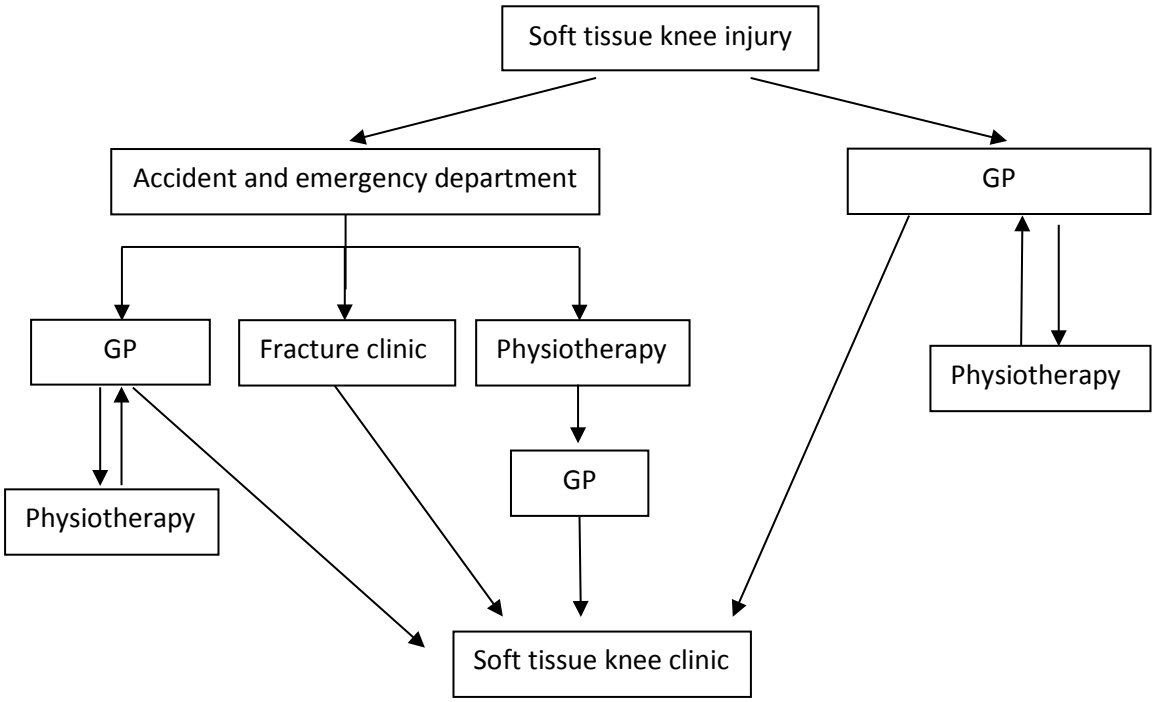
has occurred in the majority of cases. Whilst some physical examination tests possess high diagnostic accuracy rates, even when performed in isolation, general clinical examination incorporating a combination of physical tests and examination of the subjective history appears to be a suitable non-invasive method to diagnose ACL deficiency which compares favourably with MRI. MRI can be used in conjunction with the clinical examination findings to assist diagnosis especially where clinical examination is equivocal with the American Academy of Orthopaedic Surgeons guideline on management of ACL injuries concluding that there is strong evidence that MRI can provide confirmation of ACL injury (AAOS, 2014).

Although evidence is scant, it appears that clinical examination is less accurate in the acute phase post injury and therefore reassessment of knee injuries with a history potentially suggestive of ACL injury is warranted once initial pain and swelling have subsided. As the accuracy of clinical diagnosis appears to be highly dependent upon the experience of the clinician performing the examination, it raises questions regarding the most efficient means of ensuring that patients who have potentially suffered and ACL injury are reviewed by a specialist as early as possible.

## 1.3 Pathway from patient presentation to specialist consultation

With the acknowledged difficulty in diagnosing acute ACL injuries, especially when the clinical examination is undertaken by clinicians with limited experience in the assessment of soft tissue knee injuries, the pathway to specialist review as a mechanism to assist timely diagnosis of ACL injuries has received some attention (Parwaiz et al., 2015; Ball and Haddad, 2010; Sapsford and

Sutherland, 2008). Standard referral pathways (see figure 9) have been criticised as the process of facilitating access to specialist led services is inefficient and they have been reported to increase diagnostic delays, the number of medical visits and it has been speculated the overall cost of treating an injury (Ball and Haddad, 2010). A streamlined approach which allows direct access to a specialist led acute knee clinic is shown in figure 10.




GP= General practitioner

**Figure 9: Standard referral pathway for soft tissue knee injuries (Ball and Haddad, 2010 fig.1 p.686)**

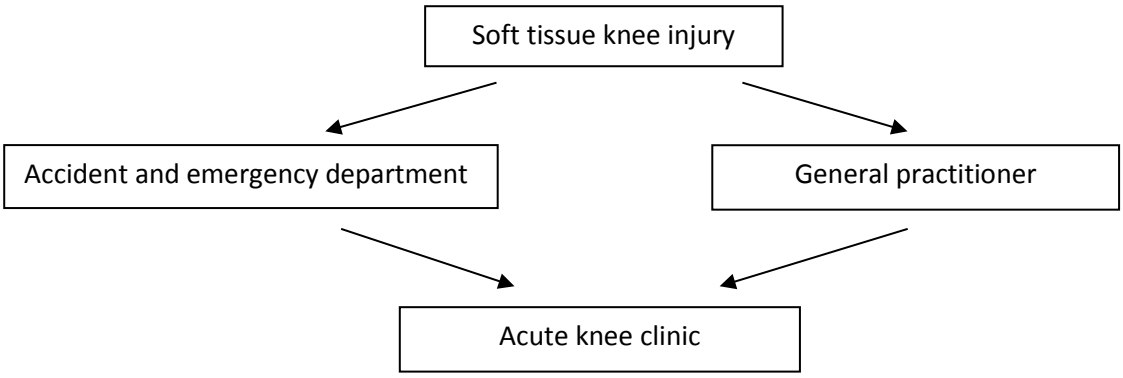



**Figure 10: Streamlined referral pathway for soft tissue knee injuries (Ball and Haddad, 2010 fig.2 p.686)**

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Despite the logical case that streamlining the pathway for acute knee injuries to specialist knee clinics will reduce the time to see a specialist, it is unclear how much this influences the overall picture of delay for patients with ACL injuries. Sapsford and Sutherland (2008) found that only 40% of patients undergoing ACL reconstruction were referred via their acute knee clinic pathway, the majority being seen through the standard referral pathways. This may suggest that such streamlining processes may only benefit a minority of patients with ACL injuries.

Ball and Haddad (2010), in a before-after study design, showed a significant reduction in the number of medical appointments prior to seeing a specialist from 5 to 1 following introduction of a streamlined pathway. They also reported significantly reduced delay to diagnosis (89% for accident and emergency [A&E] patients and 32% for General Practitioner [GP] referrals) but the time of diagnosis was taken as that of initial attendance at the knee clinic; no attempt was made to ascertain whether a comparable diagnosis had been made earlier. A number of other concerns existed including notable between group differences in injury type and a 37% reduction in waiting list times (which would

account for at least some of the observed improvements). With regards to ACL injury, separate figures were not reported and could not be obtained despite contacting the authors. In spite of these limitations, the study by Ball and Haddad (2010) showed the potential of a streamlined approach in reducing time to diagnosis and specialist consultation. However, the magnitude of improvements in delay may only be appreciated once delay for ACL injuries are investigated in isolation, taking into account all patients presenting with ACL injury and not solely those who attend via the streamlined pathway.

More recently, the effect of an acute knee clinic on delay specifically relating to patients with ACL injury has been published (Parwaiz et al., 2015). Whilst modest and potentially clinically meaningful reductions in delay were found following the introduction of an acute knee clinic, these failed to reach statistical significance. Further discussion of this paper can be found in section 2.5.

## 1.4 Management of ACL injuries

Management strategies for ACL injury includes specific rehabilitation either in isolation or combined with surgical intervention. A survey of practice amongst UK orthopaedic surgeons in 2004 revealed that 58% surgeons would advocate surgical reconstruction for managing an acute ACL rupture in a young skeletally mature patient with a further 18% adopting a policy of review after rehabilitation (Kapoor et al., 2004). Whilst there is some debate about the most effective management strategies, internationally guidelines suggest that all ACL injuries should be reviewed by a specialist as early as possible to determine the most appropriate treatment plan (AAOS, 2014; BMJ Best Practice, 2014; SMA, 2010; BOA, 2009; NZGG, 2003).

A document produced by Sports Medicine Australia (SMA, 2010) suggested that the decision on whether surgical reconstruction is required will depend upon numerous factors including:

- Degree of instability
- Associated injuries
- Social factors (time off work etc.)
- Demands on the knee

British Orthopaedic Association (BOA) guidelines on the best practice for primary isolated ACL reconstruction suggest the 'prime indications for ACL reconstruction are symptomatic instability or a desire to return to high risk activities' (BOA, 2009 p. 3), although structured rehabilitation programme with an option to undertake ACL reconstruction at a later date has also been suggested even in an athletic population (Frobell et al., 2010; Frobell et al., 2013). A prospective cohort study in Norway showed that 70% of patients opted for ACL reconstruction over rehabilitation alone (Grindem et al., 2014).
Whilst ACL reconstruction has been suggested to moderately reduce risk of developing osteoarthritis (Mather et al., 2013) other authors have concluded that there is insufficient evidence that reconstructive surgery decreases the risk of developing osteoarthritis (Chalmers et al., 2014; Fu and Lin, 2013; Kessler et al., 2008; Lohmander et al., 2007; Lohmander et al., 2004). The strongest evidence for a reduction in the level of osteoarthritis comes from a systematic review and meta-analysis incorporating studies with minimum mean follow-up of 10 years (Ajuied et al., 2013). This study found that relative risk of developing osteoarthritis (to any degree) was significantly lower (RR, 3.62; $p<0.00001$) in knees treated with reconstruction than those treated conservatively (RR, 4.98;

p<0.00001); however, the relative risk of progressing to moderate or severe osteoarthritis (based on Kellgren & Lawrence[1] classification) at 10 years was significantly higher in the group who underwent surgical reconstruction. The study did not perform a stratified analysis for return to sports and therefore it is not possible to determine whether these results were affected by any between group differences in the level of sporting activity undertaken post injury. Another systematic review did not support the findings of Ajuied and colleagues and concluded that at a mean of 13.1 +/- 3.1 years after injury there were no significant differences in the development of radiographically evidenced osteoarthritis (Chalmers et al., 2014). They did, however, note that patients who underwent ACL reconstruction had fewer episodes of meniscal injuries, less need for further surgery and higher activity levels based on Tegner scores. The mean time between ACL injury and surgery in the study by Chalmers et al. (2014) was 20.8 months and it is therefore likely that further meniscal and chondral damage would have occurred which may overinflate the rate of development of osteoarthritis and fail to display the true benefit of reconstruction if undertaken in the acute or sub-acute phase post injury. Ageberg et al. (2007) showed that good functional outcomes and knee muscle strength can be maintained at 15 year follow-up with rehabilitation and early activity modification without the need for reconstructive surgery.

There is a consensus that surgery should be offered to patients who experience repeated instability episodes. At the very least patients should expect to be counselled on measures which will reduce the likelihood of further injury; this is only possible once correct identification of the ACL injury has taken place.

[1] Kellgren & Lawrence is a method of classifying the degree of degenerative change on an X-ray

## 1.5 Consequences of delayed management of ACL injuries

A primary concern following ACL injury is the potential for further injury and the development of early degenerative change in the knee. Multiple studies have reported increases in meniscal and/or chondral injury with treatment delays (Michalitsis et al., 2015; Sri-Ram et al., 2013; Chhadia et al., 2011; Tayton et al., 2009; Yoo et al., 2009; Meunier et al., 2007; Yüksel et al., 2006; Church and Keating, 2005; Laxdal et al., 2005; de Roeck and Lang-Stevenson, 2003; Karlsson et al., 1999; Cipolla et al., 1995; Irvine and Glasgow, 1992). A systematic review incorporating meta-analysis undertaken by Snoeker et al. (2013) reported an overall odds ratio of 3.5 (95% CI: 2.09 TO 5.88) for medial meniscal tears and 1.49 (95% CI: 0.94 to 2.38) for lateral meniscal tears when surgery was performed more than 12 months following injury compared to cases where surgery was provided within 12 months. The results show a significant increase in the likelihood for medial meniscal tears if surgery was delayed past one year whilst increased meniscal tears have also been shown when surgery is delayed by more than 5 or 6 months (Sri-Ram et al., 2013; Chhadia et al., 2011; Tayton et al., 2009).

The presence of meniscal tears at the time of surgery are of importance as they have been shown to correlate to an increased chance of developing degenerative changes within the knee joint (Meunier et al., 2007; Hart et al., 2005; Gillquist and Messner, 1999). A high quality systematic review investigating longer term (>10 years) prevalence of osteoarthritis following ACL injury concluded that isolated ACL rupture resulted in a lower prevalence of osteoarthritis (0 to 13%) compared to subjects with a combined injury (21 to 48%); the main risk factor identified in the development of osteoarthritis was

meniscal injury (Øiestad et al., 2009). A prospective cohort study undertaken also found a higher prevalence of knee osteoarthritis in subjects with meniscal or chondral damage compared to those with isolated ACL injuries (Øiestad et al., 2010). A meta-analysis of 1554 ACL reconstructions reported an odds ratio of 3.54 for the development of OA if medial meniscectomy was also performed, confirming the significance of concomitant meniscal injury at the time of surgery (Claes et al., 2012).

There is evidence that if a meniscal injury is sustained prior to surgery it reduces quality of life in the long term. A systematic review of health related quality of life noted that studies with longer than 10 year follow-up showed lower health related quality of life scores for patients having concomitant meniscal tears at the time of ACL reconstructive surgery (Filbay et al., 2013).

A cost-utility analysis study comparing ACL reconstructive surgery to structured rehabilitation reported lower overall costs and higher effectiveness with surgery (Mather et al., 2013). Another study on cost effectiveness also found surgical reconstruction to be superior to conservative treatment, although contradictory to the values reported in Mather et al. (2013) they reported overall costs were higher with surgery (Farshad et al., 2011).

Whilst there is a body of evidence supporting early ACL reconstruction over delayed reconstruction, especially in individuals wishing to return to high risk activity, the quality and design of studies mean that uncertainty remains as to how much the risk of meniscal injury decreases following ACL reconstruction. In contrast to reports of higher rates of meniscal injury, a high quality randomised controlled trial comparing early ACL reconstruction with rehabilitation versus

rehabilitation with the option of delayed ACL reconstruction amongst young active adults found no evidence that delayed reconstruction resulted in lower activity levels, increased radiographic evidence of osteoarthritis, reduced functional levels or increased requirement for meniscal surgery (Frobell et al., 2013). However, more than half (51%) of those initially treated with rehabilitation did go on to have reconstructive surgery (Frobell et al., 2013). The authors concluded that a conservative treatment of structured rehabilitation could be considered as a primary treatment option in patients with acute ACL tear. When interpreting the results from Frobell and colleagues it must be remembered that the five year follow up period may not be sufficient to identify long term consequences of delayed surgical treatment.

## 1.6 Chapter summary

This chapter has presented evidence that ACL injuries frequently occur and are associated with common history features at the time of and shortly following injury. Clinical examination, incorporating both subjective and physical examination, is accurate for diagnosing ACL injury when undertaken by a specialist clinician and compares favourably with MRI. Evidence presented within this chapter suggests that physical examination tests for ACL injury are less accurate in the acute post-injury phase and the rate of diagnosis of ACL injuries at initial presentation is low. The review has confirmed that delays in appropriate advice and treatment have potentially significant consequences for patients who have suffered an ACL injury and international guidelines recommend that ACL injuries should be seen by a specialist clinician at the earliest opportunity in order to avoid treatment delays.

The following chapter presents a literature review of current evidence on delay to diagnosis and specialist consultation following ACL injury.

# Chapter 2: Literature review

## 2.1 Introduction

Chapter 1 has shown the importance of ensuring that delay to diagnosis is minimised so that appropriate treatment strategies can be put in place and reduce the risk of concomitant injury. This chapter explores the current information on delay following ACL injury through a review of germane evidence. According to Oliver (2012) the literature review demonstrates how the research is connected to other related areas and enlightens the reader on how the research fits into a broader context. It should critically appraise other research in order to provide an objective and logical summary of current knowledge (Coughlan et al., 2013) and assists the author in acquiring understanding of the topic including what has already been researched, how it has been done and what key issues remain unresolved (Hart, 1998). Aveyard (2014) suggests that only once the information can be seen in its context to other work is it possible to develop new insights, crucial to wider understanding of a phenomenon. In order to evaluate the current literature pertaining to pathway delay for those with ACL injury a literature review, incorporating a clear and comprehensive search strategy, was undertaken in a systematic manner. If a systematic approach is not adopted when undertaking a literature review results and conclusions may be biased and unreliable (Aveyard, 2014). The purposefully devised strategy for searching and reviewing the literature was based on established guidelines from the Centre for Reviews and Dissemination (CRD, 2009) and the Preferred Reporting Items for Systematic

reviews and Meta-Analyses (PRISMA) statement and its explanation and elaboration document (Liberati et al., 2009; Moher et al., 2009).

## 2.2 Research question and review objectives

Research questions and objectives are critical in providing direction and sufficient specificity to inform the data that should be collected (White, 2009; CRD, 2009).

The broad research question upon which the search strategy was based was:

'What is the current evidence on delay to patient presentation, diagnosis and specialist consultation for patients with anterior cruciate ligament injuries?'

The review objectives based on the research question were to:

- summarise literature reporting delay (in time) to patient presentation, diagnosis and/or specialist consultation following ACL injury;
- summarise studies investigating causes of, or factors associated with delay following ACL injury in regards to time to patient presentation, diagnosis and/or specialist consultation;
- summarise studies investigating initiatives to reduce delay to patient presentation, diagnosis and/or specialist consultation.

## 2.3 Methods

### 2.3.1 Search strategy

From the research question and review objectives key components of the PICOS (CRD, 2009) were identified as detailed below;

- Population: Studies of participants diagnosed with an ACL injury.
- Intervention/ comparator: It was not essential for studies to have an intervention or comparator to be included in the review as one key objective was to summarise literature reporting delay. In order to achieve the objective of summarising studies investigating initiatives to reduce delay, any such initiative was deemed acceptable for inclusion.
- Outcomes: Delay reported as a measure of time.
- Study design: Single case studies were excluded due to high risk of bias. All other designs were considered for inclusion.

The search terms applied to the Medline database are shown in table 3. The search strategy was devised with assistance from a subject specialist librarian and adapted for each of the chosen databases. Truncation symbols were used to ensure that all forms of the word were identified. Proximity searches were also employed on some of the keyword search terms to help ensure that a variety of similar phrases were identified and therefore that key articles would not be missed whilst minimising spurious returns. A full copy of the search strategy used within Medline can be seen in Appendix I.

**Table 3: Literature search terms used within Medline database**

| Component | Search terms |
|---|---|
| Anterior cruciate ligament | MeSH 'Anterior cruciate ligament'<br>MeSH 'Soft tissue injuries'<br>MeSH 'Athletic injuries'<br>Knee ligament*<br>ACL<br>Anterior cruciate ligament* |
| Injury | Injur* |
| Delay/time to diagnosis<br>Delay/time to consultation<br>Delay/time to referral<br>Delay/time to presentation | MeSH 'Delayed diagnosis'<br>MeSH 'Diagnostic errors'<br>Delay* diagnos*<br>Delay* consult*<br>Delay* refer*<br>Delay* present*<br>Time diagnos*<br>Time consult*<br>Time refer*<br>Time present*<br>Time interv*<br>Interv* diagnos*<br>Interv* refer*<br>Interv* present*<br>Late diagnos*<br>Late present* |

Databases searched via the EBSCOhost interface are listed in table 4.

**Table 4: Electronic databases searched via EBSCOHost**

| |
|---|
| **AMED**: Database of allied health and complementary medicine |
| **CINAHL**: Database with a focus on nursing and allied health literature |
| **MEDLINE**: Biomedical and life sciences database covering medical, nursing and health care |
| **SPORTDiscus**: Database with a focus on sports medicine |

In addition to the database search the following sources were also searched: Cochrane Library (CDSR) a database of systematic reviews; Cochrane Library (CENTRAL) a register of controlled trials; EMBASE (biomedical literature database); Proquest (Thesis repository); Opendoar (Academic open access repository); Orthopaedic proceedings (Orthopaedic conference abstracts); British Association for Surgery of the Knee (BASK) website; and Google search engine.

### 2.3.2 Identification of eligible studies

Papers were deemed eligible if they included any figures reporting time to initial patient presentation (the time from injury to first contact with a health professional), time to diagnosis and/or specialist consultation. 'Specialist' was defined based on the Oxford English Dictionary definition as 'a person highly trained in a particular branch of medicine' (Oxford University Press, 2015). For the purpose of this review this was interpreted as meaning someone trained in the management, including surgery, of the ACL deficient knee. The search was limited to '*human*' and '*published date: 1995-present*'. Whilst non-English articles were excluded from final analysis the titles and abstracts were reviewed so that the existence of eligible non-English papers could be documented. Resulting papers were exported into Endnote® X6 (Thomson Reuters [Scientific] LLC, Philadelphia). Following removal of duplicate papers, the title and abstract of remaining articles were reviewed against the inclusion and exclusion criteria (see table 5). Full text articles were obtained when the eligibility criteria were satisfied or in instances where it was not possible to make a decision as to whether the study was suitable for inclusion into the review.

**Table 5: Inclusion and exclusion criteria**

| Inclusion criteria | Exclusion criteria |
|---|---|
| • Primary research studies reporting time/ delay to patient presentation, diagnosis and/or specialist review for subjects with ACL injury<br>• Review articles reporting time/ delay to patient presentation, diagnosis and/or specialist review for subjects with ACL injury | • Studies reporting only delay/ time to surgical intervention<br>• Single case studies<br>• Non-English articles |

### 2.3.3 Justification of eligibility criteria

Single case studies were excluded due to the unacceptable risk of bias from such reports. It was anticipated that the majority of the studies would be case series or cross-sectional studies. Studies using either retrospective or prospective data collection methods were deemed acceptable for inclusion as each possess advantages and may therefore supply differing perspectives of delay. An advantage of identifying cases retrospectively is that data has been routinely collected in medical records without prior knowledge of hypotheses, and therefore has been regarded as more objective potentially reducing information bias (Ignatius and Shelly, 2011). However, prospective designs reduce the chance of missing or incomplete data which may be problematic when data is gathered retrospectively and consequently may afford more accurate and complete information (Nagurney et al., 2005).

Studies focussing solely on time from injury to surgical intervention were not included in this review. Whilst they provide information on another important aspect of delay, the time from clinical consultation to surgery is not directly applicable to delays to diagnosis or specialist review as they are heavily influenced by surgical waiting lists which are in turn linked to government policy such as the 18 week wait to treatment targets (Ball and Haddad, 2010). Moreover, surgery may be delayed for other reasons and it has been suggested that all patients should have a trial of conservative treatment which may result in patients never requiring surgical intervention (Frobell et al., 2013; Frobell et al., 2010).

As the number of peer reviewed journal articles reporting delay measures following ACL injury applicable to the present study was expected to be low, a decision was made to include abstracts, conference posters and proceedings

where eligibility criteria were satisfied. These may be regarded as grey literature sources (Alberani et al., 1990); defined in the twelfth conference on grey literature as ....'document types of sufficient quality to be collected and preserved by library holdings or institutional repositories, but not controlled by commercial publishers' (Schöpfel, 2010). It has been shown that grey literature reports are more likely to include negative or inconclusive data and exclusion of such evidence may bias review findings (Hopewell et al., 2007). Grey literature searching is therefore important in overcoming problems of publication bias thus ensuring that the results of a review are valid (Rothstein et al., 2006). In cases where grey literature suitable for inclusion was identified, attempts were made to contact the authors to gain additional information and ascertain whether the findings had been published elsewhere. In circumstances where two sources of the same dataset were available only the full text paper or most recent version was used in order to avoid duplication of results.

The search was limited to human subjects in keeping with the review aims and only included records published from 1995 onwards. This decision was taken as MRI availability substantially increased around this time (CDC, 2011) impacting on the diagnostic pathway for ACL injuries.

A decision to only include articles reported in English was made due to practical reasons but following the advice from the CRD (2009) all titles and abstracts were reviewed so that the existence of any non-English papers could be documented.

### 2.3.4 Data extraction and analysis

A data extraction form was devised in order to obtain pertinent information which could be used for the literature review (see Appendix II for example of completed form). All data were extracted by a single reviewer (CA). The duration of delay in days or months was transformed into number of weeks whenever necessary to allow for comparison between studies.

## 2.4 Results

### 2.4.1 Included studies

The search strategy yielded 1096 citations from AMED, CINAHL, EMBASE, MEDLINE, and SPORTDiscus with 18 citations identified using other sources (Cochrane Library, Proquest, Google, Opendoar, Orthopaedic Proceedings and BASK) (see PRISMA flow diagram- figure 11 (Moher et al., 2009)).

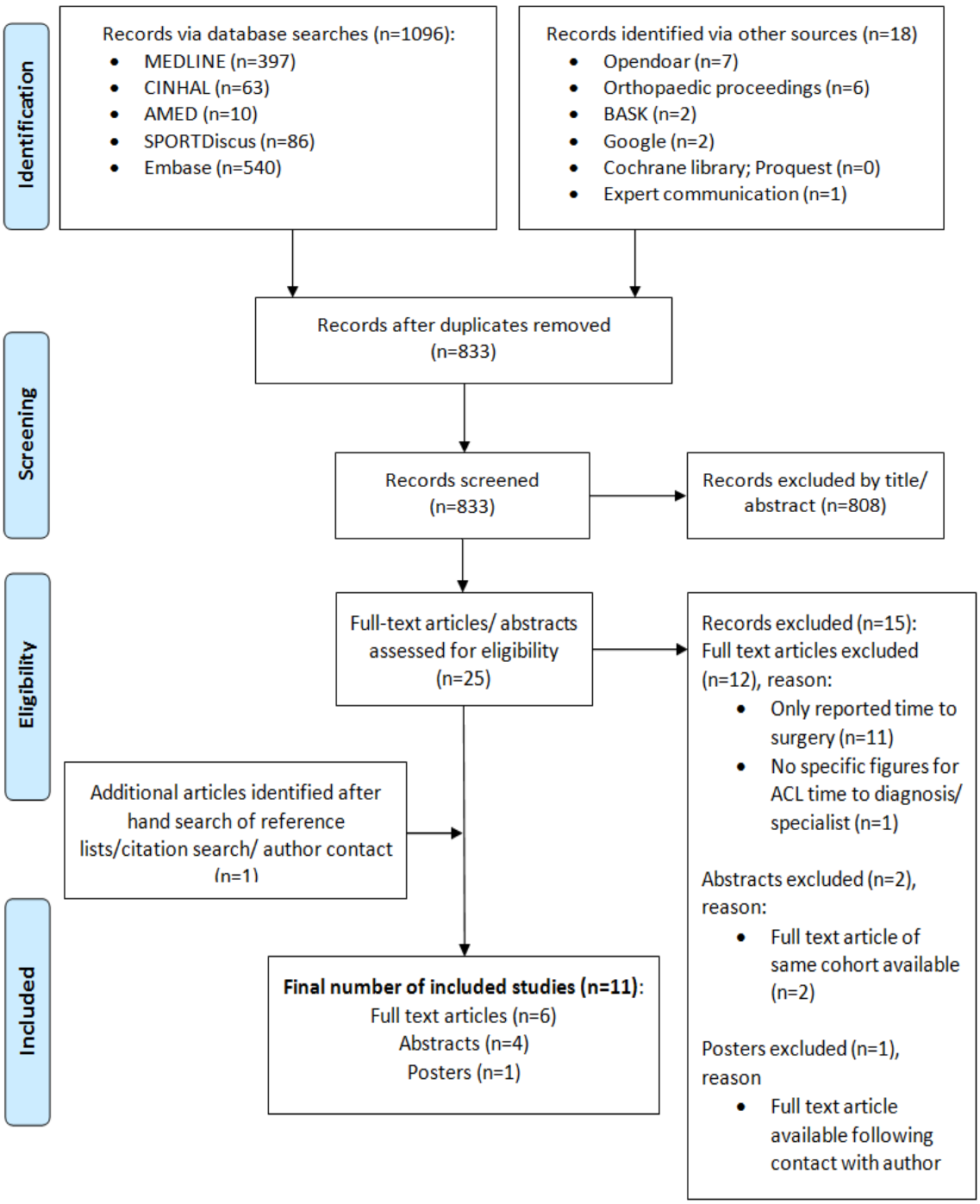


**Figure 11: PRISMA flow diagram of study selection process (adapted from Moher et al, 2009)**

In total 25 records were retrieved including 17 full text articles, 6 conference abstracts and 2 posters. No papers were excluded on the basis of language.

A full list of the records excluded after final review together with the reason for exclusion is shown in table 6.

**Table 6: Records excluded after full text review**

| Reference | Reason for exclusion |
|---|---|
| de Roeck and Lang-Stevenson (2003)<br>Ghodadra et al. (2013)<br>Jacob and Oommen (2012)<br>Joseph et al. (2008)<br>Lawrence et al. (2011)<br>Månsson et al. (2015)<br>Newman et al. (2014)<br>Tambe et al. (2006)<br>Tayton et al. (2009)<br>Yoo et al. (2009) | Only reported time to surgery |
| Ball and Haddad (2010) | No specific figures available for ACL injuries |
| Guenther et al. (2014) | Only reported time to MRI scan and surgery |
| Arastu and Twyman (2012)<br>Arastu and Twyman (2011) | Abstracts discarded as full text article of same cohort available |
| Teo et al. (2013) | Poster discarded as unpublished version of article available |

The authors of the posters were contacted with one (Teo et al., 2013) able to provide a full text version of the study which was subsequently used in the review (Parwaiz et al.). Table 7 shows the 11 studies included in the literature review.

**Table 7: Research included in the final review by publication type**

| Type of publication | Number of studies | Reference of study |
|---|---|---|
| Published full text articles | 5 | (Arastu et al., 2015; Perera et al., 2013; Baraga et al., 2012; Hartnett and Tregonning, 2001; Bollen and Scott, 1996) |
| Unpublished full text article | 1 | (Parwaiz et al., 2015)[2] |
| Abstracts | 4 | (Alaker et al., 2012; Nagy et al., 2012; Porteous and Kennet, 2008; Veysi and Bollen, 2008) |
| Poster | 1 | (Davidson et al., 2014) |

[2] The article by Parwaiz et al was published subsequent to the literature review.

### 2.4.2 Summary of current evidence on delay

The results of the literature review are divided according to the type of delay reported as follows:

1. Patient delay (time from injury to initial presentation)
2. Health system delay (time from initial attendance to diagnosis)
3. Delay to diagnosis (time from initial injury to diagnosis)
4. Delay to specialist review (time from initial injury to specialist consultation)

It was not possible to combine the results and report summary figures for delay due to considerable heterogeneity between studies with differences in methodology, reported definitions of delay, type of patients included, methods of determining how a correct diagnosis was established and summary measures reported (median and mean). In such situations it is more appropriate to summarise data narratively (CCACE, 2013) and, due to the factors identified above, this approach was adopted. The purpose of a narrative synthesis is to organise, describe, explore and interpret study findings in an attempt to provide explanations for, and moderators of, those findings (Bourgeault et al., 2010). The studies reporting delay included in the review and delay by type are summarised in tables 8 and 9 respectively. A discussion follows.

**Table 8: Summary of studies included in the review**

| Reference | Location of study | n | Study period | Patient group | Data collection method | Summary measures of delay | |
|---|---|---|---|---|---|---|---|
| | | | | | | Central tendency | Spread |
| **(Alaker et al., 2012)** | UK | 50 | Not stated | ACL reconstruction | Retrospective notes review | Mean | |
| **(Arastu et al., 2015)** | UK | 117 | 2005-2009 | ACL reconstruction | Prospective data collection form | Median | Range |
| **(Baraga et al., 2012)** | USA | 80 | 2010- 2011 | ACL injuries attending clinic | Prospective data collection form | Median | Range |
| **(Bollen and Scott, 1996)** | UK | 119 | 1993-1994 | Attending specialist clinic | Retrospective notes review | Mean | Range |
| **(Davidson et al., 2014)** | UK | 78 | Not stated | ACL reconstruction | Retrospective notes review | Mean | Range |
| **(Hartnett and Tregonning, 2001)** | NZ | 70 | 1989- 1998 | Sports injuries ACL reconstruction | Telephone questionnaire | Mean | Range |
| **(Nagy et al., 2012)** | UK | 50 | 2007- 2008 | ACL reconstruction | Retrospective notes review | Mean | |
| **(Parwaiz et al., 2015)** | UK | 160 | 2004-2011 | ACL reconstruction | Retrospective notes review | Median | Range |
| **(Perera et al., 2013)** | UK | 136 | Not stated | ACL reconstruction | Retrospective notes review | Mean | |
| **(Porteous and Kennet, 2008)** | UK | 100 | Not stated | ACL reconstruction | Retrospective notes review | Mean | |
| **(Veysi and Bollen, 2008)** | UK | 103 | Not stated | Attending specialist clinic | Prospective data collection form | Mean | |

**Table 9: Summary of delay by type. Mean (range) reported unless stated. Values reported in weeks**

| Reference | Type of delay | | | |
|---|---|---|---|---|
| | Patient delay | System delay to diagnosis | Total delay to diagnosis | Delay to specialist consultation |
| **(Alaker et al., 2012)** | | 9 | | |
| **(Arastu et al., 2015)** | Median= 0 (0 to 72) | | Median= 6 (0 to 192) | |
| **(Baraga et al., 2012)** | | | By insurance type (median):<br>• uninsured=17 (6 to 62)<br>• government insured 8 (2 to 57)<br>• privately insured= 2 (0 to 67)<br>By initial attendance (median):<br>• primary care physician or orthopaedic surgeon= 1.5 (0 to 62)<br>• emergency department= 4 (0 to 55) | |
| **(Bollen and Scott, 1996)** | | 91 † | | |
| **(Davidson et al., 2014)** | | | 60 † | |
| **(Hartnett and Tregonning, 2001)** | | | 9 (0 to 260) | |
| **(Nagy et al., 2012)** | | | | 69 |
| **(Parwaiz et al., 2015)** | Median=0 (0 to 885) | Median= 10 (0 to 924) | Median= 13 (0 to 926) | Median=24 (0 to 1006) |
| **(Perera et al., 2013)** | | 9 | | 24 |
| **(Porteous and Kennet, 2008)** | 14 | 19 | | |
| **(Veysi and Bollen, 2008)** | | | 92 | |

† reported range in months therefore range not included

#### *2.4.2.1 Patient delay*

Three papers reported median or mean times from initial injury until first accessing healthcare services (Arastu et al., 2015; Parwaiz et al., 2015; Porteous and Kennet, 2008). Arastu et al. (2015) and Parwaiz et al. (2015) both reported median delays to diagnosis of 0 weeks, while Porteous and Kennet (2008) reported a mean time from injury to presentation of 3.2 months. Two studies reported the range of delay to initial presentation with the upper limit reported as 72 weeks (Arastu et al., 2015) and 885 weeks (Parwaiz et al., 2015).

Details on the percentage of patients presenting to health care services within given timescales following injury confirmed that the majority of patients do not delay presentation, with more than two thirds of patients presenting within one week of injury, the majority of whom attend on the day of injury (Arastu et al., 2015; Hartnett and Tregonning, 2001; Bollen and Scott, 1996).

Whilst the majority of patients present early following ACL injury, it is also evident that some patients wait a considerable time before accessing healthcare services. The reasons for delayed patient presentation were not explored within these studies.

#### *2.4.2.2 Health system delay*

Studies reporting health system delay reported mean/median values ranging between 9 and 91 weeks (Parwaiz et al., 2015; Perera et al., 2013; Alaker et al., 2012; Porteous and Kennet, 2008; Bollen and Scott, 1996). The only study summarising health system delay using median values reported a median delay of 10 weeks (Parwaiz et al., 2015). One study reported considerably higher

values for delay to diagnosis from the time of initial presentation at 91 weeks (Bollen and Scott, 1996) with the next highest 19 weeks (Porteous and Kennet, 2008). It is unclear why such discrepancies exist between these studies although it is possible that at least some of the variation may be explained by the fact that Bollen and Scott (1996) included all patients diagnosed with ACL injury attending an outpatient clinic as opposed to the other studies which only included patients who had undergone ACL reconstructive surgery. A further explanation is that waiting list times may have differed between studies with the study by Bollen and Scott (1996) undertaken at a time when waiting list delays were often considerable. By the end of the 1990's, many patients in the UK referred to NHS orthopaedic services by a GP waited more than 26 weeks for an initial outpatient appointment (National Audit Office, 2001; House of Commons Library, 1999) prompting the introduction of waiting list targets by the UK Government (Department of Health, 2000). However, without specific information on waiting list delay it is not possible to appreciate the impact of waiting list initiatives and targets on health system delay.

#### *2.4.2.3 Delay to diagnosis*

Delay to diagnosis varied considerably between studies with reported mean/median values ranging between 6 and 92 weeks. Studies reporting median time to diagnosis (Arastu et al., 2015; Baraga et al., 2012) reported lower time to diagnosis than studies reporting mean values (Veysi and Bollen, 2008; Hartnett and Tregonning, 2001). This would be expected due to the positively skewed nature of the data, where the mean will often be substantially greater than the median due to the impact of the small number of patients experiencing lengthy delay. Interestingly, studies from outside of the UK (USA

and New Zealand) reported lower times to diagnosis than those within the UK although no clear explanation for this was evident. Baraga et al. (2012) reported the lowest time to diagnosis of all the studies but results were reported by insurance type and initial attendance and therefore it is not possible to give an accurate single figure summary measure of central tendency. All but two of the studies reported figures based on patients undergoing ACL reconstruction (Arastu et al., 2015; Davidson et al., 2014; Hartnett and Tregonning, 2001). The two who included all patients diagnosed with ACL injury attending specialist clinics reported disparate times to diagnosis. The study by Baraga et al. (2012) only included patients who had undergone an MRI scan in addition to clinical diagnosis. As patients who never have an MRI scan may systematically differ from those who do, the possibility of biased estimates of delay within the study must be considered; the impact of this on reported results is uncertain. The study by Veysi and Bollen (2008) included all patients with a clinical diagnosis of ACL injury and reported a much higher average time to diagnosis of 92 weeks. This study reported mean values which are not directly comparable to the median values reported by Baraga et al. (2012). However, the wide disparity in delay suggests the importance improved understanding of factors affecting the total delay time in order to better appreciate how to minimise diagnostic delays.

#### *2.4.2.4 Delay to specialist review*

Three studies reported delay to specialist consultation with mean/median values ranging between 24 and 69 weeks with only a single study reporting a range (0 to 1006 weeks) (Parwaiz et al., 2015; Perera et al., 2013; Nagy et al., 2012). Of these, Parwaiz et al. (2015) reported median values precluding direct

comparison with the others. Of the two other studies, large discrepancies existed in the reported mean values which cannot be explained by methodological differences as both studies were retrospective notes reviews undertaken in the UK on subjects who had undergone ACL reconstruction. The lack of detail on the make-up of delay (e.g. delayed patient presentation, waiting list delays) and factors influencing delay makes it impossible to appreciate where discrepancies in delay occurred and therefore to meaningfully compare results.

### 2.4.3 Summary of articles reporting causes of, or factors associated with delay following ACL injury

A number of factors affecting the time to diagnosis and specialist consultation following ACL injury were identified although little is based upon substantive empirical evidence. Baraga et al. (2012) noted that insurance status affected the time to diagnosis with uninsured patients waiting longer for a diagnosis and specialist review than those who had health insurance. There were conflicting reports over the effect of initial presentation site on delay with some authors reporting that presentation to primary care (GP or community physiotherapy) resulted in longer waits to diagnosis (Davidson et al., 2014) and initial specialist clinic attendance (Nagy et al., 2012). In contrast, Alaker et al. (2012) reported that patients initially presenting to their GP waited less time for a correct diagnosis than those attending an A&E department. As all of these studies took place within the UK in NHS hospitals using similar patient population groups (patients who had ACL reconstruction) and retrospective designs, the reasons for reported variation in delay and influence of site of initial presentation remain

unclear. Further, these variations demonstrate the importance of understanding specific factors which influence the level of delay within the diagnostic pathway in order to identify how and where improvements are required.

A number of other factors were reported as being responsible, at least in part, for observed delays but no empirical evidence of their effect was presented raising doubts over their true importance. A key factor reported to affect diagnostic delay is the skill of the clinician assessing the injury with poor diagnostic rates highlighted most notably in clinicians working within A&E departments (Arastu et al., 2015; Parwaiz et al., 2015; Perera et al., 2013; Hartnett and Tregonning, 2001; Bollen and Scott, 1996) although other studies have also suggested poor recognition amongst non-specialist orthopaedic surgeons (Veysi and Bollen, 2008; Bollen and Scott, 1996). Five studies reported the failure to identify characteristic ACL injury features (Arastu et al., 2015; Parwaiz et al., 2015; Perera et al., 2013; Hartnett and Tregonning, 2001; Bollen and Scott, 1996) with pain and swelling in the acute phase following injury suggested to impede early diagnosis resulting in delays (Perera et al., 2013). Two studies reported an underlying problem of repeated attendances prior to having a specialist review or obtaining a correct diagnosis (Arastu et al., 2015; Parwaiz et al., 2015) and the failure of surgeons to identify ACL lesions via arthroscopy has also been reported as a factor in increasing delay to diagnosis (Bollen and Scott, 1996).

### 2.4.4 Summary of reported initiatives to reduce delay following ACL injury

There was only one article which reported the effect of introducing an acute knee clinic (AKC) on time to diagnosis (Parwaiz et al., 2015). They reported a

non-significant (p=0.067) reduction of median delay from presentation to diagnosis from 15 to 8 weeks. However, as figures for waiting list delay were not presented it is not possible to ascertain the influence this had on reported results.

## 2.5 Critical analysis of included articles

Bollen and Scott (1996) undertook a single site retrospective notes review to highlight delay between first medical consultation and diagnosis. They found a substantial mean delay of 21 months; however this figure warrants caution in interpretation as the range (0 to 154 months) suggests a skewed dataset and the mean is an inappropriate summary measure in such circumstances as it does not reflect the typical delay experienced. Positively, this study included consecutive cases over a defined time period minimising bias and included clear criteria on which diagnosis was established within the specialist clinic, reducing bias. A significant limitation of the study was a lack of investigation into other component parts of delay such as time spent on the waiting list to attend the specialist clinic or the number of appointments patients received prior to attending the specialist clinic and how this impacted on the overall delay period. Further, they did not report the time taken for patients to initially present to health care services although 70% were noted to have attended an A&E department immediately following injury. The study found only 9.2% of diagnoses were made by the original treating physician and only 27% of patients were diagnosed within the first month following injury. The authors suggested that as a typical history (defined as a non-contact twisting injury or valgus/external rotation strain, feeling or hearing a pop or ‘feeling something go’

in the knee and swelling of the knee within 4 hours) was identified in almost 90% of cases, the high percentage of injuries apparently overlooked was worrying. They also highlighted a substantial number of missed opportunities to diagnose the ACL injury, where patients had attended appointments with health professionals inexperienced in assessing acute knee injuries, suggesting the importance of all such injuries having an early review with a soft tissue knee specialist.

Hartnett and Tregonning (2001) undertook a study based in New Zealand, one of only two studies in the review from outside the UK. This study used a prospective questionnaire to gather detail on the rate and timing of diagnosis of ACL injuries and identify any associated diagnostic features. The mean time to diagnosis was reported as two months (9 weeks), considerably lower than most studies and may reflect the different methods employed within their study or differences in the health care system. The study inclusion criteria were such that external validity of the results is compromised: patients had all suffered a sporting injury within five years of their initial orthopaedic consultation and all had undergone, or were awaiting ACL reconstruction. As a result, it cannot be assumed that the time to diagnosis is reflective of the population of ACL injuries although it does provide some evidence that it is possible to make the diagnosis of ACL injury within an earlier time frame. As with the majority of studies included in this review, component parts of delay were not investigated.

Porteous and Kennet (2008) carried out a retrospective medical notes review of 100 patients who had undergone ACL reconstruction at a single site operating an AKC. They supplied detail on where delays were present in the pathway from injury to surgery. Mean delay from injury to presentation was 3.2 months and mean delay from presentation to correct diagnosis was 4.3 months with

delayed presentation accounting for 43% of the total delay to diagnosis. As this study did not consider delay to be a single entity, it has advantages over many of the other identified studies but is not without limitations. Mean delays were used to summarise delay periods, although the range values reported for time to surgery confirmed that delay data was positively skewed. The impact of the use of mean to summarise central tendency in positively skewed datasets has been discussed previously (see 2.4.2.3). Along with concerns over the choice of central tendency measure, there were discrepancies in the figures reported as the component parts of delay did not add up to the given total delay, raising concerns over data handling and reporting. This study reported notably higher percentage of patients correctly diagnosed at initial attendance (43%) compared to other studies. However, as the rate of correct diagnosis was calculated using only cases where a diagnosis was stated, it is highly likely to provide an inflated estimate and is therefore of questionable worth. A further concern was the failure to define the period of study or explicitly state whether included cases were consecutive raising the possibility of selection bias. It is suggested that using consecutive cases, a method of random sampling or including all cases over a defined time period minimises the risk of selection bias in cross-sectional or case series studies (Chan and Bhandari, 2011; Ignatius and Shelly, 2011).

A follow-up study to the original by Bollen and Scott (1996) was undertaken at the same site in order to determine whether delay had improved over the intervening 10 years following the original publication (Veysi and Bollen, 2008). These were the only UK based studies to report delay figures based on a cohort of patients attending a clinic without restricting the sample to those who had undergone ACL reconstruction. They reported similar results to the first study with a mean delay of 92 weeks for the 103 included cases although reported a

different outcome (time to initial specialist consultation as opposed to delay to diagnosis). As a result, direct comparison of findings is not possible. Selection bias was a possibility within this study as the authors did not state whether data was taken from consecutive patients. Nevertheless, considerable diagnostic delays remained a major finding of the study which the authors suggested showed little evidence of improvement over time. In both studies, component elements of the total delay were overlooked making it difficult to determine whether the make-up of delay within the pathway to diagnosis and specialist consultation had altered. Reported values for rate of correct diagnosis showed that A&E staff made a correct diagnosis in 13% of patients at initial attendance; a marginal improvement but it confirmed the difficulty of making a diagnosis in the acute trauma setting.

Another retrospective case series undertaken at a single site UK hospital investigated 50 consecutive cases having undergone ACL reconstruction (Alaker et al., 2012). The reported mean delay to diagnosis was amongst the lowest in this study at 61 days with differences noted in the time taken to diagnose patients referred via a primary care physician route (40 days) compared to those attending A&E (90 days) although no clear definition of 'delay to diagnosis' was given making it unclear as to whether the reported delay was taken from first presentation or initial injury. Another limitation of the study was the lack of explanation as to how a correct diagnosis was established. Again, diagnostic rate was low with only 13% noted to have had a correct diagnosis on first presenting to health care services.

A study undertaken in the USA by Baraga et al. (2012) included 80 patients who were seen over a single year period in a county sports medicine clinic and University sports medicine practice. The study aimed to examine the effect of

insurance status on delay to diagnosis for patients with ACL injuries and consequently reported delay data based on insurance category. As a result it was not possible to determine the overall delay to diagnosis but the median delay to diagnosis was significantly different between uninsured (121 days) and insured patients (14 days). Median figures for delay to diagnosis based on initial attendance showed that patients who saw a primary care physician or orthopaedic surgeon initially waited less time for a correct diagnosis (median= 10 days) compared to patients initially attending the emergency department (median= 29 days). Although this study also reported collecting information on patient delay, figures were not presented in their paper. However, statistical analysis was undertaken on the unpublished data and did not reveal any significant between group differences in patient delay, suggesting that system delay accounted for the observed variation in time to diagnosis. The study had a strong method giving clear definitions of delay periods and criteria for diagnosing ACL injury. Selection bias was minimised by assessing consecutive cases and recruitment rates were high with only one patient refusing to participate. The potential for recall bias was noted with some injuries sustained more than a year prior to enrolment but the authors attempted to minimise this by corroborating patient reports with medical records wherever possible. This study also reported median values to summarise delay which are more appropriate as data were not normally distributed. A limitation of the study was the fact that it had a relatively low sample size and was undertaken within a single geographical location which limits generalisability of results. The authors suggested the need for a wider population based study in the future. Importantly, this study did highlight a factor influencing delay periods (insurance status) and reported lower levels of delay than most other studies.

Nagy et al. (2012) performed a retrospective notes review on 50 cases undergoing ACL reconstruction between July 1997 and November 2008 within a single site UK hospital to determine the time to initial orthopaedic consultation. They noted large discrepancies in the time to initial orthopaedic consultation based on the location of initial attendance with mean figures of 10 days for those presenting to A&E and 30 months for those presenting to a GP. The overall mean figures calculated from the paper were 15.8 months (69 weeks) based on the assumption that 10 days= 0.33 months. The reasons for the observed differences based on presentation site is not clear and no information was supplied on the make-up of delay with resulting uncertainty as to how much delay may be attributable to differences in patient delay. Between group differences may well exist which raises the possibility that confounding factors could have accounted for at least some of the observed differences. The figures contradicted those from the study by Alaker et al. (2012) who found a lower time to diagnosis for patients seen via their GP than those seen via an A&E pathway. A notable omission limiting appreciation of delay was the omission of waiting list delay. This was especially pertinent within this study due to the considerable length of the data collection phase (11 years) during which it is possible that a systematic change in waiting times could have occurred. There was the possibility of selection bias as it was unclear whether all cases in the study period were included.

A further study recruiting patients seen within a specialist knee clinic involving a larger cohort of 136 cases undergoing ACL reconstruction reported delay to diagnosis from initial consultation (Perera et al., 2013). The retrospective nature of the design meant that six cases were excluded from the analysis due to incomplete and inaccurate records. They reported mean system delay of 65

days and mean delay to consulting a soft tissue knee consultant of 165.5 days. A positive aspect of this study was the decision to include a graph showing the percentage of patients being diagnosed by month allowing greater understanding of system delay and an improvement on previous evidence. Limitations within this study were the lack of definition for delay to specialist consultation (no start point identified), a lack of information regarding patient delay to presentation and the reporting of mean values for delay, a recurring problem within much of the literature. Furthermore, the time to diagnosis was open to interpretation and potential bias as it was defined as the point at which ACL injury was 'clearly documented'. The figures reported in this study may have underestimated the true level of delay as an initial presentation to the emergency department was only taken if a card was present within the onsite medical notes, a limitation acknowledged by the authors.

A study of patients within a single UK hospital having ACL reconstruction between 2005 and 2009 (Arastu et al., 2015) analysed cases to re-evaluate the accuracy of initial diagnosis in order to find out whether it had improved in the interval from the study by Bollen and Scott (1996). Delay to diagnosis was a median of 6 weeks (range 0 to 192 weeks) with a correct diagnosis at initial consultation made in 28.2% of cases. As with the other studies using only patients who had ACL reconstruction the study was at risk of selection bias and the delay figures may not be representative of all patients with ACL injuries. A positive aspect of this study was that delay had been broken down into component parts with figures for patient delay low in most of the presentation sites. Patient delay was noted to be greater in those seen by their primary care physician and would have accounted for greater time to diagnosis amongst this group. As with other studies reporting patient delay the vast majority of cases

appear to present early with a minority waiting for a considerable time before presenting (up to 72 weeks). Positive aspects to this study were the use of median values to summarise delay and the attempt to report component parts of delay. However, there was a lack of clarity on how a ‘correct diagnosis’ was assumed.

A conference poster by Davidson et al. (2014) reported on 98 cases who had undergone ACL reconstructive surgery using a retrospective data collection method. Delay to diagnosis was defined as time from rupture to diagnosis although they failed to define what constituted a ‘correct diagnosis’. Mean time from rupture to diagnosis in this study was higher than most other studies although the use of mean values to summarise the delay make it susceptible to outliers that can substantially inflate the results. The range of delay to diagnosis within the study cohort (0 to 274 months) supports the view that data were positively skewed. Time to diagnosis was also summarised by group with mean delays of 72 days for patients seen via A&E compared to 643 days for patients referred from primary care. The lack of data on patient, waiting list or system delays makes it impossible to determine how much each factor contributes to overall diagnostic delay. The authors concluded that there are still considerable delays in diagnosing ACL rupture which while justifiable does little to further understanding of the phenomenon.

Parwaiz et al. (2015) undertook perhaps the most comprehensive study of delay within the UK, including more cases than previous studies (n=160). The retrospective notes review of patients having ACL reconstruction by a single surgeon over a period from 2004 to 2011 reported delay from injury to presentation (median= 0 weeks; range 0 to 885 weeks), delay from presentation to diagnosis (median= 10 weeks; range 0 to 924 weeks) and presentation to

knee clinic (median= 24 weeks; range 0 to 1006 weeks). A significant improvement in understanding delay was the included tables which gave a far more comprehensive picture of delay than all prior studies. These revealed that 84% of patients attended within 6 weeks of injury with only 12% delaying presentation until 13 weeks or more following injury. 22% of patients had to wait more than a year following injury before receiving a correct diagnosis and whilst just under half of patients had received an appointment at the specialist knee clinic within six months, 32% did not receive an appointment at the knee clinic for more than a year after the index injury. The reported upper range of delay confirms the importance of presenting median as opposed to mean values which are heavily influenced by such outliers. This study was one of the few to investigate an initiative to reduce delay (introduction of an AKC) through sub-group analysis. They noted a modest non-significant reduction in the median delay from presentation to diagnosis from 15 weeks to 8 weeks. Finally this study also reported the level of correct diagnosis at initial presentation (14.4%) within the range of reported values given in other studies. This study had a stronger method and supplied greater information on the component parts of delay following injury to being seen in a specialist clinic but was not without limitations. A key problem in interpreting time to diagnosis was the lack of a definition on how they established when a correct diagnosis was first made. Almost 20% of patients were excluded from analysis due to an incomplete dataset, raising the possibility of bias. Waiting list delays were not taken into account and due to the retrospective methodology it is not possible to understand reasons why such considerable delays are present in certain cases. In spite of modest methodological limitations this study provides strong evidence that diagnosis of ACL injury occurs at extremely disparate time points.

## 2.6 Conclusions

Considerable delays are present in the diagnosis and specialist review of ACL injuries although there is disparity in the amount of delay reported between studies. Patient delay appears to be a contributory factor in some cases although the majority of cases appear to present early following injury. There is little in the way of empirical evidence on the factors which affect delay or on ways that delay can be reduced.

## 2.7 Limitations in the current evidence base

There are a number of limitations with the current evidence base that have been identified in this review. Delay has not been defined adequately in many of the included studies making it difficult to draw conclusions from their work and impossible to compare reported delay between studies. Summary measures used to describe delay have in general been inadequate, with the majority of studies reporting mean values which are inappropriate as delay data are not normally distributed. In cases of skewed data the mean is unrepresentative of the general mass of the data and is not thought to be an appropriate summary measure (Oliveira, 2013; Arora and Malhan, 2010; McCluskey and Lalkhen, 2007; Bowers et al., 2006). Whilst median values may be more appropriate in these circumstances and have been reported by some articles this fails to give a clear picture of delay as it only accounts for a single observation. The only summary measure of data spread used has been the range. The range is unstable, affected by outliers, and is therefore an unsuitable measure of spread in most circumstances (Bowers et al., 2006). Certainly, within the studies reporting delay use of the range affords little information regarding the way the

data are spread. All studies have been undertaken within single geographical locations or at single sites and therefore lack external validity. Few studies have reported figures based on a defined population and as a result reports of delay may be biased as cohorts seen within a single isolated clinic or by an isolated surgeon may not be representative. A further limitation in understanding the true picture of delay following ACL injury is that the majority of studies have only included patients who have undergone ACL reconstructive surgery and as these cases may potentially differ from those managed conservatively, the overall nature of delay cannot be fully appreciated. A significant problem is the lack of a framework for investigating delay with only a small minority of studies reporting individual elements of delay and no studies have included data on waiting list times limiting understanding of the components of delay.

Whilst most studies are critical of the time it takes to diagnose ACL injuries and for them to receive appropriate specialist review to determine treatment plans there is a paucity of evidence on factors associated with delay or on interventions to improve delay.

## 2.8 Justification for study

It is clear from this review that there was a need for further investigation to understand delay following ACL injury. The quality of much of the evidence base is limited and does not allow true appreciation of the time period from injury until specialist consultation. A study was required to identify more accurately where delays occur in the pathway and identify factors that are associated with delay in order to facilitate recommendations on how and where improvements are required. A key area suggested to substantially increase the

time to diagnosis is the assessment of acute knee injuries by inexperienced staff but it is unclear how this affects the diagnosis of knee injuries and whether or not differences are present in the assessment of acute knee injuries which may account for observed differences in accuracy. AKCs have been suggested as a way of reducing the time to diagnosis and specialist consultation by streamlining the patient pathway but at present the only study reporting delay figures for ACL injuries in isolation failed to show statistically significant improvements.

The current research aimed to address the issues raised and provide a more comprehensive understanding of delay by incorporating multiple sites, providing greater information on the variation in delay by developing a model incorporating elements making up total delay, summarising delay using appropriate statistics, including all cases diagnosed with ACL injury and not solely those who have reconstructive surgery and further knowledge by ascertaining the factors most influential in delay. Further, the current research aimed to establish whether acute knee clinics are effective in reducing delay and whether/how assessment practices differ between clinicians with varying levels of experience providing information on how delay may be minimised. The philosophical and methodological approach used to achieve this is discussed in the following chapter.

## 2.9 Research questions

As the literature review highlighted contradictory and disparate levels of delay, the primary purpose of this study was to elaborate on the nature of delay

following ACL injury and factors which influence delay. The overarching research question is:

- What is the nature of, and factors associated with, delay to diagnosis and specialist consultation following ACL injury?

The review also suggested that ACL injury is poorly identified in the acute injury setting and may be affected by the level of skill and experience of the clinician assessing the injury. Despite repeated suggestion that improving skill levels of clinicians working with acute knee injuries could lead to improvements in diagnosis following initial assessment (e.g. Perera et al. (2013); Bollen and Scott (1996)), there is little sign of improvement. At the time of review, no studies had investigated whether differences occur in the approach to assessment with regard to the questions asked or tests undertaken. Such knowledge may allow greater appreciation of why the reported diagnosis of acute ACL injuries remains low, in addition to providing suggestions for *how* improvements can be made rather than a mere recognition that improvement is required. AKCs have also been reported to reduce the time to diagnosis for acute knee injuries in general but the only study reporting figures in isolation for ACL injury failed to show a significant difference. Consequently, the secondary research questions were:

- Do sites operating an acute knee clinic have reduced periods of delay to diagnosis and specialist review for patients with ACL injuries?
- What, if any, are the differences that exist in the clinical examination of acute knee injuries by specialist orthopaedic, non-specialist orthopaedic and A&E clinical staff?

# Chapter 3: Philosophy and methodology

## 3.1 Introduction

This chapter presents a discussion on the philosophical stance, theoretical perspectives and methodology underpinning this thesis. The research methodology for the two studies undertaken is justified based on the research questions identified with reference to the adopted philosophical approach. Research approaches (e.g. quantitative/qualitative or deductive/inductive) are considered in the context of both the theoretical framework and research methodology. It also explores the two studies undertaken within this thesis giving an overview of the research methods used to collect data. Finally, the chapter introduces the concepts of reliability and validity.

## 3.2 Epistemology and ontology

Holden and Lynch (2004) suggest the purpose of a philosophical review may be twofold; firstly to open the researchers mind to other possibilities, and secondly to enhance their confidence in the appropriateness of their methodology to the research problem. It has been argued that 'paradigm (theoretical framework) issues are crucial: no inquirer ought to go about the business of inquiry without being clear about just what paradigm informs and guides (their) approach' (Guba and Lincoln, 1994 p116). Bowling (2014) suggests that clarification of underlying theoretical assumptions is of additional importance as it allows a reader to critically appraise values inherent in research.

The philosophical basis for any research project arises from the researcher's ontological and epistemological position. Ontology relates to the nature of reality whilst epistemology is concerned with the relationship between the researcher and reality. 'While ontology embodies understanding *what is,* epistemology tries to understand *what it means to know*….providing a philosophical background for deciding what kinds of knowledge are legitimate and adequate' (Gray, 2013 p17). Ontological and epistemological issues tend to emerge together and the conceptual difficulty of keeping ontology and epistemology apart has been recognised (Crotty, 1998). It is suggested that epistemology and ontology inform theoretical perspective which in turns influences methodology and methods (Crotty, 1998) (figure 12).

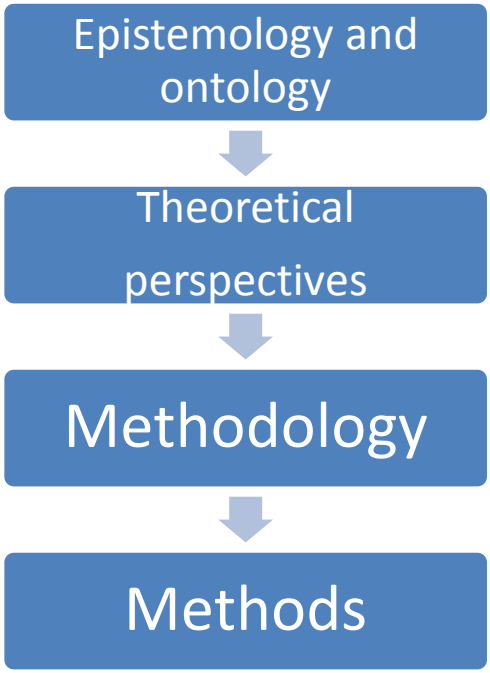


**Figure 12: Elements of research design (adapted from Crotty (1998 fig.1 p4))**

Smith (1908) distinguished between two alternative philosophical world views, *subjectivism* and *realism*. Subjectivism is linked to the philosophical works of Descartes in the 17th century and proponents of this paradigm believe 'that the objects immediately apprehended in sense-experience exist only in the mind of

the individual observer, and that they are numerically and existentially indistinct from each other' (Smith, 1908 p138). Alternatively, realists believe that physical objects exist independently of our perception of them, 'the truth is out there' independent of the observer and therefore objective methods can be employed to establish the truth (Gray, 2013; May and Williams, 2002; Guba, 1990). Whilst realism may be regarded as an ontological position it is often aligned with the objectivist epistemology; a 'notion asserting that meanings exist in objects independently of any consciousness' (Crotty, 1998 p10). Crotty (1998 p42), in addition to subjectivism and objectivism suggests a third epistemology, constructivism which he defined as; 'the view that all knowledge, and therefore all meaningful reality as such is contingent upon human practices, being constructed in and out of interaction between human beings and their world'. Whilst Crotty distinguished between subjectivist and constructivist epistemologies, Guba and Lincoln (1989) do not suggesting that the constructivist epistemological position is akin to subjectivism.

In this thesis the realist ontology and objectivist epistemology are preferred; this is considered further in relation to the theoretical perspective.

## 3.3 Theoretical perspective

Theoretical perspective has been defined as 'the philosophical stance informing the methodology and thus providing a context for the process and grounding its logic and criteria' (Crotty, 1998 p3).

There are a number of theoretical perspectives which have been proposed including, but not limited to; positivism, post-positivism, critical theory,

advocacy, interpretivism and pragmatism (Gray, 2013; Robson, 2011; Creswell, 2003; Crotty, 1998; Guba and Lincoln, 1994). Of these, positivism and post-positivism have been associated with the realist and objectivist views and warrant discussion. In pragmatism, truth may be defined as 'what works' and any philosophical approach is regarded as acceptable if it is the best at answering a particular research problem (Robson, 2011). The pragmatic approach will therefore also be considered.

### 3.3.1 Positivism

Positivism is linked to the realist viewpoint and the belief that 'true reality' can be measured objectively underpins the positivist ontology (Guba, 1990). The positivist paradigm of exploring reality has its origins based on the work of the French philosopher Auguste Comte (Lenzer, 1998; Andreski, 1974). This was expanded upon in the 1920's by a group of scientists, mathematicians and philosophers known collectively as the 'Vienna circle' who held a common belief that there is knowledge only from sensory/ observable experience. The philosophy of the Vienna circle has been described as logical positivism or logical empiricism, logical relating to the circles reliance on logic and concern with use of language (Hanfling, 1981). At the heart of logical positivism is the verification principle, that a procedure can be carried out to determine whether a statement (hypothesis) is true or false (May and Williams, 2002). Logical positivism differed from earlier versions of positivism as it stressed the logical character of scientific method as well as the empirical (Hughes and Sharrock, 1997).

The positivist paradigm has been criticised as it necessitates complete detachment of the researcher from the research process; yet researchers are part of the world they are observing and it has been argued that the underlying beliefs of the researcher inevitably influence the findings produced (Somekh and Lewin, 2005; Guba, 1990). Hunt (1993) articulates the difficulty in complete detachment suggesting that the researcher is inherently biased based on their background, status, beliefs, skills, values and resources. Furthermore, Creswell (2003) argues that researchers are sensitive to the audience to whom they will report their research findings and the approach to research is shaped by such considerations. With reference to this study, the researcher acknowledges that past experience working with patients who have suffered ACL injuries makes complete detachment impossible; however, in keeping with the positivist traditions there remains a desire to search for 'truth'. Whilst positivism has been the dominant research paradigm for much of the twentieth century, Gray (2013) argues that this has largely been replaced by other philosophical stances such as post-positivism.

### 3.3.2 Post-positivism

Post-positivism, still with an underpinning of realism, is allied to the 'scientific method' of enquiry (Creswell, 2003). A key assumption of the post-positivist position which differs from the traditional positivist ontology is that absolute 'truth' can never be found; all evidence in research is imperfect and fallible (Creswell, 2003). Moreover, from an epistemological perspective, post-positivists 'recognise the absurdity of assuming that it is possible for a human enquirer to step outside the pale of humanness while conducting inquiry' (Guba,

1990 p20). The position taken in this thesis most closely allies with that of a post-positivist researcher with a belief that it is possible to gain secure objective knowledge with a research focus of generalisability (Carson et al., 2001). Post-positivists take a structured scientific approach in the design and conduct of research, using rational, logical approaches and employ mathematical and statistical techniques to uncover objective reality. The development of numerical measures of observation is of paramount importance to the post-positivist philosophy (Creswell, 2003), thus quantitative rather than qualitative methodologies are allied to this paradigm. Whilst the philosophy of post-positivism is, in general, representative of the position taken by the author with regard to the studies undertaken, this does not convey a dogmatic attachment to this paradigm.

The approach taken in this study is largely forged from research questions although it has been argued that the formulation of research questions are themselves inextricably linked to the theoretical stance of the researcher (Hesse-Biber and Leavy, 2010). One of the primary research questions focussed on the level of delay within the pathway from ACL injury to specialist consultation. From the subjectivist perspective it could be argued that delay (and all of its consequences) may only be truly appreciated by the individual and the experience of each individual differs. This belief is allied to the philosophy of *phenomenology*, which regards 'reality' as multiple, socially constructed and assigned meaning through interaction, perception and experience (Bowling, 2014). However, ACL injury and delay in its diagnosis may be perceived as a 'truth' which exists independent of whether it is being observed. In this respect it may be regarded that the ontology, epistemology and theoretical perspective has been forged from the questions under

consideration along with a desire to adopt the most appropriate research methodology and not from a preconceived adherence to a particular philosophical stance. This approach has its underpinnings in the 'pragmatism' paradigm.

### 3.3.3 Pragmatism

Pragmatism does not commit to a single entity of philosophy and reality and is often allied to mixed methods research (Denscombe, 2014; Creswell, 2003). Jha (2008) suggests that design validity is more likely to be assured when the researcher is open to both qualitative and quantitative paradigms (see 3.4.1) rather than precluding one over the other. Pragmatists argue that the epistemological perspective is not particularly meaningful for the researcher and the guiding principle when choosing an approach to research should be how well it addresses the topic under investigation (White, 2009; Creswell, 2003). Proponents of the pragmatic approach reject traditional dualisms (e.g. objectivism and subjectivism) preferring to adopt a common sense philosophical approach to problem solving (Denscombe, 2014; Robson, 2011). Furthermore, pragmatists endorse fallabalism (research conclusions are imperfect and uncertain) (Robson, 2011), a position aligned with that of post-positivism. Although methods led research is commonplace, it has been argued that new researchers should use a question led approach rather than focussing on particular methods, designs or techniques; an approach described as more easily defensible as a practice (White, 2009). As opposed to the model proposed by Crotty (1998) this approach does not begin with an ontological

and epistemological position but places research questions at the heart of the research design (see figure 13).

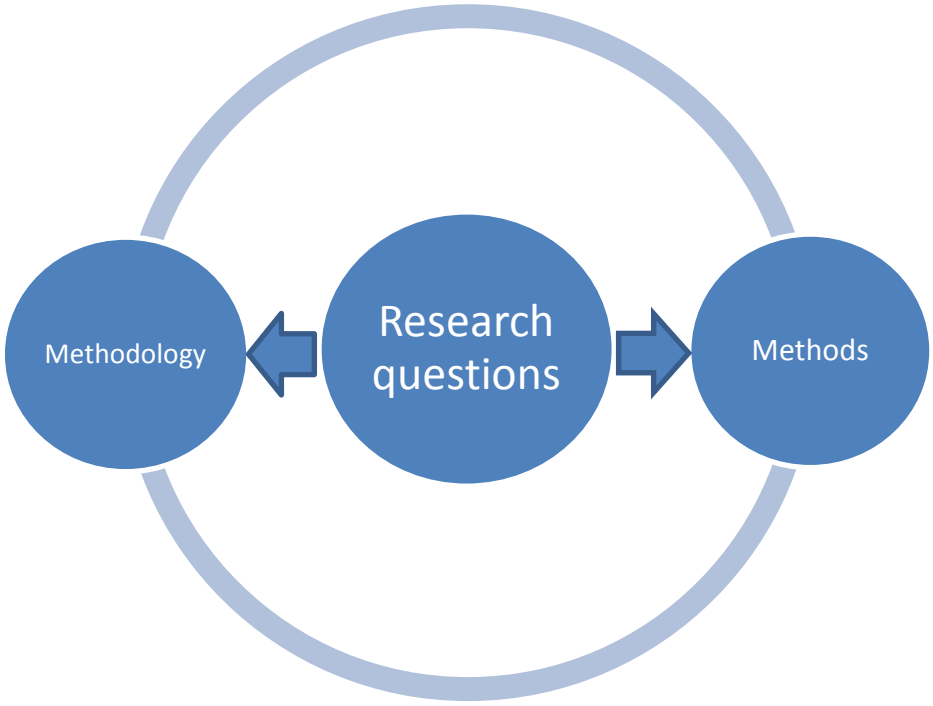


**Figure 13: Pragmatic approach to research design**

Within this thesis the adopted theoretical perspective is post-positivism although the decision to use this approach is largely based on the pragmatic paradigm, considering the topic and questions under investigation.

## 3.4 Research approach

### 3.4.1 Quantitative and qualitative approaches

Creswell (2003) suggests that there are three approaches to research; quantitative, qualitative or mixed. Quantitative research is based on a scientific approach through measurement and quantification, with an importance placed on reliability and validity of measures and on the generalisability of findings

(Robson, 2011). The use of a scientific approach is thought to increase the likelihood that information is reliable and unbiased (Davies and Hughes, 2014). In contrast, qualitative research produces little or no numeric data and describes situations from the perspective of those involved; generalisability of findings is not paramount (Robson, 2011). Qualitative research places the observer in the setting of interest and uses an interpretive and naturalistic approach to this world (Denzin and Lincoln, 2011). Punch (2005) suggests that there is a knowledge payoff between quantitative and qualitative approaches and the researcher should determine which affords more useful knowledge. There are a number of key differences in the quantitative and qualitative research approaches: their underlying philosophical assumptions; analytical objectives; strategies of enquiry; methods employed (question format, data format); flexibility in study design; and practices used (Mack et al., 2005; Creswell, 2003) (table10).

This study is based on a scientific approach and may therefore be classified as quantitative research. Adoption of the post-positivist perspective necessitates the quantification of diagnostic delay through the systematic collection and analysis of pertinent information. Delay relates to an interval between two time points, measured in numerical data. Thus, logically, a quantitative approach is best suited to describe delay. Furthermore, the consequences of delayed diagnosis (e.g. meniscal tears) have been linked to time periods following ACL injury, and as one of the key reasons for improving time to diagnosis and specialist consultation is to minimise these complications, investigating delay in a quantitative manner allows meaningful discourse to take place. Other primary research questions ‘whether delay times are lower in sites operating acute knee clinics’, and ‘whether there are differences in the assessment of acute knee

injuries between specialist orthopaedic, non-specialist orthopaedic and A&E clinical staff' ask more specific questions relating to comparison.

**Table 10: Comparison between qualitative and quantitative research approaches**

| | Quantitative | Qualitative |
|---|---|---|
| Philosophical assumptions | • Positivist/ post-positivist knowledge claims | • Constructivist/ advocacy/ participatory knowledge claims |
| Strategies of enquiry | • Surveys and experiments | • Phenomenology, grounded theory, ethnography, case study, narrative |
| General framework/ Research practices | • Identifies variables to study<br>• Relates variables in questions or hypotheses<br>• Uses standards of validity and reliability<br>• Seek to confirm hypotheses about phenomena<br>• Use highly structured methods such as questionnaires, surveys and structured observation<br>• Objectivity is sought<br>• Detailed specification of procedures | • Collects participant meanings<br>• Focus on a single concept or phenomenon<br>• Brings personal values into the study<br>• Studies the context or setting of participants<br>• Instruments use more flexible, iterative style of eliciting and categorising responses to questions<br>• Use semi-structured methods such as in-depth interviews, focus groups and participant observation |
| Analytic objective | • To quantify variation<br>• To predict causal relationships<br>• Generalisation of findings is sought | • To describe variation<br>• To describe and explain relationships<br>• To describe individual experiences<br>• To describe group norms |
| Question format | • Closed-ended | • Open-ended |
| Data format | • Observes and measures information numerically | • Textual (obtained from audiotapes, videotapes and field notes) |
| Flexibility of study design | • Study design stable | • Some aspects of the study are flexible |

adapted from (Robson, 2011; Mack et al., 2005; Creswell, 2003)

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Creswell (2003) argues that research problems which identify factors that influence an outcome or the utility of an intervention, such as those examined in this thesis, are also best managed with a quantitative approach.

### 3.4.2 Deductive and inductive approaches

Deductive reasoning starts with a theory developed from more general ideas which can be tested through observation and analysis (Bowling, 2014). It can be

regarded as the process of developing specific observations from general principles (Brink et al., 2006). Conversely, inductive reasoning starts with factual observations which can be used to make generalisations and develop testable hypotheses (Bowling, 2014; Brink et al., 2006).

Inductive learning, developed in the sixteenth and seventeenth centuries by Francis Bacon, and popularised by John Locke who established *empiricism*, was thought to be preferable to a hypothetico-deductive approach as it uses observation to avoid the problem of poor hypothesis generation and resulting tendency to defend the indefensible (Gabbay and Guenthner, 2002). Whilst the inductive and deductive approaches may seem diametrically opposed they are not mutually exclusive and can be used in combination depending upon the research question(s) under investigation (Gray, 2013; Speziale et al., 2011).

Within this thesis, elements of both inductive and deductive approaches are appropriate. For the question regarding the nature of delay following ACL injury an inductive approach is used to observe elements of delay upon which patterns may be identified and theories developed. However, for more specific theories such as whether AKCs reduce time to diagnosis and specialist consultation, a deductive approach is regarded as more appropriate.

### 3.4.3 Exploratory, descriptive and explanatory approaches

Studies may be classified based on research methodology but also according to the purpose of research. Three purposes of research have been proposed; to *explore*, to *describe* and/or to *explain* (Robson, 2011). It has been claimed that research should, in the main, seek to provide explanations and therefore exploratory and descriptive research has been regarded as inferior (Robson,

2011). However, it is also argued that exploratory and descriptive studies are more appropriate where there is a paucity of descriptive information and little is known about a phenomenon (Gray, 2013). Robson (2011) points out that under these circumstances achieving a clear description is a reasonable priority and many research questions are better suited to a focus on exploration or description. With reference to this study, as identified in the literature review, information regarding delay is incomplete and therefore exploratory/descriptive research is appropriate to provide a clearer picture of the phenomenon. This will afford greater appreciation of the elements of, and factors associated with, overall delay. However, there is also an acknowledgement that there is a clear need to identify causal factors responsible for, or contributing to, delay; something that only an explanatory design will be able to supply. Only once an explanation has been established will it be possible to identify the key areas that need to be addressed in order to improve the overall experience of those suffering ACL injury. Whilst the primary aim of this study was to provide a greater understanding of the factors which affect delay to diagnosis, some factors have been identified from the literature review as being potentially impactful on delay to diagnosis. This includes the limited success of inexperienced or non-specialist clinicians in diagnosing acute ACL injury and also the role AKCs might play in reducing time to diagnosis. Both of these areas warrant an explanatory approach.

## 3.5 Methodology

Crotty (1998 p3) defines methodology as 'the strategy, plan of action, process or design lying behind the choice and use of particular methods, linking the

choice of methods to the desired outcomes'. Methodology bridges the gap between the philosophical framework and methods design (Hesse-Biber and Leavy, 2010). Methodological considerations are linked closely with the philosophical stance (post-positivism). Table 11 shows some of the key methodological perspectives in this study.

**Table 11: Key methodological perspectives**

| Methodological element | Description |
|---|---|
| Focus of research | • Concentrates on description and explanation |
| Role of researcher | • Detached, external observer<br>• Clear distinction between reason and feeling<br>• Strive to use rational, consistent, verbal, logical approach<br>• Seek to maintain clear distinction between facts and value judgements |
| Techniques used | • Formalised statistical and mathematical methods. Quantitative data |

(adapted from Carson et al. (2001) table 1.1 p6)

In keeping with the adopted theoretical stance (post-positivism) the aim of the methodological approach is to discover external reality rather than creating the object of study (Carson et al., 2001). Allied to the post-positivist paradigm, this study involved the researcher being external and detached, maintaining a clear distinction between facts and value judgements whilst concentrating on description and explanation of the field under investigation; the purpose being to uncover a 'true' reality that exists regardless of whether it is being observed. Within this thesis two separate studies have been undertaken to answer the research questions; in study 1 a cross-sectional survey methodology was adopted and study 2 used a structured observational methodology. These choices are justified within the following subsections.

### 3.5.1 Methodological choice for study 1: Cross-sectional survey

Study 1 addressed the first two research questions (see 2.9). Bowers et al. (2006) suggests that quantitative research may be broadly classified into observational or experimental studies. Experimental studies involve the allocation of subjects to receive a treatment, service or experience whilst observational research involves active observation, without intervention, of treatment or care (Bowers et al., 2006). Observational studies can be sub-divided into descriptive and analytic with the latter involving a comparison of groups (Bowers et al., 2006). Observational research designs may be classified as cross-sectional, cohort or case-control studies (Bowers et al., 2006). Cross-sectional designs involve data collection from a specific point in time as opposed to longitudinal studies (cohort or case control studies) which follow study participants over a period of time (Abramson and Abramson, 2011; Bowers et al., 2006). Types of analytic experimental and observational study methodologies are shown in figure 14.

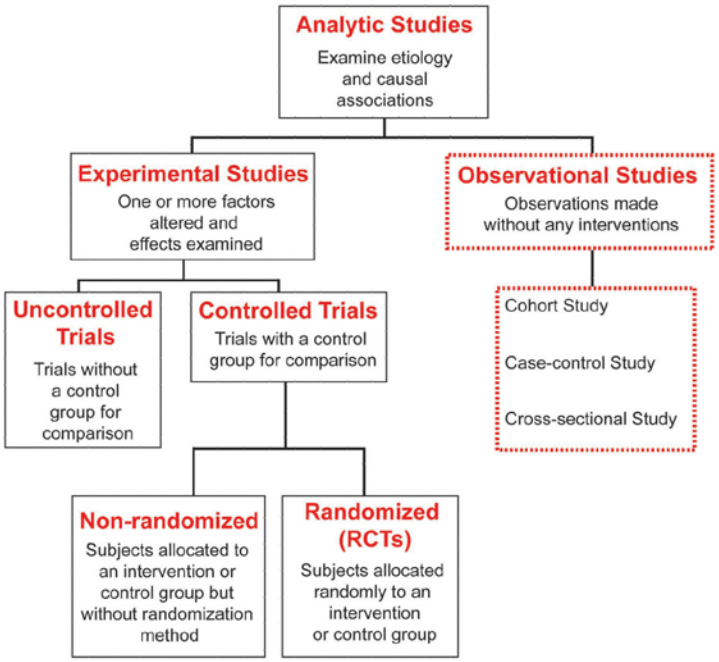


**Figure 14: Analytic study methodologies (Song and Chung, 2010 fig.1 p9)**

Denscombe (2014) suggests that five conditions need to be met in order for experimental research to be selected as the most suitable approach (see table 12).

**Table 12: Conditions where experimental research is most appropriate**

- Explanatory (and not exploratory) research
- Well established body of knowledge exists
- Existing knowledge should allow formulation of research hypotheses
- Observations produce numeric data which can be statistically analysed
- Ability to implement controls over factors studied

(adapted from Denscombe (2014).

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The lack of an established body of knowledge on delay supports the view that experimental research is not indicated; descriptive research methods are appropriate when answering the question '*what is going on'*? (de Vaus, 2001). However, for the question regarding the effectiveness of AKCs it could be argued that experimental research would be appropriate. The randomised

controlled trial (RCT), a form of experimental study, is regarded as the pinnacle of research or ‘gold standard’ when assessing the effectiveness of an intervention (Polit and Beck, 2012; Lock and Nguyen, 2011; Robson, 2011; Eccles et al., 2003). Robson (2011 p99) contests this suggesting that reliance on RCTs as the sole criterion for scientific rigour ‘detracts from the main question when one is assessing an inquiry….; has the overall case made by the investigator been established to a degree that warrants tentative acceptance of the theoretical or empirical claims that were made’? Experimental research has also been criticised as it does not capture service inputs which may contribute to outcomes in natural settings (Bowling, 2014; Blaxter, 2010) and it has been acknowledged that experimental approaches tend to work better with relatively straightforward matters (Denscombe, 2014). In this instance the causes of delay are complex with numerous factors contributing to it and therefore any intervention to reduce delay is unlikely to have a clear causal pathway. As a consequence there is great difficulty in choosing control variables to exclude all confounding variables, another recognised drawback of experimental designs (Bowling, 2014; Blaxter, 2010). Experimental designs possess further disadvantages; they are costly, time consuming and methodologically challenging and it is argued that they should only be used where there is doubt as to whether an intervention is effective (Eccles et al., 2003). Furthermore, due to a lack of information on effect size it is not possible to determine accurately the appropriate sample size for a trial. A final significant downfall of experimental research is that whilst such designs are effective in isolating the impact of an experimental variable and can therefore determine the size of effect it has, it does not allow appreciation of the reasons *how* or *why* it affects outcome (de Vaus, 2013). Due to concerns regarding the appropriateness and

suitability of an experimental design, non-experimental (observational) designs were considered.

Retrospective designs (such as case notes review) as previously stated (2.3.3) are subject to missing and incomplete data (Nagurney et al., 2005) and therefore were deemed unsuitable to gather the required information. A prospective longitudinal cohort design would reduce the chance of recall bias compared to a cross-sectional design but was not a suitable choice in the present study because:

- Whilst ACL injuries are the most common cause of pathologic motion they still make up a low overall percentage of knee injuries encountered.
- Cases may present at many different sites making it unfeasible to ensure all potential cases are identified at initial presentation.
- Recall bias would not be eliminated as patients would still have to recall the time of initial injury.
- On the basis of previous evidence of delay to diagnosis and specialist consultation the cohort would have to be followed up over many years.

The methodology chosen was a cross-sectional survey. This allowed data to be collected simultaneously at a number of sites within a relatively short time period.

Surveys involve the systematic collection of data without active intervention and is regarded as inherently positivistic and quantitative (de Vaus, 2013; Abramson and Abramson, 2011; Robson, 2011; Creswell, 2003). As with any research methodology there are advantages and disadvantages to surveys (table 13).

**Table 13: Advantages and disadvantages of surveys**

| Advantages | Disadvantages |
|---|---|
| • Can aim at representation and provide generalised results<br>• Simple and straight forward, easy to administer<br>• High amounts of data standardisation<br>• With a good response rate can provide lot of data relatively quickly | • Data are affected by the characteristics of respondents (memory, knowledge etc.)<br>• Surveys rely on breadth rather than depth for validity (a particular problem for small scale research) |

(Adapted from Robson (2011 box 10.2; p240-241); Blaxter (2010 box 3.15; p79-80))

The survey methodology possessed a number of benefits when considering the aims of this research. It allowed a large amount of data to be collected and was compatible with the aim of generalisation. As opposed to experimental designs it can also provide information on *how* independent variables affect dependent variables (e.g. why AKCs affect delay) (de Vaus, 2013). Furthermore, surveys can be used for both descriptive and analytic purposes (Abramson and Abramson, 2011; Robson, 2011; Greenfield, 2002), an advantage for the outlined research purposes and allowed the first two research questions to be answered with a single study.

### 3.5.2 Methodological choice for study 2: Structured observation

The third research question aimed to understand whether differences occurred in the clinical examination of acute knee injuries by specialist orthopaedic, non-specialist orthopaedic and A&E clinical staff and was addressed in study 2. A longitudinal or experimental design was not required as the purpose was not to determine outcome, which in the case of ACL injury can take months or even

years to determine and is subject to multiple factors which are unrelated to initial clinical examination. A non-experimental observational design was therefore chosen. 'Observation involves the systematic viewing of people's actions and the recording, analysis and interpretation of their behaviour' (Gray, 2013 p397). In keeping with the theoretical perspective observation was structured, an approach that is primarily quantitative and focusses on the frequency of actions (Gray, 2013). The advantages and disadvantages of a structured observational design are given in table 14.

**Table 14: Advantages and disadvantages of structured observation**

| Advantages | Disadvantages |
|---|---|
| • It should result in more reliable data because the results can be replicated<br>• It allows data to be collected at the time they occur and therefore does not rely on recall of participants or their interpretation of events<br>• It collects data that participants themselves may not realise are of importance | • The researcher must be at the place where the events are occurring and at the appropriate time<br>• Only overt actions can be observed, from which often subtle inferences have to be made |

adapted from Gray (2013 page 407)

## 3.6 Data collection methods

The choice of data collection methods is an important consideration as part of the wider study design in determining how reliable and valid the data will be. Such considerations are of importance when considering the overall worth of a study. A broad overview of the methods of data collection for each of the two studies is given within the following subsections.

### 3.6.1 Data collection method for study 1: Questionnaire administered by interview

A questionnaire, most commonly used within cross-sectional survey designs (Greenfield, 2002), was chosen as the data collection instrument in the first study. Whilst other methods of obtaining survey data have been acknowledged (e.g. observation, content analysis, in depth interviews (de Vaus, 2013)) the questionnaire was deemed the most efficient way of gaining the data required. With any research design ensuring data quality is paramount and in the instance of a questionnaire the mode of data collection can seriously affect the quality of data obtained (Bowling, 2005). Modes of questionnaire administration include self-completion (e.g. postal), internet based, face-to-face via interview and telephone (Robson, 2011; Bowling, 2005).

The principle weakness of self-completed questionnaires (internet, in person or postal) is a low response rate which is particularly problematic as responders and non-responders may systematically differ (Mann, 2003). Furthermore, added to the high probability that some questions will be ignored, questions may also be misinterpreted and/or answers inadequately detailed (Hicks, 2004). Telephone administration has also been criticised due to the difficulty in contacting respondents and therefore the potential for lower response rates (de Vaus, 2013). The mode of administration chosen was face-to-face interview with completion of the questionnaire by the attendant health professional. Face-to-face interviews are more likely to elicit serious, considered responses to questions and overcome respondent literacy problems (Gillham, 2000). This reduced the threat of non-response bias to data quality, and was anticipated to be the most convenient data collection approach as patients would already be attending a clinic. A further advantage in using the health professional to

interview patients was that medical notes could be reviewed simultaneously to ensure data was as accurate as possible. In the present study this was especially pertinent to most accurately determine date of injury, dates and type of clinic attendance and number of healthcare appointments reducing recall bias. Face-to-face interviews have been criticised as the quality of answers can be compromised in cases where questions may be sensitive or controversial (de Vaus, 2013). However, the topic under investigation did not produce such problems.

Prospective designs identify a group of people and collect information at the time of attendance in a particular service (Hicks, 2004). Whilst prospective designs involve a longer data collection phase it has the advantage of reducing non-response bias compared to retrospective designs and can enhance data quality (Hicks, 2004). Patients were therefore identified prospectively within this study.

### 3.6.2 Data collection method for study 2: Non-participant direct observation

A number data collection methods could be used to determine what takes place during a clinical encounter including direct observation of the clinical encounter, review of medical notes, audiotape, interview, questionnaire and video observation.

The review of medical notes to determine the content of clinical examination has an advantage over direct observation by reducing or negating the observer effect but poses a number of disadvantages. Large discrepancies have been found between directly observed assessment or audio recorded assessment and that reported in medical records (Sharma, 2011; Wilson and McDonald,

1994). Furthermore, data obtained from medical records as a method for determining assessment quality in an outpatient clinical setting has been criticised as time constraints may result in recording bias leading to an incomplete picture of the assessment (Peabody et al., 2000). The result of recording bias has been shown to underestimate clinician performance through a high false negative rate whereby a significant proportion of the clinical examination is not recorded, but may also overestimate clinician performance in some cases due to false positive reporting (Dresselhaus et al., 2002).

Interviews and questionnaires are further data collection methods that could have been used to determine what occurred in the clinical encounter but it has been suggested these methods are of limited value in determining behaviour as the correlation between what people do, and say they do, is often low (French et al., 2001).

Audio tape recording of the clinical examination was discounted as it would not allow appreciation of the physical examination tests, a key area of interest.

Video observation has been proposed as a reliable data collection method in cases where fleeting events, simultaneous interventions or brief interactions occur when direct observation may not reliably capture all data (Mackenzie and Xiao, 2003). However, in study 2 the observation was undertaken on a single patient assessment in a setting with only the clinician and patient present and therefore simultaneous events would not be encountered. Video observation also posed a number of disadvantages. It has been shown to be intrusive and influential in clinical decision making (Ram et al., 1999). Further, the presence of video cameras is unacceptable for some patients with 13% refusing to be filmed in a study within a doctors surgery (Martin and Martin, 1984). Among

patients who did consent, 11% disapproved of being filmed, 16% were constantly aware they were being filmed and 11% reported that the video camera made them feel nervous. In contrast to this a study undertaken in a similar setting, Servant and Matheson (1986) reported that only 10% of patients consented to having their consultation video recorded. Whilst these studies took place in a different generation and cannot be applied directly to an A&E or orthopaedic environment, they show that recording clinical examinations may lead to problems with consent and participation. Video observation also poses significant logistical difficulties; in the observational study multiple cameras would have been required to ensure that all physical examination tests could be appreciated and the clinical examination would have had to be undertaken outside of the usual environment, negating one of the potential benefits of observation.

The method chosen was direct observation of the clinical encounter. Observation is of use in situations where the interaction of interest is hidden such as in a clinical examination whereby only the assessor and patient would normally be present. Direct observation has the advantages of providing a 'real life' setting (Robson, 2011; French et al., 2001) and allows appreciation of the clinical encounter in real time. Robson (2011 p316) states that 'direct observation…permits a lack of artificiality which is all too rare with other techniques'. A further advantage is that no effort is required from research participants (French et al., 2001).

Non-participant, as opposed to participant, observation was chosen as the method to determine what happens in the clinical assessment and is in keeping with the adopted post-positivist philosophical stance. Participant observation (associated with an ethnographic methodology) involves engagement with

people in the research setting with the researcher becoming a member of the group (Gray, 2013). This posed notable disadvantages; the timescale required to integrate within the groups and the potential for the researcher to change usual practice.

## 3.7 Reliability and validity

French et al. (2001) emphasise the importance of critically considering the quality of the data that will be gathered in any research project. 'Within quantitative studies, rigour is determined through an evaluation of the validity and reliability of the tools or instruments used in the study' (Heale and Twycross, 2015 p2). Issues of reliability and validity for the studies undertaken are considered in chapters 4 and 7 but the concepts are introduced here.

### 3.7.1 Reliability

Reliability relates to the consistency, accuracy, stability and predictability of a measure (Heale and Twycross, 2015; Burns, 2000). If a method or instrument for collecting data is reliable it would provide the same results when repeated at another time or by another person (McNeill, 2005). This relates to two types of reliability; intra-rater and inter-rater reliability. French et al. (2001) also suggest that reliability relates to the extent that research participants would supply the same answers on a given test at a different occasion, a concept related to the stability of a measure (Heale and Twycross, 2015; Gray, 2013). However, even a reliable measurement will not yield constant results where change occurs in the domain of measurement (Sapsford, 2007). Reliability is of paramount importance; if a research instrument is unreliable it has been stated that it

cannot be valid (Gray, 2013). Even when reliable, the relevance or quality is not guaranteed; for this to be achieved the research should be valid (French et al., 2001).

### 3.7.2 Validity

'Validity refers to the problem of whether the data collected is representative of what is being studied' (McNeill, 2005 p15). It has been defined as 'the extent to which a concept is accurately measured' (Heale and Twycross, 2015 p1). In a broader sense this relates to the appropriateness of the entire research design and confidence in acquired knowledge (French et al., 2001). More simplistically, it may relate to a validity of a specific research instrument; will it measure that which it was intended to measure (Gray, 2013).

## 3.8 Chapter summary

This chapter has set out the philosophical position and provided detail on the methodological choices based on the research questions. A summary of the philosophy, theoretical perspective, methodology and data collection methods forming the overall research design are indicated in table 15. The following chapter explores the methods used to undertake study 1 including the formulation of the questionnaire used to obtain data.

**Table 15: Summary of the research design**

| Ontology and epistemology | Theoretical perspective | Methodology | Data collection methods |
|---|---|---|---|
| Realist<br>Objectivist | Post-positivist<br>Pragmatist | **Study 1:**<br>Cross-sectional survey | **Study 1:**<br>Questionnaire completed by face to face interview |
| | | **Study 2:**<br>Cross-sectional Non-experimental | **Study 2:**<br>Non-participant direct observation |

based on the model by Crotty (1998)

# Chapter 4: Methods: Study 1: A multi-site survey into the nature of, and factors associated with delay.

## 4.1 Introduction

The literature review established the deficiencies in the existing evidence base on delay to diagnosis and specialist consultation in a number of areas, principally in the nature of delay and the factors which contribute towards it. Furthermore, an intervention proposed to reduce delay, the streamlining of patients to an AKC facilitating earlier specialist review, had not been effectively evaluated. This chapter details the formulation of the questionnaire used during the multi-site survey into delay to ensure a more complete understanding of the phenomenon. It also presents and justifies the methods used to accomplish the aims of the study including sampling, data collection, methods of data analysis and ethical considerations.

## 4.2 Aims, objectives and hypotheses

The aim of this exploratory study was to explore the period of delay between time of initial injury and specialist consultation amongst patients who have suffered ACL injury and attended specialist led orthopaedic services as a result. Research questions have been stated previously (see 2.9).

Specific objectives of this study were:

- To describe key elements of delay (defined in 4.3.1.1) specifically:
    - Patient delay to initial health service presentation

    - Waiting list delay to see a specialist
    - Delay to diagnosis
    - System delay to diagnosis
    - Delay to specialist consultation
    - Adjusted delay to specialist consultation
- To determine the injury features at the time of, and shortly following, injury specifically:
    - Giving way
    - Swelling (knee effusion)
    - Inability to continue activity
    - Hearing or feeling a pop at the time of injury
- To determine factors which impact on delay periods, specifically:
    - Age
    - Sex
    - Activity at the time of injury
    - Location of initial attendance
    - Attending an acute trauma service (A&E or minor injury unit [MIU])
    - Whether follow-up appointment arranged following initial attendance to A&E or MIU
    - MRI scan
- To determine consequences of delay:
    - Number of health care service appointments until diagnosis
    - Number of episodes of giving way
- To ascertain the outcome of MRI scans
- To determine the impact of an AKC on delay

The final research aim was to investigate whether the operation of an AKC impacted upon the following measures of delay:

- Total delay to diagnosis
- System delay to diagnosis
- Adjusted delay to specialist consultation
- Total delay to specialist consultation

In each case the null hypothesis (that delay periods would not differ between sites) was tested.

## 4.3 Questionnaire development

A structured questionnaire with closed questions was developed for the study in order to answer the research questions and fulfil the outlined objectives. Closed ended questions were used as they are better suited to quantitative analysis (Gillham, 2000) and therefore aligned with both the adopted philosophical approach and methodology. With regard to the study aims and objectives, in comparison to open questions, closed questions are useful when testing specific hypotheses, make group comparisons easier and require less interviewer training (Oppenheim, 2000). This was an advantage in this study where interviewers were located at geographically distant locations and therefore it was only possible for the lead researcher to make sporadic visits to included sites.

### 4.3.1 Content

When constructing a questionnaire it is important to identify the information which needs to be collected to describe the phenomenon (Greenfield, 2002). De Vaus (2013) states that in order to conduct a survey it is imperative that concepts are clarified, defined and justified prior to questionnaire construction. The following subsection details a framework used to report delay including definitions for delay periods and key time points.

#### *4.3.1.1 Definitions of delay*

The literature review highlighted a lack of agreement on how delay is defined with many studies failing to clarify definitions or provide a framework for establishing the elements making up overall delay. In order to achieve the aim of describing important elements of delay a model was created encompassing key periods from the time of injury to specialist consultation (figure 15).

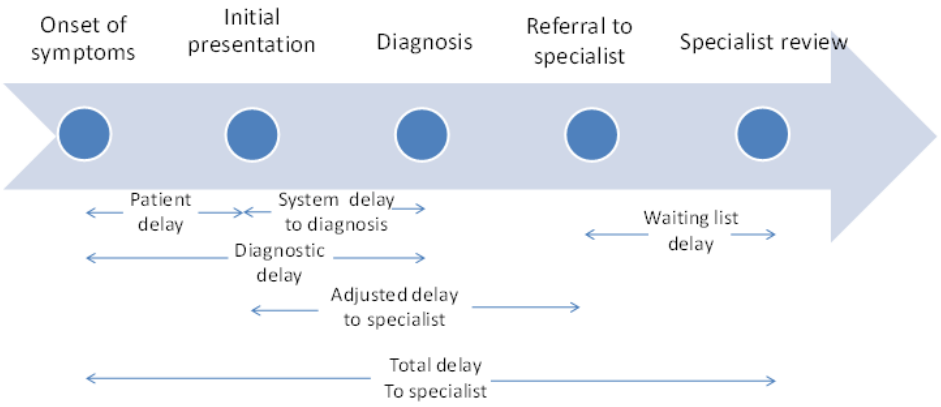



**Figure 15: Model of delay**

In order to provide clarity of the delay period, key time points and timescales were defined (tables 16 and 17).

**Table 16: Key time points**

| |
|---|
| **Injury date:** Date patient suffered *initial* injury causing event or, in the event that they were unable to recall injury, when they first became aware of symptoms. |
| **Initial presentation date:** The point at which the patient first presented to a healthcare professional about their knee complaint following ACL injury. |
| **Date of diagnosis:** The point at which the patient was made aware of a correct diagnosis of the knee complaint (i.e. ACL injury). |
| **Referral date to specialist:** The point at which the patient was referred through to a specialist with experience in the management, including surgery, of the ACL deficient knee. |
| **Specialist review date:** The point at which the patient first has contact with a specialist with experience in the management, including surgery, of the ACL deficient knee. |

**Table 17: Key timescales**

| |
|---|
| **Patient delay:** Time from initial injury causing event, or first awareness of symptoms, to initial presentation to a health professional. |
| **Delay to diagnosis:** The time from initial injury until the patient is made aware of a diagnosis of anterior cruciate ligament injury. |
| **System delay to diagnosis:** The time from initial presentation to diagnosis |
| **Waiting list delay:** The time period from referral to a specialist until first specialist consultation |
| **Adjusted delay to specialist:** The time from first contact with the healthcare system to specialist review removing waiting list delay. |
| **Delay to specialist consultation:** Time from initial injury until first seen in a specialist led clinic. |

### 4.3.2 Pre-pilot phase

Questions regarding delay were devised from the literature review and the subsequently developed model of delay. Four key domains for question development were identified to provide logical ordering within the questionnaire:

- Background information
- Details about the injury

- Symptoms following the injury
- Details about the medical consultations

The identified domains were populated with individual questions based upon the model of delay and the stated aims and objectives.

To establish face and content validity three specialists working with soft tissue knee injuries reviewed the document in relation to the study objectives and for question clarity. This led to further minor rewording and change in the ordering of questions.

### 4.3.3 Pilot phase

The questionnaire was piloted by three clinicians working in specialist knee clinics in a large urban teaching hospital on 20 patients and this resulted in further amendments. Originally the questionnaire contained separate items on whether the patient had ‘heard’ or ‘felt’ a pop at the time of injury. This led to confusion as some patients were aware they had experienced a ‘popping’ sensation but could not determine whether this was audible or felt; this was therefore combined into a single question. In addition, further clarification regarding the use of medical records was incorporated onto the form to ensure that the most accurate date was presented for date of injury and date of diagnosis. For example, if the patient presented to the hospital on the date of injury medical records could be reviewed in order to establish the exact date of injury. It was felt that this change would minimise the effect of recall bias. The final version of the questionnaire contained 29 questions (see Appendix III).

### 4.3.4 Inter-rater agreement

Agreement has been defined as the degree to which scores, values or ratings on an instrument are identical, and differs from reliability which aims to determine extent of variability and inherent error (Gisev et al., 2013). Within the context of this study it was important to ascertain the extent to which different raters assign the same value for each item on the questionnaire, thus agreement was sought. As the study included a number of raters across different sites it was important to establish inter-rater agreement of the tool. A test-retest method was employed as it is the only acceptable method when assessing single item indicators (de Vaus, 2013).

The inter-rater agreement was established from data collected within two hospital trusts. Two questionnaires were completed via face-to-face interview for 16 patients with the clinician completing the second questionnaire blinded to responses obtained during the first interview. Based on suggestions from de Vaus (2013) a minimum time period of two weeks was chosen between completion of the first and second questionnaire in order to minimise the chance that patients could recall answers given previously. Whilst the answers to most questions were generally deemed stable (not subject to short term change) there were some where answers may have legitimately changed between the first and second administration of the questionnaire (e.g. number of episodes of giving way). Therefore all patients had the second questionnaire completed within four weeks of the first. Questions related to background information (i.e. patient identification number, clinic date, referral source and referral date) were not included in the agreement study as this information was obtained directly from medical records.

#### *4.3.4.1 Analysis*

Kappa values were calculated for categorical variables and weighted Kappa was calculated for ordinal and interval level variables. In instances where the response was a date (e.g. date of injury, date of diagnosis) percentage agreement is reported along with median and range. All analysis for the inter-rater agreement of the survey questionnaire was undertaken in Stata Software: Release 14 (StataCorp, College Station, TX).

#### *4.3.4.2 Results*

The results of the inter-rater agreement are shown in table 18.

**Table 18: Inter-rater agreement of the survey questionnaire**

| Question number | Agreement (%) | Expected agreement (%) | Kappa | Standard error. | z | p value |
|---|---|---|---|---|---|---|
| 5 | 100 | 62.5 | 1.0 | 0.25 | 4 | <0.001 |
| 7 | 100 | 50.8 | 1.0 | 0.25 | 4 | <0.001 |
| 8 | 100 | Not possible to calculate (too few ratings categories) | | | | |
| 9 | 100 | 35.2 | 1.0 | 0.13 | 7.72 | <0.001 |
| 11 | 100 | 53.1 | 1.0 | 0.25 | 4 | <0.001 |
| 12 | 100 | 77.3 | 1.0 | 0.19 | 5.16 | <0.001 |
| 13 | 93.75 | 50.8 | 0.87 | 0.23 | 3.87 | <0.001 |
| 14 | 100 | 78.1 | 1.0 | 0.25 | 4 | <0.001 |
| 15 | 100 | Not possible to calculate (too few ratings categories) | | | | |
| 16* | 95.31 | 59.57 | 0.88 | 0.18 | 4.84 | <0.001 |
| 17 | 93.75 | 56.6 | 0.86 | 0.20 | 4.2 | <0.001 |
| 18* | 96.88 | 65.62 | 0.91 | 0.18 | 5.19 | <0.001 |
| 19 | 100 | 60.2 | 1.0 | 0.20 | 4.89 | <0.001 |
| 21 | 100 | 78.1 | 1.0 | 0.25 | 4 | <0.001 |
| 22 | 100 | 69.5 | 1.0 | 0.25 | 4 | <0.001 |
| 22a | 100 | Not possible to calculate (too few ratings categories) | | | | |
| 23 | 100 | 85.8 | 1.0 | 0.28 | 3.61 | <0.001 |
| 25 | 100 | 46.1 | 1.0 | 0.18 | 5.51 | <0.001 |
| 26* | 98.6 | 62.8 | 0.96 | 0.17 | 5.69 | <0.001 |
| 27 | 100 | 57.0 | 1.0 | 0.25 | 4 | <0.001 |
| 28 | 100 | 34.0 | 1.0 | 0.22 | 4.45 | <0.001 |
| 29 | 100 | Not possible to calculate (too few ratings categories) | | | | |

*weighted kappa

There was 100% agreement on patient age. It was not possible to use Kappa statistics to determine the agreement among dates due to the nature of the data. Inter-rater agreement on the date of injury was 68.8% (n=11/16). For the five discordant pairs median discrepancy was 3 days (range 1 to 14 days). There was agreement on the number of days to initial presentation following injury in 87.5% of cases (n=14/16) with discrepancies of 1 day noted in the other two cases. Percentage agreement on date of diagnosis was 62.5% (n=10/16). For discordant pairs the median discrepancy was 14 days (range 1 to 30 days).

#### *4.3.4.3 Discussion of agreement for the survey questionnaire*

Results of the Cohen's Kappa and weighted Kappa analysis for categorical, ordinal and interval level questions showed 'very good' and 'almost perfect' agreement for the majority of questions based on interpreting guidelines (Altman, 1991; Landis and Koch, 1977). The percentage agreement for dates indicated that the majority were in agreement and where discrepancies occurred differences were found to be minor. Consequently the questionnaire was deemed suitable for use in the cross-sectional survey.

## 4.4 Sampling methods

Two separate sampling strategies were employed; the first to identify hospital sites and the second to sample cases within each of the chosen sites.

### 4.4.1 Sampling of hospital sites

Hospital sites for the service evaluation were chosen through a purposive and convenience sampling method. Heterogeneous (a.k.a. maximum variation) sampling is a type of purposive sampling used to capture a wide range of perspectives from the study of interest in order to gain greater insight into a particular phenomenon (Patton, 1990). Whilst this sampling method does not allow results to be generalisable to an entire population it can still permit analytic, theoretical and/or logical generalisations to be made from the study under sample (de Vaus, 2013). A strength of using a maximum variation sample is that any common patterns emerging are of value in understanding core experiences or impacts of an intervention (Patton, 1990). To provide a varied sample and to fulfil the stated study aims, sites were sought that varied in unit size and type (e.g. district general hospital or teaching hospital), catchment area (urban and rural) and on whether they streamlined patients with acute knee injuries to a specialist. Undertaking a multi-centre study and recruiting different hospital types allowed the research to be more representative of the variation in delay as opposed to previous research of single sites which may be more likely to show exceptional cases. Due to financial and time constraints all of the study sites approached were located within the West Yorkshire and North Lincolnshire regions.

Specialist clinicians from six hospital trusts were contacted by telephone or email and provided with information regarding the purpose and requirements of involvement in the study. A follow-up face-to-face visit was undertaken at all sites in order to meet the clinicians, further explain the purposes of the study and answer emergent questions regarding expectation and requirements on

study involvement. All clinicians approached agreed to participate in the study following which hospital Research and Development process was followed in order to ensure organisational approval of work (4.7). At one site, despite numerous telephone conversations and emails, it was not possible to gain organisational approval for the study to take place within the study timeframes and therefore five sites were recruited into the study. The detail of included sites is displayed in table 19.

**Table 19: Detail of study sites**

| Organisation name | Approximate population covered by the organisation | Number of soft tissue knee specialist consultants | Acute knee clinic |
|---|---|---|---|
| Airedale NHS Foundation Trust | 200,000 | 1 | No |
| Bradford Teaching Hospitals NHS Foundation Trust | 500,000 | 2 | No |
| Leeds Teaching Hospitals NHS Trust | 780,000 | 3 | Yes |
| Mid Yorkshire Hospitals NHS Trust | 500,000 | 3 | No |
| North Lincolnshire and Goole Hospitals NHS Foundation Trust | 400,000 | 1 | No |

### 4.4.2 Sampling at each site

In order to limit selection bias, a consecutive cases sampling strategy was employed at each site. It is suggested that random sampling methods are the most appropriate way to ensure the sample is representative (Gillham, 2000; Oppenheim, 2000), however inclusion of all emergent cases allowed a clear representation of the current levels of delay and also minimised selection bias (Ignatius and Shelly, 2011). Further, this was the most efficient way to obtain the desired number of patients within an acceptable timeframe.

### 4.4.3 Sample size

The total planned sample size was 250 spread equally between the sites (50 per site). As this study was primarily exploratory in nature and, at the time of study commencement, insufficient evidence on the effect size of AKCs on delay was available, a formal sample size calculation was not undertaken. The sample was larger than any identified studies investigating diagnostic delay following ACL injury and expected to be achievable within the logistical constraints of the study (time-frame [see also 4.9], local site accessibility and cost).

## 4.5 Inclusion and exclusion criteria

*Inclusion criteria:*

- Patients with a primary ACL injury attending a specialist clinic
- Diagnosis based on at least one of: clinical diagnosis, MRI or arthroscopy

*Exclusion criteria:*

- Patients with multiple ligament injuries
- Previous history of diagnosed ACL injury with attendance to a specialist clinic
- Previous ACL reconstructive surgery

## 4.6 Bias

Cross-sectional studies are prone to bias (Bowers et al., 2006) and it was therefore important to recognise possible causes of bias arising from the study design and ensure the chosen methods minimised risk. Table 20 details the potential sources of bias together with the methods to minimise their effect.

Table 20: Bias and methods employed to control

| Bias | Methods employed to control bias |
|---|---|
| Selection bias | • Aimed to recruit consecutive cases at each site.<br>• Clear eligibility criteria. |
| Recall bias | • Prospective case identification allowing earlier completion of the questionnaire.<br>• Patient case notes available for review at the time of interview to ensure information recorded was as accurate as possible. |
| Non-response bias | • Completion of the questionnaires via a face-to-face interview at the time of specialist consultation. |
| Measurement bias | • Piloting of the questionnaire<br>• Content review by soft tissue knee specialists<br>• Closed unambiguous questions<br>• Face-to-face interview method used reducing question misinterpretation and allowing clarification when required.<br>• Patient case notes used alongside interviews to maximise accuracy. |

## 4.7 Ethical approval

Based on NHS guidance document entitled 'Defining Research' the study was considered to be a service evaluation and as such did not require research ethics committee (REC) review (HRA [Health Research Authority], 2013). Ethical approval was gained from the Humanities, Social Sciences and Health Studies Research Ethics Panel at the University of Bradford (ref: EC1554) and at each participating site via research and development/clinical governance departments prior to study commencement (see Appendix IV).

## 4.8 Administration of the questionnaire

The mode of questionnaire administration has been discussed and justified previously (see 3.6.1). The questionnaire was completed by the clinician assessing the patient within the specialist knee clinic with the patient in attendance at a single outpatient appointment.

## 4.9 Feasibility and timescales

Prior to commencing the study, data on the number of ACL injuries was collected from two of the hospital sites (Bradford and Leeds) to identify the expected length of time to recruit cases. Based on data on ACL case levels from the preceding 12 months it suggested that, for a hospital site covering a population base of 500,000, it would take approximately 6-8 months to obtain data on 50 patients with ACL injuries.

## 4.10 Procedures

A flow chart detailing the process is shown in figure 16.

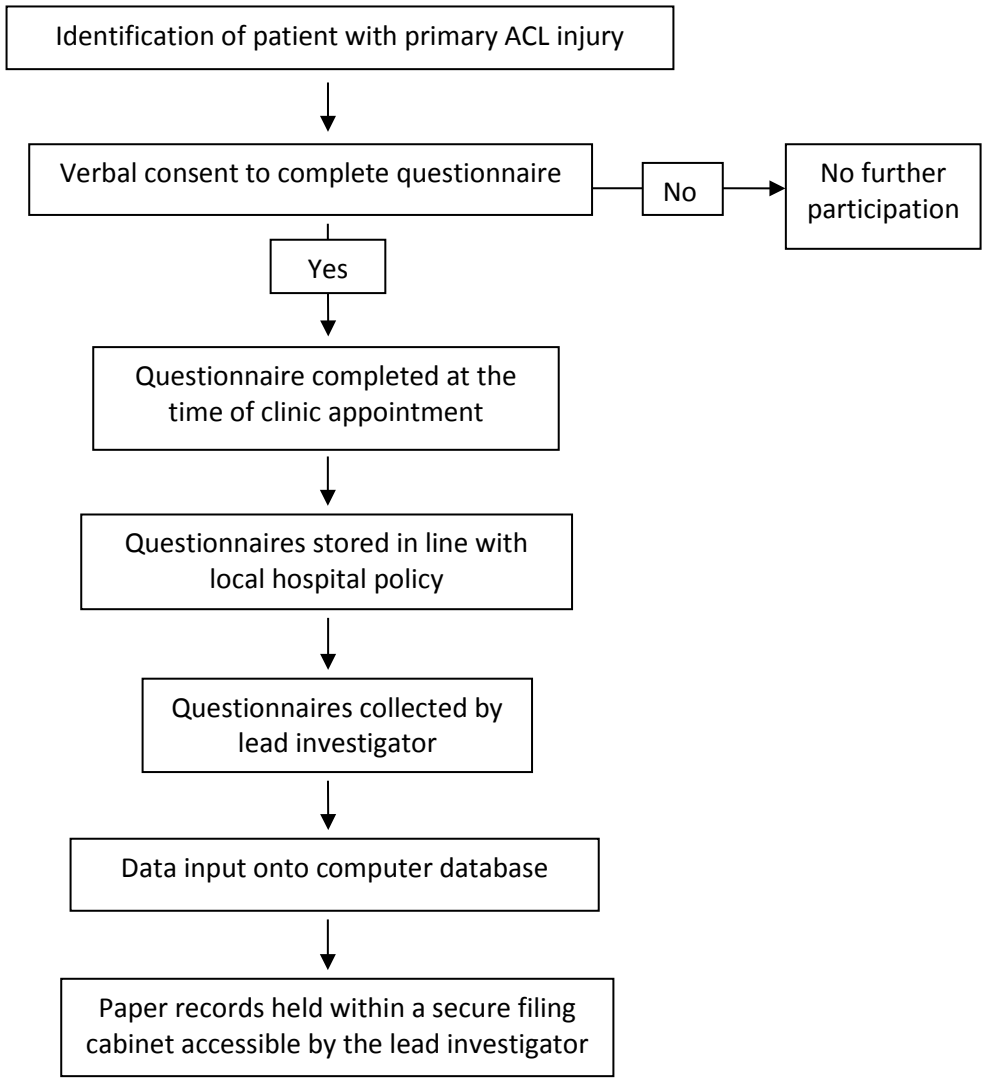



**Figure 16: Flow chart showing process for completion, handling and storage of data**

## 4.11 Data storage

Data extracted from the data collection forms were stored within an Excel database (Microsoft Excel [computer software], 2010: Redmond, Washington: Microsoft) on a password protected computer. A unique study identifier was included on the paper questionnaires and imported into the database for each case to allow cross checking of data. No patient identifiable data (name, date of birth, address) were contained either on the questionnaire or database. Paper copies of the completed data collection forms were held within a locked filing cabinet accessible by the lead investigator (CA).

## 4.12 Data handling

All delay periods were calculated in days based on the difference between dates within the returned survey questionnaires. Where reported dates were inexact, midpoint rules were applied to estimate the actual date for analysis purposes (Usher-Smith et al., 2015; Allgar and Neal, 2005). Specifically, where the month was supplied but not an exact date, the mid date of the month was used. If the date was reported as ‘early’ or ‘late’ within a given month, the first or last date of the month was used respectively.

## 4.13 Statistical methods

### 4.13.1 Descriptive statistics

Descriptive statistics were used to summarise patient characteristics, information about the initial injury (including reported injury history features),

symptoms following the initial injury, information regarding consultations and delay periods.

Normality of data was assessed through visual inspection of histograms and where data were not normally distributed, log transformation was attempted. Median values were presented for all types of delay in order to allow comparison with other research, with geometric mean values reported where appropriate. Despite the widespread use of arithmetic mean values to summarise delay within other research studies, it was deemed inappropriate to report this in conditions where data were not normally distributed (2.7). Both the interquartile range (IQR) and range were used to summarise the spread of the data as each affords different information regarding the data and allowed comparison with other research.

### 4.13.2 Bivariate analysis

De Vaus (2013 p.241) states that 'the heart of bivariate analysis is to see whether two variables are related (associated) with the main purpose being to assist in explanation as to *why* variation in delay exists. Although bivariate analysis has limitations, principally that it does not account for the impact of other variables, it is a fundamental first step in achieving explanations (de Vaus, 2013).

Bivariate analysis was undertaken to determine the influence of identified factors (4.2) on delay to diagnosis and specialist consultation. In order to account for patient and waiting list delay, system delay to diagnosis and adjusted delay to specialist consultation were also incorporated to allow maximal understanding on how each factor impacts on delay.

Parametric analysis was undertaken where conditions for its use were satisfied. Where conditions were not immediately satisfied data were log transformed and the conditions for undertaking parametric analysis reassessed (table 21). Prior to log transformation, any values for delay of 0 days were revalued to 0.5 days to ensure that data were not lost during the process.

**Table 21: Conditions for undertaking parametric analysis**

| Statistical test | Conditions for undertaking parametric analysis | Assessment measures |
|---|---|---|
| Independent samples t-test | • Normal distribution of both groups<br>• Equality of variance | • Inspection of histograms<br>• Comparison of between group standard deviation |
| Linear regression | • Residuals normally distributed for each value of the predictor variable | • Histogram of residuals |
| | • Variance of the dependent variable constant for each value of the explanatory variable (homoscedasticity) | • Scatter plot of residuals vs. explanatory variable |
| | • Relationship between continuous variables is linear | • Scatter plot of residuals vs. fitted values |

Bivariate analysis of dichotomous explanatory variables was undertaken using independent samples t-tests (parametric) or Mann Whitney U tests (non-parametric). The influence of explanatory variables containing three categories were assessed using regression analysis (parametric) or Kruskal-Wallis tests (non-parametric). Relationships between ordinal and continuous variables and delay were analysed using linear regression (parametric) or Spearman's rank correlation (non-parametric). Where parametric analysis was appropriate, emphasis was placed upon estimation of effect size and its uncertainty rather than simple hypothesis testing.

Summary tables were used to display the results of the bivariate analysis with geometric mean and 95% confidence intervals used as summary measures for categorical explanatory variables analysed with parametric tests. Categorical

data analysed using non-parametric tests were summarised using median and interquartile range. The relationship between statistically significant categorical variables was displayed using box-and-whisker plots with scatter plots used to display relationships between ordinal/continuous explanatory variables and delay.

### 4.13.3 Multivariable analysis

Multivariable regression analysis has a distinct advantage over bivariate analysis by accounting for multiple explanatory variables simultaneously, yielding more precise information on the association between explanatory variables when considered individually or grouped (Marill, 2004). However, this approach is not immune from confounding which can impede analysis and threaten accurate interpretation (Graham, 2003).

Multicollinearity, a phenomenon where two or more variables are highly correlated, can be problematic when using multiple regression as it reduces model validity to determine the influence of individual variables on the outcome variable (Alin, 2010). This was critical to this study as it was undertaken to determine the contribution of individual variables rather than the ability of the model as a whole to predict delay. It was recognised that two variables were closely associated (initial attendance location and whether the patient attended A&E or MIU). Consequently, in order to avoid problems with collinearity, the variable identified as least predictive of delay in the bivariate analysis was omitted. Site of attendance also posed problems with collinearity as it directly relates to whether an acute knee clinic pathway was operated. In order to take site into account, a random effects multivariable regression model was

developed. Collinearity amongst the remaining explanatory variables was assessed via Variance Inflation Factor (VIF)[3] testing.

Multivariable regression analysis was undertaken using all other explanatory factors regardless of whether it was noted to have a statistically significant influence on delay within the bivariate models. This decision was taken as each explanatory variable made a potentially important contribution to the multivariable regression model even when non-significant in the bivariate model and had the potential to become significant when considered alongside other factors.

Methods to adjust for multiple testing were not used as each variable was considered of individual importance. Whilst reducing the chance of rejecting the null hypothesis when it is true (type I error), methods of adjusting for multiple testing are not without critics, Perneger (1998) notes that type II error rates are increased with the use of Bonferroni adjustment and this method is concerned with a general null hypothesis, which is of questionable value to a researcher. Further criticism arises from the theoretical basis for adjustment for multiple comparisons, that observed differences are based on the first-order explanation of 'chance' (Rothman, 1990). It is argued that this undermines a basic assumption of empirical research that observation can be used to make sense of a phenomenon as regular laws are followed in nature (Rothman, 1990).

[3] Variance Inflation Factor (VIF) is a method of quantifying the severity of multicollinearity in an ordinary least squares regression analysis. A VIF of 1 for a given predictor variable indicates no correlation between it and the remaining predictor variables. A VIF of > 10 is a potential indicator of collinearity issues (Yan, X. (2009) Linear regression analysis: theory and computing. New Jersey: World Scientific).

### 4.13.4 Statistical software and significance levels

Figures were produced using Microsoft Excel ([computer software], 2010: Redmond, Washington: Microsoft) and Stata Statistical Software: Release 14 (StataCorp, College Station, TX). All statistical analysis was undertaken using Stata Statistical Software: Release 14 (StataCorp, College Station, TX). Statistical significance was set at $\alpha = 0.05$ for the bivariate and multivariable analysis.

## 4.14 Chapter summary

This chapter has presented the methods for undertaking the multisite survey into delay. The suitability of the questionnaire and interview method of administration has been established. The following chapter presents the results from the survey.

# Chapter 5: Study 1: Results

## 5.1 Introduction

This chapter presents the results from study 1, the multi-site survey of delay. It is organised into the following sections.

- 5.2 Summary of recruitment
- 5.3 Patient characteristics
- 5.4 Information about the injury
- 5.5 Symptoms following the initial injury
- 5.6 Information about consultations
- 5.7 Summary of delay periods following ACL injury
- 5.8 Bivariate analysis
- 5.9 Multivariable regression analysis

Sections 5.2 to 5.7 are primarily summarised using descriptive statistics. Section 5.8 explores the association between individual explanatory variables and delay through bivariate analysis. Section 5.9 presents the multivariable regression analysis considering the effect of each explanatory variable on delay whilst adjusting for all other variables within the model.

## 5.2 Summary of recruitment

### 5.2.1 Data collection

Data collection took place between April 2013 and November 2014. Table 22 shows the date of study approval and first and last patient recruitment at each site.

Table 22: Approval and recruitment dates by site

| Organisation | Date of study approval | Date of first patient recruitment | Date of last patient recruitment |
|---|---|---|---|
| Airedale NHS Foundation Trust | 26/04/13 | 29/04/13 | 19/09/14 |
| Bradford Teaching Hospitals NHS Foundation Trust | 05/12/12 | 02/05/13 | 09/01/14 |
| Leeds Teaching Hospitals NHS Trust | 20/05/13 | 17/06/13 | 18/02/14 |
| Mid Yorkshire Hospitals NHS Trust | 03/05/13 | 25/07/13 | 11/09/14 |
| North Lincolnshire and Goole Hospitals NHS Foundation Trust | 23/04/13 | 23/04/13 | 10/11/14 |

### 5.2.2 Study participants

In total 195 questionnaires were returned of which 194 were included in the analysis. A further single returned survey was excluded from the analysis as it related to a patient who had previously attended a specialist clinic with a correctly diagnosed ACL injury and therefore did not fulfil the eligibility criteria. There were no reported instances of patients refusing to participate.

The number of included questionnaires by site is reported in table 23.

Table 23: Number of included questionnaires by site

| Organisation | Number of questionnaires |
|---|---|
| Airedale NHS Foundation Trust | 33 |
| Bradford Teaching Hospitals NHS Foundation Trust | 50 |
| Leeds Teaching Hospitals NHS Trust | 50 |
| Mid Yorkshire Hospitals NHS Trust | 33 |
| North Lincolnshire and Goole Hospitals NHS Foundation Trust | 28 |
| **Combined Total** | **194** |

### 5.2.3 Individual item response rate

Missing data by question are summarised in Table 24. Question 1 was not used for analysis purposes and has therefore not been included in the table. One item, asking which A&E or MIU department had been attended, was not

completed in 18.2% (n=30/165) of forms with the percentage of missing data 3% or less for all other items on the questionnaire.

**Table 24: Missing data by question**

| Question number | Number of possible inclusions | Number of missing data | Percentage of data missing |
|---|---|---|---|
| 2 | 194 | 1 | 0.5 |
| 3 | 194 | 2 | 1.0 |
| 4 | 194 | 3 | 1.5 |
| 5 | 194 | 0 | 0 |
| 6 | 194 | 0 | 0 |
| 7 | 194 | 0 | 0 |
| 8 | 194 | 0 | 0 |
| 9 | 193 | 1 | 0.5 |
| 10 | 193 | 1 | 0.5 |
| 11 | 193 | 0 | 0 |
| 12 | 193 | 0 | 0 |
| 13 | 193 | 0 | 0 |
| 14 | 193 | 0 | 0 |
| 15 | 193 | 0 | 0 |
| 16 | 188 | 2 | 1.1 |
| 17 | 194 | 0 | 0 |
| 18 | 194 | 0 | 0 |
| 19 | 194 | 1 | 0.5 |
| 20 | 194 | 2 | 1.0 |
| 21 | 194 | 1 | 0.5 |
| 22 | 194 | 1 | 0.5 |
| 22* | 165 | 30 | 18.2 |
| 23 | 165 | 1 | 0.6 |
| 24 | 194 | 3 | 1.5 |
| 25 | 194 | 2 | 1.0 |
| 26 | 194 | 3 | 1.5 |
| 27 | 194 | 2 | 1.0 |
| 28 | 132 | 2 | 1.5 |
| 29 | 132 | 4 | 3.0 |

* refers to the question of which A&E or MIU attended

## 5.3 Patient characteristics

### 5.3.1 Age

The median age of the patients was 26 years (IQR= 22 to 33) with the mean age of 29 years (s.d.= 9.3). Patient age ranged from 11 to 65 years (table 25 and figure 17).

**Table 25: Age by recruitment site (n=194)**

| Organisation | Median age (IQR) | Mean age (s.d.) |
|---|---|---|
| Airedale NHS Foundation Trust | 32 (24 to 42) | 32 (10.8) |
| Bradford Teaching Hospitals NHS Foundation Trust | 26 (20 to 32) | 28 (8.4) |
| Leeds Teaching Hospitals NHS Trust | 24 (20 to 32) | 27 (10.3) |
| Mid Yorkshire Hospitals NHS Trust | 26 (22 to 30) | 27 (6.8) |
| North Lincolnshire and Goole Hospitals NHS Foundation Trust | 27 (24 to 34.5) | 29 (9.2) |
| Combined total | 26 (22 to 33) | 29 (9.3) |

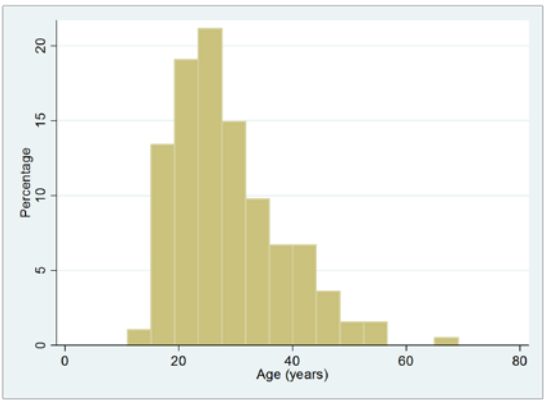



**Figure 17: Histogram of age by percentage**

### 5.3.2 Sex

The majority of patients recruited at all sites investigated were male (n=158/194; 80.4%) (table 26).

**Table 26: Sex by recruitment site (n=194)**

| Site | Number (%) of male patients n (%) | Number (%) of female patients n (%) |
|---|---|---|
| Airedale NHS Foundation Trust | 27 (82) | 6 (18) |
| Bradford Teaching Hospitals NHS Foundation Trust | 44 (88) | 6 (12) |
| Leeds Teaching Hospitals NHS Trust | 34 (68) | 16 (32) |
| Mid Yorkshire Hospitals NHS Trust | 28 (85) | 5 (15) |
| North Lincolnshire and Goole Hospitals NHS Foundation Trust | 25 (89) | 3 (11) |
| Combined total | 158 (80) | 36 (20) |

## 5.4 The initial injury

The right leg was injured in 52.1% (101/194) of cases and the left in 47.9% (93/194) of cases.

### 5.4.1 Activity at time of injury

Football was the most frequently cited activity at the time of injury (114/194; 58.8%) (see figure 18) followed by rugby (23/194; 11.9%) and skiing (12/194; 6.2%). Other sporting activities accounted for 24 cases (24/194; 12.4%). Non sporting activities accounted for 20 cases (20/194; 10.3%). A single patient was unable to recall any specific event where the ACL was first injured.

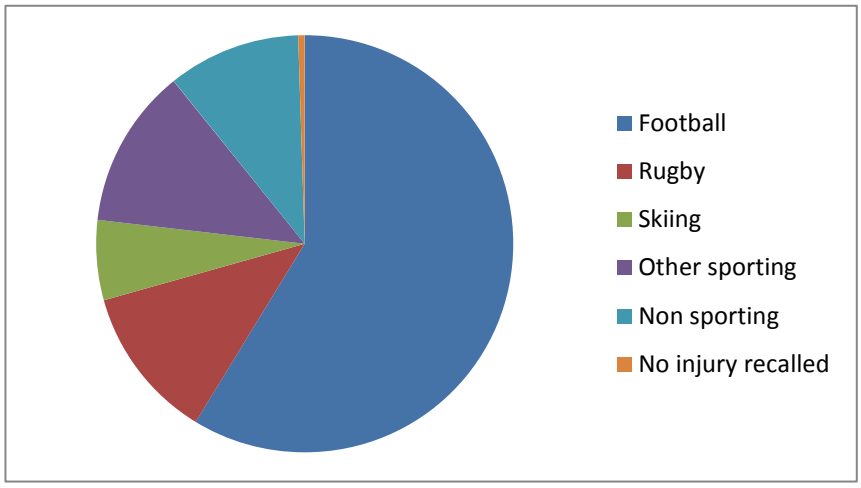



Figure 18: Activity at the time of injury (n=194)

### 5.4.2 Contact/ non-contact injury

The majority of injuries were non-contact (n=132/193; 68.4%) with contact injury reported in less than one third of patients (n=60/193; 31.1%). One patient was unable to recall whether or not contact had occurred at the time of injury (n=1/193; 0.5%).

### 5.4.3 Injury features

Reported injury features are summarised in table 27.

**Table 27: Reported injury features**

| Injury history feature (number of records available for analysis) | Number (percentage) |
|---|---|
| **Giving way at time of injury (n=193)** | |
| Yes | 172 (89.1) |
| No | 15 (7.8) |
| Not sure | 6 (3.1) |
| **Heard/ felt pop at the time of injury (n=193)** | |
| Yes | 141 (73.1) |
| No | 37 (19.2) |
| Not sure | 15 (7.8) |
| **Inability to continue activity (n=194)** | |
| Yes | 175 (90.2) |
| No | 14 (7.2) |
| Not applicable | 5 (2.6) |
| **Swelling following injury (n=193)** | |
| Yes | 187 (96.9) |
| No | 4 (2.1) |
| Not sure | 2 (1.0) |
| **Swelling time (n=192)** | |
| within a few minutes | 104 (54.2) |
| within 1 hour | 147 (76.6) |
| within 6 hours | 165 (85.9) |
| within 1 day | 176 (91.7) |

The most frequently reported feature at the time of, or shortly following, injury was swelling (n=187/193; 96.9%). Most patients recalled swelling occurring within the first day following injury (n=176/192; 91.7 %), with 54.2% (n=104/192) reporting that the knee swelled within a few minutes increasing to 76.6% (n=147/192) within one hour. Giving way of the knee at the time of injury was reported in 89.1% (n=172/193) of cases, and inability to continue activity in 90.2% (n=175/194) of cases. The least frequently reported symptom was hearing or feeling a pop at the time of injury (n= 141/193; 73.1%).

The majority of patients reported all four injury features (giving way, heard or felt a pop, inability to continue activity and swelling within 6 hours) (n=111/192;

57.8%) and 95.8% (n=184/192) reported at least 2 of the four injury features investigated. The numbers of symptoms reported per patient (out of a possible maximum of 4) are shown in figure 19.

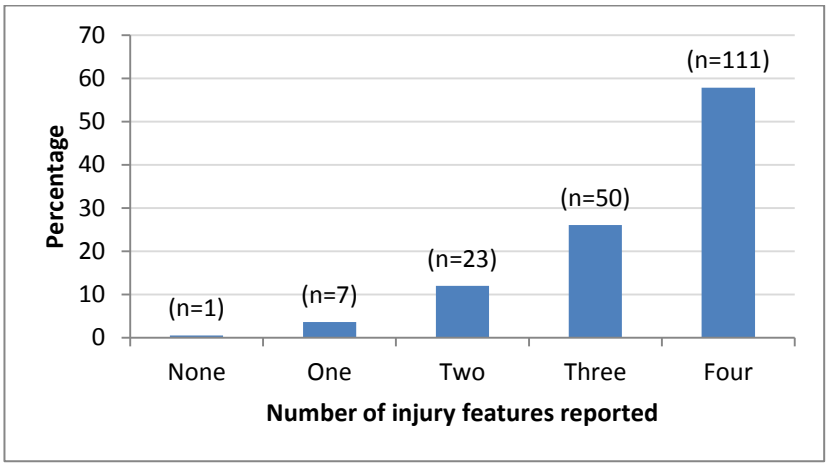



**Figure 19: Number of injury features reported per patient (giving way at injury, hearing or feeling a pop, inability to continue activity and swelling within 6 hours) (n=192).**

## 5.5 Subsequent giving way episodes following the initial injury

Subsequent episodes of giving way, following the initial injury, were reported in 80.4% (n=156/194) of cases. The majority of patients experienced multiple episodes of giving way following their injury with more than 10 episodes reported in 34% of cases (n=66/194) (see figure 20).

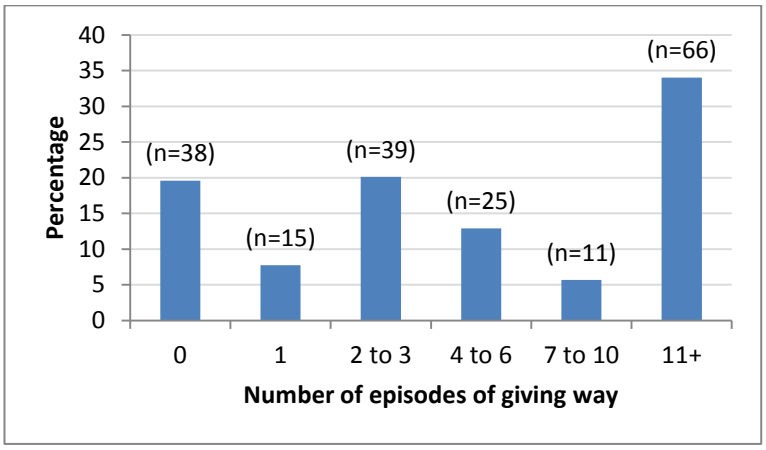



**Figure 20: Number of subsequent episodes of giving way per patient (n=194)**

Patients who initially presented to a location where an AKC was in operation were significantly less likely to have suffered a subsequent episode of giving way ($\chi^2_{(1)}$= 17.82; p<0.001). Linear regression revealed that delay to diagnosis was significantly and positively associated with number of subsequent episodes of giving way ($F_{(1,188)}$= 52.47; $R^2$= 0.22; p<0.001)(see figure 21).

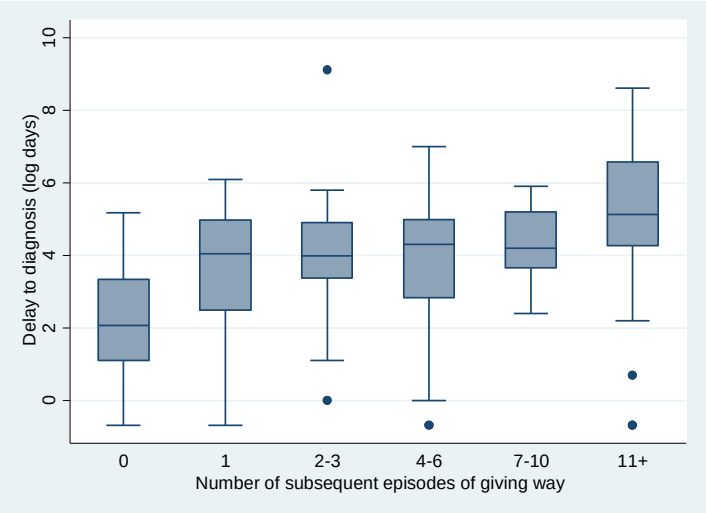



**Figure 21: Box-and-whisker plot of delay to diagnosis by number subsequent of episodes of giving way.**

## 5.6 Information about consultations

### 5.6.1 Initial attendance location by type

The initial presentation location for almost three quarters of patients was to an A&E department with presentation to a GP the next most common (table 28). Only 1 in 10 patients presented to a site other than these.

Table 28: Location of initial presentation by type (n=193)

| Location of initial presentation | Number | Percentage |
|---|---|---|
| Accident and emergency department | 143 | 74.1 |
| Minor injury unit | 7 | 3.6 |
| General practitioner | 30 | 15.5 |
| Physiotherapist | 8 | 4.2 |
| Private specialist (doctor) | 3 | 1.6 |
| Other | 2 | 1.0 |

### 5.6.2 Diagnosis at initial presentation

The ACL injury was correctly identified at initial presentation in only 15.5% (n=30/193) of cases and not identified in 83.4% (n=161/193) cases. In two cases there was uncertainty as to whether a correct diagnosis had been made on initial attendance (n=2/193; 1.0%). The lowest proportion of correctly diagnosed ACL injuries was for patients attending A&E. Table 29 shows the rate of diagnosis by initial attendance location.

Table 29: Number and percentage of ACL injuries correctly identified at initial attendance by location of attendance

| Location of initial attendance | Number | Correctly identified | |
|---|---|---|---|
| | | (n) | (%) |
| Accident and emergency department | 143 | 18 | 12.6 |
| Minor injury unit | 7 | 1 | 14.3 |
| General Practitioner | 30 | 5 | 16.7 |
| Physiotherapist | 8 | 4 | 50.0 |
| Private specialist (doctor) | 3 | 1 | 33.3 |
| Other | 2 | 1 | 50 |
| Combined total | 193 | 30 | 15.5 |

### 5.6.3 Follow-up for patients attending accident and emergency or minor injury unit

Of the 165 patients who attended an A&E department or MIU at some point following injury, 73.3% (n=121/165) had a further appointment arranged and 26.7% (n=44/165) were discharged without follow-up.

### 5.6.4 Diagnosing clinician by profession

The correct diagnosis of ACL injury was most frequently made by a medical consultant within the hospital setting (n=112/192; 58.3%) followed by a physiotherapist (n=38/192; 19.8%). A&E doctors and GP's both diagnosed 20 cases (20/192; 10.4%) (table 30).

**Table 30: Number and percentage of patients correctly diagnosed by profession**

| Profession | Number diagnosed | Percentage |
|---|---|---|
| Accident and emergency doctor | 20 | 10.4 |
| GP | 20 | 10.4 |
| Hospital consultant | 112 | 58.3 |
| Physiotherapist | 38 | 19.8 |
| Other | 2 | 1.0 |
| Combined total | 192 | 100 |

### 5.6.5 Number of appointments to diagnosis

The median number of appointments with a health professional, including the one where the patient was first made aware of a correct diagnosis of ACL injury, was 4 (IQR= 2 to 6). A wide variation in the number of appointments patients attended was noted (range= 1 to 31 appointments) (figure 22).

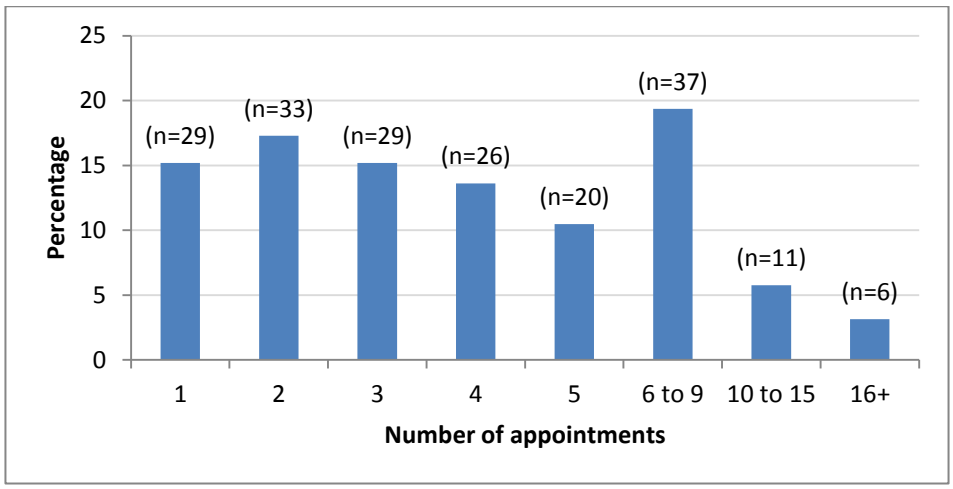



Figure 22: Number of appointments to correct diagnosis of ACL injury per patient (n=191)

Mann Whitney test revealed that patients attending a location operating an AKC pathway had significantly fewer appointments to diagnosis (n=50; Median=2 appointments; IQR= 2 to 5) than those patients attending locations without an AKC (n=141; Median=4 appointments; IQR= 3 to 6; $z_u$= 4.11; p<0.001). For patients who attended A&E or MIU, those who had a follow-up appointment arranged (n= 120; Median= 3; IQR= 2 to 5) had significantly fewer appointments to diagnosis than those who did not have a follow-up referral arranged (n=44; Median= 5; IQR= 3 to 7; $z_u$= -3.62; p<0.001).

### 5.6.6 MRI scan

An MRI scan was performed on 132 patients (n=132/192; 68.8%). Of these an ACL injury was identified in 122 (n=122/132; 92.4%) and not identified in 4 cases (n=4/132; 3%). The MRI result was not recorded or remained uncertain in the remaining 6 cases (n=6/132; 4.5%).

The profession requesting the MRI scan was recorded in 131 cases and patients were most frequently referred by a medical consultant within the hospital (n=89/131; 67.9%). GPs referred 22 patients (n=22/131; 16.8%) and

physiotherapists 13 patients (n=13/131; 9.9%) with other professions accounting for 7 referrals (n=7/131; 5.3%).

## 5.7 Delay periods following ACL injury

Wide variations in delay were identified both when considering delay at individual sites (table 31) and across all sites (table 32). Kruskal-Wallis tests showed that between site variation in delay was statistically significant for all delay types other than patient delay, indicating that site attendance influences delay to diagnosis and specialist consultation (table 31). Key results on overall levels of delay including all subjects are summarised within the following subsections.

**Table 31: Summary of key delay periods by site. Median (IQR) reported. Values in days**

| Site | Patient delay | System delay to diagnosis | Delay to diagnosis | Waiting list delay | Adjusted delay to specialist consultation | Delay to specialist consultation |
|---|---|---|---|---|---|---|
| **Airedale** | 1 (0 to 42) | 49 (2 to 96) | 71 (17 to 158) | 36 (17 to 58) | 49 (4 to 111) | 123 (68 to 267) |
| **Bradford** | 1 (0 to 7) | 93.5 (23 to 210) | 97 (31 to 267) | 27 (15 to 55) | 91 (41 to 271) | 158.5 (60 to 343) |
| **Leeds** | 1 (0 to 2) | 13.5 (3 to 40) | 14.5 (7 to 42) | 18.5 (8 to 47) | 7 (0 to 28) | 46.5 (10 to 96) |
| **Mid Yorkshire** | 1 (0 to 2) | 99 (71 to 225) | 131 (72 to 307) | 48 (27 to 69) | 98.5 (61 to 199.5) | 175 (113.5 to 291.5) |
| **North Lincolnshire and Goole** | 1 (0 to 2.5) | 46 (21 to 706) | 79.5 (28 to 731) | 22 (13 to 31) | 7 (0 to 684) | 96 (30 to 732) |
| **$\kappa^2$ (with ties)** | 3.01 | 38.28 | 36.68 | 12.86 | 35.04 | 32.47 |
| **p value** | p=0.56 | p<0.001* | p<0.001* | p=0.012* | p<0.001* | p<0.001* |

*significant at p≤0.05

**Table 32: Summary of delay by type. Values are given in numbers (%). Median, IQR and range reported in days**

| | Patient delay (n=192) | System delay to diagnosis (n=190) | Delay to diagnosis (n=190) | Waiting list delay (n=191) | Adjusted delay to specialist consultation (n=190) | Delay to specialist consultation (n=191) |
|---|---|---|---|---|---|---|
| **0 to 6 days** | 147 (76.6) | 35 (18.4) | 33 (17.4) | 22 (11.5) | 55 (28.9) | 6 (3.1) |
| **7 to 41 days** (1 to 6 weeks) | 25 (13.0) | 52 (27.4) | 46 (24.2) | 96 (50.3) | 33 (17.4) | 46 (24.1) |
| **42 to 83 days** (6 to 12 weeks) | 8 (4.2) | 32 (16.8) | 26 (13.7) | 59 (30.9) | 31 (16.3) | 25 (13.1) |
| **84 to 182 days** (12 weeks to 6 months) | 6 (3.1) | 33 (17.4) | 40 (21.1) | 12 (6.3) | 23 (12.1) | 51 (26.7) |
| **183 to 364 days** (6 to 12 months) | 5 (2.6) | 13 (6.8) | 19 (10.0) | 2 (1.0) | 22 (11.6) | 26 (13.6) |
| **≥365 days** (≥1 year) | 1 (0.5) | 25 (13.2) | 26 (13.7) | 0 (0) | 36 (18.9) | 37 (19.4) |
| **Median** | 1 | 52 | 67.5 | 28 | 50.5 | 108 |
| **IQR** | 0 to 4 | 13 to 138 | 15 to 178 | 14 to 56 | 3 to 183 | 38 to 292 |
| **Range** | 0 to 710 | 0 to 1930 | 0 to 1931 | 0 to 303 | 0 to 9085 | 1 to 1931 |

### 5.7.1 Patient delay

Figures for patient delay were available for 192 patients. Most of the patients presented either on the day of injury (n=78/192; 40.6%) or day following injury (n=50/192; 26.0%). 76.6% of patients (n=147/192) presented within one week of injury causing event. Presentation was delayed by six weeks or more in 10.4% of cases (n=20/192) with 3.1% (n=6/192) waiting more than six months to seek medical attention. The longest delay from injury to initial presentation was two years (710 days) (figure 23).

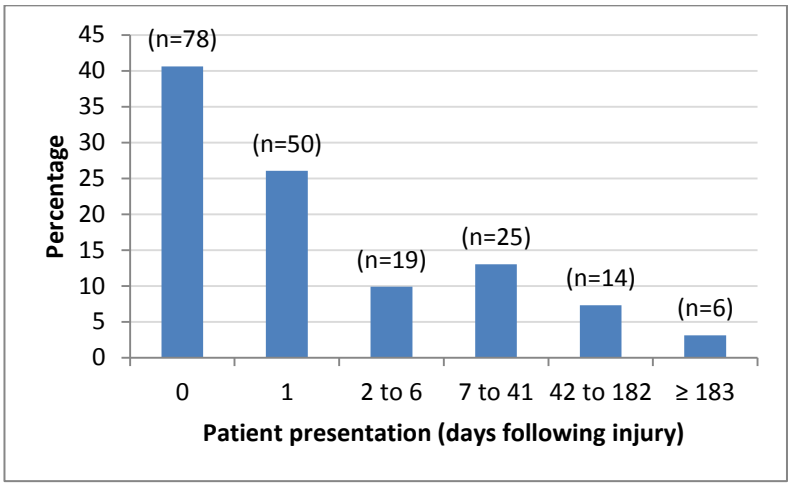



Figure 23: Patient delay to presentation following injury (n=192)

### 5.7.2 Delay to diagnosis

Information on delay to diagnosis was available for 190 patients and was strongly positively skewed. Following log transformation, histogram inspection revealed data to be of a roughly normal distribution (figure 24).

(a) (b)

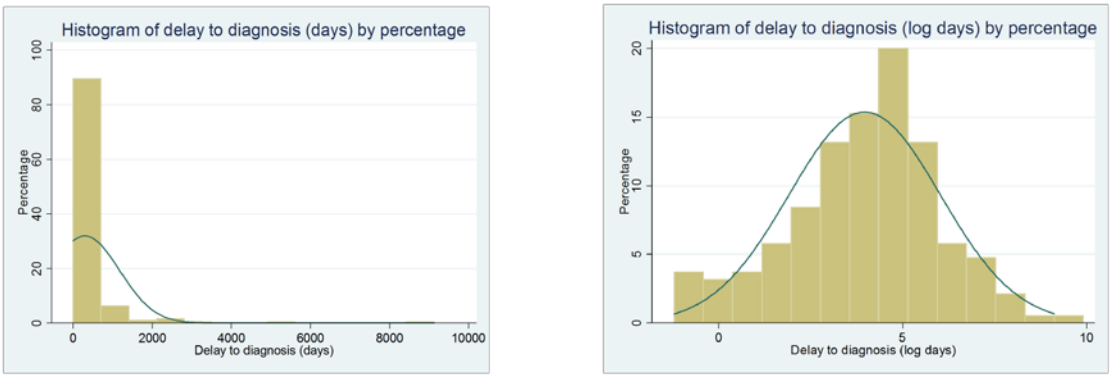



**Figure 24: Histograms of delay to diagnosis (a) prior to and (b) following log transformation**

The geometric mean delay to diagnosis was 51.8 days (95% CI= 38.5 to 69.6) with median time to diagnosis 67.5 days. There was a wide variation in the time to diagnosis with 10.5% (n=20/190) of patients diagnosed within 3 days and just under a quarter of patients diagnosed within 2 weeks of injury (n=44/190; 23.2%). Conversely, 10% (n=19/190) of patients were correctly diagnosed more than two years after the initial injury, the longest delay being 25 years, and almost a quarter of patients (n=45/190; 23.7%) waited more than six months for a correct diagnosis.

### 5.7.3 System delay to diagnosis

Information on system delay (delay to diagnosis minus patient delay) was available for 190 patients. System delay to diagnosis was positively skewed and did not follow a normal distribution following log transformation (figure 25).

(a) (b)

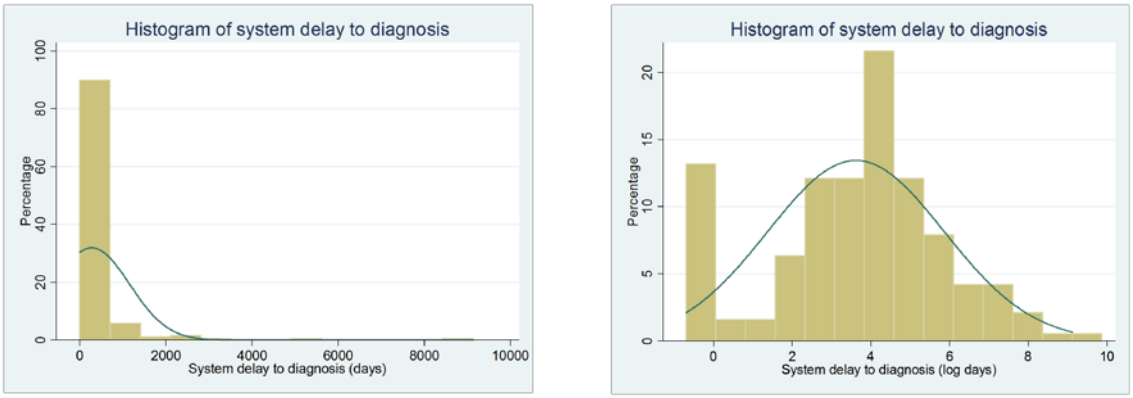



**Figure 25: Histograms of system delay to diagnosis (a) prior to and (b) following log transformation**

Median system delay to diagnosis was 52 days. Within one week of presentation 21% of patients (n=40/190) had been made aware of a correct diagnosis but at six months, 20.5% (n=39/190) patients were still awaiting a correct diagnosis. The system delay to diagnosis extended to more than two years for 8.9% (n=17/190) of patients.

### 5.7.4 Waiting list delay

Information on waiting list delay was available for 191 patients. The median delay between referral to, and initial appointment with, a specialist was 28 days (IQR= 14 to 56 days). The majority of patients (n=118/191; 61.8%) saw a specialist within six weeks of their referral date although 17.3% (n=33/191) of patients waited more than 9 weeks (see figure 26).

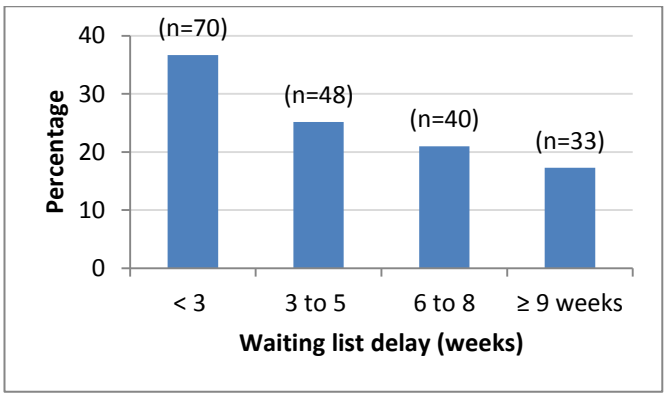



Figure 26: Waiting list delay to initial specialist consultation (n=191)

Analysis with Mann Whitney test revealed that the waiting list delay to seeing a specialist was significantly lower for patients who attended a site operating an AKC (n=50; Median= 18.5 days; IQR= 8 to 47 days) than those who attended a site without an AKC (n=141; Median= 31 days; IQR= 15 to 57 days); $z_U$= 2.30; p=0.02.

### 5.7.5 Adjusted delay to specialist consultation

Information on adjusted delay to specialist consultation (patient delay and system delay removed) was available for 190 patients (n=190/194; 97.4%). Histogram inspection revealed that data were not normally distributed even following log transformation (see figure 27). A wide disparity in the adjusted delay to see a specialist clinician was evident with 23.2% of patients (n=44/190) being referred directly to a specialist at the time of initial attendance and therefore having no delay. In total 46.3% of patients experienced a delay of less than six weeks (n=88/190) and this increased to 63.2% of patients experiencing a delay of 12 weeks or less (n=120/190). Nearly a quarter of patients experienced a delay of six months or more for specialist consultation (n=47/190; 24.7%) and 13.2% delays of more than one year (n=25/190).

(a) (b)

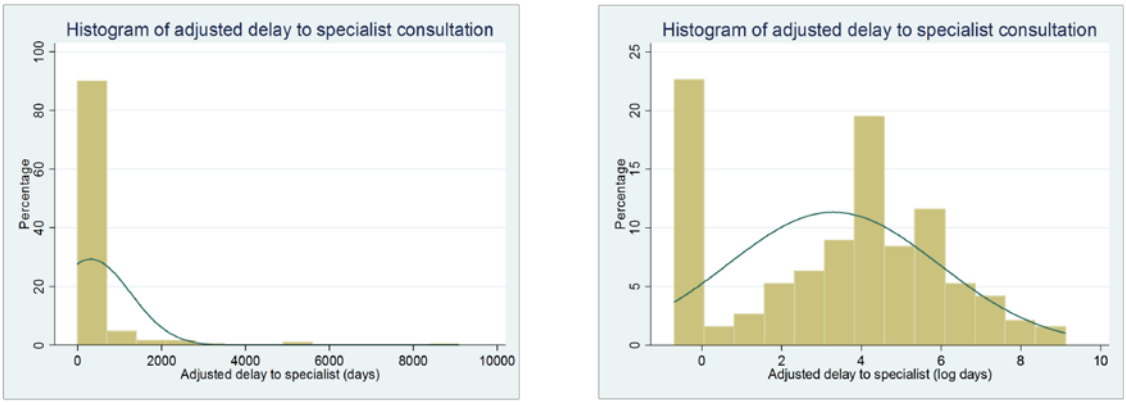



**Figure 27: Histograms of adjusted delay to specialist consultation (a) prior to and (b) following log transformation**

### 5.7.6 Total delay to specialist consultation

Information on total delay to specialist consultation was available for 191 cases; the measure was highly positively skewed (figure 28a). Following log transformation histogram inspection revealed a pattern consistent with a normal distribution (figure 28b).

(a) (b)

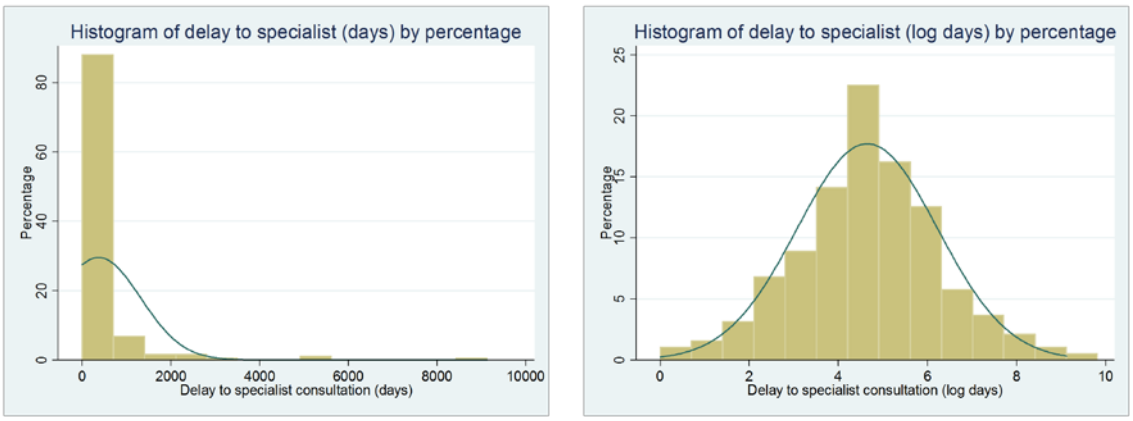



**Figure 28: Histograms of adjusted delay to specialist consultation (a) prior to and (b) following log transformation**

The delay to specialist consultation based on geometric mean values was 104.5 days (95% CI= 83.4 to 130.9 days) and was similar to the median delay of 108 days. There was a wide variation in delay with 10% (n=19/191) of patients having seen a specialist by two weeks and a little over a quarter (52/191; 27.2%) of patients had seen a specialist within 6 weeks of the initial injury. One year following initial injury 19.4% (37/191) of patients had not received a consultation with a specialist, and 11.5% (22/191) of patients did not see a specialist until more than two years following the initial injury.

## 5.8 Bivariate analysis

This section reports the results from the bivariate analysis for delay to diagnosis, system delay to diagnosis, adjusted delay to specialist consultation and delay to specialist consultation. It ends with a summary of factors which were found to significantly influence delay.

### 5.8.1 Delay to diagnosis

#### *5.8.1.1 Dichotomous explanatory variables; influence on delay to diagnosis*

Inspection of histograms for delay to diagnosis data revealed that it was not normally distributed for any of the dichotomous variables (listed in table 33). Log transformation resulted in satisfaction of the conditions to undertake parametric analysis detailed previously (4.13.2).

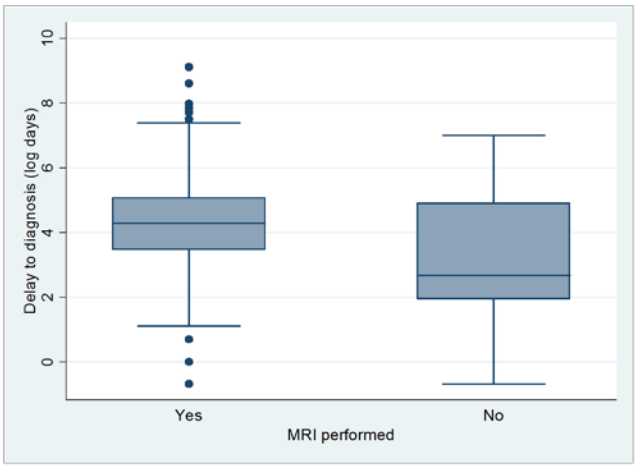
**Table 33: Bivariate analysis of dichotomous independent variables compared by delay to diagnosis**

| Explanatory variable | n | Geometric mean delay to diagnosis (days) | (95% CI) | *p* value |
|---|---|---|---|---|
| **Sex** | | | | |
| Male | 154 | 57.3 | (41.4 to 79.2) | *p*=0.17 |
| Female | 36 | 33.6 | (16.0 to 70.4) | |
| **Injury type** | | | | |
| Contact | 58 | 53.7 | (30.1 to 95.8) | *p*=0.87 |
| Non-contact | 131 | 50.8 | (35.8 to 72.2) | |
| **MRI performed** | | | | |
| Yes | 130 | 70.6 | (50.1 to 99.6) | *p*=0.002* |
| No | 60 | 26.4 | (15.3 to 45.7) | |
| **Attendance to A&E or MIU** | | | | |
| Yes | 163 | 48.3 | (35.0 to 66.6) | *p*=0.26 |
| No | 27 | 78.5 | (35.3 to 174.8) | |
| **Follow-up appointment after initial attendance** | | | | |
| Yes | 120 | 29.1 | (20.4 to 41.5) | *p*<0.001* |
| No | 43 | 198.3 | (116.7 to 336.8) | |
| **Acute knee clinic** | | | | |
| Yes | 50 | 14.6 | (8.9 to 24.0) | *p*<0.001* |
| No | 140 | 81.4 | (58.3 to 113.6) | |

*significant at p≤0.05

MRI- Magnetic resonance imaging; A&E- Accident and emergency; MIU- Minor injury unit; CI- Confidence interval

Patients who had an MRI scan (n=130; geometric mean= 70.6 days) waited significantly longer to receive a diagnosis of ACL injury than those who had not (n=60; geometric mean= 26.4 days; $t_{188}$= 3.11; p=0.002); ratio of geometric means= 2.67 (95% CI= 1.43 to 4.99) (figure 29).




MRI- Magnetic resonance imaging

**Figure 29: Box-and-whisker plot of delay to diagnosis by whether MRI performed**

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Patients seen in an A&E department or MIU who were referred for a follow-up appointment (n=120; geometric mean= 29.1 days) waited significantly less time to diagnosis than those who were discharged without follow-up (n=43; geometric mean= 198.3 days; $t_{161}$= -5.67; p<0.001); ratio of geometric means= 6.81 (95% CI= 3.49 to 13.27) (figure 30).

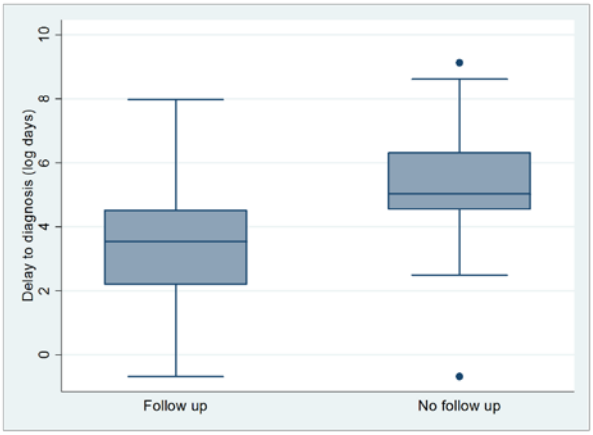



**Figure 30: Box-and-whisker plot of delay to diagnosis by follow-up appointment**

Patients seen at a site operating an AKC (n=50; geometric mean= 14.6 days) had less delay to diagnosis to those seen at sites without an AKC (n=140; geometric mean= 81.4 days; $t_{188}$= 5.40; p<0.001); ratio of geometric means= 5.58 (95% CI= 2.98 to 10.46) (figure 31).

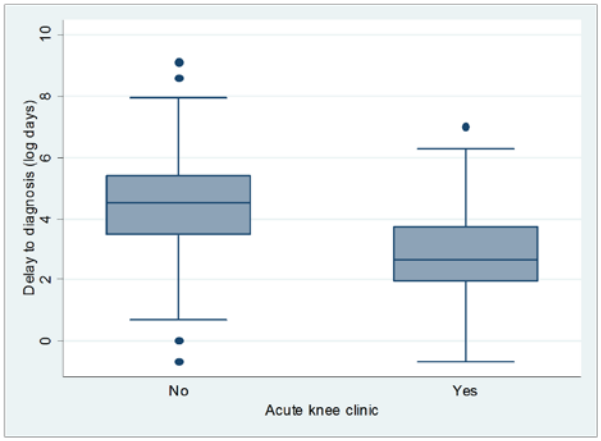



**Figure 31: Box-and-whisker plot of delay to diagnosis by whether site operated an acute knee clinic**

No significant differences were noted in delay to diagnosis for sex, injury type or whether the patient had attended an A&E department or MIU.

### *5.8.1.2 Explanatory variables with three categories; influence on delay to diagnosis*

Prior to undertaking analysis on time to diagnosis by activity at the time of injury, regression was undertaken to see whether there were any significant differences in time to diagnosis between football and rugby. Analysis revealed that there was no significant difference in time to diagnosis for those injured playing football (n= 112; geometric mean=63.8 days) to those playing rugby

(n=23; geometric mean= 43.8 days; p=0.42) and therefore these were combined into a single group for analysis.

Regression analysis revealed that there was a significant difference in delay to diagnosis depending upon the activity undertaken at the time of injury ($F_{(2,187)}$= 5.33; $R^2$= 0.05; p= 0.006) with those injured during other sporting activities (n=36; geometric mean= 20.5 days) diagnosed significantly earlier than those injured playing football/rugby (n= 135; geometric mean= 59.9 days; p=0.005) or injured during a non-sporting activity (n=19; geometric mean= 106.8 days; p=0.005). No significant difference was noted between those injured during football/ rugby and those injured during a non-sporting activity (p=0.245; table 34 and figure 32).

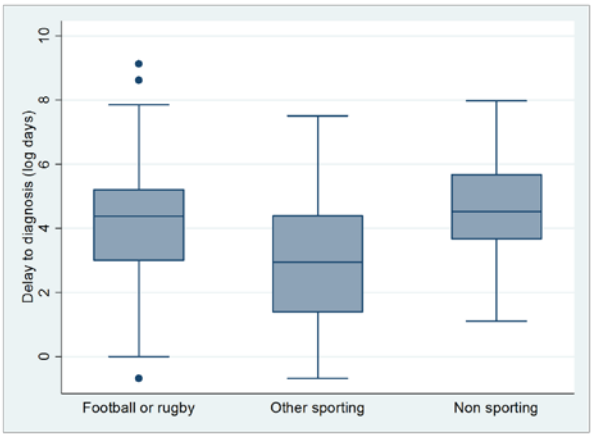



**Figure 32: Box-and-whisker plot of delay to diagnosis by activity at time of injury**

Initial attendance location was also a significant predictor of delay to diagnosis ($F_{(2,187)}$= 9.53; $R^2$= 0.09; p<0.001). Patients initially presenting to 'other' locations (e.g. private orthopaedic specialist, physiotherapy; n=13; geometric mean= 5.0 days) were diagnosed earlier than those seen at a GP surgery (n=29; geometric mean=160.8 days; p<0.001) or in A&E/ MIU (n=148;

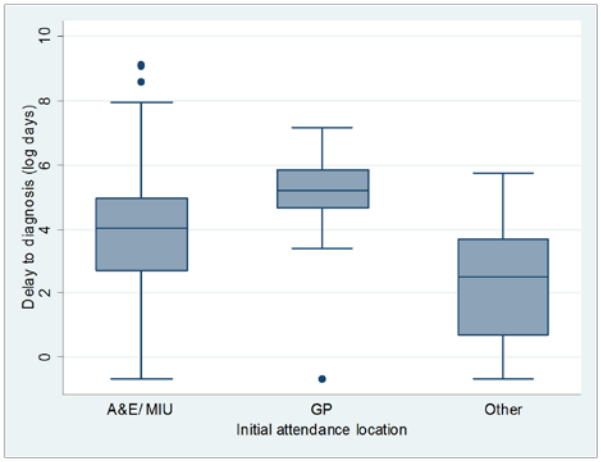
geometric mean= 48.1 days; p=0.006). Those seen in A&E/ MIU had significantly less delay to diagnosis than those seen at GP sites (p=0.003).

**Table 34: Bivariate analysis of explanatory variables with three categories by delay to diagnosis**

| Explanatory variable | n | Geometric mean delay to diagnosis (days) | (95% CI) | *p* value |
|---|---|---|---|---|
| **Activity at time of injury** | | | | |
| Football/ Rugby | 135 | 59.9 | (42.4 to 84.4) | |
| Other sporting | 36 | 20.5 | (9.7 to 43.4) | *p*= 0.006* |
| Non sporting | 19 | 106.8 | (40.1 to 284.3) | |
| **Initial attendance location** | | | | |
| A&E/MIU | 148 | 48.1 | (34.8 to 66.3) | |
| GP | 29 | 160.8 | (72.6 to 356.2) | *p*<0.001* |
| Other | 13 | 5.0 | (3.1 to 29.8) | |

*significant at p≤0.05

A&E- Accident and emergency; MIU- Minor injury unit; GP- General Practitioner; CI- Confidence interval




A&E- Accident and emergency; MIU- Minor injury unit; GP- General Practitioner

**Figure 33: Box-and-whisker plot of delay to diagnosis by initial attendance location**

### *5.8.1.3 Ordinal and continuous explanatory variables; influence on delay to diagnosis*

Regression analysis revealed that neither age ($F_{(1,188)}$= 0.03; $R^2$<0.001; p=0.87) nor number of symptoms reported ($F_{(1,188)}$= 0.05; $R^2$<0.001; p=0.82) had a significant effect on time to diagnosis (table 35 and figures 34 and 35).

Table 35: Bivariate analysis of ordinal and continuous explanatory variables against delay to diagnosis

| Explanatory variable | n | F | $R^2$ | *p* value |
|---|---|---|---|---|
| **Number of symptoms reported** | 190 | 0.05 | <0.001 | *p*=0.82 |
| **Age** | 190 | 0.03 | <0.001 | *p*=0.87 |

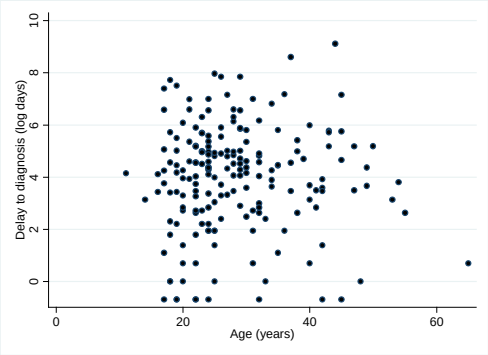



Figure 34: Scatter plot showing delay to diagnosis by age

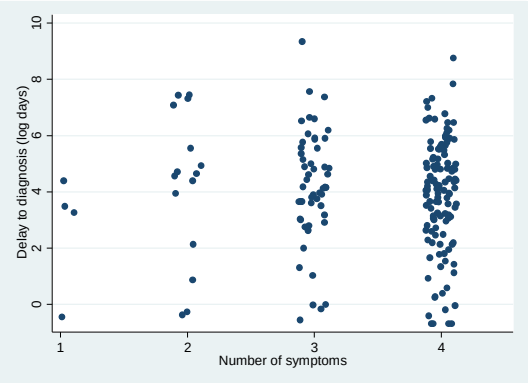


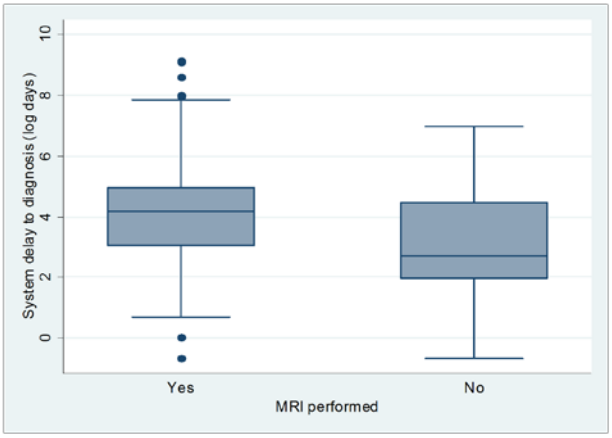

Figure 35: Scatter plot showing delay to diagnosis by number of symptoms reported

## 5.8.2 System delay to diagnosis

Conditions for undertaking parametric tests were not satisfied with histogram analysis revealing a zero inflated model of system delay to diagnosis.

### *5.8.2.1 Dichotomous explanatory variables; influence on system delay to diagnosis*

Mann Whitney U tests revealed that system delay to diagnosis was significantly greater for patients who had an MRI scan (n=130; Median= 66.5 days) than those who had not (n=60; Median= 15 days); $z_U$= 3.19; p=0.001 (figure 36).




MRI- Magnetic resonance imaging

**Figure 36: Box-and-whisker plot of system delay to diagnosis by whether MRI performed**

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Patients who attended an A&E department or MIU and had a follow-up appointment arranged had significantly less system delay to diagnosis (n=120; Median= 26 days) than those who were discharged without follow-up (n= 42; Median= 135 days); $z_U$= -5.19; p<0.001 (figure 37).

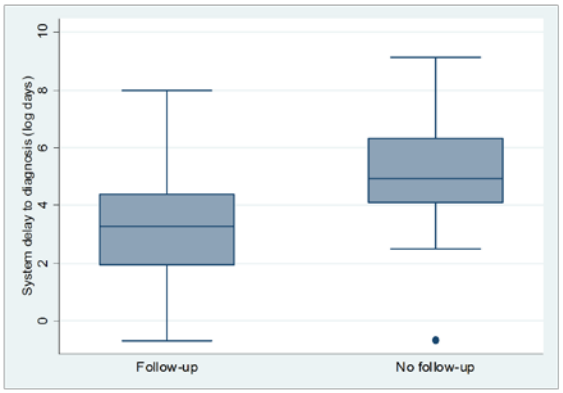



**Figure 37: Box-and-whisker plot of system delay to diagnosis by whether follow-up appointment arranged**

Patients attending a site operating an AKC service had significantly less system delay to diagnosis (n=50; Median= 13.5 days) than those attending sites without (n= 140; Median= 78.5 days); $z_U$= -5.34; p<0.001 (figure 38).

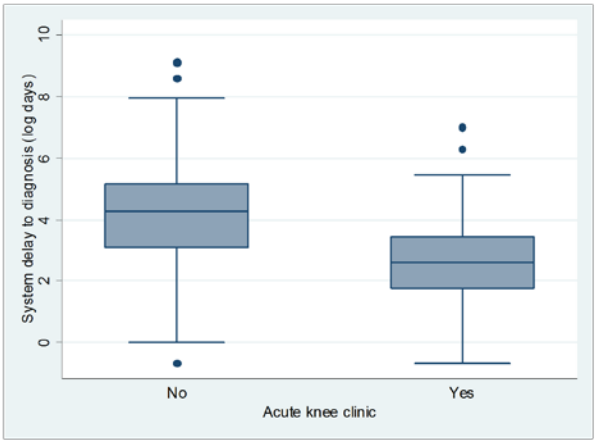



**Figure 38: Box-and-whisker plot of system delay to diagnosis by whether attended site with acute knee clinic**

There were no significant differences noted in system delay to diagnosis for the other explanatory variables (table 36).

**Table 36: Bivariate analysis of dichotomous independent variables compared by system delay to diagnosis**

| Explanatory variable | n | Median delay (days) | IQR | $Z_U$ | *p* value |
|---|---|---|---|---|---|
| **Sex** | | | | | |
| Male | 154 | 59 | (14 to 145) | 1.62 | *p*=0.11 |
| Female | 36 | 21.5 | (7.5 to 77.5) | | |
| **Injury type** | | | | | |
| Contact | 58 | 40 | (7 to 123) | -1.11 | *p*=0.27 |
| Non-contact | 131 | 58 | (14 to 147) | | |
| **MRI performed** | | | | | |
| Yes | 130 | 66.5 | (21 to 147) | 3.19 | *p*=0.001* |
| No | 60 | 15 | (7 to 89) | | |
| **Attendance to A&E or MIU** | | | | | |
| Yes | 163 | 50 | (13 to 135) | -0.45 | *p*=0.65 |
| No | 27 | 91 | (0 to 182) | | |
| **Follow-up appointment after initial attendance** | | | | | |
| Yes | 120 | 26 | (7 to 81.5) | -5.19 | *p*<0.001* |
| No | 43 | 135 | (60 to 545) | | |
| **Acute knee clinic** | | | | | |
| Yes | 50 | 13.5 | (3 to 40) | -5.34 | *p*<0.001* |
| No | 140 | 78.5 | (22 to 180) | | |

*significant at p≤0.05

MRI- Magnetic resonance imaging; A&E- Accident and emergency; MIU- Minor injury unit; CI- Confidence interval

### *5.8.2.2 Explanatory variables with three categories; influence on system delay to diagnosis*

A Kruskal-Wallis test revealed a significant between group difference in the system delay to diagnosis based on the type of activity undertaken at the time of injury ($\chi^2_{(2)}$= 8.55; p=0.014; table 37 and figure 39). Those injured during other sporting activities (n= 36; Median= 16.5 days) had less system delay to diagnosis than those injured playing football or rugby (N=135; Median= 60 days) or during non-sporting activity (n=19; Median= 82 days).

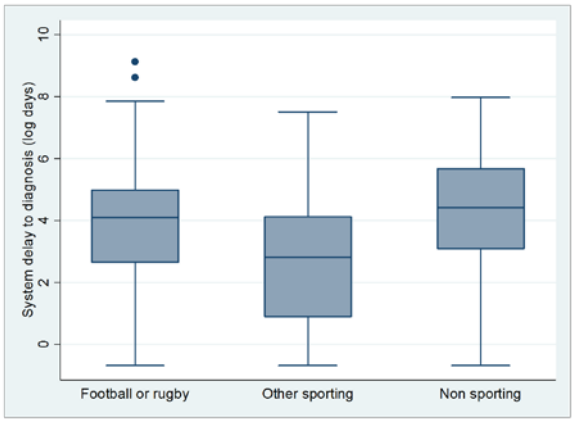
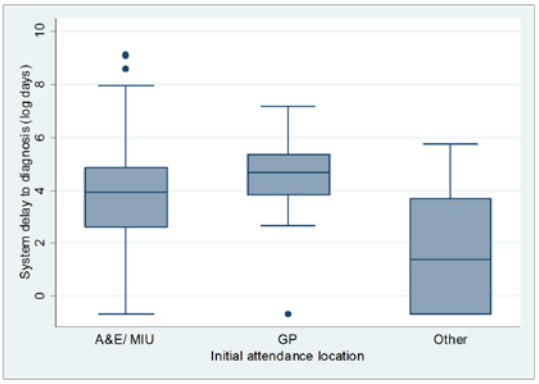



**Figure 39: Box-and-whisker plot of system delay to diagnosis by activity at time of injury**

Initial attendance location was also shown to significantly affect the system delay to diagnosis ($\chi^2_{(2)}$= 9.58; p=0.008) with those initially presenting to 'other' locations (n=13; Median= 4 days) having less delay than those presenting A&E/MIU (n= 148; Median= 50 days) or to a GP (n= 29; Median= 108 days) (table 37 and figure 40).




A&E- Accident and emergency; MIU- Minor injury unit; GP- General Practitioner

**Figure 40: Box-and-whisker plot of system delay to diagnosis by initial attendance location**

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**Table 37: Bivariate analysis of explanatory variables with three categories by system delay to diagnosis**

| Explanatory variable | n | Median delay (days) | IQR | $\chi^2$ | *p* value |
|---|---|---|---|---|---|
| **Activity at time of injury** | | | | | |
| Football/ Rugby | 135 | 60 | (14 to 145) | | |
| Other sporting | 36 | 16.5 | (2.5 to 61) | 8.55 | *p*= 0.014* |
| Non sporting | 19 | 82 | (22 to 292) | | |
| **Initial attendance location** | | | | | |
| A&E/MIU | 148 | 50 | (13.5 to 128.5) | | |
| GP | 29 | 108 | (45 to 210) | 9.58 | *p*= 0.008* |
| Other | 13 | 4 | (0 to 40) | | |

*significant at p≤0.05

A&E- Accident and emergency; MIU- Minor injury unit; GP- General Practitioner; IQR- Interquartile range

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### *5.8.2.3 Ordinal and continuous explanatory variables; influence on system delay to diagnosis*

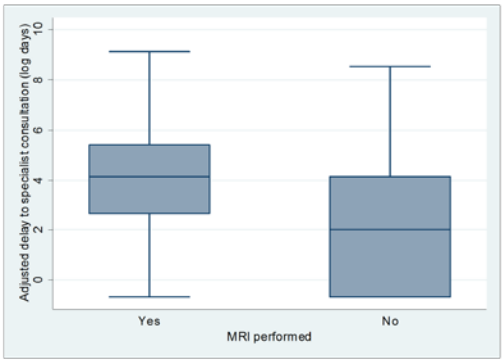
Spearman's rank correlation revealed that there was no significant association between age (n= 190; Spearman's rho= 0.045; p= 0.54) or number of reported symptoms (n=190; Spearman's rho= -0.033; p= 0.66) and system delay to diagnosis.

### 5.8.3 Adjusted delay to specialist consultation

Data for adjusted delay to specialist consultation was not normally distributed and remained so following log transformation.

#### *5.8.3.1 Dichotomous explanatory variables; influence on adjusted delay to specialist consultation*

Analysis with Mann Whitney test revealed that the adjusted delay to specialist consultation was significantly greater for patients who had an MRI scan (n=129; Median= 63 days) than those who had not (n=60; Median= 7.5 days); $z_U$= 4.08; p<0.001 (figure 41).




MRI- Magnetic resonance imaging

**Figure 41: Box-and-whisker plot of adjusted delay to specialist consultation by whether MRI performed**

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Patients who attended an A&E department or MIU and had a follow-up appointment arranged had significantly less adjusted delay to specialist consultation (n=119; Median= 16 days) than those who were discharged without follow-up (n= 43; Median= 213 days); $z_U$= -5.35; p<0.001 (figure 42).

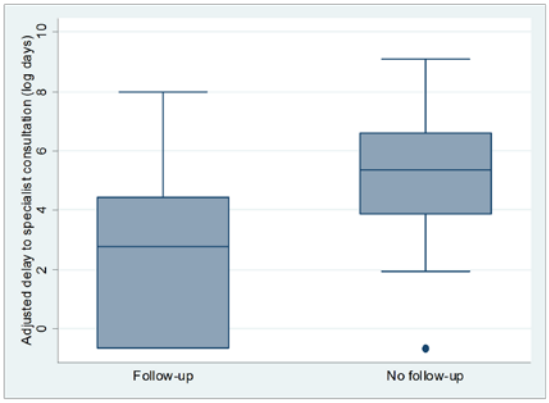


**Figure 42: Box-and-whisker plot of adjusted delay to specialist consultation by whether follow-up arranged**

Patients seen at a site operating an AKC service had significantly less adjusted delay to specialist consultation (n= 50; Median =7 days) compared to patients seen at sites without this service (n=140; Median= 71 days); $z_u$= -4.97; p<0.001 (figure 43).

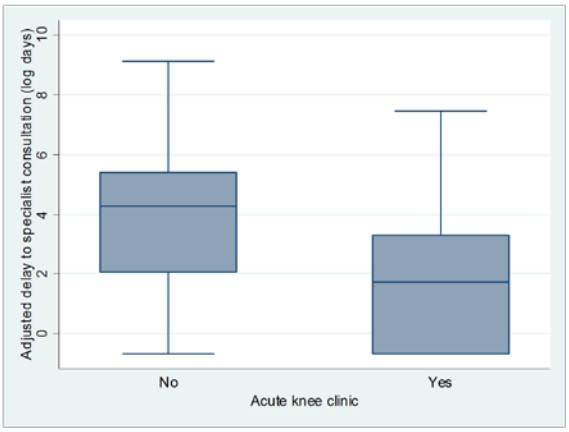


**Figure 43: Box-and-whisker plot of adjusted delay to specialist consultation by whether attended site with acute knee clinic**

No significant differences in adjusted delay to specialist consultation were found for the other explanatory variables (table 38).

**Table 38: Bivariate analysis of dichotomous explanatory variables compared by adjusted delay to specialist review**

| Explanatory variable | n | Median delay (days) | IQR | $Z_U$ | *p* value |
|---|---|---|---|---|---|
| **Sex** | | | | | |
| Male | 154 | 58.5 | (2 to 210) | 1.28 | *p*= 0.20 |
| Female | 36 | 19.5 | (3.5 to 61.5) | | |
| **Injury type** | | | | | |
| Contact | 59 | 33 | (0 to 169) | -1.03 | *p*= 0.30 |
| Non-contact | 130 | 54.5 | (7 to 210) | | |
| **MRI performed** | | | | | |
| Yes | 129 | 63 | (14 to 221) | 4.08 | *p*<0.001* |
| No | 60 | 7.5 | (0 to 62) | | |
| **Attendance to A&E or MIU** | | | | | |
| Yes | 162 | 46 | (0 to 169) | -1.40 | *p*=0.16 |
| No | 27 | 71 | (21 to 241) | | |
| **Follow-up appointment after initial attendance** | | | | | |
| Yes | 119 | 16 | (0 to 84) | -5.35 | *p*<0.001* |
| No | 43 | 213 | (48 to 732) | | |
| **Acute knee clinic** | | | | | |
| Yes | 50 | 7 | (0 to 28) | -4.97 | *p*<0.001* |
| No | 140 | 71 | (10 to 224) | | |

*significant at p≤0.05

MRI- Magnetic resonance imaging; A&E- Accident and emergency; MIU- Minor injury unit; CI- Confidence interval

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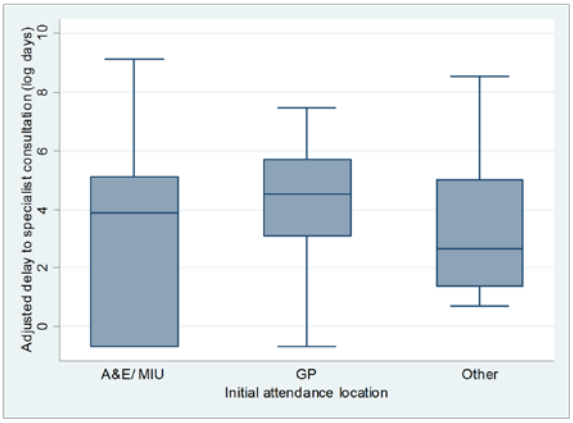
### *5.8.3.2 Explanatory variables with three categories; influence on adjusted delay to specialist consultation*

A Kruskal-Wallis test showed that initial attendance location significantly affected adjusted delay to specialist consultation with those seen at a GP surgery having the longest delay (n= 29; Median= 91 days) followed by those attending A&E or MIU (n= 147; Median= 48 days) and the shortest delays seen for those attending other sites (n= 13; Median= 14 days) (figure 44 and table 39).




A&E- Accident and emergency; MIU- Minor injury unit; GP- General Practitioner

**Figure 44: Box-and-whisker plot showing adjusted delay to specialist consultation by initial attendance location**

There were no significant between group differences in the adjusted time to specialist consultation by activity undertaken at the time of injury ($\chi^2_{(2)}$= 4.29; p=0.11).

**Table 39: Bivariate analysis of explanatory variables with three categories by adjusted delay to specialist consultation**

| Explanatory variable | n | Median delay (days) | IQR | $\chi^2$ | *p* value |
|---|---|---|---|---|---|
| **Activity at time of injury** | | | | | |
| Football/ Rugby | 134 | 56.5 | (2 to 209) | | |
| Other sporting | 36 | 13 | (1.3 to 101) | 4.29 | *p*= 0.11 |
| Non sporting | 20 | 77.5 | (36 to 221.5) | | |
| **Initial attendance location** | | | | | |
| A&E/MIU | 147 | 48 | (0 to 169) | | |
| GP | 29 | 91 | (22 to 303) | 3.17 | *p*= 0.008* |
| Other | 13 | 14 | (4 to 151) | | |

*significant at p≤0.05

A&E- Accident and emergency; MIU- Minor injury unit; GP= General Practitioner; IQR- Interquartile range

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### *5.8.3.3 Ordinal and continuous explanatory variables; influence on adjusted delay to specialist consultation*

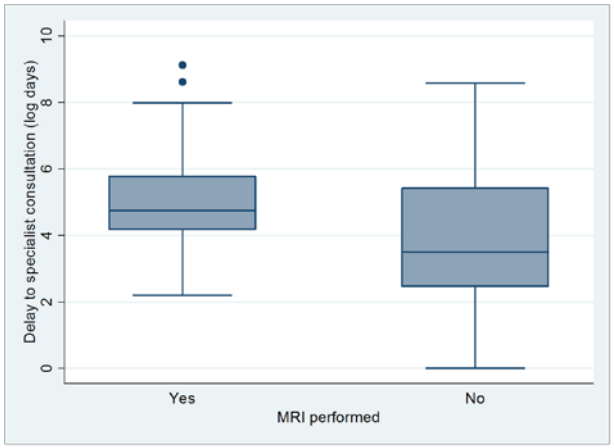
Spearman's rank correlation revealed that there was no significant association between age (n= 190; Spearman's rho= 0.085; p= 0.24) or number of

symptoms reported (n=190; Spearman's rho= -0.08; p= 0.27) and adjusted delay to specialist consultation.

### 5.8.4 Delay to specialist consultation

#### *5.8.4.1 Dichotomous explanatory variables; influence on delay to specialist consultation*

Patients who had an MRI scan (n=130; geometric mean= 148.4 days) waited significantly longer to see a specialist than those who did not (n=60; geometric mean= 48.3 days; $t_{187}$= 4.80; p<0.001); ratio of geometric means= 3.07 (95%CI= 1.94 to 4.87) (figure 45).




MRI- Magnetic resonance imaging

**Figure 45: Box-and-whisker plot showing delay to specialist consultation depending on whether an MRI was performed**

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Patients who had a follow-up appointment arranged (n= 120; geometric mean= 61.3 days) after attending an A&E department or MIU waited significantly less time to see a specialist than those who were discharged without follow-up (n=42; geometric mean= 327.5 days; $t_{160}$= -6.43; p<0.001); ratio of geometric means= 5.35 (95% CI= 3.19 to 8.94) (figure 46).

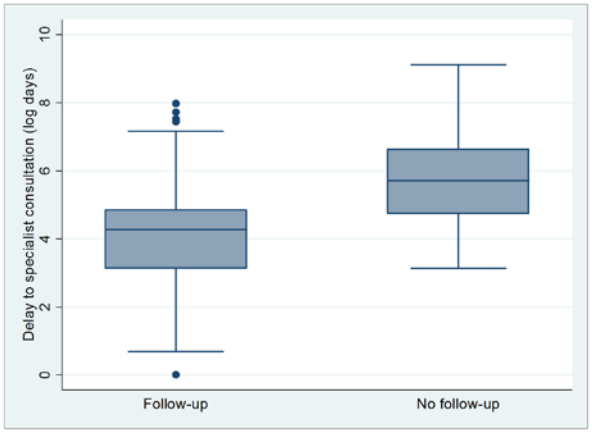


**Figure 46: Box-and-whisker plot showing delay to specialist consultation by whether follow-up arranged**

Patients seen at a site operating a specialist led AKC (n=50; geometric mean= 37.1 days) had less delay to specialist consultation to those seen at sites without an AKC (n=141; geometric mean= 150.7 days; $t_{189}$= 5.84; p<0.001); ratio of geometric means= 4.06 (95%CI= 2.53 to 6.52) (figure 47).

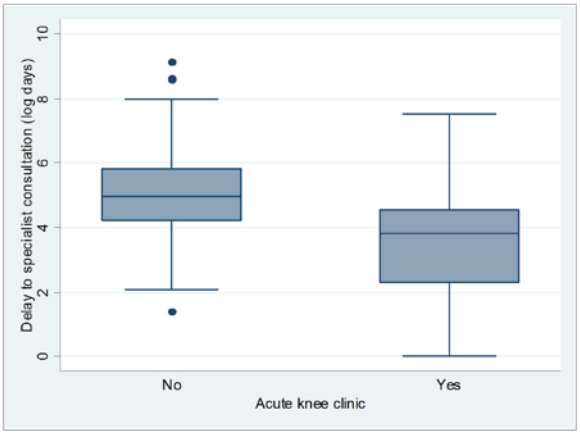


**Figure 47: Box-and-whisker plot showing delay to specialist consultation by whether acute knee clinic**

No other dichotomous variables significantly affected time to specialist consultation although attendance to A&E or MIU approached statistical significance (table 40).

**Table 40: Bivariate analysis of dichotomous independent variables compared by delay to specialist consultation**

| Explanatory variable | n | Geometric mean delay to specialist (days) | (95% CI) | *p* value |
|---|---|---|---|---|
| **Sex** | | | | |
| Male | 155 | 114.1 | (89.5 to 145.4) | *p*=0.11 |
| Female | 36 | 71.5 | (39.5 to 129.5) | |
| **Injury type** | | | | |
| Contact | 59 | 108.4 | (70.2 to 167.4) | *p*=0.83 |
| Non-contact | 131 | 102.8 | (78.6 to 134.4) | |
| **MRI performed** | | | | |
| Yes | 130 | 148.4 | (118.2 to 186.3) | *p*<0.001* |
| No | 60 | 48.3 | (30.0 to 77.8) | |
| **Attendance to A&E or MIU** | | | | |
| Yes | 163 | 95.3 | (74.0 to 122.9) | *p*=0.059 |
| No | 27 | 177.3 | (116.0 to 270.9) | |
| **Follow-up appointment after initial attendance** | | | | |
| Yes | 120 | 61.3 | (46.8 to 80.2) | *p*<0.001* |
| No | 43 | 327.5 | (213.4 to 502.7) | |
| **Acute knee clinic** | | | | |
| Yes | 50 | 37.1 | (24.0 to 57.4) | *p*<0.001* |
| No | 141 | 150.7 | (118.8 to 191.3) | |

*significant at p≤0.05

MRI- Magnetic resonance imaging; A&E- Accident and emergency; MIU- Minor injury unit; CI- Confidence interval

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### *5.8.4.2 Explanatory variables with three categories; influence on delay to specialist consultation*

Regression analysis revealed that activity undertaken at the time of injury was associated with significant differences in the delay to specialist consultation ($F_{(2,188)}$= 4.17; $R^2$= 0.043; p= 0.017). Cases who were injured during other sporting activities (n= 36; geometric mean= 56.5 days) had an initial specialist appointment sooner than those injured playing football or rugby (n=135; geometric mean= 113.8 days; p=0.017) or cases who were injured during non-sporting activities (n=20; geometric mean= 177.1 days; p=0.009). There were no significant differences in delay to specialist consultation for those injured playing football or rugby to those injured during non-sporting activity (p=0.24) (table 41 and figure 48).

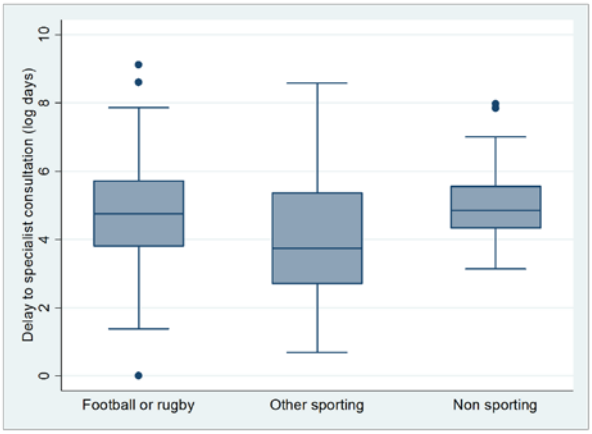



**Figure 48: Box-and-whisker plot showing delay to specialist consultation by activity at the time of injury**

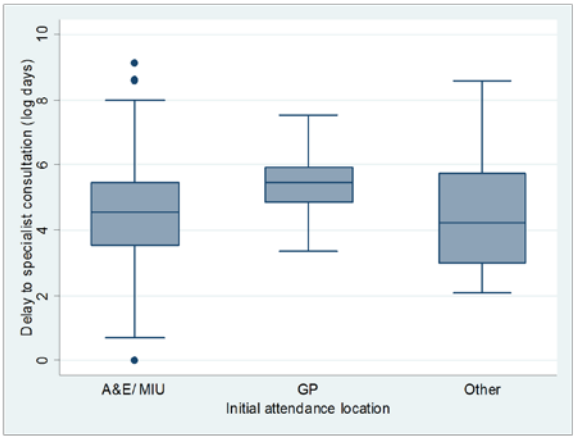
Exploration of initial site of presentation revealed significant differences in delay to specialist consultation ($F_{(2,187)}$= 5.10; $R^2$= 0.052; p=0.007). Patients presenting to a GP (n= 29; geometric mean= 242.5 days) waited significantly more time to specialist consultation than patients seen in A&E/ MIU (n= 148; geometric mean= 89.9 days; p= 0.002) or at other sites (n=13; geometric mean= 83.8 days; p=0.042). The difference in delay for patients seen in A&E/ MIU compared to other sites was not significant (p=0.88) (table 41 and figure 49).

**Table 41: Bivariate analysis of explanatory variable with three categories by delay to specialist consultation**

| Explanatory variable | n | Geometric mean delay to specialist (days) | (95% CI) | *p* value |
|---|---|---|---|---|
| **Activity at time of injury** | | | | |
| Football/ Rugby | 135 | 113.8 | (64.0 to 202.2) | |
| Other sporting | 36 | 56.5 | (33.9 to 94.3) | *p*= 0.017* |
| Non sporting | 20 | 177.1 | (75.4 to 416.9) | |
| **Initial attendance location** | | | | |
| A&E/MIU | 148 | 89.9 | (69.9 to 115.6) | |
| GP | 29 | 242.5 | (130.3 to 451.2) | *p*=0.007* |
| Other | 13 | 83.8 | (34.6 to 203.0) | |

*significant at p≤0.05

A&E- Accident and emergency; MIU- Minor injury unit; GP- General Practitioner; CI- Confidence interval




A&E- Accident and emergency; MIU- Minor injury unit; GP- General Practitioner

**Figure 49: Box-and-whisker plot showing delay to specialist consultation by initial attendance location**

#### *5.8.4.3 Ordinal and continuous explanatory variables; influence on delay to specialist consultation*

Regression analysis showed that neither age ($F_{(1,189)}$=0.11; $R^2$<0.001; p=0.74) nor number of symptoms reported ($F_{(1,189)}$= 2.59; $R^2$= 0.014; p=0.11) were significantly associated with time to specialist consultation (table 42).

**Table 42: Bivariate analysis of ordinal and continuous explanatory variables against delay to specialist consultation**

| Explanatory variable | n | F | $R^2$ | *p* value |
|---|---|---|---|---|
| **Number of symptoms reported** | 191 | 2.59 | 0.014 | *p*=0.10 |
| **Age** | 191 | 0.11 | <0.001 | *p*=0.74 |

### 5.8.5 Summary of results for bivariate analysis

Factors with a significant influence on delay in all of the bivariate models were MRI scan, follow-up appointment if attended A&E/MIU, attending a location operating an AKC and initial attendance location. Activity at the time of injury had a significant influence on delay in all of the models except adjusted delay to

specialist consultation. All other factors were not found to have a significant influence on delay in any of the models.

Factors associated with reduced delay in the bivariate models were not having an MRI scan, having a follow-up appointment arranged if attended A&E/MIU, attending a location operating an AKC and not initially attending a GP surgery.

## 5.9 Multivariable regression

Due to concerns with collinearity attendance at A&E was omitted from the multivariable regression analysis whilst initial location of attendance was retained as it was more predictive of delay in the bivariate analysis. All other variables were retained in the model. Analysis following regression did not reveal any concerns over collinearity for the remaining explanatory variables (Variance Inflation Factor<10 for all variables). It was not possible to include hospital site in the fixed effect multivariable models due to collinearity, however, its potential to have an additional effect was considered and all of the regression models were repeated incorporating site as a random effect variable. This did not materially affect the values of coefficients and therefore fixed effect multivariable models (excluding site) are presented.

### 5.9.1 Multivariable regression for delay to diagnosis

The multivariable regression model was statistically significant accounting for 33% of the variability in delay to diagnosis ($R^2$= 0.33; $F_{(13, 176)}$= 6.78; p<0.001).

Factors which had significant regression coefficients were initial attendance location, whether the site operated an AKC, whether a follow-up appointment was arranged for patients initially attending A&E or MIU and whether an MRI scan was performed (see table 43). The β coefficients indicated that follow-up appointment had the greatest impact on delay to diagnosis, followed by whether the patient attended a site with an AKC. Factors significantly associated with reduced delay to diagnosis were having a follow-up appointment arranged, attending a site with an AKC, not having an MRI performed and not initially presenting to a GP (table 43).

Table 43: Multivariable regression for delay to diagnosis

| Explanatory variables | Linear regression coefficient | (95% CI) | Standardised coefficient β | *p* value |
|---|---|---|---|---|
| **Sex** | | | | |
| Male | Ref. | Ref. | | |
| Female | 0.057 | (-0.70 to 0.81) | 0.011 | *p*=0.88 |
| **Injury type** | | | | |
| Contact | Ref. | Ref. | | |
| Non-contact | -0.46 | (-1.04 to 0.12) | -0.103 | *p*=0.12 |
| **MRI performed** | | | | |
| Yes | Ref. | Ref. | | |
| No | -0.64 | (-1.22 to -0.05) | -0.143 | *p*=0.034* |
| **Follow-up appointment after initial attendance** | | | | |
| Yes | Ref. | Ref. | | |
| No | 1.77 | (1.11 to 2.43) | 0.358 | *p*<0.001* |
| **Acute knee clinic** | | | | |
| Yes | Ref. | Ref. | | |
| No | 0.94 | (0.28 to 1.60) | 0.200 | *p*<0.001* |
| **Activity at time of injury** | | | | |
| Football/ Rugby | Ref. | Ref. | | |
| Other sporting | -0.50 | (-1.32 to 0.32) | -0.095 | *p*=0.28 |
| Non sporting | 0.30 | (-0.65 to 1.26) | 0.044 | |
| **Initial attendance location** | | | | |
| A&E/MIU | Ref. | Ref. | | |
| GP | 0.56 | (-0.61 to 1.74) | 0.098 | *p*=0.002* |
| Other | -1.61 | (-2.82 to -0.40) | -0.197 | |
| **Number of symptoms reported** | 0.07 | (-0.31 to 0.44) | 0.023 | *p*=0.73 |
| **Age** | -0.003 | (-0.03 to 0.03) | -0.011 | *p*=0.87 |

*significant at p≤0.05

MRI- Magnetic resonance imaging; A&E- Accident and emergency; MIU- Minor injury unit; GP- General Practitioner; CI- Confidence interval

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### 5.9.2 Multivariable regression for system delay to diagnosis

The multivariable regression model was statistically significant accounting for 26% of the variability in system delay to diagnosis ($R^2$= 0.26; $F_{(13, 176)}$= 4.68; p<0.001).

Factors which had significant regression coefficients were initial attendance location, whether the site operated an AKC and whether a follow-up was

arranged for patients initially attending A&E or MIU (table 44). Similar to the model for overall delay to diagnosis having a follow-up appointment had the greatest impact on delay followed by whether the patient attended a site with an AKC.

**Table 44: Multivariable regression for system delay to diagnosis**

| Explanatory variables | Linear regression coefficient | (95% CI) | Standardised coefficient β | *p* value |
|---|---|---|---|---|
| **Sex** | | | | |
| Male | Ref. | Ref. | | |
| Female | 0.081 | (-0.80 to 0.96) | 0.014 | *p*=0.86 |
| **Injury type** | | | | |
| Contact | Ref. | Ref. | | |
| Non-contact | -0.086 | (-0.77 to 0.59) | -0.017 | *p*=0.80 |
| **MRI performed** | | | | |
| Yes | Ref. | Ref. | | |
| No | -0.49 | (-1.18 to 0.19) | -0.010 | *p*=0.16 |
| **Follow-up appointment after initial attendance** | | | | |
| Yes | Ref. | Ref. | | |
| No | 1.76 | (0.98 to 2.54) | 0.322 | *p*<0.001* |
| **Acute knee clinic** | | | | |
| Yes | Ref. | Ref | | |
| No | 1.07 | (0.30 to 1.85) | 0.207 | *p*=0.007* |
| **Activity at time of injury** | | | | |
| Football/ Rugby | Ref. | Ref. | | |
| Other sporting | -0.43 | (-1.39 to 0.52) | -0.074 | |
| Non sporting | 0.46 | (-0.65 to 1.57) | 0.060 | *p*=0.34 |
| **Initial attendance location** | | | | |
| A&E/MIU | Ref. | Ref. | | |
| GP | 0.043 | (-1.42 to 1.34) | -0.007 | *p*=0.022* |
| Other | -1.79 | (-3.21 to -0.38) | -0.198 | |
| **Number of symptoms reported** | 0.13 | (-0.32 to 0.57) | 0.040 | *p*=0.58 |
| **Age** | -0.007 | (-0.04 to 0.03) | -0.028 | *p*=0.70 |

*significant at p≤0.05

MRI- Magnetic resonance imaging; A&E- Accident and emergency; MIU- Minor injury unit; GP- General Practitioner; CI- Confidence interval

### 5.9.3 Multivariable regression for adjusted delay to specialist consultation

The multivariable regression model was statistically significant accounting for 30% of the variability in adjusted delay to specialist consultation ($R^2$= 0.30; $F_{(13, 175)}$= 5.84; p<0.001).

Factors with significant regression coefficients and predictive of reduced delay, in the order of impact (greatest first) based on β coefficients, were; having a follow-up appointment arranged, attending a site with an AKC and not having an MRI performed (table 45).

**Table 45: Multivariable regression for adjusted delay to specialist consultation**

| Explanatory variables | Linear regression coefficient | (95% CI) | Standardised coefficient β | *p* value |
|---|---|---|---|---|
| **Sex** | | | | |
| Male | Ref. | Ref. | | |
| Female | -0.16 | (-1.16 to 0.84) | -0.023 | *p*=0.76 |
| **Injury type** | | | | |
| Contact | Ref. | Ref. | | |
| Non-contact | 0.11 | (-0.66 to 0.88) | 0.019 | *p*=0.78 |
| **MRI performed** | | | | |
| Yes | Ref. | Ref. | | |
| No | -1.51 | (-2.29 to -0.73) | -0.263 | *p*<0.001* |
| **Follow-up appointment after initial attendance** | | | | |
| Yes | Ref. | Ref. | | |
| No | 2.39 | (1.51 to 3.27) | 0.374 | *p*<0.001* |
| **Acute knee clinic** | | | | |
| Yes | Ref. | Ref | | |
| No | 0.99 | (0.11 to 1.86) | 0.163 | *p*=0.027* |
| **Activity at time of injury** | | | | |
| Football/ Rugby | Ref. | Ref. | | |
| Other sporting | -0.12 | (-1.21 to 0.96) | -0.018 | *p*=0.46 |
| Non sporting | 0.70 | (-0.56 to 1.96) | 0.079 | |
| **Initial attendance location** | | | | |
| A&E/MIU | Ref. | Ref. | | |
| GP | -0.18 | (-1.74 to 1.38) | -0.025 | *p*=0.86 |
| Other | 0.27 | (-1.34 to 1.87) | 0.025 | |
| **Number of symptoms reported** | -0.025 | (-0.53 to 0.48) | -0.007 | *p*=0.92 |
| **Age** | -0.003 | (-0.04 to 0.04) | -0.009 | *p*=0.90 |

*significant at p≤0.05

MRI- Magnetic resonance imaging; A&E- Accident and emergency; MIU- Minor injury unit; GP- General Practitioner; CI- Confidence interval

### 5.9.4 Multivariable regression for delay to specialist consultation

The multivariable regression model was statistically significant accounting for 40% of the variability in delay to specialist consultation ($R^2$= 0.40; $F_{(13, 176)}$= 8.97; p<0.001).

The factors which were significantly associated with reduced delay to specialist consultation were, in order of impact (greatest first); having a follow-up appointment arranged, not having an MRI performed and attending a site with an AKC (table 46).

**Table 46: Multivariable regression for delay to specialist consultation**

| Explanatory variables | Linear regression coefficient | (95% CI) | Standardised coefficient β | *p* value |
|---|---|---|---|---|
| **Sex** | | | | |
| Male | Ref. | Ref. | | |
| Female | -0.13 | (-0.67 to 0.42) | -0.031 | *p*=0.65 |
| **Injury type** | | | | |
| Contact | Ref. | Ref. | | |
| Non-contact | -0.26 | (-0.68 to 0.16) | -0.077 | *p*=0.22 |
| **MRI performed** | | | | |
| Yes | Ref. | Ref. | | |
| No | -0.98 | (-1.41 to -0.56) | -0.289 | *p*<0.001* |
| **Follow-up appointment after initial attendance** | | | | |
| Yes | Ref. | Ref. | | |
| No | 1.48 | (0.99 to 1.96) | 0.391 | *p*<0.001* |
| **Acute knee clinic** | | | | |
| Yes | Ref. | Ref | | |
| No | 0.64 | (0.16 to 1.16) | 0.122 | *p*=0.010* |
| **Activity at time of injury** | | | | |
| Football/ Rugby | Ref. | Ref. | | |
| Other sporting | -0.36 | (-0.96 to 0.23) | -0.090 | *p*=0.31 |
| Non sporting | 0.19 | (-0.50 to 0.88) | 0.036 | |
| **Initial attendance location** | | | | |
| A&E/MIU | Ref. | Ref. | | |
| GP | 0.60 | (-0.25 to 1.46) | 0.138 | *p*=0.33 |
| Other | 0.01 | (-0.80 to 0.96) | 0.013 | |
| **Number of symptoms reported** | -0.15 | (-0.43 to 0.12) | -0.071 | *p*=0.27 |
| **Age** | -0.01 | (-0.03 to 0.01) | -0.045 | *p*=0.50 |

*significant at p≤0.05

MRI- Magnetic resonance imaging; A&E- Accident and emergency; MIU- Minor injury unit; GP- General Practitioner; CI- Confidence interval

## 5.10 Chapter summary

The results of the multisite survey of delay presented in this chapter provide evidence to further extend understanding of delay periods following ACL injury including factors which contribute to delayed diagnosis and specialist consultation. The following chapter discusses the key findings from the study and explores the inherent strengths and limitations of the research.

# Chapter 6: Study 1: Discussion

## 6.1 Introduction

The results of this study provide evidence of the wide disparity in delay to diagnosis and specialist consultation following ACL injury in NHS hospitals in the UK from a sample derived from a large population base. It explicates the relationship between explanatory factors and observed variability in delay permitting recommendations on measures to improve ACL injury pathways. It extends, expands and refines current knowledge through the use of a conceptual model and, uniquely, is the first study to include multiple sites allowing appreciation of delay in a variety of settings. This enables insight into the impact of an AKC and is the first study to show a statistically significant reduction in delay to diagnosis and specialist consultation from such a service.

This chapter discusses the key findings and implications of study 1 into the nature of, and factors associated with delay, based on data from the multi-site survey incorporating a critical discussion of the adopted methodology and methods.

## 6.2 Critical discussion of methodology and methods

This section discusses the key aspects of the research design focusing on the strengths and limitations of study 1.

### 6.2.1 Study design

The cross-sectional survey methodology employed in study 1 was used to fulfil both descriptive and analytic purposes. Survey designs are appropriate for elaboration purposes, but as opposed to experimental designs which use group randomisation to minimise the chance of confounding, surveys rely on control at the analysis stage rather than data collection stage (de Vaus, 2013). Consequently, a number of factors were identified and incorporated into the analysis, but the possibility remains that some of the observed differences could be due to the influence of unknown confounding variables.

Surveys are prone to non-response which can lead to bias or unacceptable reduction in sample size (de Vaus, 2013). The adopted method of interviewing patients at the time of clinic attendance was successful in limiting non-response with no instances of patients refusing to participate. Response rates for individual questions were also generally high although the question concerning site of initial A&E/MIU attendance was not completed on 18.2% of forms (5.2.3; table 24). In hindsight the formatting of this question could have been improved and would likely have increased response rate. As this question was not related to a factor investigated it did not compromise the results of the regression analysis.

### 6.2.2 Site and staff sampling and recruitment

The purposive method of site recruitment ensured a varied sample in terms of site type (e.g. large inner-city teaching hospitals and district general hospitals), setting (rural and urban) and service provided (AKC or not). The undertaking of a multi-site study, including a large population base from which the sample was

derived, helped to ensure greater external validity than previously achieved by single site studies. However, it is acknowledged that the non-random sampling method does not permit direct generalisation to the population although transferability of results is possible (Teddlie and Yu, 2007). As this study did not include patients with ACL injuries seen and treated outside of the NHS Trusts included, the findings should be interpreted with caution as they may not be representative of delays experienced by patients attending private hospitals, other healthcare services in the geographical area or other NHS hospitals outside of the region.

### 6.2.3 Patient recruitment

The study aimed to recruit a sample of 250 consecutive cases but fell short of this with only 195 returned questionnaires. There were a number of reasons why the recruitment was lower than initially anticipated. Firstly, service reconfiguration at one hospital trust reduced the potential sample of patients with ACL injuries. Secondly, whilst the questionnaires took only a few minutes to complete, it became apparent that on occasions some clinicians felt unable to complete forms where clinics were significantly overrunning. In these circumstances clinicians were asked to complete the questionnaire at the next available opportunity. An oversight and limitation of the study was the failure to record the details of patients who did not have the survey completed at the time of initial assessment in the specialist clinic, although this in itself may have proved onerous given the circumstances for not completing the questionnaire at the first opportunity. Completion of questionnaires by the researcher at each site was considered but deemed impractical due to time constraints, the

overlapping of clinics and prohibitive costs associated with travel. Altering the mode of data collection to a telephone interview could have overcome this but potentially compromised validity (3.6.1). The recruitment rate was also reduced by the decision to exclude patients with multiple ligament injuries, a past history of ACL reconstruction or those who had previously been diagnosed within a specialist clinic.

Despite a failure to obtain the initially desired sample size, this study remains the largest to consider delay to diagnosis and specialist consultation for patients suffering ACL injury. A distinct advantage of this study over much previous research was the inclusion of all patients suffering primary ACL injury and therefore not limiting the sample to those who had undergone ACL reconstruction.

### 6.2.4 Recruitment phase

It was anticipated from the data on the number of ACL injuries treated at two included hospital trusts that the recruitment phase would last 6-8 months but this significantly overran. Data collection was within anticipated levels at three of the included hospital trusts, accounting for the service reconfiguration as discussed previously (6.2.3), but lower than expected in the other two hospital trusts. One reason for the extended recruitment phase was the smaller population base covered by these hospital trusts but this alone does not fully explain the observed differences in recruitment. It is possible that some observed differences result from the decision of patients residing in between catchment areas to attend the larger hospital. It might also reflect differences in the number patients at high risk of suffering ACL injury residing within the

catchment area; for instance, both of the sites where the full 50 patients were recruited have large Universities with associated population of students regularly participating in sporting activity.

A further explanation for the lower than expected recruitment rate was the potential failure to complete questionnaires for all eligible patients raising the possibility of selection bias. If this was the case then it might have been expected that the pattern of delay reported at these sites would differ from other similar sites; however, patterns and length of delay were consistent across sites offering similar service provision suggesting selection bias was unlikely.

### 6.2.5 Comparison with other studies

A strength of the study was the adoption of summary measures of delay which were appropriate to the positively skewed nature of the data on delay rather than the mean and range most commonly used in other research. Further, more detailed descriptions of delay periods allowing greater appreciation of the phenomenon were made possible by collecting data on patient and waiting list delay. However, this precluded direct comparison with the majority of studies due to variation in the data collected and summary measures of delay.

### 6.2.6 Measurement and data quality

Whilst concerted efforts were made to ensure accurate measurement in designing the data collection tool, the possibility of recall bias remains, most notably with regard to key dates used to calculate delay periods. To overcome this, medical records were used where possible in conjunction with patient

interviews in order to confirm dates of injury and initial attendance. In some instances exact dates were not supplied on the returned questionnaires necessitating the use of mid-point rules to estimate dates. Whilst this compromises the accuracy of delay data, the methods adopted are believed to be superior to the majority of previous research in this field solely reliant on medical records to estimate delay as these may be incomplete or contain erroneous information. Analysis of questionnaire agreement (4.3.5) confirmed the suitability of the tool and mode of administration.

The accuracy of responses on the questionnaire relied upon precise, consistent interpretation and recording of information gleaned from the patient interview or medical records. Site visits were undertaken prior to, and at regular intervals during the data collection phase to educate staff on the survey completion process. In addition, a guidance document was also provided at each site to support consistency in data collection. However, the use of multiple staff to complete the interviews may have resulted in observer variation. Further, whilst there was little change of personnel within the clinics themselves, a few had rotational members of staff with whom the lead researcher did not have an opportunity to meet directly prior to them commencing data collection. Whilst the questionnaire was designed to minimise errors in interpretation through closed, unambiguous questions, the possibility of interviewer and recording bias cannot be completely discounted.

### 6.2.7 Analysis

Bivariate analysis was undertaken within this study but caution is warranted when interpreting the findings of the influence of individual factors on delay as,

whilst it provides useful information on associations, it does not account for other potentially important factors. In order to adjust for this, multivariable regression analysis was undertaken but a limitation of this approach is that it cannot guarantee that important but hitherto unknown confounders did not influence the results.

Whilst the analysis was successful in identifying factors which were significantly associated with delay, the confidence intervals were wide and consequently so were the range of plausible values for the actual effect. This lack of precision gives rise to uncertainty over the magnitude of impact for each variable and must be considered when applying the results.

The decision not to perform an adjustment for multiple comparisons has been discussed previously (4.13.3). This reduced the chance of type II (false negative) error, however, the chance of type I (false positive) error was increased which requires consideration when interpreting the findings.

## 6.3 Main findings

The following subsections discuss the key findings from study 1. In section 6.4 the descriptive results including information on the delay periods investigated are discussed. The results from the bivariate and multivariable analysis, including the influence of investigated factors on delay periods, are discussed in section 6.5.

## 6.4 Main findings: descriptive results

### 6.4.1 Patient characteristics

The majority of patients fell within the high risk age group for sustaining an ACL injury and average ages were similar to those previously reported (Parwaiz et al., 2015; Perera et al., 2013; Baraga et al., 2012; Nordenvall et al., 2012; Veysi and Bollen, 2008; Hartnett and Tregonning, 2001; Bollen and Scott, 1996). One study reported a notably lower median age of 18 years (Arastu et al., 2015), reasons for this remain unclear. The proportion of male patients in this study is similar to the other UK based studies of delay (Arastu et al., 2015; Parwaiz et al., 2015; Perera et al., 2013; Bollen and Scott, 1996). However, lower proportions of male patients have been reported in New Zealand and Sweden (Nordenvall et al., 2012; Hartnett and Tregonning, 2001) suggesting that the population group within this study, whilst typical of that seen in the UK, may not be representative of other global societies.

### 6.4.2 The initial injury

Sporting activity was being undertaken at time of injury in the vast majority of cases with football and rugby being most frequently reported. These figures are consistent with previous studies (Arastu et al., 2015; Perera et al., 2013; Bollen and Scott, 1996).

Just over two-thirds of patients had non-contact injuries, slightly lower than reported in previous delay literature (Hartnett and Tregonning, 2001; Bollen and Scott, 1996) but within the levels of non-contact injury reported for sporting

activity (1.1.3). Differences may be accounted for by the criteria used to determine whether it was classified as a contact injury. In this study, patients were questioned as to whether they had had a collision with someone/something at the time of injury whilst Hartnett and Tregonning (2001) took contact to be a direct blow to the knee.

The activity undertaken at the time of injury also differed between this study and Hartnett and Tregonning (2001) with only sporting injuries included in their study and a higher proportion of injuries sustained in non-contact pursuits (netball and skiing). As a definition of how contact injury was determined in Bollen and Scott (1996) was not supplied it is not possible to account for differences. The findings here bring into question the belief that ACL injury should ever be discounted on the basis of a history of contact injury (Bollen and Scott, 1996).

### 6.4.3 Injury features

The four injury features investigated within this study (giving way, inability to continue activity, swelling and hearing or feeling a pop) were all found to be frequently reported by patients supporting the opinion that history may be a useful way of identifying patients who have potentially suffered an ACL injury. The percentage of patients reporting each feature is consistent with previous data obtained both prospectively and retrospectively (Noyes et al., 1980b). This study did not investigate some other features suggested in previous studies such as '*recurrent episodes of giving way*' and '*1-2 weeks to show improvement in weight bearing*' (Arastu et al., 2015) as these can only be appreciated

sometime after the initial injury and are therefore unhelpful when assessing patients who present acutely.

In comparison to Wagemakers et al. (2010) who reported that only 18% of patients reported all three features of effusion, popping sensation and giving way, we noted much higher percentages of patients reporting the symptoms investigated (5.4.3). There were a number of methodological differences which may explain these inconsistent findings. Firstly, the study by Wagemakers et al. (2010) was undertaken in a primary care setting with patients who may differ from those presenting to acute trauma services. Secondly, they based findings on far fewer patients with ACL injury (28 vs 194). Thirdly, we used an interview method to establish giving way as opposed to a proxy measure of giving way obtained from a self-completed questionnaire, and finally almost 40% of patients in the study by Wagemakers et al. (2010) had partial ACL injuries identified on MRI which may not be clinically relevant if the ACL remains functional.

Whilst 57.8% of patients in this study reported all four features investigated, the variation in the number and type of features reported casts doubt over ever defining a 'typical' injury history as stated in previous studies (Arastu et al., 2015; Davidson et al., 2014; Perera et al., 2013; Bollen and Scott, 1996). For injury history features to be of use in identifying patients who have suffered an ACL injury, a lower threshold for onward referral would be required. In this study, using a threshold of at least 2 of the 4 features would have ensured that 95.8% of patients in our cohort would have been referred for a follow-up appointment thereby reducing risk of delay to diagnosis. The significance of this finding is discussed further in section 6.6.

### 6.4.4 Diagnostic rate at initial presentation

This study confirms that the chance of being correctly diagnosed with an ACL injury at initial presentation is low. At only 15.5%, the rate falls within the range of values previously reported (Arastu et al., 2015; Parwaiz et al., 2015; Perera et al., 2013; Veysi and Bollen, 2008; Hartnett and Tregonning, 2001; Bollen and Scott, 1996; Noyes et al., 1980b). Previous discussion has highlighted possible reasons for the low level of correct diagnosis (see chapter 1.2.4).

Of note was the disparity in the percentage of ACL injuries identified at each initial attendance location with comparably low rates in A&E, MIU and General Practice and much higher rates for those seen outside of these settings (e.g. physiotherapy, private specialists) (5.6.4) suggesting differing ability to identify ACL injuries. These findings were similar to those found by Hartnett and Tregonning (2001) who noted a significantly higher rate of diagnosis for patients initially seen by an orthopaedic surgeon or sports medicine doctor. The reasons for this discrepancy remain uncertain but it is postulated that approaches to and/or interpretation of the clinical examination may differ and important history features suggestive of ACL injury may not be recognised by less experienced clinicians who, due to the variety of patient groups and conditions seen, may see comparatively few ACL injuries. Even when a less experienced clinician makes a provisional diagnosis of ACL injury there may also be a lack of confidence in giving a definitive diagnosis to the patient until they have been reviewed by a specialist.

This study highlights the belief that the diagnosis of ACL injury is challenging, especially when performed on acute knee injuries by non-specialist clinicians. The failure to see any notable improvement over a number of decades suggests

that it is unrealistic to expect the majority of ACL injuries to be diagnosed at initial presentation.

### 6.4.5 Diagnosing clinician by profession

Despite almost three quarters of patients initially presenting to a clinician in A&E, only 10.4% were diagnosed by clinicians working in this setting. Orthopaedic doctors and physiotherapists made the majority of diagnoses (78%) in our cohort, a similar pattern to that reported by Parwaiz et al. (2015), despite only a minority of patients presenting initially to these clinicians. As most patients are not diagnosed within the A&E department it further suggests that facilitating streamlined pathways through to clinicians experienced in the diagnosis of ACL injury is of paramount importance to address delay to diagnosis.

### 6.4.6 Follow-up for patients attending accident and emergency or minor injury unit

In this study, 26.7% of patients who had an ACL injury were inappropriately discharged after initial attendance to A&E or MIU, whereas 73.3% had a follow-up appointment arranged. The proportion having a follow-up appointment, being much higher than the proportion diagnosed with ACL injury at initial presentation, suggests that in the majority of cases the potential seriousness of the injury is recognised along with the need for further assessment, even in the absence of definitive diagnosis.

Reasons for the failure to refer patients with an ACL injury for a follow-up appointment were initially considered to result from patients attending A&E departments outside of their area of residency thereby negating the responsibility of arranging a follow-up appointment. If this was the sole reason for failure to arrange follow-up, the percentage of patients attending an out of area A&E department would have been expected to be similar to the percentage inappropriately discharged. This was not the case with only 8.1% attending an out of area A&E department, suggesting that there are alternative reasons why follow-up appointments are not arranged. The most plausible explanation is that patients are initially reassured that they have not suffered a significant injury and do not seek further medical assistance until such time as they experience further episodes of instability or an inability to resume previous levels of activity.

### 6.4.7 The nature of delay

Types of delay investigated were highly positively skewed and questions the reliance on mean values to summarise the central tendency of delay in the majority of existing evidence (Davidson et al., 2014; Perera et al., 2013; Alaker et al., 2012; Nagy et al., 2012; Porteous and Kennet, 2008; Veysi and Bollen, 2008; Hartnett and Tregonning, 2001; Bollen and Scott, 1996). At the time of commencing this thesis there were no studies which reported median values; more recently 3 studies have been published which used median values to summarise delay (Arastu et al., 2015; Parwaiz et al., 2015; Baraga et al., 2012). Whilst this represents an improvement, median values fail to allow true appreciation of the nature of delay as they are based only on a single case. Moreover, the range has been used almost exclusively to summarise spread of

data. Limitations of this choice have been discussed previously (2.7). The following subsections discuss the key findings for the delay periods investigated, concluding with a summary on the nature of delay.

#### *6.4.7.1 Patient delay*

In the majority of cases patient delay was minimal with three quarters of patients presenting to health services within a week of injury, the majority on the day of, or the day following, injury. This finding is consistent with previous reports (Arastu et al., 2015; Parwaiz et al., 2015; Hartnett and Tregonning, 2001; Bollen and Scott, 1996) but belies the true extent of patient delay.

The findings in this study (5.7.1) reflect those of Parwaiz et al. (2015) and reveal that patient delay is a significant contributory factor to overall delay to diagnosis and specialist consultation, albeit in a minority of cases. The failure to specify patient delay in the majority of previous research appears unjustified. Delays of more than 12 weeks are not uncommon (6% in this study; 12% Parwaiz et al. (2015)) and approximately half of these cases will not present until six months or more following injury (5.7; table 32).

The reasons for such extended delays to initial presentation remain unclear. It is proposed that the significance of the injury is not initially recognised by the patient and only when further problems arise is medical assistance sought. In support of this theory, Hartnett and Tregonning (2001) noted that only 5.7% of patients subsequently confirmed with ACL rupture initially considered this diagnosis with 30% having ‘no idea’ of the injury sustained.

#### *6.4.7.2 Waiting list delay*

Waiting list delay has not been investigated in other research studies despite recognition that excessive waiting list delay may prejudice outcomes for patients with functional instability (BOA, 2009). The findings of this study indicate that whilst two thirds of patients waited less than six weeks from specialist referral to initial consultation, waiting list delay was an important source of overall delay with 17.8% waiting more than 9 weeks and 7.3% of patients more than 12 weeks. Waiting list delay was taken from the time of referral to specialist appointment but as data were not collected on missed or rearranged appointments, the reported waiting list delays may have overestimated usual waiting times to see a specialist in some cases. Despite this, the total time spent on waiting lists is more likely to be underestimated as this study only considered waiting list delay to see a specialist and not the time spent on waiting lists to have diagnostic tests (e.g. MRI) or see other healthcare professionals.

The magnitude of waiting list delay suggests its importance should not be overlooked by service providers. Further, as many patients only receive a correct diagnosis of ACL injury following specialist consultation, reducing time spent on waiting lists could also lead to improvements in diagnostic delay.

#### *6.4.7.3 Delay to diagnosis*

Delay to diagnosis was extremely disparate for patients suffering ACL injury, a pattern which was apparent both within and between sites.

As with other studies reporting range of delay (Arastu et al., 2015; Parwaiz et al., 2015; Hartnett and Tregonning, 2001) the survey showed that in extreme

cases, a correct diagnosis is not made until many years following injury. Timely diagnosis is possible as evidenced by the fact that almost a quarter of patients were diagnosed within 2 weeks of injury. Median delay to diagnosis, based on the entire sample, was just under 10 weeks and was similar to those previously reported in the UK (Arastu et al., 2015; Parwaiz et al., 2015). However, the amount of delay experienced by some patients is of considerable concern as it renders them liable to further injury and may consequently negatively impact on prognosis.

Whilst the overall pattern of delay to diagnosis found in this study was similar to that reported by Parwaiz et al. (2015), the proportion of patients waiting more than six months (23.7% vs 35%) or one year (13.7% vs 22%) was lower. Discrepancies are not explained by differences in service type as Parwaiz et al. (2015) had a greater proportion of patients seen following the introduction of an AKC in their cohort.

The median number of appointments to correct diagnosis was 4, higher than the 3 reported by Parwaiz et al. (2015) and Arastu et al. (2015). Parwaiz et al. (2015) acknowledged that their study was likely to underestimate the true number of appointments as it did not account for multiple appointments with the same healthcare professional and only included attendances documented in patient notes. It is therefore suggested that the present study provides more representative figures. A wide variation in the number of appointments to diagnosis was noted with 9% having 10 or more appointments with the potential consequences for repeatedly failing to diagnose these patients manifest.

Analysis revealed a positive linear relationship between delay to diagnosis and subsequent episodes of giving way. This is perhaps unsurprising; Bollen and

Scott (1996) noted that patients with chronic ACL injuries typically reported further episodes of giving way prior to diagnosis. However, this new evidence confirms that achieving earlier diagnosis is of paramount importance in reducing further trauma associated with episodes of instability. A third of patients suffered more than 10 subsequent episodes of giving way prior to diagnosis, a highly unsatisfactory proportion. Informing patients of the diagnosis of ACL injury and advising on activity modification may be effective in limiting further episodes of giving way and therefore additional injury. In support of this hypothesis Arastu et al. (2015) noted that patients who had an MRI or arthroscopy prior to ACL reconstruction and were given advice on activity modification did not suffer additional meniscal or chondral injury in the intervening period compared to patients who had similar waits for surgery but had not been given this advice.

#### *6.4.7.4 System delay to diagnosis*

The figures presented for system delay to diagnosis confirm that the majority of delay to diagnosis is attributable to delay experienced subsequent to initial patient presentation.

The results indicate that 1 in 5 patients with an ACL injury remain undiagnosed for six months following initial presentation and alarmingly, 1 in 11 patients wait more than 2 years before being informed of a correct diagnosis. This provides clear evidence of the need for improvement.

The only other study reporting median values (Parwaiz et al., 2015) reported longer delays compared to the entire sample of this study (70 vs 52 days). The study by Parwaiz et al. (2015) also showed that 18% of patients waited more than a year after presentation to gaining a diagnosis of ACL injury, marginally

higher than in this study but reveals a consistent pattern of patients suffering prolonged delays to diagnosis and therefore to appropriate treatment.

Evidence from this study shows that it is far from inevitable for patients to have lengthy system delay to diagnosis; across the entire sample 46% were diagnosed within 6 weeks similar to the 44% reported by Parwaiz et al. (2015) showing that the potential to diagnose patients within an acceptable timeframe of presentation exists.

#### *6.4.7.5 Delay to specialist consultation*

Median delay to specialist consultation was 108 days (15 weeks) a figure lower than the 27 weeks reported by the only study reporting median delay to specialist consultation ((Parwaiz et al., 2015).

It has been recommended that ACL reconstruction, when indicated, should take place within 5 months (22 weeks) of injury (AAOS, 2014). However, it is clear that for many patients this will not be achieved with a third of patients having an initial specialist consultation more than six months following injury and almost 1 in 5 patients waiting more than one year. This compares favourably to the 52% of patients experiencing delays to attending a specialist knee clinic of more than six months reported by Parwaiz et al. (2015). It is difficult to explain the observed differences between these studies with only slight differences in patient delay. It is not possible to determine whether waiting list delay to see a specialist accounted for the differences as these were only reported in the current study but it may reflect more recent improvement as the data collection phase was undertaken much earlier (2004-2011) by Parwaiz et al. (2015).

#### 6.4.7.6 Adjusted delay to specialist consultation

Adjusted delay to specialist consultation had not been considered in previous studies. In the majority of cases, best practice guidelines suggesting that patients who sustain ‘a significant injury should be referred to a surgeon with an interest in knee injuries at the earliest opportunity’ (BOA, 2009 p4) are not being met with less than a quarter of patients referred directly to a specialist at the time of initial presentation. Of concern, is the fact that even with patient and waiting list delay removed,  a quarter of the sample had delays to see a specialist of more than six months making clinically meaningful treatment delays inevitable.

#### 6.4.7.7 Summary of the nature of delay

The survey revealed that delay periods are highly variable following ACL injury. Both patient and waiting list delays, often overlooked in previous research, are important contributors towards overall delay to diagnosis and specialist consultation. The levels of delay observed confirm that current practices for identifying patients with ACL injury are not effective for many patients delaying appropriate advice and treatment.

The potential importance of undertaking surgical reconstruction, when indicated, in a timely fashion has been discussed previously (section 1.5). Whilst meniscal or chondral injury may occur simultaneously to ACL injury, the risk of further injury increases consistently over time with potential long term implications on developing osteoarthritis. It is manifest from the reported delays to diagnosis and specialist consultation that many patients will not have the option of surgical reconstruction within the recommended five months to limit further meniscal and

chondral injury (AAOS, 2014). This study shows that the majority of delay occurs following patient presentation and therefore confirms that improvement is required to clinical pathways when dealing with acute knee injuries. An important consideration in facilitating improvement is to identify factors which influence delay; the following section discusses the results from the bivariate and multivariable regression analysis investigating the factors associated with delay.

## 6.5 Main findings: bivariate and multivariable analysis

A criticism of previous research investigating delay was the lack of empirical evidence on factors which influence delay. This meant that whilst the problem of delayed diagnosis has been reported over many years recommendations to improve delay were speculative and their impact uncertain. The regression models used in this study were limited in their ability to predict delay periods accounting for only 26-40% of the observed variation but ultimately, they were successful in identifying important factors which influence delay.

### 6.5.1 Factors significantly associated with delay

Within this study a number of factors have been identified that significantly influence delay to diagnosis and specialist consultation. These are discussed in the following subsections.

#### *6.5.1.1 Follow-up appointment*

Of all the factors investigated, arrangement of a follow-up appointment after initial attendance to an A&E department or MIU had the single greatest impact on delay to diagnosis within the multivariable models. The decision to refer onwards after initial assessment was critical in reducing both the time to diagnosis (29 vs 198 days) and specialist consultation (61 vs 328 days) based on geometric mean values. Whilst there is remaining imprecision on the true extent of differences, even at the most conservative estimates the increase in time to diagnosis and specialist consultation when patients are discharged from acute trauma services without follow-up remains clinically relevant.

Analysis revealed that patients referred for follow-up at initial assessment had significantly fewer appointments to diagnosis explaining some of the difference in diagnostic delay. However, the considerable discrepancies in delay indicate that many patients who are not initially referred for follow-up are lost to the healthcare service for an extended period of time prior to diagnosis.

#### *6.5.1.2 MRI scan*

Having an MRI was shown to increase delay and was statistically significant in all models excepting the multivariable model for system delay to diagnosis (5.9). The differences in delay found are clinically relevant and are highly likely to result in meaningful delays to treatment. This finding could be interpreted as an issue of additional time spent waiting for the scan and its report lending support to the belief that clinical diagnosis of ACL injury, where possible, is desirable (Parwaiz et al., 2015). This would appear to be the case for delay to diagnosis as differences were consistent with time spent waiting for an MRI. However,

differences in delay to see a specialist were greater than would have been accounted for by scan waiting and reporting times alone.

Two thirds of MRI requests were made by orthopaedic consultants in this study. Consequently, it is plausible that the patients who had an MRI may have been more complex cases where clinical examination was equivocal. The benefits of MRI in assisting diagnosis in challenging cases are unquestionable; however, where it is possible to make a clinical diagnosis it is apparent that delay is reduced. Further research is required in order to determine the role that MRI should play in assisting timely diagnosis of ACL injuries but the results suggest that a high index of suspicion should be maintained until ACL injury has been effectively ruled out.

#### *6.5.1.3 Acute knee clinic*

Results confirmed that delay periods were significantly reduced where an acute knee pathway existed in all bivariate and multivariable models. The significant differences in diagnostic delay (15 vs 81 days) and delay to specialist consultation (37 vs 151 days) are of clinical relevance. Patients seen at a site where an AKC was in operation saw additional benefits over those who were not, most notably fewer subsequent episodes of giving way prior to diagnosis. This is an important finding not considered in other research into the effectiveness of an AKC.

There were a number of reasons identified which might help to explain the impact of the acute knee clinic including reduced time spent on a waiting list to see a specialist and improved rates of follow-up arranged for patients initially presenting to A&E or MIU. However, the multivariable regression analysis

confirmed that the AKC was associated with statistically significant reductions in delay even after taking these factors into consideration.

This is the first study to confirm that ACL injuries are diagnosed earlier at sites where an AKC pathway is in operation. Ball and Haddad (2010) reported overall improvement in time to diagnosis for soft tissue knee injuries in general where an AKC is implemented (methodological limitations of this study discussed previously [1.3]). Similarly, Parwaiz et al. (2015) showed improvements in all types of delay following the introduction of an AKC. However, in contrast Parwaiz et al. (2015) failed to show statistically significant differences in delay to diagnosis or specialist consultation, although median system delay to diagnosis reduced from 15 weeks to 8 weeks after its introduction. It is possible that the differences between studies were due to the larger sample size and use of parametric analysis in this study which may have increased statistical power over the non-parametric analysis undertaken by Parwaiz et al. (2015). However, this study also showed larger differences in delay to diagnosis attributable to an AKC than those reported by Parwaiz et al. (2015). One possible explanation for this finding was that less than half of patients presented first to an emergency department in the study by Parwaiz and colleagues, the majority presenting to their GP. In this study, bivariate analysis showed that patients who present first to a GP wait longer for diagnosis and specialist consultation potentially accounting for this finding.

Importantly, the study into delay presented here included delay times for all patients seen at the site (and not only those passing through the AKC). This allows greater confidence in the worth of an AKC which has to consider the effect on delay when taken across a service.

#### *6.5.1.4 Initial attendance location*

Patients who were initially seen by a private specialist or physiotherapist had significant less diagnostic delay than those seen by a GP, or a trauma clinician (A&E /MIU). This finding was not replicated in the models for delay to specialist consultation. A potential explanation initially considered for this was that despite an earlier diagnosis, it was not possible to refer patients directly to a specialist, therefore patients could only access services via a GP or A&E/MIU. If this was the case then it would have been expected that a similar pattern would be seen in the bivariate models. This was not apparent with statistically significant differences in time to specialist consultation observed within the bivariate models. Whilst the relatively low numbers initially seen by a physiotherapist or private specialist reduced the statistical power to detect a significant difference, the most likely explanation is that other factors have a greater influence over delay to specialist consultation than site of initial attendance.

#### *6.5.1.5 Factors only significant in the bivariate models*

Activity at the time of injury was only found to be significantly associated with delay in the bivariate models (excepting the adjusted delay to specialist consultation model) (5.8). ACL injury occurring during other sporting activity, with skiing being the most common, had significantly less delay to diagnosis (20.5 days) and specialist consultation (56.5 days) than the other groups. Interestingly, whilst ACL injuries occurring during non-sporting activity, compared to rugby or football, were associated with markedly longer and clinically important delays to diagnosis (106.8 vs 59.9 days) and specialist consultation (177.1 vs 113.8 days) these were not statistically significant (5.8). It is possible the failure to find a statistically significant difference between these

groups is due to a lack of study power. However, when taking other factors into account, activity at the time of injury did not significantly influence delay. Although imprecision in this study means that it is not possible to conclude that activity at the time of injury does not influence delay, the results suggest that it has less impact than other factors considered in the multivariable models.

### 6.5.2 Factors not significantly associated with delay

A number of variables were not associated with significant variation in delay in either the bivariate or multivariable models including age, sex, number of symptoms reported, injury type (contact/ non-contact) and whether the patient attended A&E/MIU. When considering these findings it should be noted that the confidence intervals for many were wide with some resulting uncertainty over their influence. Further research incorporating a larger sample is required to clarify the effect of these variables on delay with greater precision, however, as they were not significantly associated with delay in the present study, the findings suggest that they warrant less attention when designing initiatives to minimise delay.

## 6.6 Enhancing early diagnosis of ACL injury

The key intervention for reducing delay periods following ACL injury identified in this study is to decrease the proportion of patients attending A&E/MIU who are discharged without follow-up. Previous studies exploring ACL injuries have suggested the importance of identifying a ‘typical’ injury history in assisting diagnosis but have failed to agree on what constitutes a ‘typical’ injury history (Arastu et al., 2015; Davidson et al., 2014; Perera et al., 2013; Bollen and Scott,

1996). As a result, it has been impossible for clinicians to discern the most pertinent injury features relevant to ACL injury diagnosis from the research evidence for application in to practice.

The potential for the injury history features investigated in this study to improve follow-up referral rates is evident. Using a threshold for onward referral of at least 2 of the 4 features investigated, the percentage of patients inappropriately discharged following initial presentation would have been reduced from 26.7% to 4.2%. It is acknowledged that this could have significant resource implications as many non-ACL knee injuries may exhibit these symptoms but use of this threshold would also potentially reduce the number of patients having multiple appointments prior to diagnosis and consequently the risk of complications associated with treatment delays. Further study would be required to determine the cost effectiveness of using this threshold to determine which patients should be referred for a follow-up appointment. However, the current status quo is highly unsatisfactory for patients with ACL injuries and maintaining a high index of suspicion may be the only effective way to improve follow-up rates.

This study has identified the potential role that an AKC can play in reducing the time to diagnosis and specialist consultation following ACL injury. A number of benefits of an AKC service were shown including improved follow-up rates, reduced waiting list delay to see a specialist, fewer appointments to diagnosis and reduction in the number of subsequent episodes of giving way. The potential cost benefits from an AKC service have also been promoted previously (Ball and Haddad, 2010).

As initial attendance location was noted to significantly impact on delay to diagnosis, the findings support a streamlined pathway to see someone suitably qualified in assessing acute knee injuries. This may obviate the need for many MRI scans and also reduce the amount of delay. Where MRI is required to assist diagnosis, a further recommendation is to expedite these examinations to minimise patient wait times when required.

Patient delay may also be reduced though greater education of patients on the possible mechanisms of injury and features which may be evident at the time of, and shortly following, injury. However, this will require further investigation and is outside the scope of the current study.

Waiting list delays, heavily influenced by policy and resources are potentially difficult to control, but the results in this study have shown the potential to streamline patients for early assessment thereby reducing overall delays. A further recommendation is to introduce acute knee pathways which may obviate lengthy waiting list delay.

## 6.7 Chapter summary

Evidence presented demonstrates that the current system fails many patients who have suffered an ACL injury. The new knowledge derived from this study provides a basis for developing initiatives to decrease time to diagnosis and specialist consultation thereby improving patient experience and outcomes.

# Chapter 7: Methods: Study 2: Direct observation study of specialist, non-specialist orthopaedic and accident and emergency department assessment of acute knee injuries

## 7.1 Introduction

Study 1 highlighted the considerable delays that exist in diagnosing ACL injury, despite early presentation to health services for the majority of patients, and permitted greater appreciation of the factors that impact on delay. Consistent with previous evidence, study 1 confirmed that a significant proportion of ACL injuries are not recognised upon initial clinical examination.

It has been suggested that additional education is required for non-specialist staff, most notably within the A&E setting, in order to facilitate earlier identification of ACL injuries (Arastu et al., 2015; Parwaiz et al., 2015; Bollen and Scott, 1996). However, these findings were based on the poor rate of identification of ACL injuries and not directly related to observed deficiencies in the clinical examination of knee injuries. Therefore, it was unclear whether the approach to clinical examination differs between professional groups and whether key information is missed during the subjective examination or simply misinterpreted. The challenges when physically examining acute knee injuries have been discussed previously (1.2.4) but it was also uncertain how, or indeed whether, approaches to the physical examination differ between clinicians working in different settings and with alternative skill sets. Such information is imperative in order to gain understanding of deficiencies in the examination of

acute knee injuries allowing for specific recommendations on how it may be improved and directing the type and content of any education required.

Study 2 explores the examination of acute ACL injuries within an A&E and orthopaedic trauma clinic setting, identifying how approaches in the clinical examination of acute knee injuries differ between staff working in A&E (all grades and relevant roles), specialist and non-specialist orthopaedic roles. Whilst Donabedian (1988) suggests that the process (what is actually done in giving care) is one of the key determinants of quality of care, in order to appreciate variation in the clinical examination from an alternative perspective this study also includes an investigation into patient satisfaction with the clinical encounter.

This chapter outlines the method used to undertake a direct observation study of acute knee injury assessment including choice and justification of data collection instruments. It details the formulation of a checklist used to record the clinical examination and determining items which are expected as part of a standard (routine) examination of all acute knee injuries. Justifications for the choice of functional and patient satisfaction outcome measures are provided and issues pertaining to validity and reliability of the chosen measures are considered.

### 7.1.1 Definitions

The following key definitions are used in study 2:

**Specialist**- a medical professional working in an orthopaedic role highly trained in the assessment and management, including surgery, of soft tissue knee injuries.

**Non-specialist**- a medical professional working in an orthopaedic role assessing soft tissue knee injuries not fulfilling the criteria to be classified as a specialist.

**Accident and emergency (A&E) clinician**- a health professional assessing soft tissue knee injuries within the A&E department setting.

These and additional definitions for terms used within this study are listed within the glossary of terms (xxii).

## 7.2 Aims, objectives and hypotheses

### 7.2.1 Aims

The overriding aim of study 2 was to understand whether there are differences in the approach to examining acute knee injuries between specialist, non-specialist orthopaedic and A&E clinicians with a view to understanding whether these could explain observed differences in diagnostic accuracy. The key research question has been stated previously (2.9).

### 7.2.2 Objectives relating to study instruments

- To produce an observation checklist of items to record the clinical examination of acute knee injuries.
- To determine which items from the observation checklist are expected as part of a standard (routine) examination.
- To produce an instrument for recording pain and function for patients with acute knee injuries.

- To produce an instrument for assessing patient satisfaction with a clinical encounter.

### 7.2.3 Overall study objectives

- To determine background pain and functional levels for patients with acute knee injuries.
- To identify the number, range and specific type of tests undertaken during the clinical examination of acute knee injuries.
- To identify the number, range and specific type of tests related to ACL injury undertaken during the clinical examination of acute knee injuries.
- To compare the subjective and physical examination performed to an expected standard (routine) examination.
- To compare the subjective and physical examination specific to ACL injury performed to the ACL specific items expected in a standard (routine) examination.
- To determine the time taken to examine patients with acute knee injuries.
- To determine whether differences in patient satisfaction exist depending upon whether they were assessed by clinicians classified as a specialist, non-specialist or working within A&E.

### 7.2.4 Hypotheses

- Background pain levels will differ between groups.
- Pain induced during the physical examination will differ between groups.

- Background functional levels will differ between groups.
- There will be between group differences in the number of checklist items specific to ACL injury observed during the subjective and physical examination.
- There will be between group differences in the number of checklist items observed during the subjective and physical examination.
- There will be no between group differences in the time taken to examine acute knee injuries.

## 7.3 Research instruments

In order to fulfil the aims, objectives and hypotheses instruments were required which could be used to record the clinical assessment, provide information on background levels of pain and function and assess patient satisfaction. Reasoning behind the decision to use non-participant direct observation has been discussed previously (3.6.2). The following sections (7.4 to 7.7) detail the development of the observation checklist and choice of pain, function and patient satisfaction measures.

## 7.4 Development of the acute knee injury assessment observation checklist

### 7.4.1 Introduction

In order to appreciate differences in the clinical examination of acute knee injuries it was imperative to employ an instrument which could be used to accurately record the examination. Whilst the primary focus of this thesis relates

to ACL injury, the checklist also incorporated items pertinent to other soft tissue knee injuries. This allowed greater understanding into broader differences in the approach to the clinical assessment of acute knee injuries thereby placing ACL injury assessment in a wider context.

One method of recording specific observable actions is to use a checklist, which can also reduce bias compared to alternative methods of observation (e.g. field notes) (Taylor-Powell and Steele, 1996). Whilst no such available checklist had been specifically designed to record an acute soft tissue knee injury assessment, more general guidelines on assessing acute knee injuries were available from the  (NICE, 2011; NZGG, 2003). However, the use of guidelines as a sole basis for recording the clinical examination in this study was unsuitable for a number of reasons. Firstly, the guidelines did not include the range of possible items which may be used during the examination of an acute knee injury; this meant that it could not be used to accurately record important elements of the clinical examination as it occurred. For example, whilst the guidelines suggest a series of clinical examination items regarded as most appropriate, clinicians may use a different series of tests with the same ultimate purpose. Secondly, the guidelines were dated with the NICE guidelines largely based on those initially developed by the New Zealand Guidelines Group (NZGG, 2003). Consequently, in the intervening period it was plausible that practice may have changed and tests previously regarded as best practice could have been superseded as a result of emergent evidence. It was therefore apparent that a new purposeful checklist needed to be developed.

The objectives necessitated a checklist consisting of a comprehensive list of items which *may* be considered important in the assessment of acute knee injuries. This allowed accurate recording of the clinical examination whilst

avoiding inclusion of items which were not directly relevant to acute soft tissue knee injury assessment. In order to compare the observed clinical examinations against an expected standard, it was also necessary to identify the items which, under normal circumstances, would be expected in a routine clinical examination of an acute soft tissue knee injury. The checklist included items pertinent to both the patient interview (subjective examination) and physical examination tests as both are regarded as essential elements in completing a thorough clinical examination (NICE, 2011; Magee, 2008; Solomon et al., 2001).

### 7.4.2 Methods

A number of approaches to formulate the checklist and establish content validity were considered but many have significant limitations. Consistency estimates (e.g. coefficient alpha) were unsuitable as they do not provide information on individual items within an instrument (Polit et al., 2007). Consensus estimates which provide a simple proportion level of agreement have been criticised as they fail to take into account chance agreement and consequently may inflate estimates of agreement (Polit et al., 2007). A number of content validation processes which account for chance agreement have been proposed (e.g. (Polit et al., 2007; Wynd et al., 2003; Lynn, 1986; Lawshe, 1975)). Lawshe's (1975) method used extensively since its inception in numerous fields including healthcare (Wilson et al., 2012) allows calculation of both individual item and scale agreement values, is simple to compute and interpret, and accounts for chance levels of agreement. The two stage approach of Lawshe's content validation was suitable for producing both a comprehensive checklist of items used to record the clinical examination and a subset of items which were regarded as expected from a 'standard' examination. It therefore fulfilled the

desired characteristics to achieve content validation of the direct observation checklist.

Lawshe's content validity ratio (CVR) (Lawshe, 1975) is a method used to quantify consensus amongst panel members who work independently and respond to each item by deciding if they are:

- 'essential'
- 'useful, but not essential'
- 'not necessary'

to the task, in this case an expected 'standard' when performing an acute knee examination.

It is essentially a linear transformation of the proportion level of agreement amongst panel members with values ranging from -1 to +1. CVR is calculated based on the following formula (Lawshe, 1975):

$$CVR = \frac{n_e - (N/2)}{N/2}$$

CVR =content validity ratio; $n_e$ = Number of panel members indicating an item 'essential'; N = Number of panel members

Lawshe's content validity method is used to determine the individual items which should be included in the final instrument, removing those which fail to achieve a proportion level of agreement amongst panel members of 0.5 or above after accounting for chance agreement. This threshold was based on assumptions consistent with established psychometric principles that 'any item, performance on which is perceived to be ''essential'' by more than half of the panellists, has some degree of content validity' (Lawshe, 1975 p. 567).

In Lawshe's original article on content validation it was suggested that subject experts could be used to define the content domain (Lawshe, 1975). Lynn (1986) takes an alternative approach and suggests an initial development stage should involve a literature review to define the domain and identify content for the instrument. This study incorporated elements of both a literature review and expert panel working independently to identify content for the checklist to help ensure that the instrument was comprehensive and therefore fit for purpose.

A three stage process, modified from the content validation methods proposed by Lawshe (1975), was used in order to formulate a comprehensive checklist of items and determine which of these items were expected in a 'standard' acute knee examination, establish content validity for the expected 'standard' examination items and determine the inter-rater and intra-rater agreement of the checklist (figure 50).

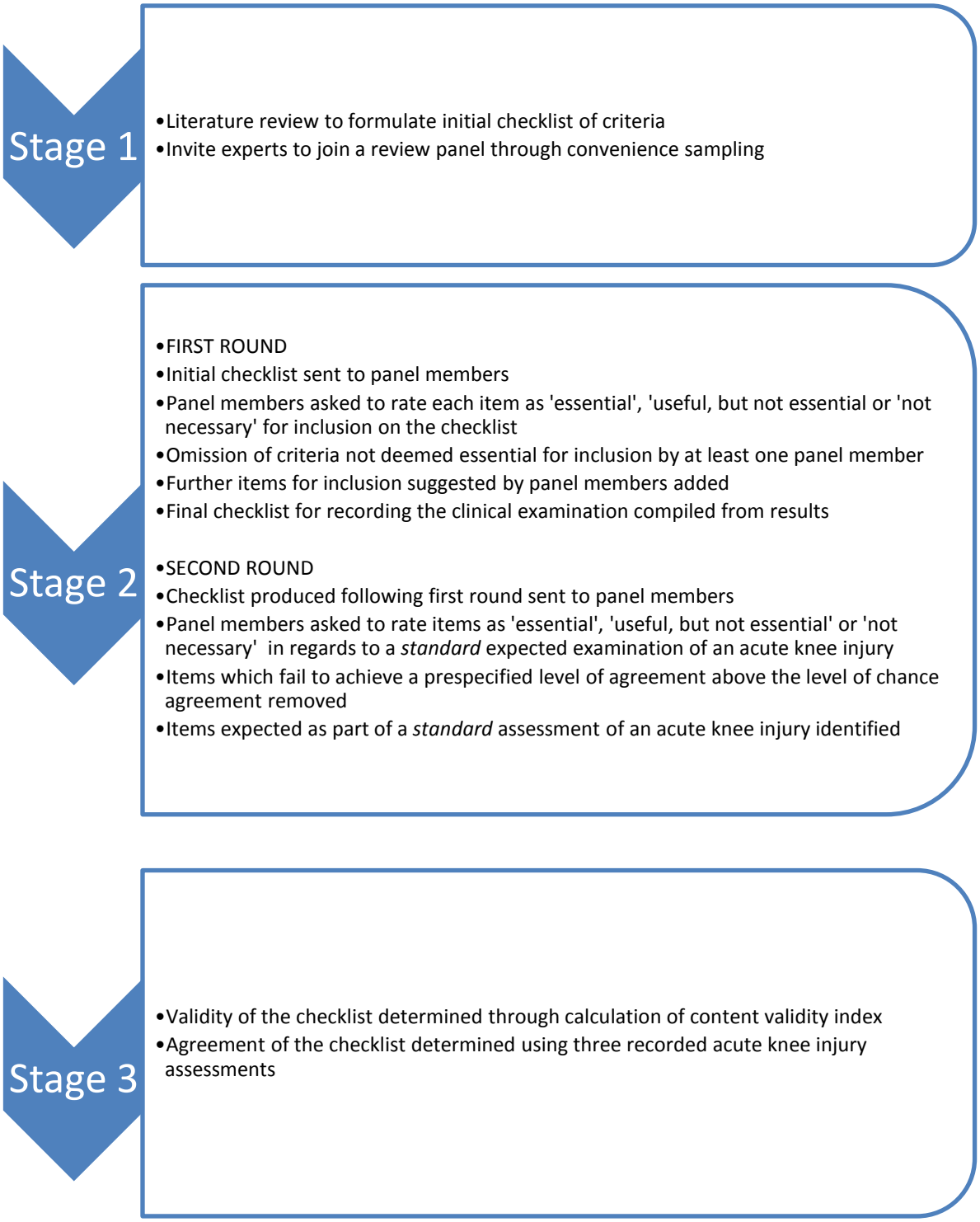


**Figure 50: Stages in the development of the direct observation checklist**

### 7.4.3 Stage 1: Literature review and formulation of panel

#### *7.4.3.1 Literature review*

Items for inclusion in the initial checklist for panel review were first established from textbooks on orthopaedic assessment and guidelines on acute knee injury assessment (Buckup, 2011; NICE, 2011; Hattam and Smeatham, 2010; Magee, 2008; Konin et al., 2006; McRae, 2004; NZGG, 2003). This was supported by a literature search of physical examination tests undertaken in the Medline and CINAHL databases from October 2002 until October 2012 using the EBSCO interface in order to ensure tests within the checklist were current. The MeSH terms “Knee injuries/ Diagnosis” and “Physical Examination” were used. Limits of ‘human’, ‘abstract available’ and ‘English language’ were applied. From the literature review domains relevant to the assessment of acute soft tissue knee injuries (e.g. meniscal tests, ACL tests, PCL tests) were established and populated with individual items which had to be audibly or visually observable to be included. Items specific to bony injury or circulatory injury were not included on the checklist as patients with fractures or circulatory disturbance (e.g. compartment syndrome, deep vein thrombosis) were excluded from study participation as these conditions would prohibit a full clinical examination. The literature review identified 111 items (23 subjective and 88 physical examination tests). For the physical examination test items 87 were identified from orthopaedic texts with one further meniscal test (knee compression-rotation test) identified from the literature search (Sae-Jung et al., 2007) (see also 7.4.4.1).

#### *7.4.3.2 Checklist item style*

Direct observation can be susceptible to both bias and error which may ultimately compromise the reliability and validity of the findings (USAID, 1996). In keeping with recommendations on limiting bias and error, the observation checklist consisted of closed-ended items and unambiguous response categories (USAID, 1996). Prior to expert panel review, the checklist items were ordered alphabetically within the established domains of interest in order to minimise order effect bias where the relative position of an item elicits a particular response rather than the item content (Perreault, 1975).

#### *7.4.3.3 Panel size*

Panel size was an important consideration in determining items which should be performed as part of an expected 'standard' acute knee assessment as the proportion level of agreement required to exceed that of chance generally reduces with increasing panel size. Recruiting a large panel could prove challenging but with few panel members, agreement beyond that of chance would only be assured if all panel members agreed an item essential. Lawshe (1975) incorporated a table of critical values for CVR ($CVR_{critical}$) which indicated, for a given panel size, the minimum CVR required such that agreement exceeded that of chance. Items achieving the threshold level of $CVR_{critical}$ are included on the final checklist with the rest discarded. Some concern had arisen regarding the values in this table as the original methods of calculation of the $CVR_{critical}$ were never reported and, as the original authors had since passed away, no clarification was possible (Wilson et al., 2012). This led Wilson et al. (2012) to produce a further table of $CVR_{critical}$ values based on the normal approximation to the binomial distribution. Discrepancies between the

$CVR_{critical}$ reported in Lawshe (1975) and Wilson et al. (2012) and concerns by the use of normal approximation to the binomial distribution, which yields unachievable CVR values based on the discrete nature of both panel size and the number of panel members who can agree any item essential, led to the calculation of exact binomial probabilities for $CVR_{critical}$ (methods shown in table 47). The findings formed the basis of an article which was subsequently published (Ayre and Scally, 2014).

**Table 47: Methods used to calculate $CVR_{critical}$ based on exact binomial probabilities**

| |
|---|
| As the CVR is designed to show a level of agreement above that of chance in one direction a one-tailed hypothesis test was used.<br><br>Exact $CVR_{critical}$ values were calculated for panel sizes between 5 and 40, based on the discrete binomial distribution, computed using Stata Statistical Software: Release 12 (StataCorp (2011), College Station, TX: StataCorp LP). The following command was used:<br><br>bitesti N $n_e$ p<br><br>Where N= total number of panel members, $n_e$ = number of experts agreeing 'essential', p = the hypothesised probability of success (agreeing the item as essential) = ½<br><br>Null hypothesis ($H_0$): $n_e$ =N/2<br><br>Significance (α) was set at 0.05.<br><br>Using a one-tailed test $H_0$ would be rejected if $P(n_e \geq n_{critical}) \leq 0.05$; where $n_{critical}$ = the lowest number of experts required to agree an item 'essential' for agreement to be above that of chance, $n_e$ = the number of experts rating an item as 'essential'. |

Using this method a table was produced reporting the minimum number of experts ($n_e$) required for each panel size to agree an item essential such that $H_0$ (i.e. the minimum number of experts such that $p \leq 0.05$) could be rejected. Values for $CVR_{critical}$ were then calculated on the basis of the minimum number of experts required using the formula for calculating CVR (7.3.2). The table of exact binomial probabilities can be seen in Appendix V.

Based on the calculated values for $CVR_{critical}$ it was decided to recruit a panel of 16 members as this would mean that 75% (i.e. 12 out of 16 panel members) were required to agree that an item was 'essential' for it to be included in the 'standard' examination items. This panel size was deemed achievable and preferential as it necessitated a lower overall proportion level of agreement for items to be included compared to a panel size of either 15 or 17. From the table (Appendix V) it can be seen that for panel sizes of 7 or less 100% agreement between panel members would be required and even with 10 panel members 90% agreement would be required for any given item to be included. This level of agreement was not considered possible without the exclusion of potentially important items from the expected 'standard' examination even in cases where there was a high proportion level of agreement amongst panel members that its inclusion was essential. A further advantage of the chosen panel size, compared to recruiting a smaller panel, was that the additional members would help to ensure item content was comprehensive.

#### *7.4.3.4 Panel selection*

It is suggested that the panel formed as part of the judgement quantification process in evaluating content validity is made up of 'experts' (Lynn, 1986; Lawshe, 1975). Whilst there is no clear indication of whom may be approached to be a panel member, each must be justifiable as a subject matter 'expert', someone familiar with the domain of interest (Lawshe, 1975). For the purposes of the present study a clinician was deemed 'expert' if they worked as a musculoskeletal clinician, regularly encountered knee injuries and had at least five years' experience of independently assessing knee injuries. Panel members were recruited through a convenience sampling method. In order to

ensure that the sample was diverse, panel members were approached from a range of different workplace settings and from a number of different disciplines. Potential panel members were approached and sent a letter detailing the purpose of the validation process (see Appendix VI).

#### *7.4.3.5 Final panel*

In total, 16 out of 18 health professionals approached participated in the validation of the checklist with two failing to respond to initial emails inviting them to consider participation. The panel consisted of 4 orthopaedic consultants specialising in soft tissue knee injuries, 3 GPs specialising in musculoskeletal practice, 1 sports medicine physician, 1 sports physiotherapist, 1 lecturer in physiotherapy and 6 further physiotherapists all specialising in musculoskeletal practice. Panel members were recruited from ten separate organisations and had been qualified for a mean of 19.5 years (range 8 to 34 years) assessing knee injuries independently for a mean of 15.75 years (range 5 to 30 years). Eight (50%) of the panel members had experience of assessing knee injuries within an A&E department setting.

### 7.4.4 Stage 2: First and second round checklists

#### *7.4.4.1 First round checklist*

The initial stage involved identification of any additional items not identified in the literature review which were deemed potentially important by the panellists when examining an acute knee injury. This ensured that the final checklist was comprehensive and exhaustive. Any item which was felt to be essential for inclusion by at least one panel member was retained at this stage. The low

threshold for retaining items following the first round checklist ensured that the list was suitable for recording all potentially important items. The first round checklist review should ensure item clarity in addition to relevance (Lynn, 1986) and therefore panel members were also asked to make suggestions on improving clarity.

There were three further items identified by the panel for the subjective examination; desired level of functional attainment; how often any giving way occurred and response to any previous treatment. One further physical examination test was included, assessment of hip movement. All items identified from the literature review were retained and therefore a total of 26 subjective items and 89 physical examination items were retained on the checklist following the first round.

#### *7.4.4.2 Second round checklist*

A letter detailing the purpose of the second stage of validation was sent to participants (appendix VII) along with the checklist produced following the first round (Appendix VIII). Panel members were asked to indicate against each item whether they considered it to be 'essential', 'useful but not essential' or 'not important' for inclusion in a 'standard' (routine) examination of an injured knee. In this instance a 'standard' knee examination referred to the tests which, under normal circumstances would be expected in *all* clinical examinations of acute soft tissue knee injuries. This would ensure that the actual clinical examination as observed could be compared to the expected standard examination agreed by the expert panel.

Results from returned checklists were compiled and CVR was calculated based on the methods described by Lawshe (1975) (7.4.2). The results of the validation of the checklist can be seen in Appendix IX. In total 34 items were deemed essential to include as part of a 'standard' examination (18 subjective and 16 physical examination items). The 'standard' examination items were contained within separate sections of the checklist to allow easy identification. The final checklist including all 115 items can be seen in Appendix X.

### 7.4.5. Stage 3: Validity of the direct observation checklist

It has been suggested that an instrument is given an overall content validity in addition to item level content validity (Polit et al., 2007; Lynn, 1986; Lawshe, 1975). Validity of the two portions of the checklist (subjective and physical examination test items), in addition to the overall validity of the checklist, was determined using the content validity index (CVI) proposed by Lawshe (1975). The CVI is the mean CVR score for the items achieving the threshold for inclusion in the 'standard' knee examination following the second round checklist review. CVI values for the subjective, physical examination items and the overall instrument were 0.80, 0.75 and 0.77 respectively.

#### *7.4.5.1 Discussion of checklist validity*

Whilst agreement that any given item was 'essential' among 12 of the 16 panel members was sufficient for it to be considered as expected during a standard soft tissue knee examination, the CVI values indicate that average levels of agreement for included items surpassed this threshold. Lawshe (1975) stated that the more panellists agreeing an item as 'essential', after accounting for

chance agreement, corresponds to greater content validity. An average of 14 out of 16 panel members agreed that inclusion of the physical examination items included in the ‘standard’ examination were ‘essential’, with marginally higher agreement amongst panellists for included subjective examination items. The substantial agreement among panel members on items which should be included within a ‘standard’ acute knee examination suggests high content validity.

### 7.4.6 Stage 3: Agreement of the direct observation checklist

The checklist needed to return consistent results under similar conditions; that is, the interpretation of what takes place in any single clinical examination should remain stable. Without such assurances of stability it is argued that any interpretation of results obtained are of little use (Viera and Garrett, 2005). Whilst reliability and agreement parameters are often used interchangeably in the literature, they are separate concepts addressing different questions (de Vet et al., 2006). Agreement differs from reliability in that it is only concerned with measurement error. In contrast, reliability is concerned with measurement error in relation to between subject variation (de Vet et al., 2006). Whilst it is important for the checklist to be reliable, in that it is able to detect differences in the clinical assessment if they exist, the checklist was primarily used for evaluative rather than discriminative purposes and in such circumstances it is more appropriate to report a measure of agreement (de Vet et al., 2006; Guyatt et al., 1987). Determining intra-rater agreement was essential as the study involved completion of checklists by a single observer. However, in order to ensure that the observation checklist produced an accurate and consistent record of the clinical examination inter-rater agreement was also sought.

#### *7.4.6.1 Sample and setting*

Three video recordings of assessments undertaken on patients with acute knee injuries within a large NHS teaching hospital were used in the agreement study. The recorded assessments took place within two outpatient orthopaedic knee clinics. Potential participants were informed of the planned use for the recording and written consent obtained for all patients who agreed to have their examination recorded.

#### *7.4.6.2 Raters*

Three raters were used to establish the inter-rater agreement of the checklist. The raters, musculoskeletal physiotherapy clinicians, had a mean of 15 years of experience in the independent assessment of knee injuries. Intra-rater agreement was established through a single observer (CA) viewing the three recorded assessments on three separate occasions.

#### *7.4.6.3 Procedure*

Video recordings of the clinical examinations were made by someone who took no further part in the agreement study. The recordings were assigned a number and remained unedited in order to provide an accurate account of the clinical examination as it had occurred. Raters were given time to become familiar with the checklist and had a training session on its use. A further recording of a knee assessment, not used in the agreement study, was viewed and the checklist completed as part of the training process. Each recorded assessment was played in real time on a single occasion with raters marking all items they deemed to have taken place. Checklists were completed whilst viewing the

recorded assessment with up to five additional minutes allowed once the recording had finished ensuring adequate time to consider all items. All observation checklists were completed independently during separate viewings of the recorded assessments and not discussed between raters. In order to limit order effect bias a random number table was used to determine the sequence the recordings would be played in. To minimise recall bias during the evaluation of intra-rater agreement, the second and third viewing of each recorded assessment was not less than one month apart. The data from the checklists were converted into binary data (0= not observed, 1= observed) and input into an excel database (Microsoft Excel [computer software], 2010: Redmond, Washington: Microsoft).

#### *7.4.6.4 Analysis*

Observed and expected levels of agreement were calculated against the expected 'standard' clinical examination items on the acute knee injury checklist. Expected levels of agreement corresponds to that which would be expected by chance, taking into account the overall proportion of instances where an item was marked as observed.

Comparisons between each set of completed observation checklists (intra-rater) and between each pair of raters (inter-rater) were tabulated. Whilst percentage levels of agreement are easy to comprehend they do not take into account chance levels of agreement (Altman, 1991). Therefore analysis using the Kappa statistic was also performed to determine intra-rater and inter-rater agreement. Kappa values and p values were computed using Stata Statistical Software: Release 12 (StataCorp (2011), College Station, TX: StataCorp LP).

#### *7.4.6.5 Results*

Percentage agreement (expected and observed) for the intra-rater reliability study is presented in table 48.

**Table 48: Observed and expected levels of intra-rater agreement by viewing**

| Viewing | Expected level of agreement (%) | Observed level of agreement (%) |
|---|---|---|
| 1 and 2 | 51.7 | 92.6 |
| 1 and 3 | 52.5 | 94.4 |
| 2 and 3 | 52.0 | 92.6 |

The intra-rater agreement across the observation checklist was Kappa (κ) = 0.89 (95% CI= 0.84 to 0.92; p<0.001). The intra-rater agreement for the subjective and physical examination sections of the checklist were κ = 0.83 (95%CI= 0.74 to 0.89; p<0.001) and κ = 0.95 (95%CI= 0.91 to 0.97; p<0.001) respectively.

Observed and expected levels of inter-rater agreement for each pair of raters are presented in table 49.

**Table 49: Observed and expected levels of inter-rater agreement between pairs of raters**

| Rater pair | Expected level of agreement (%) | Observed level of agreement (%) |
|---|---|---|
| 1 and 2 | 51.6 | 88.9 |
| 1 and 3 | 52.9 | 92.6 |
| 2 and 3 | 51.6 | 90.7 |

The inter-rater agreement for the observation checklist was Kappa (κ) = 0.86 (95%CI= 0.83 to 0.89; p<0.001). The inter-rater agreement for the subjective and physical examination sections of the checklist were κ = 0.72 (95% CI= 0.54 to 0.77; p<0.001) and κ = 0.89 (95%CI= 0.87 to 0.95; p<0.001) respectively.

#### *7.4.6.6 Discussion of checklist agreement*

Intra-rater was marginally higher than inter-rater agreement but substantial agreement was found in both cases. Using interpretation guidelines from Landis and Koch (1977) the overall Kappa values of 0.86 and 0.89 may be regarded as 'almost perfect'. Altman (1991) puts this slightly more conservatively and considers these values to be 'very good'. Kappa scores were higher for the physical examination items of the assessment than for the subjective. This may reflect that raters found it harder to interpret auditory information compared to visual information. Notwithstanding differences between the subjective and physical examination portions, the checklist showed high levels of agreement and for the subjective examination items alone, the interpretation would be at least 'good' or 'substantial' agreement (Altman, 1991; Landis and Koch, 1977). Results suggested that the checklist was suitable for use as a tool to record the clinical examination of acute knee injuries.

## 7.5 Pain measure

A visual analogue scale (VAS) was chosen to determine pain level before and following the clinical examination to compare background levels of pain between patients assessed by each clinical group. Visual analogue scales have been shown to be both valid and reliable in the assessment of acute pain (Ostelo and de Vet, 2005). A non-hatched VAS was chosen over a numerical analogue or four point categorical verbal rating scale as it is more sensitive to differences in pain intensity with a 100mm line, measured in millimetres, having the potential for 101 response levels (Breivik et al., 2008; Ostelo and de Vet,

2005). Minimum clinically significant differences of between 9mm and 13mm have been shown from studies investigating the use of a 100mm patient completed VAS for acute pain in an A&E setting (Kelly, 2001; Kelly, 1998; Todd et al., 1996). The minimum clinically significant difference was valid for pain resulting from trauma and was stable regardless of the pain intensity (Kelly, 2001; Kelly, 1998) an important characteristic in study 2.

## 7.6 Functional measure

A number of measures were considered for evaluating the background level of function in patients; the Lysholm scale, Knee injury and Osteoarthritis Outcome Score (KOOS), International Knee Documentation Committee (IKDC), Cincinnati knee rating system, Knee Outcome Survey- Activities of Daily Living Scale (KOS-ADLS) and the Lower Extremity Functional Scale (LEFS). The Cincinnati knee rating system and IKDC were unsuitable as they both involve objective assessment of the individual. The KOOS, IKDC and the Lysholm scale all ask patients to rate their symptoms over an extended period of time (1 week for the KOOS and 4 weeks for the Lysholm and IKDC scales) and are consequently inappropriate for use with acute knee injuries. The LEFS is sensitive to changes amongst patients with acute musculoskeletal conditions but is a generic lower limb measure of function not specific to knee complaints (Binkley et al., 1999).

The chosen measure, the KOS-ADLS (Irrgang et al., 1998) is a patient reported measure of knee function which includes information on symptoms. It has been found to be valid and have high reliability  and has been described as being clearly worded, well understood by patients and can be completed in a relatively

short time period (Marx et al., 2001). It was found to have superior construct validity compared to the subjective components of the Cincinnati knee rating system, Lysholm scale and American Academy of Orthopaedic Surgeons sports knee rating scale and has been suggested for use above these other scales (Marx et al., 2001). As the present study was not limited to a single knee condition, a further advantage of the KOS-ADLS was that it is not condition specific and is designed to assess functional limitations and symptoms from a wide variety of knee pathologies including ligament and meniscal injuries (Marx et al., 2001; Irrgang et al., 1998).

The KOS-ADLS has been suggested to have a standard error of measurement of approximately ± 5 points and a clinically meaningful difference of 10 points (Irrgang et al., 1998).

## 7.7 Patient satisfaction measure

No patient satisfaction measures specific to a single orthopaedic clinical encounter were identified. As the questionnaire was only required to measure patient satisfaction specifically relating to the clinical encounter it was important that it did not contain superfluous information on elements that were not directly relevant, such as hospital environment, other staff (e.g. reception staff, other clinical staff), cost of service and facilities (e.g. parking).

The CARE (Consultation And Relational Empathy measure) is a patient satisfaction measure developed for the purpose of evaluating a single clinical encounter and is designed to be reflective of the ‘process’ rather than the ‘outcome’ of a consultation (Mercer et al., 2004). Face and content validity of the measure have been established through a rigorous process of interviews

with patients. The CARE measure showed strong concurrent validity when assessed against other satisfaction measures, the Reynolds empathy scale (r = 0.84) and the Barret-Lennard empathy subscale (r =0.85). Internal reliability of the questionnaire is high with an overall Cronbach's alpha of 0.93 (Mercer et al., 2004). The test retest reliability established with intraclass correlation coefficient over a 24 hour period is 0.97 (Irrgang et al., 1998).

The CARE measure has been commended as having clear appropriate wording throughout with appropriate response options in a review of patient satisfaction measures (Chisholm and Askham, 2006). However, in relation to the purposes of this study it was missing questions relating to key domains of patient satisfaction, namely overall satisfaction and technical competence, identified in a Picker Institute[4] document (Chisholm and Askham, 2006). For the direct observation component of the study it was deemed important for the questionnaire to include elements relating to technical competence as this was one of the primary foci of the study. In addition, overall patient satisfaction was included to give a holistic opinion of the clinical encounter in keeping with recommendations for patient satisfaction measures (Chisholm and Askham, 2006). In order to bridge this gap, six additional questions were incorporated into the document.

## 7.8 Piloting the questionnaires

Whilst validity and reliability of the VAS and KOS-ADLS measures adopted had been rigorously established through previous research, feedback was sought on the formatting and layout of these measures. As stated above (7.7) the patient

[4] The Picker Institute is a charitable organisation with a focus on improving patient centred care

satisfaction measure contained additional questions and in order to ensure the new content had clarity in phrasing and consistency in understanding, pilot questionnaires were circulated to 20 members of a service user group during a planned meeting within the School of Health Studies, University of Bradford. Group members were informed of the new content which had been added to the original CARE measure and asked to provide written feedback directly onto the questionnaires. Specifically they were asked to comment on the clarity of the additional questions and whether they fulfilled the aim of covering the domains of technical competence and overall satisfaction. Feedback was sought from each group member, having the advantage of making comments more anonymous than if the researcher had been present. This also ensured that views of each group member could be taken into consideration and those involved would not be swayed by the views of other group members. The vast majority of feedback was positive for the included questions, response categories and the clarity of wording with only a minor amendment to the location of wording on the pain scales made. The final versions of the pre-assessment and post-assessment questionnaires used within study 2 can be seen in Appendices XI and XII respectively.

## 7.9 Location of study

The site operating an AKC service was not suitable to undertake the direct observation study as patients were referred directly to a specialist led clinic which precluded comparison between specialist and non-specialist orthopaedic clinicians, one of the key study 2 objectives. A single hospital (Bradford Royal Infirmary) was chosen to undertake the direct observation as the survey into

delay (Study 1) confirmed that the chosen site was typical of those which did not offer an AKC service. In circumstances where a site may be regarded as typical it has been argued that single site observation is justifiable (USAID, 1996).

## 7.10 Sample

### 7.10.1 Sample size

As the study was exploratory no formal sample size calculation was performed. A total sample size of 60 was deemed to be sufficient to gather the information required. It was reasoned that this sample was large enough to allow appreciation of any patterns in the approach to examining acute knee injuries, if they existed. The sample was split equally between the 3 study groups (20 observed patient assessments per group; specialist, non-specialist orthopaedic and A&E clinicians). The sample size was expected to be achievable within given time constraints after taking advice on the number of acute knee injury assessments performed each month within both the A&E department and orthopaedic trauma clinic.

### 7.10.2 Sampling methods

In order to avoid selection bias all acute knee injuries presenting during the data collection phase and fulfilling the eligibility criteria (7.11) were invited to participate in the study. Recruiting consecutive cases presenting for assessment during the times when the researcher was present was also deemed to be the most efficient way of obtaining the desired sample size.

## 7.11 Inclusion and exclusion criteria

Eligibility criteria (table 50) were chosen based on a need to include acute knee injuries that required clinical examination and where the examination would not be contraindicated or unduly compromised.

**Table 50: Eligibility criteria for study 2**

| Inclusion criteria: | Exclusion criteria: |
|---|---|
| • Patients with a soft tissue knee injury*<br>• Appointment within 6 weeks of initial injury<br>• Aged 16 years or over<br>• One or more of the following: locking or clicking, heard or felt a pop/tear at the time of injury, giving way or buckling of the knee at the time of injury or since, knee effusion at any point following injury.<br><br>* 'injury' defined as single physical traumatic event of identifiable origin | • Associated fractures<br>• Concomitant injuries (head injuries, involvement of more than one lower limb joint, nerve injury)<br>• Open wounds affecting ability to clinically examine<br>• Local infection<br>• Circulatory disturbance (e.g. compartment syndrome, arterial injury)<br>• Systemic joint disease (e.g. rheumatoid arthritis, psoriatic arthritis, gout)<br>• Previous surgery to the same knee which would limit the clinical examination<br>• 'Locked' knee |

## 7.12 Bias and error

Observational research is subject to a number of possible biases. Table 51 reviews key areas of bias and the measures taken to minimise the risk of bias in the direct observation study.

**Table 51: Sources of bias and methods used to minimise the risk**

| Bias | Measures to reduce bias |
|---|---|
| *Expectancy Effects*: knowing the hypothesis and aims of the research can potentially influence the observations made and recorded (as well as participant behaviour). | Participants were blinded to the observation checklist. Observer aware of study aims but use of closed questions on the data collection form minimised expectancy effects. |
| *Observer omissions*: a failure to record a behaviour that is actually specified in the observational schedule | Checklist acted as a reminder and was completed during the clinical examination |
| *Selective attention and selective data entry* | If selective attention or data entry was a significant issue it would be expected that the inter-observer and intra-observer agreement was low. Evidence presented (7.4.6.5) shows high levels of agreement for the checklist. |
| *Faulty memory, attention deficits of the observer and selective memory* | All events were recorded at the time of and immediately following the clinical assessment minimising these potential threats to validity. The checklists, used to record the observations served as mnemonic devices and accordingly reduced the chance of omission errors. |
| *Reliability decay* where data recorded during the later phases of the data collection process are likely to be less reliable | This was minimised by the requirement to record all observations at the time of assessment. |
| *Halo effect*: early impressions can influence latter observations. | Unlikely to be an issue as all observations were based on closed questions and therefore minimal interpretation from observer was required. |
| *Central tendency effect*: the tendency to avoid ticking extreme categories (i.e. use mainly midpoint scores). | No midpoint scores were included on the observation checklist. All the categories are binary based on whether items were observed to have occurred or not and therefore no such extreme values existed. |
| *Observer Drift*: the observer starts to redefine the observational variables, to the extent that the data no longer reflects the original definitions. | Closed unambiguous questions within the checklist minimised this risk. |
| *Observer effects*: when the presence/behaviour of the researcher might alter the participants' observed behaviour, quite often unintentionally (in some types of research this effect appears to fade with time). | Observer effects have been shown to diminish over time. The observer attended clinics for two weeks prior to commencing data collection. This served the purpose of reassuring the clinicians participating in the study and allowed them to become familiar with the researchers' presence. Any data collected during this time was discarded and not reported in the final results and analysis. (see also 7.13) |

## 7.13 Observer effects

The presence of an observer in a clinical setting poses issues related to bias with the potential to affect patient and clinician behaviour. This may result in clinical examinations which are unrepresentative of usual practice, biasing the study results. Whilst there is no satisfactory answer to avoiding these effects, it is argued that in spite of limitations, some understanding based on observation is better than none at all. Whilst masking the true purpose of direct observation from clinicians in order to minimise observer effects has been previously advocated (Sharma, 2011) it was not deemed ethical to do so in the present study. However, the specific aims of the research were not shared with participants and the checklist was not shown to those under observation maintaining an element of blinding. As observer effect has been shown to diminish over time (Leonard and Masatu, 2006), clinics were attended for a period of two weeks prior to formal data collection allowing the clinicians to become familiar with the observer and be reassured on study requirements.

## 7.14 Ethical approval

Ethical approval was required via the Integrated Research Application System (IRAS) as it involved an NHS site and was classified as research based on guidelines (HRA [Health Research Authority], 2013). Following review by the Caldicott guardian a minor amendment was made detailing the process for the eventual destruction of data. The initial plan was to observe only specialist and non-specialist clinicians in the orthopaedic outpatient setting but it was deemed important to also observe the assessments performed by A&E clinicians in order to improve understanding of the approach to assessment within this

setting. This had become apparent through the emergent evidence from study 1 where the most significant factor in determining delay was the failure of A&E staff to arrange a follow-up appointment. This amendment to the original study intentions resulted in a delay to commencing data collection in the A&E setting. Approval letters and confirmation of amendments can be seen in Appendices XIII to XVI.

## 7.15 Procedures

Clinical staff from each of the three study groups were approached prior to commencing the study, provided with written information (Appendix XVII) and given an opportunity to ask any remaining questions about the study. Those who indicated that they were happy to participate were asked to provide written consent (Appendix XVIII).

The nursing and healthcare staff responsible for organising clinics were briefed on the study requirements and provisionally identified patients with acute knee injuries from hospital records on days where observation was taking place. Patients were initially approached by a member of the usual care team (nursing or healthcare staff) who supplied appropriate patients with a participant information leaflet (Appendix XIX). Those happy to consider taking part after reading the information sheet were directed to the researcher (CA) to answer any additional questions about the research and expectations of involvement. Those agreeing to participate and who fulfilled the eligibility criteria were asked to provide written consent (Appendix XX), following which the form containing information on pain and functional data was completed by the patient with the researcher present. The clinical examination took place as usual and following

its conclusion patients were asked to complete the post-assessment patient satisfaction questionnaire in private prior to leaving the hospital. A flow diagram detailing the study process is shown in figure 51.

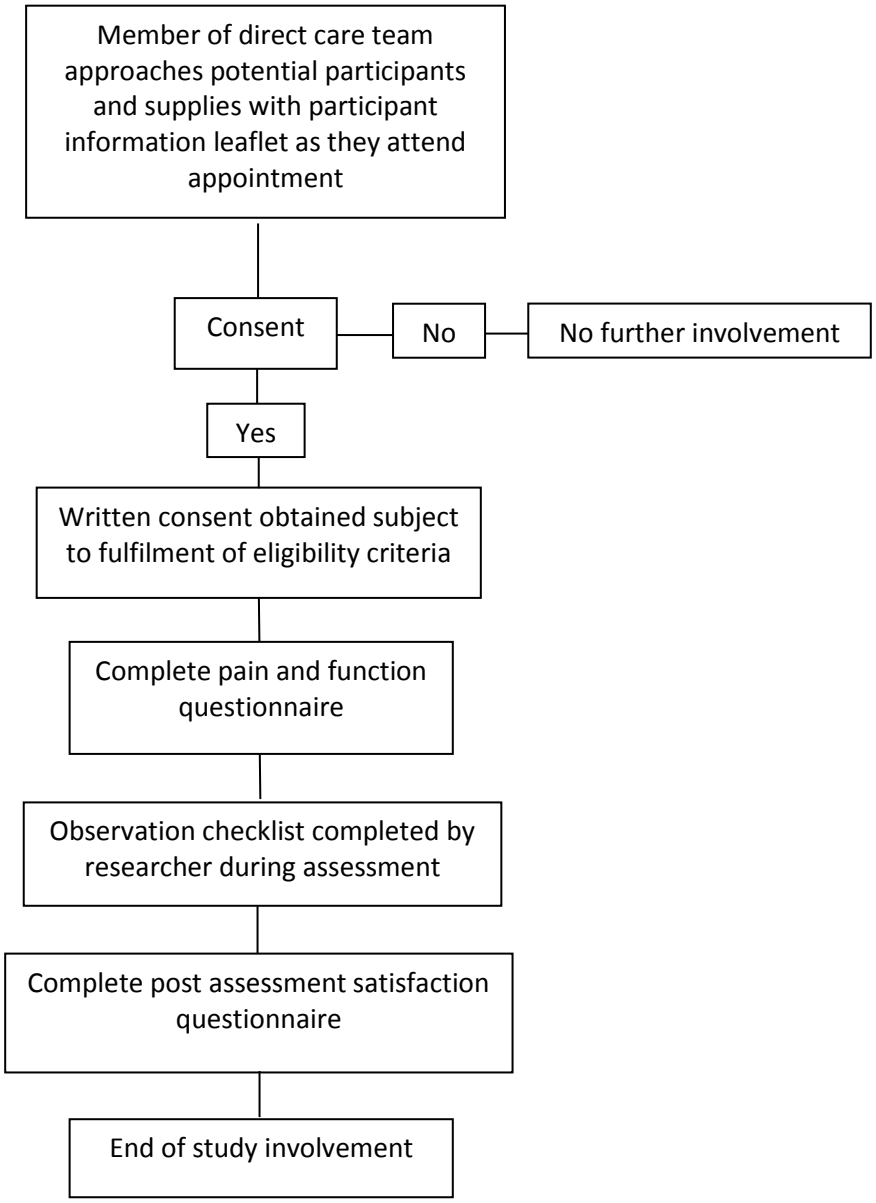


**Figure 51: Flow diagram showing the procedure for participants**

## 7.16 Data handling and storage

Data from completed checklists were converted to binary scores (0= marked as not observed, 1= marked as observed). As the relevance of some of the subjective items on the expected standard examination were dependent upon

responses to other questions (e.g. the direction of giving way was only relevant if the patient had experienced giving way) a proportion was calculated by dividing the number of completed items by the number of relevant items. Any additional items covered during the examination but not on the direct observation checklist were recorded.

The number of items (subjective and physical examination) which had specific relevance to ACL injury (1.2.1; 1.2.2; appendix X) were calculated from the completed checklists.

Responses to each item on the KOS-ADLS were scored from 0-5 with 5 representing the highest functional level and 0 the lowest. Scores of all 14 items from the KOS-ADLS were summed, divided by 70 and multiplied by 100 to give a percentage KOS-ADLS rating (Irrgang et al., 1998).

Pain scores were calculated by measuring the marked level of pain in millimetres from the left hand side (0mm= ‘no pain’) of completed visual analogue scales. Lower scores therefore indicated lower pain levels. Variation in pain levels prior to and following the clinical examination were calculated by subtracting the pre-assessment pain score from the post-assessment pain score. This difference in scores was taken to be a measure of pain induced during the clinical examination.

Items on the patient satisfaction measure were scored on a 5-point ordinal scale with a minimum score of 1 (very poor) to a maximum of 5 (excellent) (Mercer et al., 2004). Items were summed to yield a total score with the maximum possible score 80 and minimum 16. Up to three missing values or ‘does not apply’ responses were allowed, extended from the two proposed by Mercer et al. (2004) due to the inclusion of six additional items. Missing values were replaced

with an average score based on the remaining items in keeping with guidelines on the use of the CARE measure (Mercer et al., 2004).

All data were input into an Excel database (Microsoft Excel [computer software], 2010: Redmond, Washington: Microsoft) and stored on a password protected computer.

## 7.17 Data analysis

### 7.17.1 Descriptive statistics

Descriptive statistics were used to summarise background data, pain, functional scores, patient satisfaction and items observed in the subjective and objective examination as well as overall number of items observed to have taken place. Mean (SD) were reported to summarise between group differences where appropriate, and median (IQR) when data were not normally distributed. Box-and-whisker plots were used to graphically represent interval and ratio level data and bar charts for categorical data. It was not possible to summarise age with a single measure of central tendency (mean or median) as it was categorised. Due to category widths being unequal, age data were represented in a density histogram.

### 7.17.2 Inferential analysis

Parametric analysis was undertaken to compare group differences where conditions for its use were satisfied. Conditions for undertaking parametric analysis (normality of data and equality of variance) were assessed through visual inspection of histograms produced for each group and between group

comparisons of standard deviation respectively. One way ANOVA was used to compare between group differences with regards to pain, function and the number of items observed in the clinical examination. Post hoc comparisons were made, when the ANOVA was statistically significant, using Bonferroni correction in order to account for increased chance of type I error with multiple tests (Bland and Altman, 1995). Results of the Bonferroni analyses were reported as significant or not. Where non-parametric analysis was performed, Kruskal-Wallis was used to assess differences between the three groups. Differences in the completion of individual subjective and physical examination items pertinent to ACL injury were compared using a Fisher's exact test.

Due to the limited sample size and nature of the data for age (ordinal) and sex (categorical), Fisher's exact test was used to assess the statistical significance of any between group differences.

### 7.17.3 Statistical software and significance levels

All statistical analysis was undertaken using Stata Statistical Software: Release 14 (StataCorp, College Station, TX). Statistical significance was set at $\alpha = 0.05$.

## 7.18 Chapter summary

This chapter has detailed the formulation of the measures used to undertake study 2, the direct observation investigating the clinical examination of acute knee injuries. The findings of this study are presented and discussed in the following two chapters.

# Chapter 8: Study 2: Results

## 8.1 Introduction

This chapter presents the results of study 2. It is organised into the following sections:

- 8.2 Summary of recruitment
- 8.3 Background data
- 8.4 KOS-ADLS (function and symptom measure)
- 8.5 Pain
- 8.6 Direct observation
- 8.7 Patient satisfaction
- 8.8 Chapter summary

## 8.2 Summary of recruitment

Data collection took place over a period of 11 months. The first patient was recruited on 11/3/14 and the final patient on 9/2/15.

### 8.2.1 Patient recruitment

The pre-planned recruitment of patients was achieved with a total of 60 patient assessments observed (20 per group). Only a single patient, attending a non-specialist orthopaedic outpatient appointment refused consent to participate (no reasons were obtained). A further patient, also attending a non-specialist orthopaedic outpatient appointment initially verbally consented to participate but left prior to clinical assessment due to delayed appointment times as the clinic was overrunning.

### 8.2.2 Staff recruitment

All of the staff members approached (n=24) agreed to participate in the study. There were two specialists, 11 orthopaedic non-specialists all of whom were consultants and 11 A&E clinicians consisting of Emergency Nurse Practitioners (ENPs) (n=5), staff grade doctors (n=4) and emergency medicine consultants (n=2).

## 8.3 Background data

### 8.3.1 Age

Data on age was available for all 60 patients. A broad range of patient ages were covered in the study although 90% were aged between 16 and 49. The peak age group for injury was 20-24 years with just over half of the patients included in the study being aged between 16-29 years (n=31; 51.7%) (figure 52).

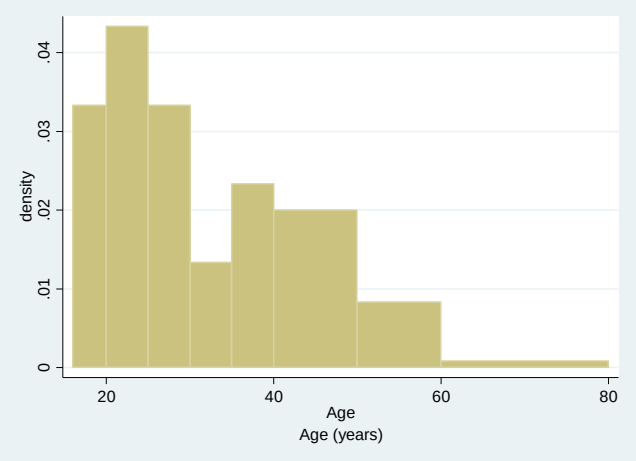


Figure 52: Density histogram showing age group in years (n=60)

Although there was a general trend towards patients seen in A&E being older, a Fisher's exact test did not show the difference to be statistically significant (p=0.66) (see figure 53).

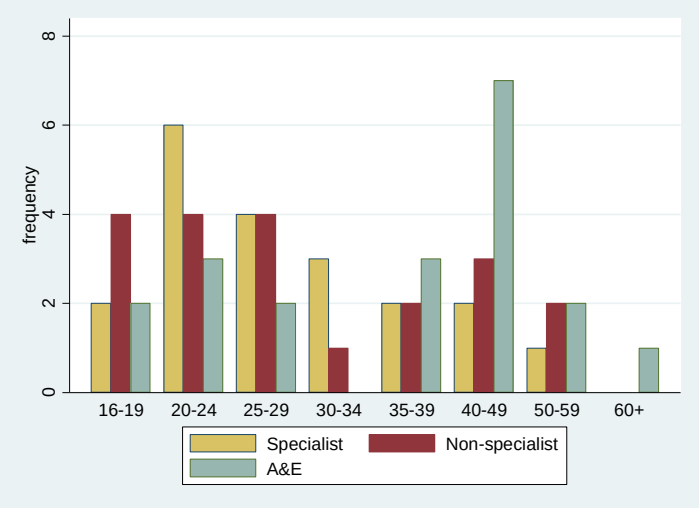


**Figure 53: Bar chart showing numbers of patients by age category and assessment group (n=60)**

### 8.3.2 Sex

The sex of participants was available in all cases (n=60). The majority of patients participating in the study were male (n=44; 73.3%). A Fisher's exact test revealed that there were no significant between group differences in the sex of subjects assessed (p= 0.81) (see figure 54).

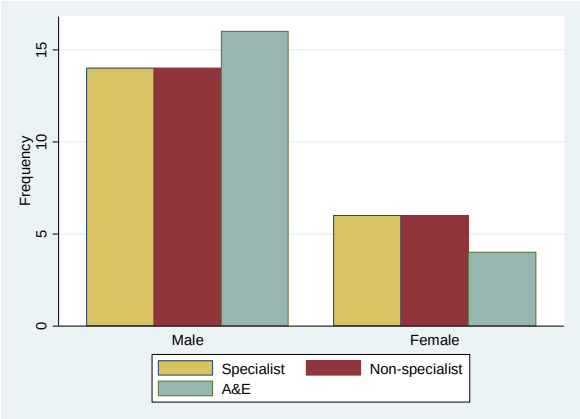


**Figure 54: Bar chart showing number of male and female patients by observation group (n=60)**

### 8.3.3 Days since injury

Information on the number of days from injury to observed assessment date was available for all patients (n=60). Results showed that 80% (n=16) of patients within the A&E group had suffered their injury in the 2 days prior to the observed assessment with a further 10% (n=2) having the observed examination 3 days after injury. In contrast, only 7.5% (n=3) of the patients in the specialist and non-specialist orthopaedic groups had suffered their injury less than a week prior to the observed assessment. A Kruskal-Wallis test confirmed that the differences between groups were statistically significant ($\chi^2_{(2)}$= 29.0; p<0.001), with the median time since injury for patients in the A&E group (n=20; Median= 1 day; IQR= 0.5 to 2) lower than the specialist (n=20; Median= 13.5 days; IQR= 9.5 to 20) and non-specialist orthopaedic groups (n=20; Median= 13 days; IQR= 12 to 14.5) (figure 55).

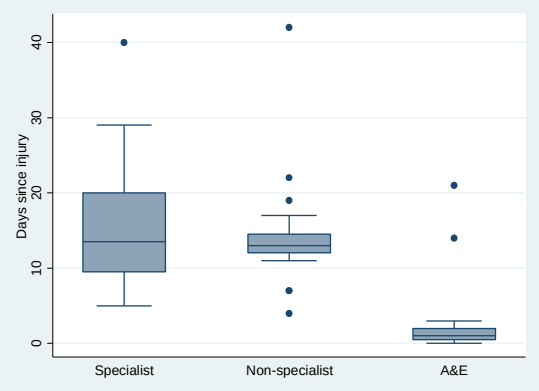


Figure 55: Box-and-whisker plot showing days since injury by assessment group (n=60)

## 8.4 KOS-ADLS (function and symptom measure)

Functional scores were available for all 60 patients. Analysis using a one-way ANOVA revealed that KOS-ADLS scores were significantly different between the three study groups ($F_{(2,57)}$= 6.14; p=0.004). Post hoc comparison

incorporating Bonferroni correction revealed that the mean KOS-ADLS score for patients in the A&E group (n= 20; mean= 31.8%) was significantly lower than for those in the specialist (n=20; mean= 50.9%) or non-specialist orthopaedic groups (n=20; mean= 48.8%). No significant differences in KOS-ADLS scores were noted between those patients seen by a specialist and non-specialist orthopaedic clinician (table 52 and figure 56).

**Table 52: KOS-ADLS scores by assessment group**

| | Number | Mean KOS-ADLS | SD | (unadjusted 95% CI) |
|---|---|---|---|---|
| Specialist | 20 | 50.9 | 16.8 | (42.4 to 59.3) |
| Non-specialist orthopaedic | 20 | 48.8 | 15.7 | (40.3 to 57.2) |
| A&E | 20 | 31.8 | 23.2 | (23.3 to 40.2) |

KOS-ADLS- Knee outcome survey- activities of daily living scale; A&E- accident and emergency; SD- standard deviation; CI- confidence interval

These results indicate that patients seen in A&E were more symptomatic and had lower levels of function than those seen in orthopaedic outpatients by a specialist or non-specialist. Based on suggestion from Irrgang et al. (1998) the difference in function (>10) for patients who were assessed in A&E are clinically meaningful.

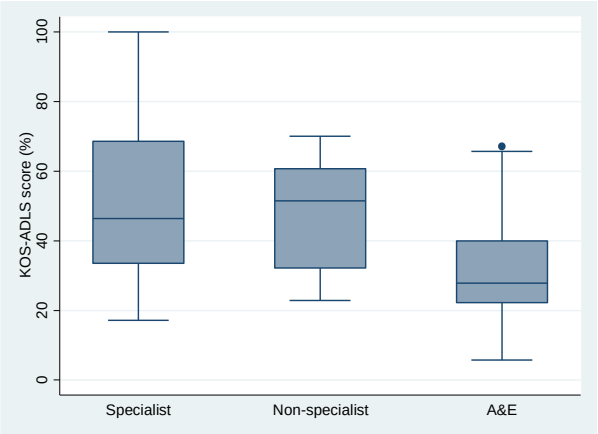


**Figure 56: Box-and-whisker plot showing KOS-ADLS score by assessment group (n=60)**

## 8.5 Pain

Pain scores prior to and following assessment were available in all cases. Pain scores whilst moving around and at rest over the preceding 24 hour period were not available in 5 cases (all from A&E) as they presented for assessment within this timescale. The data on pain scores were not normally distributed and therefore statistical analysis was undertaken using non-parametric tests. The data is summarised in table 53.

**Table 53: Pain scores measured on visual analogue scale by assessment group. Values reported are Median (IQR) (n=60)**

| | Pain moving around (24h)* | Pain at rest (24h)* | Pre-assessment pain* | Post assessment pain* | Change in pain (pre to post assessment) |
|---|---|---|---|---|---|
| Specialist (n=20) | **37.5 (28.5 to 69.5)** | **28.5 (8.5 to 44)** | **21 (0 to 50)** | **20 (0 to 62)** | **0 (-2 to 22)** |
| Non-specialist (n=20) | **48.5 (17.5 to 68)** | **28.5 (5.5 to 47.5)** | **18 (3.5 to 44)** | **32 (10 to 56)** | **4 (0 to 17)** |
| A&E (n=20) | **82 (67 to 96)** † | **66 (32 to 81)** † | **64 (43 to 88.5)** | **76 (47 to 95)** | **3 (0 to 11)** |

*pain scores in mm (100mm scale) where 0=no pain and 100=worst imaginable pain

† Pain at rest and pain moving around data only available for 15 patients

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### 8.5.1 Pain moving around

A Kruskal-Wallis test revealed a statistically significant between group difference in average pain levels moving around over the preceding 24 hours ($\chi^2_{(2)}$= 15.1; p<0.001) with patients having their examination observed in the A&E group reporting higher median pain levels (n= 15; Median= 82mm) than those observed in the specialist (n=20; Median= 37.5mm) or non-specialist orthopaedic groups (n=20; Median= 48.5mm) (figure 57).

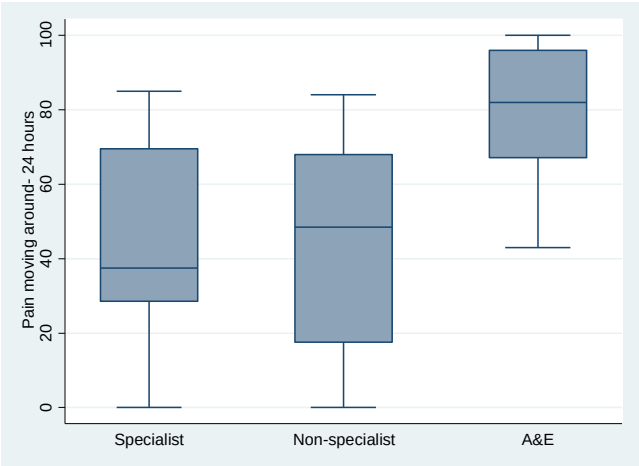


**Figure 57: Box-and-whisker plot showing average pain whilst moving around over 24 hours by assessment group (n=55)**

### 8.5.2 Pain at rest

A Kruskal-Wallis test showed that there was a statistically significant difference between group in patients average pain whilst at rest over the preceding 24 hours ($א^2_{(2)}$= 15.3; p<0.001), with a higher median pain score for those having their examination observed in A&E (n=15; Median= 66mm) than those examined in the orthopaedic outpatient setting by a specialist (n=20, Median= 28.5mm) or non-specialist (n=20, Median= 28.5mm) (figure 58).

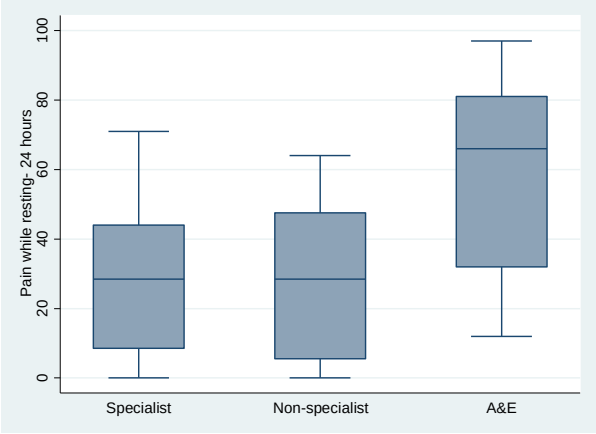


**Figure 58: Box-and-whisker plot showing average pain whilst resting over 24 hours by assessment group (n=55)**

### 8.5.3 Pre-assessment pain

A Kruskal-Wallis test showed a statistically significant between group difference in pre-assessment pain scores ($\chi^2_{(2)}$= 17.4; p<0.001), with those having their assessment observed in A&E reporting higher pain levels (n=20; Median= 64mm) than those in the specialist (n=20; Median= 21mm) or non-specialist orthopaedic groups (n=20; Median= 18mm) (figure 59).

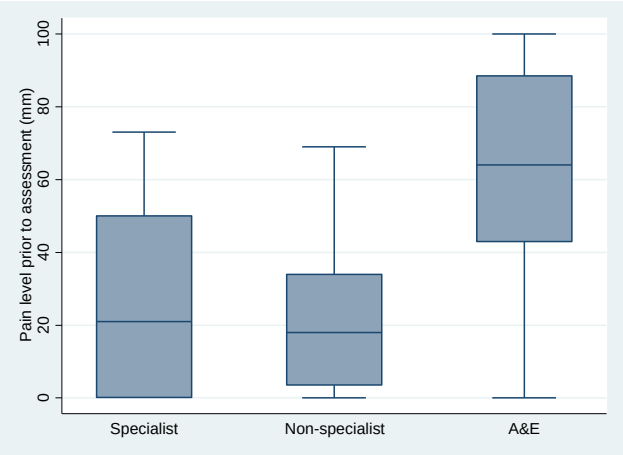


**Figure 59: Box-and-whisker plot of pre-assessment pain levels by assessment group (n=60)**

### 8.5.4 Post assessment pain

A Kruskal-Wallis test showed statistically significant between group differences in post-assessment pain scores ($\chi^2_{(2)}$= 13.0; p=0.002). The highest median pain levels were seen for patients having an observed examination in A&E (n=20; Median= 76mm), followed by those in the non-specialist orthopaedic group (n=20; Median= 32mm) with patients examined in the specialist group reporting the lowest post assessment pain levels (n=20; Median= 20mm) (figure 60).

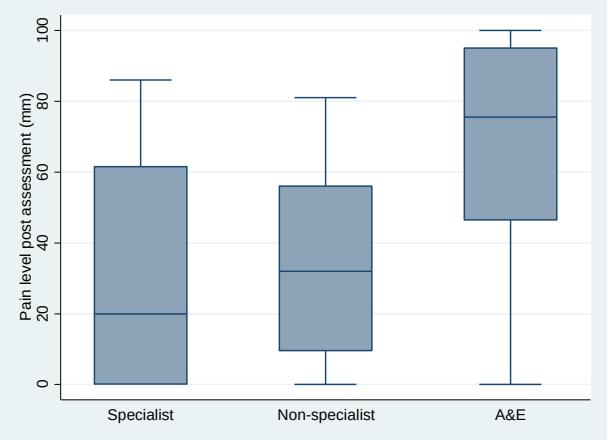


**Figure 60: Box-and-whisker plot of pre-assessment pain levels by assessment group (n=60)**

### 8.5.5 Change in pain scores (pre to post assessment)

A Kruskal-Wallis test showed that there was no significant difference in the change in pain levels from pre to post assessment between clinical assessment group ($\chi^2_{(2)}$= 1.14; p= 0.57). Median change in pain for those assessed by a specialist (n=20; Median= 0) non-specialist orthopaedic (n=20; Median= 4) and A&E clinician (n=20; Median= 3) were all similar (figure 61).

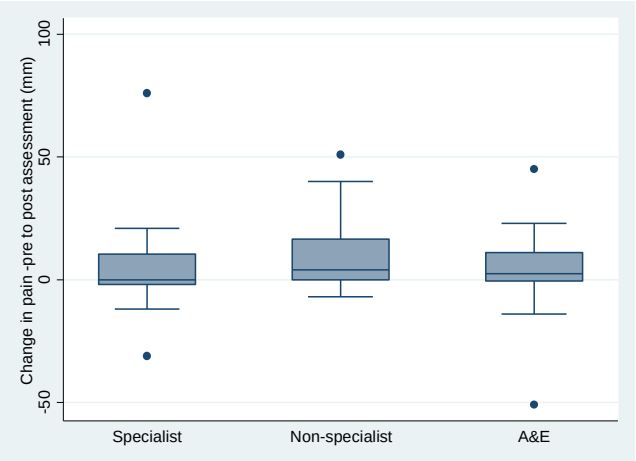


**Figure 61: Box-and-whisker plot showing change in pain scores pre-to-post clinical assessment by assessment group (n=60)**

## 8.6 Direct observation

Of the patients assessed in A&E, 11 patients were assessed by an ENP, 2 by consultant A&E physicians and 7 by staff grade doctors. All patients in the specialist and non-specialist groups were assessed by orthopaedic consultants.

### 8.6.1 Examination times

The physical and total examination times for one patient in the A&E group was excluded from analysis as the physical examination included time to assess a chest injury. Examination times are summarised in table 54.

**Table 54: Summary of examination times in seconds by group. Values reported as mean (SD) (n=60) unless stated**

| | Subjective examination time (s)† | Physical examination time (s) | Total examination time (s) |
|---|---|---|---|
| Specialist (n=20 assessments) | 128 (103 to 148) | 215 (70) | 352 (121) |
| Non-specialist orthopaedic (n=20 assessments) | 96 (62 to 116) | 146 (48) | 243 (84) |
| A&E (n=20 assessments) | 182 (82 to 219) | 190 (49)* | 359 (117)* |

* 19 patient examination times included in analysis

† Median (IQR)

#### *8.6.1.1 Subjective examination time*

Conditions for undertaking parametric analysis on the subjective examination times were violated due to unequal between group variance, therefore non-parametric analysis was performed. A Kruskal-Wallis test showed that time for the subjective examination was significantly different between groups ($\chi^2_{(2)}$= 9.14; p=0.010). The longest subjective examination was undertaken by A&E clinicians (n=20; Median= 182 seconds; IQR= 82 to 219) followed by specialists

(n=20; Median= 128 seconds; IQR= 103 to 148), with non-specialist orthopaedic clinicians completing the subjective examination in the least time (n=20; Median= 96 seconds; IQR= 62 to 116) (figure 62).

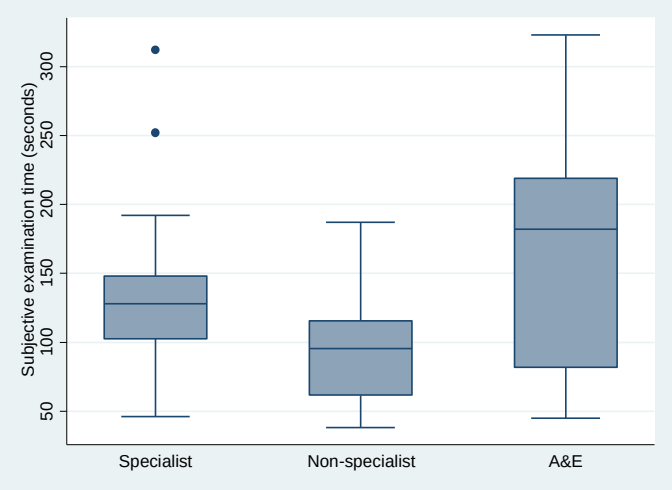


**Figure 62: Box-and-whisker plot of subjective examination time by assessment group (n=60)**

### *8.6.1.2 Physical examination time*

A one-way ANOVA revealed that time taken for the physical examination significantly differed between groups ($F_{(2,56)}$= 7.63; p=0.001). Post hoc comparison using Bonferroni correction indicated that the mean time for specialists to perform the physical examination (n=20; mean= 215 seconds; 95% CI= 190 to 241) was significantly higher than for non-specialist orthopaedic clinicians (n=20; mean= 146 seconds; 95% CI= 121 to 171). There were no differences in physical examination time noted between those assessed by A&E clinicians (n=19; mean= 190 seconds; 95% CI= 164 to 216) and the other two groups (table 54 and figure 63).

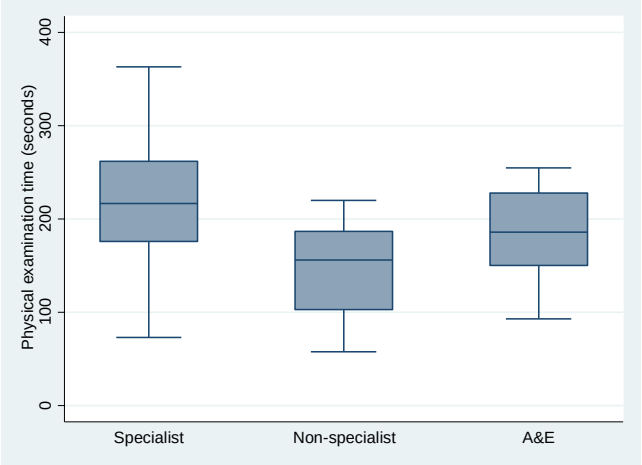


**Figure 63: Box-and-whisker plot showing physical examination time by assessment group (n=59)**

### *8.6.1.3 Total examination time*

Analysis of total examination time using a one-way ANOVA showed statistically significant between group differences ($F_{(2,56)}$= 7.15; p=0.002). Post hoc comparison using Bonferroni correction showed that the mean total examination for non-specialist orthopaedic clinicians (n=20; mean= 243 seconds; 95% CI= 194 to 292) was lower than that for specialists (n=20; mean= 352 seconds; 95%CI= 303 to 400) and A&E clinicians (n=19; mean= 359 seconds; 95% CI=309 to 409). There was no significant difference noted between total examination times for specialists and A&E clinicians (figure 64).

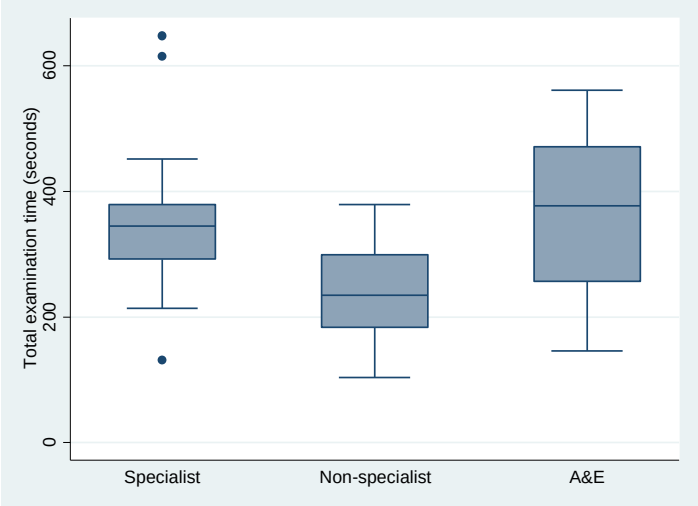


**Figure 64: Box-and-whisker plot showing total examination time by assessment group (n=59)**

### 8.6.2 Subjective examination items

The number of items observed in the subjective examination are summarised in table 55.

**Table 55: Subjective examination items observed by clinician group. Values are reported as mean number of items (SD) unless stated**

| Group | Standard subjective items | Proportion of relevant standard subjective items* | Total subjective items |
|---|---|---|---|
| Specialist (n=20 assessments) | 8.9 (2.5) | 0.55 (0.17) | 10.2 (3.4) |
| Non-specialist orthopaedic (n=20 assessments) | 6.3 (1.9) | 0.37 (0.11) | 7.0 (2.1) |
| A&E (n=20 assessments) | 5.0 (1.8) | 0.20 (0.10) | 5.4 (1.8) |

*Mean (SD) of standard subjective items reported as a proportion observed after removing inapplicable items

#### *8.6.2.1 Standard subjective items observed*

Analysis of the number of standard subjective items observed using a one-way ANOVA showed statistically significant between group differences ($F_{(2,57)}$= 18.31; p<0.001). Post hoc Bonferroni comparison revealed that specialists (n=20; mean=8.9 items; 95% CI=8.0 to 9.8) asked more subjective items

expected in a ‘standard’ examination than non-specialist orthopaedic clinicians (n=20; mean=6.3 items; 95% CI=5.4 to 7.2) and A&E clinicians (n=20; mean=5.0 items; 95% CI=4.0 to 5.9). There were no significant differences noted between non-specialists and A&E clinicians (figure 65).

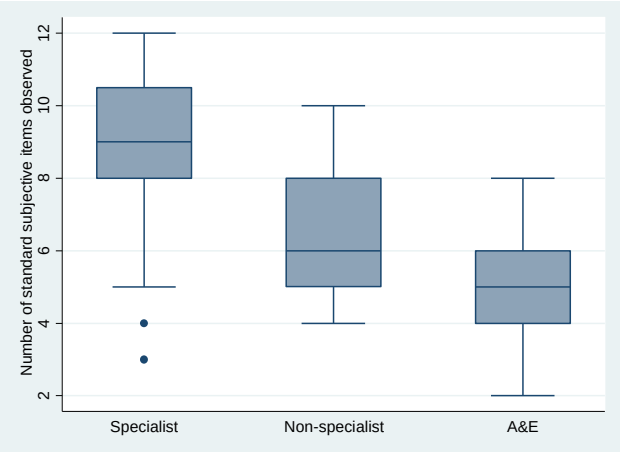


**Figure 65: Box-and-whisker plot showing number of observed standard subjective items by assessment group (n=60)**

### *8.6.2.2 Proportion of relevant subjective items observed against standard examination*

One-way ANOVA showed that the proportion of subjective items observed after removing inapplicable items (see 7.16) revealed statistically significant between group differences ($F_{(2,57)}$= 21.2; p<0.001). Post hoc analysis using Bonferroni correction showed that specialists completed a greater proportion of the expected standard subjective items (n=20; mean proportion= 0.55; 95% CI=0.49 to 0.61) than non-specialist orthopaedic clinicians (n=20; mean proportion= 0.37; 0.31 to 0.43) and A&E clinicians (n=20; mean proportion= 0.29; 95% CI=0.23 to 0.35). No statistically significant differences were shown between non-specialist orthopaedic and A&E clinicians (figure 66).

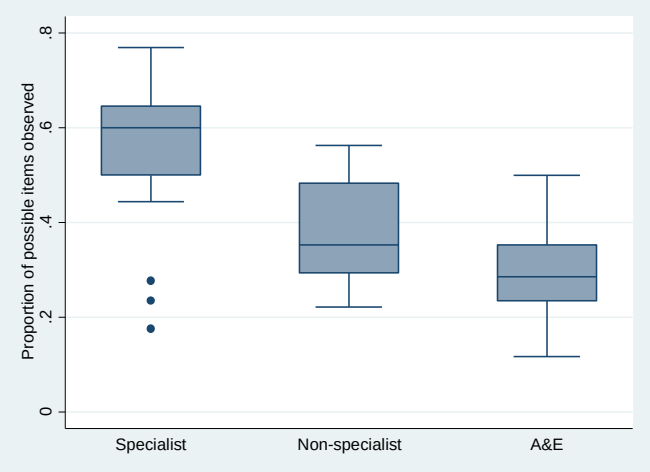


**Figure 66: Proportion of subjective items observed by group after removal of inapplicable items (n=60)**

### *8.6.2.3 Total subjective items observed*

A one-way ANOVA test showed statistically significant between group differences in the total number of subjective items observed ($F_{(2,57)}$= 18.95; p<0.001). Post hoc Bonferroni comparison showed specialists (n=20; mean=10.2 items; 95% CI=9.1 to 11.3) asked more subjective items than non-specialist orthopaedic (n=20; mean=7.0 items; 95% CI=5.8 to 8.1) and A&E clinicians (n=20; mean=5.4 items; 95% CI= 4.3 to 6.5). There were no significant differences noted between non-specialist orthopaedic and A&E clinicians (figure 67).

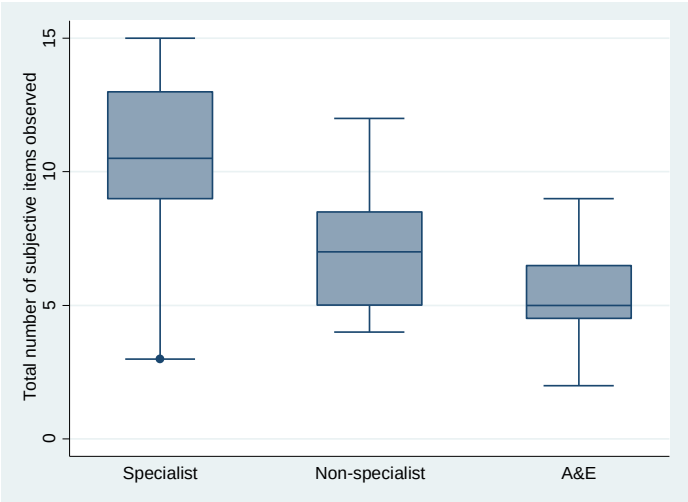


**Figure 67: Box-and-whisker plot showing total number of subjective examination items observed by assessment group (n=60)**

### *8.6.2.4 Subjective items relating to ACL injury*

Specialists were observed to complete more subjective items which have been related to ACL injury (median=5 items; IQR= 5 to 6) than non-specialist orthopaedic (median= 4 items; IQR= 3 to 5) and A&E clinicians (median= 3 items; IQR= 3 to 4). A Kruskal-Wallis test showed the differences in the number of tests undertaken between groups to be highly statistically significant ($\chi^2_{(2)}$= 14.94; p<0.001) (figure 68).

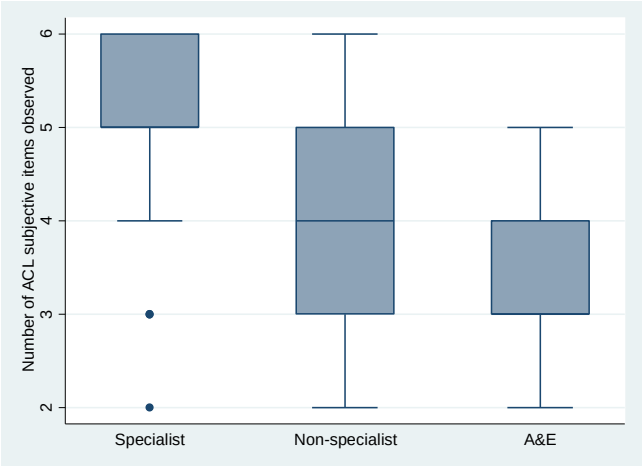


**Figure 68: Box-and-whisker plot showing number of ACL related items observed by clinical group (n=60)**

Analysis of the individual expected 'standard' subjective examination items relating to ACL injury using Fisher's exact test showed significant between group differences for the presence of giving way and area of pain (table 56). In both cases specialists were most likely to be observed completing the item and A&E clinicians least likely.

**Table 56: Subjective items relating to ACL injury observed. Values are reported as number (%)**

| Subjective examination item | Specialist (n=20 assessments) | Non-specialist orthopaedic (n=20 assessments) | A&E (n=20 assessments) | *p* value |
|---|---|---|---|---|
| Mechanism of injury | 20 (100) | 19 (95) | 20 (100) | *p*=1.0 |
| Giving way | 15 (75) | 11 (55) | 6 (30) | *p*=0.02* |
| Inability to continue sport † | 7 (58) | 5 (56) | 4 (100) | ‡ |
| Swelling | 17 (85) | 14 (70) | 11 (55) | *p*=0.14 |
| Sound/pop at time of injury | 11 (55) | 9 (45) | 7 (35) | *p*=0.50 |
| Contact/non-contact injury | 18 (90) | 17 (85) | 18 (90) | *p*=1.0 |
| Area of pain | 17 (85) | 11 (55) | 8 (40) | *p*=0.01* |

* significant at p≤0.05
† percentage calculated against the number of sporting injuries
‡ Category numbers too few to undertake statistical analysis

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### 8.6.3 Physical examination items

A summary of results for physical examination items is presented in table 57.

**Table 57: Number of physical examination items observed by clinician group. Values are reported as mean number (SD)**

| Group | Standard physical examination items | Total physical examination items |
|---|---|---|
| Specialist (n=20 assessments) | 11.1 (1.4) | 14.1 (2.3) |
| Non-specialist orthopaedic (n=20 assessments) | 6.8 (2.1) | 8.6 (2.4) |
| A&E (n=20 assessments) | 5.1 (2.1) | 5.9 (2.3) |

### *8.6.3.1 Standard physical examination items observed*

A one-way ANOVA test showed statistically significant between group differences for the number of standard physical examination test items observed ($F_{(2,57)}$= 50.76; p<0.001). Post hoc Bonferroni comparison showed specialists (n=20; mean=11.1; 95% CI=10.2 to 12.0) performed more standard physical examination tests than both non-specialist orthopaedic (n=20; mean=6.8; 95% CI=5.9 to 7.7) and A&E clinicians (n=20; mean=5.1; 95% CI=4.2 to 6.0). Non-specialists performed significantly more standard physical examination tests than A&E clinicians (figure 69).

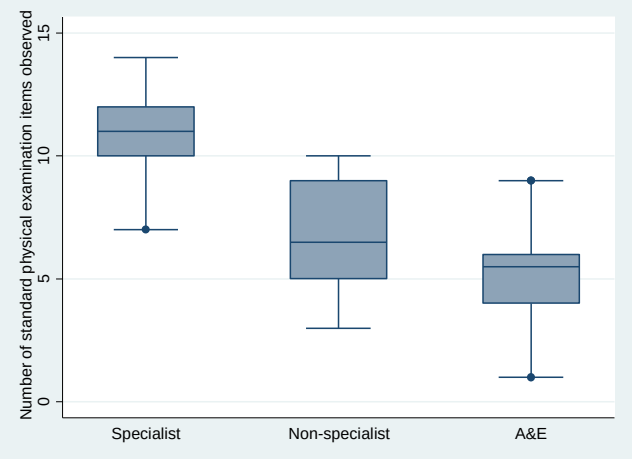


**Figure 69: Box-and-whisker plot showing number of standard physical examination items observed by assessment group (n=60)**

### *8.6.3.2 Total physical examination items observed*

A one-way ANOVA test showed statistically significant between group differences for the total number of physical examination test items observed ($F_{(2,57)}$= 65.40; p<0.001). Post hoc Bonferroni comparison showed specialists (n=20; mean=14.1; 95% CI=13.1 to 15.1) performed more physical examination tests than both non-specialist orthopaedic (n=20; mean=8.6; 95% CI=7.6 to 9.6) and A&E clinicians (n=20; mean=5.9; 95% CI=4.9 to 6.9). Non-specialist

orthopaedic clinicians performed significantly more physical examination tests than A&E clinicians (figure 70).

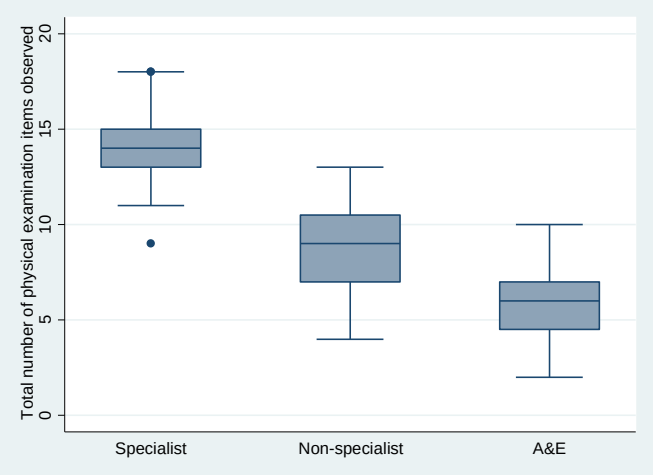


**Figure 70: Box-and-whisker plot showing total number of physical examination items observed by assessment group (n=60)**

### *8.6.3.3 Physical examination items relating to ACL injury*

Differences in the application of physical examination tests used to assess for ACL injury were apparent (table 58). A Kruskal-Wallis test showed that the number of physical examination tests specific to ACL injury performed differed between groups with specialists (n=20; median= 2 tests; IQR= 2 to 2.5) and non-specialist orthopaedic clinicians (n= 20; median= 2 tests; IQR= 1 to 3) observed performing more tests than A&E clinicians (n=20; median= 1 test; IQR= 0.5 to 1). The between group differences were highly statistically significant ($\kappa^2_{(2)}$= 22.8; p<0.001).

In the vast majority of cases (19/20; 95%) specialist clinicians performed tests designed to assess for ACL instability with the Lachman test most often observed. A similar pattern was seen among non-specialist orthopaedic clinicians with the Lachman test used most frequently, although in comparison to the specialist group they performed the anterior drawer test more regularly

and both tests were performed by non-specialists orthopaedic clinicians on 8 occasions. In contrast, A&E clinicians performed the anterior drawer test in most cases where specific ACL tests were employed and were rarely observed performing the Lachman test. Specialists were the only group seen performing a pivot shift manoeuvre. Only on a single observed examination were no ACL instability tests performed by a specialist whilst this was the case on 3 occasions for non-specialist orthopaedic, and 7 occasions for A&E clinicians. On the four occasions that the pivot shift test was performed (exclusively by specialists) it was performed in conjunction with the Lachman test.

Specific clinical testing for an effusion was performed in only a small minority of cases among the A&E group, whilst this was observed in the majority of cases for the other two groups (table 58).

Analysis of the expected standard ACL related physical examination items using Fisher's exact test showed that the between group differences were highly statistically significant for all (table 58).

**Table 58: Physical examination items relating to ACL injury observed. Numbers (%) of occasions item observed shown**

| Physical examination item | Specialist (n=20 assessments) | Non-specialist orthopaedic (n=20 assessments) | A&E (n=20 assessments) | *p* value |
|---|---|---|---|---|
| Anterior drawer | 2 (10) | 8 (40) | 11 (55) | $p$=0.001 |
| Lachman | 18 (90) | 17 (85) | 2 (10) | $p$<0.001 |
| Pivot shift* | 4 (20) | 0 (0) | 0 (0) | † |
| Effusion | 18 (90) | 15 (75) | 4 (20) | $p$<0.001 |

*Not expected as part of a standard examination
† Category numbers too few to undertake statistical analysis

### 8.6.4 Other observed items

Observed items not included on the checklist related to A&E evaluation. In particular, A&E clinicians were the only group observed to assess for neurovascular injury and for the requirement of X-ray (Ottawa knee rules) (table 59).

**Table 59: Other items observed in the physical examination**

| Group | Ottawa knee rules | Sensory examination | Vascular examination |
|---|---|---|---|
| Specialist (n=20 assessments) | 0 | 0 | 0 |
| Non-specialist orthopaedic (n=20 assessments) | 0 | 0 | 0 |
| A&E (n=20 assessments) | 11 | 12 | 11 |

## 8.7 Patient satisfaction

Bartlett's test for equality of variance showed unequal between group variance for all patient satisfaction measures. Therefore non-parametric analysis of patient satisfaction was undertaken. Table 60 summarises patient satisfaction based on all of the total patient satisfaction score and for the original CARE measure and the new questions.

**Table 60: Summary of patient satisfaction scores by group (n=60)**

| Group | CARE measure score | Additional questions patient satisfaction score | Total patient satisfaction score |
|---|---|---|---|
| Specialist (n=20) | 44 (38.5 to 49.5) | 27.5 (23 to 30) | 71.5 (62 to 79) |
| Non-specialist orthopaedic (n=20) | 41 (36.5 to 46.5) | 24 (22 to 27) | 65.5 (56.5 to 72.5) |
| A&E (n=20) | 43.5 (35.5 to 49.5) | 26 (21.5 to 29.5) | 70.5 (55.5 to 79) |

### 8.7.1 Patient satisfaction from original CARE measure questions

A Kruskal-Wallis test revealed that there was no difference in patient satisfaction levels based on the original CARE measure questions between assessment groups ($\chi^2_{(2)}$= 1.28; p=0.53) (figure 71).

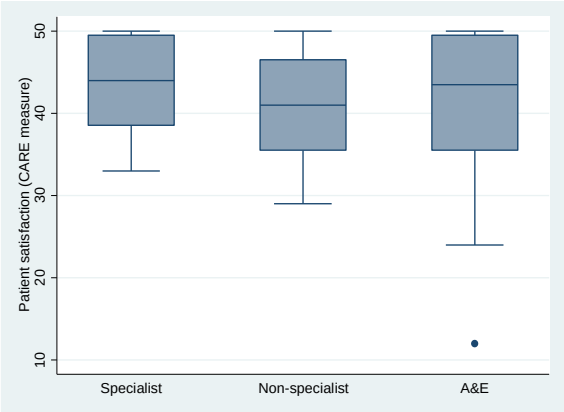


**Figure 71: Box-and-whisker plot showing patient satisfaction score based on questions from the original CARE measure**

### 8.7.2 Patient satisfaction (questions added)

A Kruskal-Wallis test revealed that there was no difference in patient satisfaction levels for the questions added to the CARE measure between assessment groups ($\chi^2_{(2)}$= 2.57; p=0.28) (figure 72).

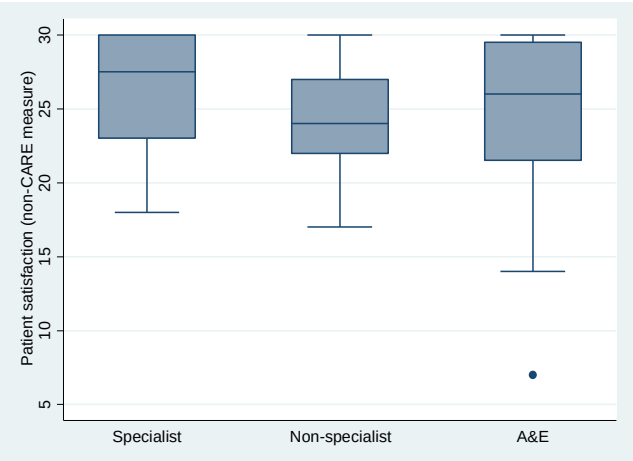


**Figure 72: Box-and-whisker plot showing patient satisfaction score based on questions not contained on the original CARE measure**

### 8.7.3 Total patient satisfaction score

A Kruskal-Wallis test revealed that there was no difference in patient satisfaction levels between assessment groups ($\chi^2_{(2)}$= 1.89; p=0.39) (figure 73).

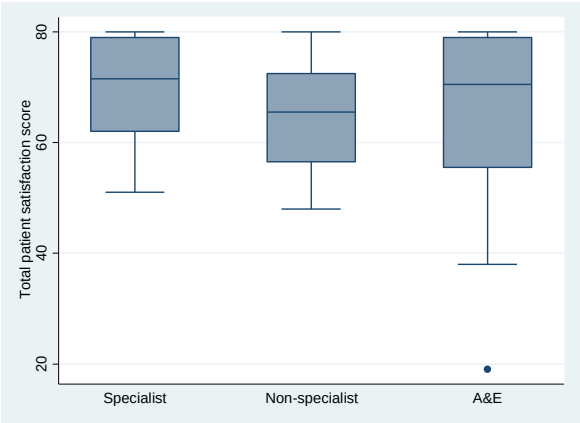


**Figure 73: Box-and-whisker plot showing total patient satisfaction score by assessment group**

## 8.8 Chapter summary

The results presented in this chapter provide evidence of differences in the approach to assessing acute knee injuries between specialists, non-specialists and A&E clinicians. The following chapter discusses the key findings and implications of study 2.

# Chapter 9: Study 2: Discussion

## 9.1 Introduction

The results of the direct observation study (study 2), the first known study of its type, provides important evidence on the range, number and specific type of ACL injury tests undertaken and more generally on the approach to the clinical examination of acute knee injuries. The findings confirm that the examination of acute knee injuries differs between clinical groups, insight which helps to provide a theoretical basis of how the clinical examination may affect diagnostic delay in ACL injuries, permitting recommendations for improvement.

This chapter reflects upon the chosen methodology including both strengths and limitations of the adopted approach and critically discusses the main findings of the study. The findings are considered in relation to study 1 and clinical implications are explored, placing the research in a wider context.

## 9.2 Critical discussion of methodology and methods.

### 9.2.1 Study design

A strength of the chosen direct observation methodology was the ability to observe clinical encounters within the setting they are performed, however, the possibility that it altered both patient and clinician behaviour must be considered (see 9.2.2).

Initially it was planned to compare the clinical examinations of specialist and non-specialist clinicians within an orthopaedic clinical setting, however, A&E clinicians were subsequently included with a recognition that decisions made

within this setting are critical in determining delay to diagnosis and specialist consultation (study 1).

Whilst between group comparison was undertaken with a view to understanding areas of consistency and discrepancy in the clinical examination, the reader should be aware that the patients seen within the A&E setting systematically differed from the other two groups as injuries were more acute (8.3.3). Moreover, the observed examinations in the A&E setting were made on patients who had not gone through an initial assessment process where fracture and neurovascular injury had been discounted. Therefore, whilst the findings are important in understanding pertinent issues to acute soft tissue knee examination this inequality and the potential for confounding must be considered when interpreting and applying the findings.

### 9.2.2 Observer bias

The presence of observers has been shown to alter behaviour within clinical settings (Hagel et al., 2015; Srigley et al., 2014; Leonard and Masatu, 2006). In the design of this study a number of measures were taken to minimise observer bias (Hawthorne effects). Firstly, specific study hypotheses were not shared with study participants (patients or clinicians), an approach used previously in direct observation research with the aim of minimising the Hawthorne effect (Fischer et al., 2005). Secondly, an additional attempt to preserve internal validity, successfully maintained during the course of data collection, was ensuring that clinicians were blinded to the observation checklist, pre-assessment and post-assessment questionnaires. Thirdly, a non-participant observational methodology was undertaken with the intention to minimise the

influence of the researcher on the clinical interaction. Fourthly, the observer attended clinics for a period of two weeks without formally collecting data to allow clinicians to become familiar with the presence of the researcher. During this period the researcher engaged with the clinicians and attempted to ensure that the experience was informal and unintimidating. In spite of these measures the possibility of observer effects remains and warrants further consideration.

The effect that observation has on clinician behaviour within an outpatient setting is somewhat uncertain, with conflicting reports in the literature. Pringle and Stewart-Evans (1990) undertook a large study in a general practice setting involving 338 examinations by four doctors, comparing instances when doctors were aware they were being video recorded to those where they were not. The study did not find any significant difference in the mean consultation length, or in the proportion of time devoted to verbal activities (e.g. medical questioning/information giving) and physical examination. Fernald et al. (2012) cast further doubt over the presence of observer effects in a health setting, finding no evidence that additional contact with a research team affected clinician behaviour in the management of skin and soft tissue infections. Whilst the results of these studies, undertaken within different clinical settings and using different methods of data collection are not directly transferable, they provide some evidence that overt observation within clinical settings may not result in significant behavioural change. In contrast, a study investigating the effect of observation on clinician behaviour found that patient reported quality of care increased by 13% immediately after the arrival of the research team compared to scores obtained before the observation period (Leonard and Masatu, 2006). It was implied that these differences revealed evidence of changes in the behaviour of clinicians. However, this effect was relatively short-

lived with patient satisfaction scores returning to prior levels after 10-15 consultations (Leonard and Masatu, 2006). Whilst this suggests that behavioural changes are transient, it is recognised that the two week period used in the present study may not have been sufficient to allow clinical examinations to return to 'usual'.

A review article concluded that 'little can be known about the conditions under which they (observer effects) operate, their mechanisms of effects, or their magnitudes' (McCambridge et al., 2014 p267). Despite evidence that observer effects in health research may not result in significant changes to practice the possibility of bias remains in this study and should be considered when interpreting findings.

Medical record review may have overcome observer effects but posed additional problems with the reliability of data and are ultimately limited in the amount and quality of information they provide (Sharma, 2011; Spies et al., 2004; Dresselhaus et al., 2002). A study which attempted to ascertain differences in the application of ACL physical examination tests between clinical groups was unable to make any firm conclusions due to the poor reporting of tests within medical records (Arastu et al., 2015), confirming that this data collection method would not have been suitable in the present study.

### 9.2.3 Sample

#### *9.2.3.1 Site*

The decision to use a single site was largely pragmatic, justified on the basis that single site observation is permissible in instances where a site is regarded as 'typical' (USAID, 1996). Study 1 confirmed that the research site chosen to

undertake the direct observation study showed typical levels of delay when compared to sites offering similar service provision. However, it is recognised that whilst single site studies may provide a basis for theoretical assumptions to be drawn, the findings are not directly transferable to other sites and this must be considered when interpreting findings and applying the results of the study.

#### *9.2.3.2 Sample size*

In descriptive research, it is suggested that the sample needs to be large enough to reflect important population variation (Hardon et al., 2004). Whilst the present study sought to describe variation in practice, inferential analysis was also performed and a potential criticism was the failure to perform a sample size calculation. However, in circumstances where data on which to base calculations is scarce it has been argued that sample size estimates are of little value (Jones et al., 2003).

Results from the study confirmed that the sample was sufficient to reveal important variation in practice. However, the findings are only representative of a modest sample and replication of findings in other studies is required to confirm whether variations in assessment practices for acute soft tissue knee injuries are typical.

### 9.2.4 Recruitment

Overt observational research, as undertaken in this study, is regarded as intrusive with the potential for it to be unacceptable to both clinicians and patients (DOPC Writing Group, 2001). Had this been the case within this study

it would have been expected that the numbers refusing to consent to participate would have been substantial; this did not materialise with only a single patient and no clinicians refusing to consent.

#### *9.2.4.1 Patient recruitment*

The high rate of consent to participate among patients fulfilling the eligibility criteria (98.3%) shows that the requirements of involvement were acceptable to the vast majority. Consequently, the study did not suffer from participation bias which can threaten the validity of findings in observational research (Kho et al., 2009). The cross-sectional design was also successful in minimising problems associated with high drop-out rates which pose an additional threat to the validity of observational research. Only a single patient, initially consenting to participate, did not have the clinical examination performed due to reasons unconnected with the research (clinic delays), confirming that this potential threat was not apparent. It is proposed that the procedure of approaching patients and documentation explaining study purpose was ultimately successful in allaying any fears of involvement. Further, the percentage of patients willing to participate in this study indicates that direct observation is well tolerated by patients who are attending with acute knee injuries.

#### *9.2.4.2 Staff recruitment*

Staff recruitment was successful in avoiding volunteer bias, with all clinicians approached consenting to participate. However, the spectrum of clinicians observed may not be reflective of all working within the area. A notable limitation of the study was the sole inclusion of consultants in the non-specialist

group; this was not pre-planned and resulted from their predominance in the observed clinics. Whilst this limits the external validity of findings, positively, it allowed more direct comparison between specialists and non-specialists (as both groups contained consultant level clinicians). A further limitation was the low number of specialist clinicians included in the study (n=2) which limits generalisability and requires consideration when interpreting findings.

### 9.2.5 Measurement tools

#### *9.2.5.1 Observation checklist*

The use of a panel of experts alongside a literature review was designed to ensure that there were no significant omissions from the checklist. However, there are acknowledged limitations in the scope of the checklist which should be considered when interpreting findings. Firstly, patients with fractures or circulatory disturbance were excluded from the study and therefore the checklist did not contain items which were specific to these conditions. Secondly, assessment of gait has been suggested as an examination item for acute knee injuries (BMJ Best Practice, 2014). This was not included on the checklist as it was deemed impossible to determine whether gait had been observed informally whilst the patient entered the examination room or when moving around during the examination. This highlights a limitation with the observational method used; that for any physical examination test to be included it had to be clearly visible to the observer as to whether it had taken place. An oversight was the failure to include a past history of knee injury on the checklist although this information was recorded. The BMJ Best Practice (2014) document produced subsequently to the observation checklist used in

study 2 contained significantly fewer physical examination tests and indicates that the content of the checklist was comprehensive.

There was a high degree of consistency between the ‘standard’ expected examination identified by the panel and the clinical knowledge summary on the assessment of acute knee injuries (NICE, 2011). Areas of consistency in the subjective examination were items regarding mechanism of injury, pain, history of giving way, locking, popping, swelling including speed of onset and whether the person was able to continue activity following injury. Additional items on the direct observation checklist included the functional level that the patient needed to return to and presence of neurological symptoms. The former of these is of questionable value in determining the diagnosis of an acute knee injury, relating more to treatment planning, but as it achieved the required level of agreement among panel members it was retained as an expected ‘standard’ examination item.

In comparison to the recommended physical examination tests there were also high levels of correlation. Agreement on the need to assess movement, palpate, evaluate for effusion and the need to assess for ligamentous laxity with all eight ligament tests consistent between the checklist produced and the guidelines from NICE (2011). There was discrepancy on the requirement to perform the McMurray’s test with the recommendation that it should not be used as a clinical test due to concerns over exacerbating injury and its questionable diagnostic accuracy (NICE, 2011). A final area of discrepancy was the active straight leg raise test recommended in the NICE (2011) guidelines and included on the observation checklist, but not deemed an essential test in a ‘standard’ clinical examination by the expert panel.

It is suggested that the checklist was therefore both comprehensive in content and consistent with guidelines on the items expected as part of a 'standard' examination.

#### *9.2.5.2 KOS-ADLS*

The KOS-ADLS had been validated for use with general knee injuries in a study which involved a sample of 397 patients with a variety of knee conditions (Irrgang et al., 1998). However, this validation was undertaken in a different setting (physical therapy) from this study, on patients with less acute injuries (Irrgang et al., 1998). It is therefore possible that the standard error of measurement (5 points) and minimum clinically meaningful difference (10 points) may differ for the patients recruited into this study. However, the differences in KOS-ADLS scores were much larger than the reported standard error of measurement (8.4) and therefore likely to represent clinically meaningful differences in symptoms and function.

#### *9.2.5.3 Pain measure*

The VAS was used to assess pain over the preceding 24 hours at rest and when moving around to support data on current pain levels. Whilst the non-hatched VAS, as used in study 2, is more responsive than verbal categorical rating scales it is acknowledged that pain memory may be inaccurate over longer time periods (Breivik et al., 2008).

Pain prior to and following the clinical examination was taken to be a measure of pain induced during the physical examination, although it is acknowledged that factors other than the physical examination could have potentially influenced pain levels during this period (e.g. mobilising to/from the examination

room and on/off the examination plinth). However, given the finding that pain levels did not differ prior to and following the clinical examination (8.5.5) this was unlikely to have been the case.

#### *9.2.5.4 Patient satisfaction measure*

The chosen patient satisfaction measure was based on measuring empathy during the clinical examination. It is arguable that this does not provide detailed information on the health professionals clinical knowledge and interview skills, but it has been suggested that the success of a consultation is dependent on the relationship that exists between patient and clinician (Epstein et al., 2008). Further, the importance of the relationship with the health professional has been shown to relate closely to patients opinions on quality of care (Lewis, 1994). A literature review by Reynolds and Scott (1999) supported the view that the level of empathy in the clinical examination is related to health outcomes. The inclusion of a patient satisfaction measure may be regarded as a strength of the study, however, there are doubts over the ability of patients to determine technical competence of health professionals (Chisholm and Askham, 2006) and this should be noted when interpreting findings.

### 9.2.6 Data quality

Non-response bias was minimal on the pre-assessment questionnaires with the only omissions occurring where pain levels over the preceding 24 hours could not be completed as the injury had been sustained within this timeframe (n=5; 8%). Having the researcher present whilst the pre-assessment questionnaires were completed allowed clarification of questions where the patient was

uncertain, and served the additional purpose of allowing a rapport to be developed with the patient, thereby allaying concerns over having an observer present in the examination.

Similarly, post-assessment questionnaires suffered little from non-response, likely due to the decision to ask patients to fill out forms immediately following the examination as suggested for the CARE measure (Mercer et al., 2004). This also had the advantage of ensuring that the clinical examination was fresh in patients' minds.

The use of non-participant observation allowed the data collection form to be completed during the assessment minimising issues with faulty and selective memory which can result in recall bias. This, along with the often significant time gaps between observed assessments, made the possibility of merging separate clinical examinations unlikely. The duration of each clinical examination was generally short (lasting just a few minutes on average; 8.6.1.3), reducing the chance of attention deficits. However, the possibility of some observer omissions cannot be completely discounted and should be considered when interpreting results.

During the subjective examination an item was deemed to have been completed even if the question was not directly asked by the clinician assessing the injury. For example, if a patient offered information that the knee had given way even when they had not directly been asked, the clinician was deemed to have completed this item. The results are therefore more likely to overestimate clinician performance in regard to items covered in the subjective examination.

Confirmation bias has been defined as 'the tendency to seek or interpret evidence favourable to existing beliefs, and to ignore or reinterpret evidence

unfavourable to already existing beliefs' (Shermer, 2002 p.299). Nickerson (1998) elaborates further, suggesting that even when attempting to be unbiased, individuals may selectively gather information to support a hypothesis while neglecting to gather, or discounting contradictory evidence. The implication is that human observations may be biased due to both conscious and subconscious expectations. Acknowledging this potential threat, a strength of the research design was the use of a closed ended checklist for recording the clinical examination, helping to reduce the likelihood of confirmation bias.

The period of observation varied between groups with data collection in the specialist and non-specialist groups occurring simultaneously and being completed prior to commencing observation within A&E. As seasonal variation has been shown to occur in regard to soft tissue knee injuries (Peat et al., 2014), it is possible that the type of knee injuries encountered varied between groups. Whilst collection of data simultaneously for all groups would have overcome this concern, this was not possible due to delays in obtaining ethical approval as a result of expanding the study to include observation within the A&E setting.

### 9.2.7 Analysis

An adjustment for multiple comparisons using Bonferroni was made in order to reduce the possibility of type I error (incorrectly rejecting a null hypothesis). However, this also increases the chance of type II (false negative) errors (Perneger, 1998) which should be considered when interpreting the findings. Whilst there are further criticisms over the use of measures to account for multiple comparisons (4.13.3), within study 2 this meant that any findings of

between group differences during the inferential analysis could be made with greater assurance that they did not merely relate to a false positive finding.

## 9.3 Main findings

### 9.3.1 Patient characteristics

The peak age of injury within this study (adolescence and early adulthood- 8.3.1) was similar to that reported previously from a population based study from southern Sweden (Peat et al., 2014). A greater proportion of the observed assessments were on male patients (8.3.2) who have been shown to suffer more knee injuries than females from a population based study (Nordenvall et al., 2012). Patient demographics for age and sex were similar to those previously reported and observed in study 1 and therefore to the population suffering ACL injury (Parwaiz et al., 2015; Perera et al., 2013; Baraga et al., 2012; Nordenvall et al., 2012; Veysi and Bollen, 2008; Hartnett and Tregonning, 2001; Bollen and Scott, 1996). However, a lower percentage of patients had suffered a sporting injury in the A&E group (n= 4/20; 20%) compared to the other two groups (n= 21/40; 52.5%). This discrepancy may be accounted for if a greater proportion of sporting injuries are referred for a follow-up appointment after initially attending A&E, but may also reflect seasonal variations in sporting injury rates. The data collection in A&E was made during December and January when adverse weather conditions (frost, ice and snow) resulted in the cancellation of many sporting fixtures. The lower proportion of patients suffering sporting injuries shows that the population studied was atypical of the ACL injury population, which may have implications for the observed assessments particularly on the number of ACL injury items observed. However, study 1 cast

doubt over the view that ACL is a sporting injury with 10.3% of injuries sustained during non-sporting activities. Therefore, it is proposed that omission of ACL injury indicators on this basis alone is not justifiable.

### 9.3.2 Days since injury

The finding that injuries seen in A&E were more acute than those seen in specialist /non-specialist orthopaedic clinics was as expected. As 90% (18/20) of the observed assessments took place within 3 days of injury, the assessments in A&E were reflective of the acute nature of the injuries. In contrast, patients in the specialist and non-specialist orthopaedic groups had the observed clinical examination undertaken at a median of two weeks post-injury when pain and swelling can reasonably be expected to have subsided making clinical examination more effective (Arastu et al., 2015). The specialist and non-specialist groups were similar in terms of age, sex and number of days since injury, suggesting that any assessment differences were unlikely due to these factors.

### 9.3.3 KOS-ADLS

As patients in the A&E group had more acute injuries, the finding of reduced KOS-ADLS scores, equating to greater loss of function and higher symptom levels, was perhaps unsurprising.

The KOS-ADLS included information on pain, stiffness and swelling, features which all have the potential to limit the physical examination and/or reduce test accuracy (Arastu et al., 2015; van Eck et al., 2013). The significant differences

in symptoms experienced by patients seen in A&E with respect to patients reporting increased stiffness and swelling lends support to the belief that physical examination within the first few days of injury may be limited. As patients in the specialist and non-specialist groups had similar KOS-ADLS scores it suggested that any differences in clinical examination are unlikely to be related to variation in patients' symptoms and/or function.

### 9.3.4 Pain

Pain levels were significantly higher among patients having observed assessments in A&E compared to those in the specialist or non-specialist groups. The key reason for this is proposed to relate to the period of time which had elapsed between injury and the observed clinical examination (9.3.2). Similar findings were apparent for pain at rest, pain moving around and for pre-assessment pain. Pre-assessment pain was rated 43mm and 46mm higher for the A&E group when compared to the specialist and non-specialist groups respectively (8.5.3). This difference in pain levels may be regarded as highly clinically significant based on minimum clinically significant differences of between 9mm and13mm when using the VAS (Kelly, 2001; Kelly, 1998; Todd et al., 1996).

Reported pain levels reported following the clinical examination revealed that there was little increase from pre-examination pain levels. The finding that the physical examination did not elicit any statistically significant or clinically meaningful increases in pain in any of the study groups suggests that clinician concerns over inducing pain during the physical examination may not, in itself, be a sufficient reason to curtail the physical examination. However, pain and

swelling limit the ability to perform physical examination tests on knee injuries due to guarding and increased inaccuracy of test procedures (Arastu et al., 2015; Parwaiz et al., 2015; Perera et al., 2013; van Eck et al., 2013; Hartnett and Tregonning, 2001) which may be a legitimate reason to avoid undertaking certain tests.

### 9.3.5 Examination times

In general, examination times were shown to be brief with a mean time of just over 4 minutes for non-specialists to just less than 6 minutes for A&E clinicians, much lower than the recommended time of 20-30 minutes for an initial consultation in a trauma clinic setting (BOA, 2014). Even accounting for the fact that time for note keeping was not incorporated into the time taken for the clinical examination, it is likely that in many cases the overall consultation length was shorter than the *minimum* recommended consultation length of 10-20 minutes (BOA, 2014). The brevity of the clinical examinations has potential implications on the number of checklist items observed.

Subjective examination times were greater for A&E clinicians than for the specialist and non-specialist orthopaedic clinicians (8.6.1). Similarly, A&E clinicians took the greatest time to complete the physical examination. The additional time taken to undertake the clinical examination in the A&E setting was largely accounted for by other tests which were completed but not included on the checklist (e.g. tests to assess for vascular compromise and bony injury discussed further in 9.3.8).

### 9.3.6 Direct observation: Subjective examination

The observed subjective examinations revealed that specialist clinicians completed significantly more checklist items and more expected 'standard' items than either non-specialists or A&E clinicians (8.6.2). However, the findings show that a notable proportion of items were omitted by all clinical groups with a mean of 8.9 of 18 items asked by the specialists equating to just less than 50% of expected 'standard' items and lower levels being recorded for the other groups. Whilst some of these items were superfluous based on other responses gained during the subjective examination, a similar pattern was noted with these items removed (8.6.2.2).

A possible explanation for the low percentage of expected 'standard' items completed is the significant time pressures which were evident in all of the clinical settings, manifest in the brevity of the clinical examination (9.3.5). It may be that with limited time, clinicians only cover items they deem essential to the presenting patient. However, if this was the sole reason for failing to include items, it would have been expected that a similar level of omissions would be evident in all groups; this was not the case with specialists completing significantly more items than non-specialist orthopaedic and A&E clinicians.

An alternative explanation is that the items covered in a subjective examination are dependent upon the presenting patient and therefore that a 'standard' subjective examination for knee injuries does not exist. In support of this hypothesis, the observed examinations did not follow a set pattern with variation in the items covered. This approach to questioning patients may appear haphazard, but potentially reflects the complexity of the examination process, with the items covered in any individual assessment guided by patient responses to previous questions and the recognition of injury patterns.

In spite of a general finding that many ‘standard’ items were not completed, it is apparent that specialists performed the most comprehensive subjective examination. The subjective examination forms a critical part in assisting the diagnosis of knee injuries (1.2.3) and therefore a greater number of omissions from the subjective examinations of both non-specialist orthopaedic and A&E clinicians are perhaps suggestive of an educational need. However, based on the findings of the direct observation study it is recommended that, where possible, specialist clinicians review significant soft tissue knee injuries to ensure that patients have the most comprehensive examination.

### 9.3.7 Direct observation: Subjective examination. Items pertinent to anterior cruciate ligament injury

The direct observation study revealed that features associated with ACL injury are frequently overlooked when assessing patients with acute knee injuries. This was most apparent for clinical examinations undertaken by A&E clinicians, although omissions from the expected ‘standard’ examination were evident within all of the study groups.

There are a number of possible explanations for this finding. Firstly, the potential for time pressures to affect the clinical examination, as discussed (9.3.5). Secondly, clinicians may believe that the possibility of ACL injury can be ascertained from other subjective items which guide subsequent questioning. An area of consistency between groups was in questioning patients on the mechanism of injury which was undertaken in all but one case (59/60), most often at the beginning of the assessment. It is possible that the format of the subjective examination may be shaped by responses to this question. However,

it has been argued that almost any history of knee trauma could potentially result in an ACL injury (Prodromos et al., 2007) indicating that additional information should be gathered during the subjective examination before the possibility of ACL injury can more reliably be discounted.

In the guidelines produced by the AAOS (2014), a minimum recommendation when performing an assessment for suspected ACL injury was to question patients regarding mechanism of injury, locking/catching, hearing/feeling a 'pop', associated swelling, localisation of pain, ability to return to play (sporting injuries) and prior history of knee injuries. It is evident that this information was frequently not gleaned during the subjective examination which may partially explain the failure to follow-up more than a quarter of patients with subsequently confirmed ACL injuries (study 1; 5.4.3).

Wagemakers et al. (2010) performed multivariate regression modelling to determine which history features were of greatest worth in assisting diagnosis of ACL injury, finding that an effusion, 'popping' sensation at trauma and giving way all showed a significant association. The potential value of these items has been discussed previously along with a critique of the study by Wagemakers et al. (2010) (6.4.3). The finding that specificity was improved when all three items were considered together suggests that additional value is gained by eliciting information on all of these features. Whilst it has been suggested that suitable exploration of the history may improve diagnostic rates (Arastu et al., 2015; Parwaiz et al., 2015; Perera et al., 2013; Hartnett and Tregonning, 2001; Bollen and Scott, 1996) a systematic review concluded that the results of individual history items produce only small differences in the probability of ACL injury, with the suggestion that tests should therefore be used in combination (Swain et al., 2014).

The direct observation study confirmed that A&E clinicians were less likely to obtain information on giving way, swelling and whether a ‘pop’ was noted at the time of injury when compared to specialist and non-specialist orthopaedic clinicians. Whilst giving way was the only item to reach individual statistical significance, the overall findings confirmed highly significant between group differences in the total number of items relating to ACL injury which were observed. Whilst these features are not in themselves pathognomonic, they are useful in raising suspicion of ACL injury and therefore in identifying patients who should be reviewed at a later date. Ensuring that clinicians assessing patients with acute knee injuries ask questions pertinent to features consistent with ACL injury (5.4.3) may be an important way of reducing the likelihood of early discharge without follow-up, identified in study 1 as the single most influential factor in delays to diagnosis and specialist consultation following ACL injury.

Whilst history features are not specific to ACL injury, even in isolation a haemarthrosis may be an important indicator of ACL injury, with either a partial or complete ACL tear confirmed arthroscopically in 61 of 85 knees (72%) with a traumatic heamarthrosis (Noyes et al., 1980a). The direct observation revealed that just over half of the patients (n= 11/20; 55%) in the A&E group were questioned about the presence of knee swelling and fewer about the time to onset. The failure of A&E clinicians to identify the presence of a haemarthrosis has been reported previously (Mitchell, 1999); the findings of study 2 suggest this remains an educational need.

Acknowledging that injury features should be used in combination to be more effective, it is also important to consider how the results of these are interpreted. Whilst a number of studies have suggested that a typical history of ACL injury exists (Arastu et al., 2015; Perera et al., 2013; Bollen and Scott, 1996) the

findings of study 1 suggested that whilst certain history features are frequently reported by patients, the combination of these varies. Therefore, it is argued that in order to reduce the number of missed diagnoses and inappropriate discharges from A&E, a high index of suspicion should be maintained and the threshold for onward referral should be accordingly conservative.

Study 1 revealed that 95.8% of patients with ACL injury reported at least two of four features (giving way, feeling or hearing a pop, swelling within six hours and inability to continue activity) showing the potential of injury history features as a tool with a high sensitivity to rule out ACL injury when an appropriate threshold is set (5.4.3). However, this would only be effective if the presence of these features is routinely established for all patients presenting to A&E with a traumatic knee injury. Therefore, a recommendation is to educate A&E clinicians on the importance of these injury features and their interpretation ensuring that potentially important indicators of ACL injury are not overlooked.

### 9.3.8 Direct observation: Physical examination observations

On average, specialists performed more tests (mean=11.1) deemed essential by the expert panel than non-specialists (mean=6.8) or A&E clinicians (mean=5.1) (8.6.3.1). With 14 checklist items deemed essential to include in a 'standard' examination, on average specialists completed 79%, non-specialists 49% and A&E clinicians 36% of these items. A similar pattern was observed when considering all checklist items.

Whilst the patients in the A&E group had increased pain, symptoms and reduced functional levels which may have legitimately reduced the number of tests undertaken, this study provides evidence of deficiencies in the

examination of knee injuries upon initial presentation. A BMJ Best Practice (2014) document suggests that following a series of examination tests on a regular basis is important to obtain a thorough and complete examination. Regardless of the underlying reasons it is apparent that this ideal does not occur.

Of importance was the finding that specialists completed a more thorough physical examination than non-specialist orthopaedic clinicians; a finding that was not explained by differences in pain or function. This has implications for follow-up appointments and who may be best placed to undertake these assessments and it is recommended that, where possible, a specialist clinician undertakes follow-up assessment of acute knee injuries.

It was noted that A&E clinicians approached the clinical examination with a different focus. They were more likely to undertake examination of bony injury (Ottawa knee rules) and perform neurovascular examination (6.3.4). In addition they were also noted to perform a straight leg raise test more often than the other groups (to investigate for extensor mechanism rupture). These tests, whilst not included on the ‘standard’ checklist have been recommended as best practice when assessing knee injuries resulting from trauma (NICE, 2011). Within the setting of this observation study it is apparent that items suggested in the NICE (2011) guidelines are not covered in every examination. Instead, A&E clinicians are more likely to assess for the possibility of bony, neurovascular and gross tendon injury whilst orthopaedic clinicians, reviewing patients at a later date, employ tests more specifically designed to determine whether ligamentous or meniscal injury has occurred. Whilst assessment of fracture is a vital first step in diagnosing traumatic knee injuries they are relatively rare accounting for only 4-8% of knee injuries presenting to the emergency

department (Gage et al., 2012; Stiell et al., 1996; Bauer et al., 1995) and less than 1% of knee injuries sustained during athletic pursuits (Majewski et al., 2006). Far more common are soft tissue knee injuries, yet it appears that the focus of the clinical examination in A&E does not reflect this. Whilst this may suggest a need for education, the value of performing physical examination tests on patients with very recent injuries is uncertain and is a recommended area for further research.

### 9.3.9 Direct observation: Physical examination. Anterior cruciate ligament tests

This study has revealed differences in the approach to examining ACL injury with A&E specialists and non-specialists more likely to perform tests specifically designed to identify ACL injury (8.6.3.3). The physical examination tests observed were almost exclusively the anterior drawer and Lachman tests, identified as expected tests in a 'standard' examination of an acute knee injury. The only other test observed (the pivot shift test) has been reported as having the highest specificity (Benjaminse et al., 2006) and was performed on four occasions by specialist clinicians.

Differences in the number of ACL tests performed were initially considered to result from the inability to perform tests in more acute injuries, a possibility given the higher pain levels reported in the A&E group. Arastu et al. (2015) have previously reported that even in an outpatient setting an orthopaedic consultant was unable to perform the Lachman and pivot shift tests in 4.3% and 12% of cases respectively. As the patients in the study by Arastu et al. (2015) had less acute injuries than the majority of those in the A&E group, this figure is likely to

underestimate the proportion of patients on whom it is not possible to perform ACL tests upon initial presentation.

When ACL physical examination tests were undertaken, between group differences were noted with A&E clinicians favouring the anterior drawer test over the Lachman test (8.6.3.3). In contrast, the specialist and non-specialist orthopaedic groups were observed performing the Lachman test more frequently than the anterior drawer test. Whilst the expert panel identified that both tests should be performed in a 'standard' examination, the Lachman test has been shown to have greater accuracy (van Eck et al., 2013; Benjaminse et al., 2006; Scholten et al., 2003; Solomon et al., 2001), and is recommended as the superior test in guidelines on ACL injury examination (AAOS, 2014; BMJ Best Practice, 2014; NICE, 2011; NZGG, 2003).

It has been suggested that the anterior drawer test has more effect on isolated rupture of the anteromedial band of the ACL, and the Lachman test for isolated posterolateral bundle ruptures based on ligament anatomy (Petersen and Zantop, 2006). This may suggest a good reason for performing both tests, although clinical evidence for the improvement in diagnostic accuracy when combining these tests is lacking. As the Lachman test, even in isolation, has been shown to have high levels of accuracy in diagnosing ACL injuries (1.2.2) the finding that the anterior drawer test was only performed alongside the Lachman test in 10% (2/20) of specialist examinations is perhaps of little concern. However, further research is required to establish whether improvements in diagnostic accuracy are gained by combining these tests before firm recommendations can be made.

Recent guidelines from the AAOS (2014) suggests that the Lachman test should be performed when assessing for ACL injury whilst the anterior drawer test was not recommended. As previously stated (1.2.2) the sensitivity of the anterior drawer test is further reduced in acute knee injuries (van Eck et al., 2013; Katz and Fingeroth, 1986; Noyes et al., 1980a). As sensitivity relates to the rate of false negatives, application of the anterior drawer test may lead to false reassurances that the ACL has not been injured. The use of the anterior drawer by A&E clinicians as the sole test to investigate ACL integrity in the majority of instances where a specific ACL instability test was undertaken would appear to indicate that the most suitable test has not been applied. However, the finding of superior levels of sensitivity and accuracy for the Lachman test over the anterior drawer has been based on studies of orthopaedic surgeons and the findings cannot be directly applied beyond this group (NICE, 2011). It is therefore possible that the anterior drawer is the most suitable physical examination test for non-specialist clinicians. In support of this, Wagemakers et al. (2010) found the anterior drawer to be marginally more predictive of ACL injury than the Lachman test when performed by an experienced physical therapist on patients with acute knee injuries. Interestingly, the overall sensitivity was higher when injury history features were used in isolation in comparison to adding the result of the anterior drawer test (0.71 vs 0.63 respectively). This raises important questions over the worth of physical examination tests performed on acute knee injuries, as even though the overall accuracy of diagnosis was improved by including the result of the physical examination tests, the proportion of false negative results also increased.

Further evidence casts doubt over the value of ACL tests when performed on patients with very acute injuries. Noyes et al. (1980a) found that in patients with

a haemarthrosis only 24% (9/37) of arthroscopically confirmed complete ACL ruptures displayed positive signs of instability when the results of the Lachman and anterior drawer tests were considered together. Within the study over 80% of patients were assessed within a week of injury and the majority within 48 hours. The percentage was lower for those with partial ACL injuries at only 12% (3/24). The results of the study by Noyes et al. (1980a) suggest that on patients with an acute haemarthrosis these tests are of little value in ruling out the possibility of ACL injury (low sensitivity), even when undertaken by a specialist clinician.

A further study showed poor agreement on the results of the Lachman test between emergency department clinicians and a sports medicine specialist who assessed the patients 5 $\pm$ 2 days later with only 7 out of 27 (26%) patients with MRI confirmed ACL ruptures identified by A&E clinicians (Guillodo et al., 2008). Whilst there remains a paucity of information on the diagnostic value of physical examination tests on acute knee injuries when undertaken by non-specialist clinicians, these studies suggest that considerable caution should be applied when interpreting the results. A suggested area for further research is to investigate the accuracy of physical examination tests performed within the A&E setting on acute knee injuries.

Whilst the Lachman test, anterior drawer and pivot shift tests are specifically designed to assess for ACL injury, knee effusion may also be an important indicator of ACL injury and it has been recommended to perform a test to assess for the presence of effusion when assessing knee injuries (AAOS, 2014; BMJ Best Practice, 2014; NICE, 2011). Whilst a physical examination test for effusion was performed in the vast majority of cases by specialist and non-specialist orthopaedic clinicians (90% and 75% respectively) this was only the

case in 20% of A&E examinations (8.6.3.3; table 58). It is suggested that this is a training requirement, especially in light of the frequent omission of questions regarding knee swelling by A&E clinicians (9.3.7).

### 9.3.10 Patient satisfaction

Patient satisfaction with the consultation was not significantly different between groups when considering findings from the original CARE measure, added questions or combined total patient satisfaction score (8.7). The management of the interpersonal relationship has been described as a vitally important element of clinical performance, and along with technical competence the relationship between clinician and patient is key in arriving at a diagnosis (Donabedian, 1988). In general patient satisfaction with the consultation was noted to be high suggesting a positive relationship between the clinicians and patients.

## 9.4 Chapter summary

The direct observation study has shown differences in the approach to examining acute knee injuries. In general the examinations fell short of the expected 'standard' clinical examination as identified by the expert panel. Whilst physical examination may be compromised due to pain, swelling and guarding the subjective examination poses no such problems and it is argued that increasing awareness of the features associated with injury may improve the identification of patients who should be followed-up until a diagnosis of ACL injury can be more accurately ruled out.

This study has provided greater understanding in the approach to assessing acute knee injuries and provides evidence of deficiencies in the examination of acute knee injuries. The new knowledge produced by this study provides a sound basis for developing initiatives to improve the clinical examination of acute knee injuries.

# Chapter 10: Conclusion

This thesis has presented and discussed the findings of two studies designed to improve understanding into the nature of, and factors associated with delay to diagnosis and specialist consultation. Existing limitations in the evidence base and contributions to knowledge from this thesis are summarised in table 61.

**Table 61: Summary of the evidence gap and contributions to knowledge**

| Evidence gap/problem | Contribution to knowledge |
|---|---|
| Inappropriate summary measures of delay for skewed data. | Data summarised using appropriate summary measures. |
| Inadequate knowledge on the variation in delay. | Comprehensive summary of variation in delay. |
| Failure to break down delay into component parts. | Component parts of delay identified through the development of a model of delay including patient delay, waiting list delay, delay to diagnosis and delay to specialist consultation. |
| Lack of knowledge of the factors influencing delay and the magnitude of effect on delay. Inadequate information on priorities to minimise delay. | The influence of factors potentially affecting delay determined using bivariate and multivariable regression analysis. This knowledge afforded information on key priorities to minimise delay. |
| Knowledge of delay based on data from single site observations. | Multi-site survey of delay increasing generalisability of findings. |
| Delay frequently based on retrospective data collection methods with consequent potential for missing and/or incomplete data compromising data quality. | Prospective identification of cases with information on delay obtained via an interview process. Data quality enhanced and recall bias minimised through cross-checking of medical records. |
| Existing knowledge on delay primarily based on patients undergoing ACL reconstructive surgery. | Inclusion of all patients with ACL injury regardless of treatment improving generalisability of findings. |
| Lack of knowledge on the effectiveness of acute knee clinics. | Comprehensive evidence on the impact of an acute knee clinic on all elements of delay. |
| Reasons for poor diagnostic rate on initial presentation unclear. | Identification of differences in assessment practices between professionals of varying experience. Comprehensive knowledge of variation in patient symptoms. |
| Uncertainty on how injury history may be used to improve delay to diagnosis and specialist consultation. Lack of detail on the injury history features reported by patients with ACL injury. | Information on the number and type of injury history features reported by patients with ACL injury. Evidence on the potential impact on delay to diagnosis and specialist consultation resulting from different referral thresholds based on injury features. |

Study 1 investigated the nature of delay in the first multi-site investigation of delay following ACL injury using a cross-sectional survey methodology, whilst study 2 explored the clinical examination of acute knee injuries within three groups (specialist, non-specialist and A&E clinicians) via non-participant observational methods.

The findings of the survey (study 1) confirmed wide disparity in delay to diagnosis and specialist consultation both within and between included study sites. It is apparent that some patients suffer unacceptable and potentially avoidable delays following ACL injury which are of a magnitude that can compromise management and prejudice outcomes. Patient delays in accessing health services contributed to overall time to diagnosis and specialist consultation but it is evident that the majority of delay is accounted for by system delays occurring subsequent to patient presentation. The factors most influential on delay to diagnosis and specialist consultation were whether a follow-up was arranged after attending A&E, whether the site operated an AKC and whether an MRI was performed.

The direct observation study (study 2) revealed differences in the approach to the clinical examination of acute knee injuries. Specialists performed the most comprehensive soft tissue knee examination undertaking more subjective and physical examination items than either non-specialist orthopaedic or A&E clinicians. In addition to between group differences in the number of physical examination tests performed there were differences in the type of tests employed. The study also highlighted significant differences in pain and functional levels in A&E patients; a finding that confirms the challenges of performing a physical examination on very recent injuries within the A&E setting.

## 10.1 Recommendations

A number of recommendations have emerged from the research and have been discussed in chapters 6 and 9. The key priorities in improving delay to diagnosis and specialist consultation are to improve follow-up rates for patients attending A&E, facilitate streamlined pathways to specialist review and reduce wait times for MRI when it is required.

In order to improve the proportion of patients who are referred for follow-up it is recommended that A&E clinicians are educated on key ACL injury features; a simple mnemonic based on an acronym of the key injury features may achieve this aim. The proposed LIMP index (Leg giving way; Inability to continue activity immediately after activity; Marked effusion; Pop (heard or felt)) would identify 95.8% of patients with ACL injury using a threshold of 2/4 features. This would substantially improve follow-up rates and result in improvements in delays to diagnosis and specialist consultation.

A streamlined acute knee injury pathway should ensure that patients are assessed in timely fashion by clinicians suitably skilled in the diagnosis of ACL injury. It is therefore recommended that follow-up appointments for patients with acute knee injuries are undertaken by clinicians who are experienced in the assessment of knee injuries. Alongside orthopaedic specialists, physiotherapists have been shown to be effective in diagnosing ACL injuries and could play a key role in ensuring patients with ACL injuries receive an early diagnosis and commence appropriate treatment. Given the increased volume of patients who should be followed-up to improve the current service delays this would also minimise the burden on orthopaedic specialists.

Education programmes raising awareness of ACL injury features in areas of high risk are also advocated to reduce patient delay.

## 10.2 Further research

A number of areas for further research have been suggested previously (chapters 6 and 9). Suggested key initial research priorities are to explore the underlying reasons for patient delay, determine the accuracy of clinical examination performed by non-specialist clinicians and how injury history features may be most effectively used to identify patients for follow-up.

Whilst the use of injury history has been shown to be sensitive in identifying patients with acute knee injuries the specificity of the four key injury features (Leg giving way, inability to continue activity immediately after activity, marked effusion, pop) requires validation through a prospective study.

The role of MRI in assisting diagnosis of ACL injury also warrants further research given the finding that diagnosis was found to be delayed in patients who had an MRI scan.

Whilst acute knee clinics have been shown to be highly effective in improving delays to diagnosis and specialist consultation the cost effectiveness of such services has yet to be determined and is an area warranting future research.

## 10.3 Outputs

Journal articles:

Ayre, C. and Scally, A. J. (2014) Critical values for Lawshes content validity ratio. Revisiting the original methods of calculation. Measurement and Evaluation in Counseling and Development, 47 (1), pp.79-86 (Appendix XXI).

Ayre, C., Hardy, M., Scally, A., Radcliffe, G., Venkatesh, R., Smith, J., Guy, S. The use of history to identify anterior cruciate ligament injuries in the acute trauma setting: The LIMP index. Submitted for publication. (Appendix XXII).

Posters:

Ayre, C., Hardy, M., Scally, A., Radcliffe, G., Guy, S. (2015). A direct observation study comparing the clinical assessment of acute knee injuries by specialists and non-specialists [poster 0137]. BASK conference, Telford; 10-11 March 2015.

Ayre, C., Hardy, M., Scally, A., Radcliffe, G., Guy, S. (2015). Reducing time to diagnosis following anterior cruciate ligament injury: Understanding the factors causing delay [poster 0142]. BASK conference, Telford; 10-11 March 2015.

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# Appendix I: Medline search strategy

| # | Query | Limiters/Expanders | Last Run Via | Results |
|---|---|---|---|---|
| S33 | S9 AND S30 | Limiters - Date of Publication: 19950101-20151231; Human<br>Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases<br>Search Screen - Advanced Search<br>Database - MEDLINE | 397 |
| S32 | S9 AND S30 | Limiters - Human<br>Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases<br>Search Screen - Advanced Search<br>Database - MEDLINE | 478 |
| S31 | S9 AND S30 | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases<br>Search Screen - Advanced Search<br>Database - MEDLINE | 507 |
| S30 | S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases<br>Search Screen - Advanced Search<br>Database - MEDLINE | 325,672 |
| S29 | late N4 present* | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases<br>Search Screen - Advanced Search<br>Database - MEDLINE | 8,350 |
| S28 | late N4 diagnos* | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases<br>Search Screen - Advanced Search<br>Database - MEDLINE | 7,963 |
| S27 | interv* N4 present* | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases<br>Search Screen - Advanced Search<br>Database - MEDLINE | 12,767 |
| S26 | interv* N4 refer* | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases<br>Search Screen - Advanced Search<br>Database - MEDLINE | 8,722 |
| S25 | interv* N4 consult* | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases<br>Search Screen - Advanced Search<br>Database - MEDLINE | 2,166 |
| S24 | interv* N4 diagnos* | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases<br>Search Screen - Advanced Search<br>Database - MEDLINE | 34,464 |
| S23 | time N4 interv* | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases<br>Search Screen - Advanced Search<br>Database - MEDLINE | 56,611 |
| S22 | time N4 present* | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases<br>Search Screen - Advanced Search<br>Database - MEDLINE | 37,858 |
| S21 | time N4 refer* | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases<br>Search Screen - Advanced Search<br>Database - MEDLINE | 5,879 |
| S20 | time N4 consult* | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases<br>Search Screen - Advanced Search<br>Database - MEDLINE | 2,690 |
| S19 | time N4 diagnos* | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases<br>Search Screen - Advanced Search<br>Database - MEDLINE | 42,262 |
| S18 | delay* N4 present* | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases<br>Search Screen - Advanced Search<br>Database - MEDLINE | 8,176 |

# Appendix I: Medline search strategy

| | | | | |
|---|---|---|---|---|
| S17 | delay* N4 refer* | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE | 1,663 |
| S16 | delay* N4 consult* | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE | 436 |
| S15 | delay* N4 diagnos* | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE | 24,175 |
| S14 | (MH "Diagnostic Errors") | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE | 31,757 |
| S13 | (MH "Delayed Diagnosis") | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE | 2,884 |
| S12 | S10 AND S11 | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE | 91,234 |
| S11 | "diagnos*" | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE | 3,535,635 |
| S10 | "delay*" | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE | 418,125 |
| S9 | S7 AND S8 | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE | 14,912 |
| S8 | S1 OR S2 OR S3 OR S4 OR S5 OR S6 | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE | 38,119 |
| S7 | "injur*" | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE | 934,650 |
| S6 | (MH "Athletic Injuries/DI") | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE | 3,915 |
| S5 | (MH "Soft Tissue Injuries/DI") | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE | 480 |
| S4 | "knee ligament*" | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE | 987 |
| S3 | "acl" | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE | 26,444 |
| S2 | "anterior cruciate ligament*" | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE | 14,666 |
| S1 | (MH "Anterior Cruciate Ligament/IN") | Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE | 6,556 |

# Appendix II: Example of completed data collection form.

| | |
|---|---|
| Author(s) | Arastu M.H., Grange S.,Twyman R. |
| Year of publication | 2014 |
| Type of publication (journal article/ conference abstract/ poster etc.) | Journal article |
| Source | Knee Surgery, Sports Traumatology and Arthroscopy. 23 (4), pp.1201-1205 |
| Title | Prevalence and consequences of delayed diagnosis of anterior cruciate ligament ruptures |
| Country of origin | UK |
| Design | Prospective cohort |
| Setting | Single site NHS Hospital |
| Aims/ Objectives | Evaluate the diagnostic accuracy at initial attendance.<br>Determine the mechanism of injury and whether early diagnosis can minimise secondary damage. |
| Numbers of participants (total sample size) | 132 |
| Numbers of ACL injuries | 132 |
| Sampling method | Consecutive cases |
| Time period of data collection | 4 years (2005-2009) |
| Inclusion criteria | ACL reconstruction |
| Exclusion criteria | Chronic ACL injury (previous trial of conservative treatment) |
| Study definition(s) of delay | 3 types of delay reported:<br>Time from injury to initial medical consultation.<br>Time from injury to accurate diagnosis.<br>Time from injury to ACL reconstruction. |
| Method of diagnosis | All arthroscopically confirmed as underwent ACL reconstruction |
| Number of participants included in analysis | 116 |
| Number of participants excluded from final analysis (including reasons) | 16; reasons: chronic ACL injury with previous correct diagnosis and trial of conservative treatment |
| Subjective and objective tests (if reported) | Took 'typical history' as low velocity, valgus/ external rotation strain/ twisting injury, audible pop or snap, inability to weight bear and immediate pain and swelling (within 4 hours) and 1-2 weeks to begin weight bearing on the injured limb with a subjective feeling of improvement but seeks medical attention early. |
| Delay results (including type of delay reported) | Median time from injury to initial medical consultation 0 weeks (range 0-72 weeks).<br>Median time from injury to diagnosis 6 weeks (range 0-192).<br>Median time to ACL reconstruction (24 weeks). |
| Other results | Typical injury pattern reported in 74.4%.<br>Correct diagnosis in 28.2% of cases at initial presentation.<br>Accuracy of diagnosis 33.3% for 'typical injury' group and lower for 'atypical' injury group (11.1%).<br>Frequently no clinical tests were documented by health care professionals other than the consultants.<br>Rate of medial meniscal tear significantly increased from 23.1% for those operated within 4 weeks to those operated on >6 weeks (72.2%) .<br>Orthopaedic consultant unable to always perform tests in outpatient setting due to pain (Lachman not performed in 4.3% of cases and pivot shift in 12% of cases). |
| Critique | Only included patients who underwent ACL reconstruction (selection bias).<br>Excluded patients due to chronic ACL injury (defined as delayed presentation as trialled non-surgical treatment after initial correct diagnosis).<br>No specific detail on how 'correct diagnosis' assumed.<br>Single site (lacks external validity)<br>Tests frequently not documented by other professionals (have not reported accessing appropriate notes therefore potentially misrepresented).<br>Median figures reported- (appropriate as skewed data).<br>Delay broken down into component parts but lack of clarity on how 'correct diagnosis' assumed. |
| Article conclusions | Diagnostic accuracy of ACL ruptures still low. Recognition of a typical injury pattern may be beneficial.<br>Lachman and pivot shift tests may not be useful in improving diagnostic accuracy when performed by non-specialists and can be difficult to perform in the acutely injured knee. |

# Appendix III. Survey questionnaire

**A service evaluation of patients' with primary injury to the anterior cruciate ligament injury attending knee specialist consultant orthopaedic clinics.**

## PLEASE COMPLETE ALL QUESTIONS

## Background information

Q1.Patient hospital number/ ID number_____

Q2. Date of clinic_____(dd/mm/yy)

Q3. Referral source (GP/ A&E/ trauma clinic/ other consultant etc.)_____

Q4. Referral date_____(dd/mm/yy)

Q5. What sex is the patient?

Please tick

| | |
|---|---|
| Male | |
| Female | |

Q6. What is the age of patient (to nearest year)?_____years

# Appendix III. Survey questionnaire

## About the initial injury

Q7. In which knee is the cruciate ligament injury (if both have been injured please give details of the most recent)?

Please tick

| | |
|---|---|
| Left | |
| Right | |

Q8. Did the patient have a specific (single) incident when the knee injury first occurred?

Please tick

| | | |
|---|---|---|
| Yes | | continue to question 9 |
| No | | go to question 17 |
| Can't remember | | go to question 17 |

Q9. What best describes the activity undertaken at the time of injury?

Please tick

| | |
|---|---|
| Football | |
| Rugby | |
| Skiing | |
| Netball | |
| Road traffic accident (RTA) | |
| Other- Sporting activity | |
| Other- Non sporting activity | |
| Can't remember | |

Q10. What date did the initial (first) injury occur*?

_____(dd/mm/yy)

*This information can be obtained from patient report or medical records if more accurate (e.g. A&E record of attendance on day of injury). **If exact date not known please report best estimate.**

Q11. Did the injury result from a collision with another person/ object?

Please tick

| | |
|---|---|
| Yes | |
| No | |
| Not sure | |

Q12. Did the patient feel the knee ***give way*** (go out of place) at the time of injury?

Please tick

| | |
|---|---|
| Yes | |
| No | |
| Not sure | |

Q13. Did the patient ***feel*** or ***hear*** the knee ***pop*** at the time of injury?

Please tick

| | |
|---|---|
| Yes | |
| No | |
| Not sure | |

Q14.Was the patient able to continue activity (e.g. sport) immediately after the initial injury?

Please tick

| | |
|---|---|
| Yes | |
| No | |
| Not sure | |
| Not applicable | |

Q15. Did the knee ***swell*** following the initial injury?

Please tick

| | | |
|---|---|---|
| Yes | | go to question 16 |
| No | | go to question 17 |
| Not sure | | go to question 17 |

Q16. If yes to Q15 which best describes how soon after the injury it swelled?

Please tick

| | |
|---|---|
| Within a few minutes | |
| Within 1 hour | |
| Within 4-6 hours | |
| Within 1 day | |
| The following day | |

## Following the initial injury

Q17. Apart from the initial injury has the knee given way (gone out of place) since?

| | Please tick | |
|---|---|---|
| Yes | | continue to question 18 |
| No | | go to question 19 |
| Not sure | | go to question 19 |

Q18. If yes to question 17 how many times has the knee given way (provide best estimate)?

| | Please tick |
|---|---|
| Once | |
| 2-3 times | |
| 4-6 times | |
| 7-10 times | |
| More than 10 times | |

# Appendix III. Survey questionnaire

## **Information about the medical consultations**

Q19. Where did the patient ***first*** attend for their current knee condition?

Please tick

| | |
|---|---|
| Accident and emergency department | |
| Minor injury unit | |
| General practitioner (family doctor) | |
| Physiotherapist | |
| Specialist doctor (private) | |
| Other (please state below) | |

Other (please state)_____

Q20. How long after the initial injury (or onset of symptoms) did the patient wait before ***first*** consulting a medical professional (i.e. number of days from the date of initial injury/onset to the date of first presentation to a medical professional for the knee condition?

Please state timescale_____ days

Q21. Was the anterior cruciate ligament injury diagnosed when the patient ***first*** attended with their knee injury (i.e. at the first appointment with a medical professional)?

Please tick

| | |
|---|---|
| Yes | |
| No | |
| Not sure | |

Q22. Did the patient attend an ***accident and emergency*** department (or minor injury unit) as a result of their knee injury (at any time)?

Please tick

| | | |
|---|---|---|
| Yes | | continue to question 23 |
| No | | go to question 24 |

If yes which A&E/ MIU did they attend_____

Q23. Following the ***initial*** attendance at accident and emergency/ minor injury unit did the patient have a follow up appointment arranged for their knee injury?

Please tick

| | |
|---|---|
| Yes | |
| No (discharged without follow up) | |
| Not sure | |

# Appendix III. Survey questionnaire

Q24. What date was the anterior cruciate ligament injury was **first** correctly diagnosed (the date the patient first became aware of the diagnosis)? **If exact date not known please report best estimate.**

_____(dd/mm/yy)

Q25. Who first ***correctly*** diagnosed the ACL injury?

Please tick

| | |
|---|---|
| Accident and emergency doctor | |
| General practitioner (family doctor) | |
| Hospital consultant (doctor) | |
| Physiotherapist | |
| Other (please state below) | |

Other (please state)_____

Q26. How many separate appointments regarding the knee did the patient have ***prior*** to receiving a diagnosis of anterior cruciate ligament injury (include ***total*** number of appointments with ***all*** medical professionals e.g. A&E/ GP/ physiotherapist/ non specialist consultant/ MRI)?

_____appointments

Q27. Has the patient had an MRI scan of the knee as a result of the injury?

Please tick

| | | |
|---|---|---|
| Yes | | continue to question 28 |
| No | | Questionnaire completed |
| Not sure | | Questionnaire completed |

Q28. If yes who organised the MRI scan?

Please tick

| | |
|---|---|
| General practitioner (family doctor) | |
| Hospital doctor (consultant) | |
| Physiotherapist | |
| Can't remember/ not recorded | |
| Other (please state) | |

Other_____

Q29. Was the ACL injury identified on the MRI scan?

Please tick

| | |
|---|---|
| Yes | |
| No | |
| Unsure | |

Airedale NHS
NHS Foundation Trust

Ref. MCU/HC

Research & Effectiveness
Fleming House
Airedale General Hospital
Steeton
KEIGHLEY
W Yorks
BD20 6TD

Tel. 01535 294655

Mr C Ayre
Honorary Lecturer
MSc, BScHons, PG Cert, MCSP HPC reg.
School of Health Studies
University of Bradford
Bradford
BD7 1DP

Dear Mr Ayre

**Title:** **Anterior cruciate ligament (ACL) injuries**
**ANHST No:** **0600**

The above study is a service evaluation and as such does not need REC approval. R&D have looked at the information you have supplied and we are happy to give permission for this to take place.

Yours sincerely,

Dr Carole Paley
Research and Development Manager

Bradford Teaching Hospitals NHS
NHS Foundation Trust

Mr Colin Ayre

Honorary Lecturer and PhD Student

School of Health Studies

University of Bradford

Richmond Road

BD7 1DP

5th December 2012

Dear Mr. Ayre

**Re: Study number 2773 A service evaluation of anterior cruciate ligament injuries attending specialist consultant orthopaedic clinics**

I can confirm that permission has been granted on 5th December 2012 for the above service evaluation to be undertaken within Bradford Teaching Hospitals NHS Foundation Trust. This has been formally registered as above with the clinical governance audit department as a recognised audit. The project is deemed to be a service evaluation and therefore does not require ethical approval.

Yours sincerely,

James Hahnel

Orthopaedic clinical governance lead (Bradford Teaching Hospitals NHS Foundation Trust)

The Leeds Teaching Hospitals NHS
NHS Trust

**Department of Trauma and Orthopaedics**

**Chapel Allerton Hospital**
**Chapeltown Road**
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Tel: (0113) 243 3144
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Direct Fax:

Mr Ayre
Honarary Lecturer and PhD Student
School of Health Studies
University of Bradford
Richmond Road
Bradford
BD7 1DP

Date Dictated: 06 Mar 2014
Date Typed: 07 March 2014
Our Ref: RM/SEH

Dear Colin Ayre

**Private and Confidential**

20 May 2013

**Service Evaluation of Anterior Cruciate Ligament Injuries attending Specialist Consultant Orthopaedic Clinics**

I can confirm that I granted permission on 20 May 2013 for the above service evaluation to be undertaken within the Orthopaedic Department of Leeds Teaching Hospitals.

The service evaluation has been registered with Stuart Nicholson, Deputy Quality Governance Manager in the Quality Improvement Team.

Yours sincerely

Electronically signed by
**Mr. Ray Monkhouse**
**Consultant Orthopaedic Surgeon**

Lead Clinician for Trauma Leeds General Infirmary Teaching Hospitals

The Mid Yorkshire Hospitals NHS
NHS Trust

***Bringing together community and hospital services***

If you need this correspondence in a larger font size please contact: 01924 543175

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jane.shewan@midyorks.nhs.uk

JS/js/N:R&D

31 March 2014

Colin Ayre
Honorary Lecturer, School of Health Studies
University of Bradford
(by email to c.a.ayre1@bradford.ac.uk)

Dear Colin

**Re: PhD study: service evaluation to determine both the presence and extent of delayed diagnosis in primary ACL injured subjects**

In April 2013, you approached the Research Office about the above project. I agreed that the project was appropriately categorised as a service evaluation. You also contacted the Clinical Governance Manager Mrs D Bickerdike; and received confirmation by email that you were authorised to proceed with the project. The Clinical Head of Service (Mr Shetty) and two Consultant Orthopaedic Surgeons (Mr Newman and Mr Cohen) had also confirmed that they were happy for the project to go ahead.

You received the authorisations to proceed by email on 3rd May 2013.

I am happy to formally confirm that the service evaluation you have undertaken as part of your PhD was authorised appropriately within Mid Yorkshire Hospitals NHS Trust.

Yours sincerely

**Jane Shewan**
**HEAD OF RESEARCH AND EFFECTIVENESS**

A Teaching Partner with H·Y·M·S THE HULL YORK MEDICAL SCHOOL

Northern Lincolnshire and Goole Hospitals NHS
NHS Foundation Trust

Research & Development Department
Direct Dial/Fax: 01724 290410
Secretary ext. 2846

Ref: c/mh/s.e./approval/ayre

23rd April 2013

Mr Colin Ayre
Honorary Lecturer and PhD Student
Bradford Teaching Hospitals NHS Foundation Trust
School of Health Studies
University of Bradford
Richmond Road
BD7 1DP

Dear Mr Ayre

**Re: A service evaluation of anterior cruciate ligament injuries attending specialist consultant orthopaedic clinics**

I can now confirm that permission is given by the Northern Lincolnshire & Goole Hospitals NHS Foundation Trust Research & Development department for the above mentioned service evaluation. This project does not need Ethical approval.

However, you are required to inform the Trust Research & Development department of any significant proposed changes to the original project.

Should you require any further assistance regarding this study, please do not hesitate to contact me

Yours sincerely

D Bates

**Debrah Bates**
**Head of Research & Professional Development**
**Northern Lincolnshire & Goole Hospitals**
**NHS Foundation Trust**

# Appendix V:

Table showing $CVR_{critical}$ one-tailed test ($\alpha$= 0.05) based on exact binomial probabilities

| N (panel size) | Proportion agreeing essential | $CVR_{critical}$ exact values | One-sided p-value | $N_{critical}$ (minimum number of experts required to agree item essential) |
|---|---|---|---|---|
| 5 | 1 | 1.00 | .031 | 5 |
| 6 | 1 | 1.00 | .016 | 6 |
| 7 | 1 | 1.00 | .008 | 7 |
| 8 | .875 | .750 | .035 | 7 |
| 9 | .889 | .778 | .020 | 8 |
| 10 | .900 | .800 | .011 | 9 |
| 11 | .818 | .636 | .033 | 9 |
| 12 | .833 | .667 | .019 | 10 |
| 13 | .769 | .538 | .046 | 10 |
| 14 | .786 | .571 | .029 | 11 |
| 15 | .800 | .600 | .018 | 12 |
| 16 | .750 | .500 | .038 | 12 |
| 17 | .765 | .529 | .025 | 13 |
| 18 | .722 | .444 | .048 | 13 |
| 19 | .737 | .474 | .032 | 14 |
| 20 | .750 | .500 | .021 | 15 |
| 21 | .714 | .429 | .039 | 15 |
| 22 | .727 | .455 | .026 | 16 |
| 23 | .696 | .391 | .047 | 16 |
| 24 | .708 | .417 | .032 | 17 |
| 25 | .720 | .440 | .022 | 18 |
| 26 | .692 | .385 | .038 | 18 |
| 27 | .704 | .407 | .026 | 19 |
| 28 | .679 | .357 | .044 | 19 |
| 29 | .690 | .379 | .031 | 20 |
| 30 | .667 | .333 | .049 | 20 |
| 31 | .677 | .355 | .035 | 21 |
| 32 | .688 | .375 | .025 | 22 |
| 33 | .667 | .333 | .040 | 22 |
| 34 | .676 | .353 | .029 | 23 |
| 35 | .657 | .314 | .045 | 23 |
| 36 | .667 | .333 | .033 | 24 |
| 37 | .649 | .297 | .049 | 24 |
| 38 | .658 | .316 | .036 | 25 |
| 39 | .667 | .333 | .027 | 26 |
| 40 | .650 | .300 | .040 | 26 |

# Appendix VI: Stage 1 panel letter

Dear

I am undertaking PhD research evaluating the effectiveness of specialist knee clinics within the acute setting. As part of this research, I am undertaking an observational study to examine whether differences exist in the clinical assessment of acute knee injuries between staff working within different clinical settings.

**You are being invited to help validate the checklist which will be used to document what occurs during the clinical assessment of acute knee injuries.**

Please read the information below which will help you to understand whether you wish to be involved in this process.

**What is the reason for the study?**

Acute knee injuries are frequently encountered in the health service with the majority involving damage to soft tissue knee structures including ligaments, menisci and tendons. A number of studies have highlighted delayed and missed diagnosis of these injuries, often resulting in delayed or inappropriate management. Although MRI scanning has been a valuable tool aiding the diagnosis of many knee injuries it is not appropriate for all patients with acute knee injury to undergo such investigation and therefore clinical examination remains critical in determining an appropriate management pathway. In order to assist the accurate diagnosis of knee injuries, a series of questions and clinical tests have been proposed in the medical literature although it is uncertain which of these are being utilised by clinical staff assessing such injuries. Furthermore, it is not known whether differences exist between specialist and non-specialist clinical groups in the questions asked or objective tests performed on patients who have suffered an acute knee injury.

**This study aims to determine whether differences exist in the clinical assessment of acute knee injuries between clinical specialists and non-specialists within an orthopaedic outpatient department setting.**

**What is required?**

In order to ensure completeness and consistency in recording of observations, I am developing a comprehensive checklist from published literature of information that may be gathered and tests which may be completed as part of clinical assessment following an acute knee injury. The checklists provide a method of easily recording what takes place during the assessment of a knee injury. However, to ensure the checklists are clinically relevant, have clarity and exhaustive, I would be grateful if you would consider the criteria in the provisional checklist and tick to indicate whether you feel the criteria are essential, useful but not essential or not important for inclusion in the final checklist. Space is also provided for you to specify additional criteria not currently on the checklist that you feel should be included and to comment on the clarity of criteria.

# Appendix VI: Stage 1 panel letter

**Why have I been chosen?**

You have been chosen to participate in the development of these checklists as a clinician encountering and assessing acute knee injuries.

**What will happen if I agree to take part?**

In total you will be asked to review 2 checklists and return them (by email or post) as is most convenient. Feedback from the first checklist review will be used to compile a second checklist. Any new criteria identified from the initial review will subsequently be sent out for your consideration. It is anticipated that each checklist review should take no more than 10 minutes so the total time involved is likely to be around 20 minutes.

Your involvement will be entirely anonymous and no details will be recorded on any of the forms. Please do not pass on any details of the checklist to other individuals as the contents of the checklist will not be made available to study participants.

Please confirm if you are happy to be involved in the study and I can send through the checklist for you to consider.

Please do not hesitate to contact me if you require further information or clarification.
Yours sincerely,

Colin Ayre

MPhil/ PhD student
University of Bradford
Richmond Road
Bradford BD7 1DP
Tel: (01274) 23 6376
Email: c.a.ayre1@bradford.ac.uk

# Appendix VII- Stage 2 panel letter

Dear panel member,

Thank you again for your participation in helping to validate the knee injury checklist. This is the second and final stage of your involvement.

What is required?

We want to identify what you think should be included as part of a **standard** (routine) examination of an injured knee. It is **not** designed to include all tests which could possibly be used; rather, the items which you feel should be included in every knee injury assessment when possible. Please complete the following questionnaire indicating whether you feel each item is '**essential**', '**useful, but not essential**' or '**not necessary**'. Please complete all items.

A guide to help you complete the form:

**'Essential'-** If marking this category you should feel it is essential to include this criterion as part of a **standard** clinical examination of an injured knee.

**'Useful, but not essential'**- If marking this category, you should feel that although it is useful, it is not essential to include the criterion as part of a **standard** clinical examination of an injured knee.

'**Not important'**- If marking this category you should feel that it is 'not important' to include the criterion as part of a **standard** clinical examination of an injured knee.

Please return the form no later than Friday 31st May 2013. Treat the information included in this document as confidential.

If you require any further information or clarification, please do not hesitate to contact me. Thank you once again for your time.

Yours sincerely,

Colin Ayre

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# Appendix VIII: Second stage evaluation form

**Information about you**

1) **What best describes your current role (e.g. Consultant, GPSI, physiotherapist, sports medicine physician etc.)?**

_____

2) **How long have you been qualified as a health professional? years**

3) **How long (in years) have you independently assessed/ treated knee injuries?**

**years**

4) **Have you ever assessed knee injuries within an emergency department or minor injury unit (tick as appropriate)?**

| | |
|---|---|
| Yes | |
| No | |

# Appendix VIII: Second stage evaluation form

**Acute knee injury assessment evaluation form- proposed checklist items**

**How to complete this form:** Please tick a single response for all given criteria. Prior to completing the form please read the attached letter.

**Example of how to complete: if you think it is essential to include the 'Slocum test' as part of a standard examination of a knee injury, please tick 'essential' as shown below:**

| | Essential | Useful, but not essential | Not necessary |
|---|---|---|---|
| Slocum Test | ✓ | | |

**A glossary of clinical examination tests is included at the end of this questionnaire to assist in accurate completion.**

## Clinical history questions

| | Essential | Useful, but not essential | Not necessary |
|---|---|---|---|
| Clicking (knee-establish presence of) | | | |
| Congenital problems with lower limb | | | |
| Contact/non-contact injury | | | |
| Depth of pain | | | |
| Family history of knee problems | | | |
| Functional level needed to return to | | | |
| Giving way (establish presence of) | | | |
| Giving way (how often) | | | |
| Giving way (which direction/ activity) | | | |
| If sporting injury, inability to continue playing immediately after injury causing event | | | |
| Locking (position of leg-flexed/extended) | | | |
| Locking (presence of) | | | |
| Locking (question whether pseudo/true) | | | |
| Mechanism of injury | | | |
| Pain level (e.g. mild/moderate/severe) | | | |
| Pain location (area of pain) | | | |
| Pain (establish whether present at rest) | | | |
| Pain (establish whether pain experienced immediately after injury) | | | |
| Presence of neurological symptoms (e.g. numbness, tingling, weakness) | | | |
| Presenting complaint (main problem) | | | |
| Response to previous treatment | | | |
| Sound/ pop at time of injury (establish whether present) | | | |
| Swelling/effusion (presence) | | | |
| Swelling/effusion (time to onset post initial injury event | | | |
| Trust/confidence in knee | | | |
| Where injury took place (location) | | | |

# Appendix VIII: Second stage evaluation form

## Clinical examination tests

| | Essential | Useful, but not essential | Not necessary |
|---|---|---|---|
| GENERAL TESTS | | | |
| Active straight leg raise | | | |
| All tests compared to unaffected side | | | |
| Apley's distraction test (general ligament test) | | | |
| Effusion tests (e.g. patellar tap/ ballottement/sweep/brush test ) | | | |
| Hip joint range of movement | | | |
| Knee joint movement- extension | | | |
| Knee joint movement-flexion | | | |
| Knee joint movement- lateral rotation | | | |
| Knee joint movement-medial rotation | | | |
| Losee 'disco' test | | | |
| Neurological testing (reflexes, dermatomes, myotomes) | | | |
| Strength testing- hamstrings | | | |
| Strength testing- quadriceps | | | |
| Swain test (medial complex injury) | | | |
| Wilson test (for Osteochondritis Dissecans) | | | |
| LIGAMENT TESTS- Anterior instability tests- single plane | | | |
| Anterior drawer test | | | |
| Anterior drawer test (modified- active drawer test) | | | |
| Anterior drawer test (modified- Jakob maximum anterior drawer) | | | |
| Anterior drawer test (modified- sitting anterior drawer) | | | |
| Anterior drawer test (modified- 90-90 anterior drawer) | | | |
| Lachman test | | | |
| Lachman test (modified- drop leg) | | | |
| Lachman test (modified- including visual observation eyes level with knee) | | | |
| Lachman test (modified- maximum quadriceps) | | | |
| Lachman test (modified- no touch/active) | | | |
| Lachman test (modified- patient sitting over edge of plinth) | | | |
| Lachman test (modified- prone) | | | |
| Lachman test (modified- stable) | | | |
| LIGAMENT TESTS- Posterior instability tests- single plane | | | |
| Genu recurvatum test | | | |
| Godfrey (gravity) test | | | |
| Posterior drawer test | | | |
| Posterior sag sign | | | |
| Quadriceps active test | | | |
| Reverse Lachman test | | | |

# Appendix VIII: Second stage evaluation form

| | | | |
|---|---|---|---|
| Step-off test | | | |
| LIGAMENT TESTS- Medial (valgus) instability | | | |
| Abduction (valgus) stress test 0 degrees | | | |
| Abduction (valgus) stress test 30 degrees | | | |
| Hughston's valgus stress test | | | |
| LIGAMENT TESTS- Lateral (varus) instability | | | |
| Adduction (varus) stress test 0 degrees | | | |
| Adduction (varus) stress test 30 degrees | | | |
| Hughston's varus stress test | | | |
| LIGAMENT TESTS- Anterolateral rotatory instability | | | |
| Crossover test (Arnold) | | | |
| Giving way test (Jakob) | | | |
| Hughston's jerk test | | | |
| Lemaire's jolt test | | | |
| Losee test | | | |
| Martens test | | | |
| Nakajima test | | | |
| Noyes flexion-rotation drawer test | | | |
| Pivot shift test (McIntiosh) | | | |
| Pivot shift test (modified- active pivot shift) | | | |
| Pivot shift test (modified- graded pivot shift) | | | |
| Pivot shift test- (modified- soft pivot shift) | | | |
| Slocum test (for anterolateral instability) | | | |
| Slocum ALRI test | | | |
| LIGAMENT TESTS- Anteromedial rotatory instability | | | |
| Dejour test | | | |
| Lemaire's T drawer test | | | |
| Slocum test (for anteromedial instability) | | | |
| LIGAMENT TESTS- Posterolateral rotatory instability | | | |
| Active posterolateral drawer sign | | | |
| Arcuate spin test | | | |
| Dial test | | | |
| Dynamic posterior shift test | | | |
| External rotation recurvatum test (Hughston) | | | |
| Posterolateral drawer sign (Hughston) | | | |
| Posterolateral rotary instability test (Loomer) | | | |
| Reverse pivot shift test (Jakob) | | | |
| Standing apprehension test | | | |
| LIGAMENT TESTS- Posteromedial rotatory instability | | | |
| Posteromedial drawer (Hughston) | | | |
| Posteromedial pivot shift test | | | |
| MENISCAL TESTS | | | |
| Anderson medial and lateral grind test | | | |
| Apley compression test | | | |
| Boehler-Kroemer test | | | |
| Bounce home test | | | |
| Cabot test (popliteus sign) | | | |

# Appendix VIII: Second stage evaluation form

| | | | |
|---|---|---|---|
| Childress sign (duck walking) | | | |
| Ege's test | | | |
| Joint line tenderness (palpation) | | | |
| Knee compression-rotation test | | | |
| McMurray test | | | |
| Merke's sign | | | |
| Modified Helfet test | | | |
| Passler's rotational compression test | | | |
| Payr test | | | |
| Payr test (in cross legged sitting) | | | |
| Steinmann test I | | | |
| Steinmann test II | | | |
| Thessaly test | | | |
| PATELLOFEMORAL JOINT TESTS | | | |
| Accessory movements | | | |
| Apprehension test | | | |

Any further comments:

_____
_____
_____
_____

Thank you once again for your time.

Please send completed forms to:

Colin Ayre

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University of Bradford
Richmond Road
Bradford BD7 1DP
Tel: (01274) 23 6376
Email: c.a.ayre1@bradford.ac.uk

# Appendix VIII: Second stage evaluation form

| | |
|---|---|
| Active straight leg raise | Patient lying supine or long sitting. Asked to lift heel off bed whilst maintaining knee extension. Test for strength and extensor mechanism injury. |
| Apley distraction test | As the Apley compression test but with distraction applied. If distraction with rotation more painful test supportive of ligament lesion. |
| Losee 'disco' test | Patient stands with weight on test leg, knee flexed 10-20$^0$. Patient rotates in either direction maintaining knee flexion. Positive test is refusal or apprehension during the test. |
| Swain test | Patient sitting with knee flexed to 90$^0$. Examiner externally rotates tibia and palpates medial side of the joint. Positive test for MCL injury is pain reproduction. |
| Wilson test | Patient sitting with knee flexed. Patient extends knee maintaining internal tibial rotation. Positive test is pain at approximately 30 degrees flexion which is abolished by externally rotating the tibia |
| LIGAMENT TESTS- One plane anterior instability | |
| Anterior drawer test | Patient supine with knee flexed to 90 degrees, hip flexed to 45 degrees. Examiner supports patient's foot by sitting on forefoot. Examiner places hands around posterior tibia and drawers tibia anteriorly. Positive test increased range. |
| Anterior drawer test (modified- active drawer test) | Position similar to the anterior drawer test. Patient performs isometric quadriceps contraction whilst the examiner maintains the position. Action of quadriceps actively draws the tibia anteriorly. Examiner notes range of displacement visually. Positive test increased anterior tibial translation on the affected leg. |
| Anterior drawer test (modified-Jakob maximum anterior draw test) | Patient supine with the knee flexed to 50-60 degrees. Examiner places their forearm under the affected knee and holds the opposite leg on distal thigh. Forearm used to maximally displace the tibia anteriorly whilst the other hand notes how much translation occurs. Positive test increased anterior translation compared to the unaffected side. |
| Anterior drawer test (modified-sitting anterior drawer test) | Modification of the anterior drawer test. Patient sitting knee flexed to 90$^0$. Examiner draws tibia anteriorly noting range. Positive test increased translation of tibia anteriorly/ abnormal end feel. |
| Anterior drawer test (modified- 90-90 anterior drawer) | Modification of the anterior drawer test with patient supine and hip and knee flexed to 90$^0$ examiner supporting tibia between trunk and forearm. Tibia drawn anteriorly with enough force to slowly lift patient's buttock off table on the test leg. Positive test increased anterior translation of tibia. |
| Lachman test | Patient supine patient's knee in 20-30 degrees of knee flexion. Patient's distal femur stabilised with one hand whilst the examiner moves proximal tibia anteriorly. Positive test soft end feel or increased translation |
| Lachman test (modified- drop leg) | Patient supine. Patient's test leg is abducted off side of examination table, knee flexed to 25 degrees. One of the examiners hand stabilises femur against table whilst anterior translation applied to proximal tibia |
| Lachman test (modified- including visual observation eyes level with knee) | As the Lachman test but examiner stands to the lateral side, eyes horizontally level with test knee and views amount of anterior tibial displacement. Positive test increased anterior translation. |

# Appendix VIII: Second stage evaluation form

| | |
|---|---|
| LIGAMENT TESTS- One plane anterior instability (continued) | |
| Lachman test (modified- maximum quadriceps) | As the no touch Lachman test but with the examiner placing a hand on the lower tibia to stop the foot lifting during the test. Valgus force applied to the knee. Positive test is lateral translation of the tibia (seen in ACL deficient knee) |
| Lachman test (modified-no touch/active) | Patient supine, knee flexed to $30^0$ over examiners forearm. Patient actively extends knee whilst examiner notes anterior tibial displacement. Positive test increased range. |
| Lachman test (modified- patient sitting over edge of plinth) | As the Lachman test but the patient sitting on the edge of the plinth. Lower leg stabilised in between examiners legs. |
| Lachman test (modified- prone Lachman test) | As the Lachman test but patient lying prone. Examiner stabilises foot between thorax and arm. Tibia displaced anteriorly by the examiner aided by gravity. Positive test increased translation and/ or abnormal and feel. |
| Lachman test (modified- stable Lachman) | As the Lachman test but the examiner stabilises the femur by placing their knee under patient's knee. |
| LIGAMENT TESTS- One plane posterior instability | |
| Genu recurvatum test | Patient supine. Examiner lifts patient foot passively extending knee. Positive test increased range of hyperextension with posterior tibial sag. |
| Godfrey (gravity) test | Patient supine with hips and knees flexed to $90^0$ examiner supporting leg. Increased posterior sag of tibia positive sign. Can also apply posterior force on proximal tibia to confirm. |
| Posterior drawer test | Patient lying supine, knee flexed to 90 degrees hip to 45 degrees. Patient's foot stabilised by the examiner who displaces the tibia posteriorly. Positive test increased movement. |
| Posterior sag sign | Patient supine knee flexed 90 degrees and hip to 45 degrees. Examiner observes relative position of tibia and femur from side. Positive test increased posterior tibial sag. |
| Quadriceps active test | Similar to active drawer test- modification of anterior drawer test but with increased anterior displacement due to initial posterior sag of tibia relative to the femur. |
| Reverse Lachman test | Patient prone. Knee flexed to 30 degrees. Examiner moves tibia posteriorly. Positive test for PCL lesion indicated by increased movement/ abnormal end feel. |
| Step-off test | Patient supine with knee flexed to 90 degrees and hip to 45 degrees. Examiner palpates the position of the tibia relative to the femur. Positive test is increased posterior tibial displacement compared to unaffected side. |
| LIGAMENT TESTS- Medial (valgus) instability tests | |
| Abduction (valgus) stress test 0 degrees | Patient supine knee fully extended. Examiner stabilises the ankle and applies a valgus (abduction) stress to the knee. Positive test is increased movement. |
| Abduction (valgus) stress test 30 degrees | As above but with the knee in 30 degrees flexion to 'unlock' the knee. |
| Hughston's valgus stress test | Patient supine, examiner facing patient's foot and stabilising femur. Valgus stress applied by examiner via the patient's big toe allowing lateral tibial rotation. Positive test increased movement. |

# Appendix VIII: Second stage evaluation form

| LIGAMENT TESTS- Lateral (varus) instability tests | |
|---|---|
| Adduction (varus) stress test 0 degrees | Patient supine knee fully extended. Examiner stabilises the ankle and applies a varus (adduction) stress to the knee. Positive test is increased movement. |
| Adduction (varus) stress test 30 degrees | As above but with the knee in 30 degrees flexion to 'unlock' the knee. |
| Hughston's varus stress test | Patient supine, examiner facing patient's foot. Varus stress applied by examiner via the patient's lateral foot allowing medial tibial rotation. Positive test is increased movement. |
| LIGAMENT TESTS- Anterolateral rotatory instability | |
| Crossover test (Arnold) | Performed with the patient standing. Examiner stabilises the foot on the affected leg by gently standing on it. The patient is asked to rotate away from the affected side by crossing uninvolved leg over the affected leg. |
| Giving way test (Jakob) | Patient leans against the wall (unaffected side) weight on both legs. Examiner places one hand proximal and the other just distal to the injured knee and applies a valgus force as the patient flexes injured knee. Positive test is an anterior subluxing of the tibia reproducing the giving way. |
| Hughston jerk test | Similar to the pivot shift test. Knee flexed to $90^0$ hip flexed to $45^0$. Leg is then extended maintaining medial tibial rotation and valgus pressure on the knee. Subluxation at $20^0$-$30^0$ indicates positive test |
| Lemaire jolt test | Patient side lying, test leg uppermost. Examiner holds patient's foot and medially rotates tibia with one hand ensuring patient is relaxed. Other hand pushes gently against the biceps femoris tendon/ fibular head as the knee is flexed and extended. Positive test is a jolt at 15-$20^0$ of flexion |
| Losee test | Patient supine, knee fully extended. Tibia laterally rotated by examiner and knee then flexed to $30^0$. Examiner's other hand presses fibular head anteriorly whilst valgus pressure applied to the knee as it is extended. Medial rotation is allowed as knee approaches extension. Positive test is clunk felt as the tibia relocates from subluxed position. |
| Martens test | Patient supine, examiner holding patients ankle between their trunk and arm. Examiner grips the leg distal to the knee whilst the other hand is on the anterior aspect of the thigh applying a posteriorly directed force on the femur. Valgus stress applied as the knee flexed and extended. Positive test if the tibia subluxes/ reduces. |
| Nakajima test | Patient lies in supine knee flexed to 90 degrees with foot held by examiner in one hand. The other hand holds the lateral femoral condyle with the thumb behind the fibular head pressing it anteriorly. Knee extended by examiner- positive test is a subluxation. |
| Noyes flexion-rotation drawer test | Patient lies supine. Examiner supports ankle between trunk and arm. Knee flexed to 20-$30^0$. Posterior force applied to tibia. Positive test reduces subluxation. |
| Pivot shift test (McIntosh) | Patient lies supine hip flexed and abducted approximately 30 degrees, in slight internal rotation (20 degrees) knee in full extension. Examiner applies slight valgus force as the knee is flexed. Positive test is tibial relocation |
| Pivot shift test (modified- active) | Patient seated with the foot on the floor, neutral tibial rotation and knee flexed to $80^0$ to $90^0$. Patient isometrically contracts quadriceps whilst examiner stabilises the foot. Positive test anterolateral subluxation of the lateral tibial plateau. |

# Appendix VIII: Second stage evaluation form

| | |
|---|---|
| LIGAMENT TESTS- Anterolateral rotatory instability (continued) | |
| Pivot shift test (modified- graded pivot shift test- Jakob) | Patient supine, knee in full extension. Examiner supports patient's foot against trunk and applies axial and valgus load on the knee. Knee flexed to 20-30$^0$. Test repeated with internal tibial rotation, neutral tibial rotation and in external tibial rotation. Positive test shift indicated by subluxing as the tibia relocates. |
| Pivot shift test (modified- soft) | Test performed similarly to the pivot shift test described above but prior to testing the examiner 'relaxes' the patient by slowly flexing and extending the knee three to five times. |
| Slocum test (anterolateral instability) | Patient supine knee flexed to 80-90 degrees and hip flexed to 45 degrees. Foot placed in 30 degrees medial rotation and stabilised by examiner sitting on patient's foot. Anterior tibial displacement applied. Positive test increased movement primarily on the lateral aspect of the knee. |
| LIGAMENT TESTS- Anteromedial rotatory instability | |
| Dejour test | Test for anteromedial rotatory instability. Examiner holds patients leg with one arm against their body. Knee moved from extension to flexion whilst examiner maintains posterior pressure on the distal femur. Positive test is a jerk felt as the tibial plateau relocates. |
| Lemaire T drawer test (Slocum test for anteromedial rotatory instability) | As Slocum anterolateral instability test (see above) but performed with the foot in 15$^0$ of lateral rotation- assesses anteromedial rotatory instability |
| LIGAMENT TESTS- Posterolateral rotatory instability | |
| Active posterolateral drawer sign | Patient sits with the knee flexed 80-90$^0$, foot on the floor in neutral rotation. Patient performs isometric contraction of the hamstrings. Positive test is observation of posterior subluxation of lateral tibial plateau. |
| Arcuate spin test | Patient sits with the knee flexed to 90$^0$. Posteriorly directed force applied to the tibia and maximum passive external tibial rotation. Positive test increased ROM. |
| Dial test | Patient prone with knees together flexed to 30 degrees. Examiner supports both ankles and laterally rotates tibia noting any differences in range of movement. Positive test increased lateral tibial rotation on affected side. Repeated in 90 degrees of flexion. Can also be performed in supine. |
| Dynamic posterior shift test | Patient supine, hip and knee flexed to 90$^0$. Examiner stabilises anterior thigh with one hand and extends the knee with the other hand. Positive test clunk as the tibia reduces anteriorly as the knee approaches full extension. |
| External rotation recurvatum test (Hughston) | Patient supine. Examiner grasps patient's big toe and lifts upwards whilst patient remains relaxed. Positive test is increased external rotation and hyperextension/varus position noted |
| Posterolateral drawer (Hughston) | Patient supine with hip and knee flexed to 80-90$^0$. Examiner laterally rotates tibia slightly and sits on foot to stabilize before applying a posterior force onto the affected tibia. Positive test is increased posterior movement and/or increased rotation. |
| Posterolateral rotary instability test (Loomer) | Patient supine both hips and knees flexed to 90$^0$. Examiner holds both tibia and passively maximally externally rotates. Positive test if both increased external rotation combined with posterior sag of tibial tubercle on affected side. |

# Appendix VIII: Second stage evaluation form

| | |
|---|---|
| LIGAMENT TESTS- Posterolateral rotatory instability (continued) | |
| Reverse pivot shift test (Jakob) | Patient supine examiner supporting patients leg against their pelvis. Examiner places other hand on lateral aspect of leg and flexes knee to 70-80$^0$ and laterally rotates tibia. Knee extended with valgus stress applied to the knee. Positive test is subluxation of the tibia at approximately 20 degrees flexion. |
| Standing apprehension test | Patient in standing weight on test leg. Examiner applies anteromedial force onto anterolateral femoral condyles patient slightly flexes knee. Positive test is increased condyle displacement and giving way sensation. |
| LIGAMENT TESTS- Posteromedial rotatory instability | |
| Posteromedial drawer (Hughston) | Patient supine with hip and knee flexed to 80-90$^0$. Examiner medially rotates tibia slightly and sits on foot to stabilise before applying a posterior force onto the affected tibia. Positive test is increased posterior rotation of the lateral tibia. |
| Posteromedial pivot shift test | Patient supine. Examiner applies combined varus stress, compression and medial tibial rotation whilts passively flexing patient's knee. Positive test is reduction of subluxed position at around 20-40 degrees of knee flexion. |
| MENISCAL TESTS | |
| Anderson medial-lateral grind test | Patient supine. Examiner holds test leg between trunk and arm. Valgus stress applied to knee by examiner whilst flexing knee. Followed by extension with valgus force. Positive test is grinding. |
| Apley compression test | Patient lays prone, knee flexed to 90$^0$. Patient's thigh held firmly to examination table by examiner's knee, who applies compression to the knee through the patient's foot. Positive test is increased pain or decreased ROM compared to unaffected side. |
| Boehler- Kroemer test | Patient supine- examiner applies varus and valgus stress to the knee at varying degrees of flexion. Pain in the compressed region is positive for meniscal lesion |
| Bounce home test | Patient supine. Examiner fully flexes patients knee then allows it to passively extend. Absence of full extension or springy end feel suggests meniscal tear |
| Cabot's test (popliteal sign) | Patient supine, test leg in figure 4 position. Examiner palpates the joint line with thumb and forefinger of one hand and the other hand just proximal to the ankle. Patient asked to isometrically extend knee against examiner's hand. Positive test pain. |
| Childress' sign (duck walking) | Patient performs a full squat (so called duck waddle). Pain, snapping or click positive. |
| Ege's test | Patient performs a full squat first with medial tibial rotation and then in lateral rotation. Positive test reproduction of knee symptoms |
| Joint line tenderness (palpation) | Examiner palpates medial and lateral joint lines. Positive test is reproduction of pain. |
| Knee compression-rotation test | As McMurrays' meniscal test but with added tibiofemoral compression. |
| McMurray test | Patient supine with knee in full flexion. Tibia rotated medially and then laterally whilst the knee is extended to 90 degrees flexion. Positive test snap/ click often with pain. |
| Merke's sign | Patient standing weight on test leg, knee flexed to 10-20$^0$. Patient rotates both sides whilst maintaining knee flexion. Positive test is reproduction of joint line pain. |

# Appendix VIII: Second stage evaluation form

| MENISCAL TESTS (continued) | |
|---|---|
| Modified Helfet test | Observation of the position of the tibial tubercle in 90 degrees of knee flexion and in full extension. Lack of rotation towards full extension may indicate meniscal injury (block to rotation) |
| Passler rotational compression test | Patient seated with knee in extension held between examiners legs just proximal to the knee. Examiner places thumbs over the medial joint line and moves knee in circular fashion including medial and lateral rotation in various degrees of flexion. Positive test reproduction of joint line pain. |
| Payr test | Patient supine test leg in figure 4 position. Medial joint line pain positive for medial meniscal lesion |
| Payr test (modified-cross legged sitting) | As above but with the patient sitting over edge of examination table test leg crossed over other. |
| Steinmann test I | Patient sitting. Knee flexed to $90^0$ and tibia medially and then laterally rotated. Test repeated in various degrees of flexion. Positive test pain |
| Steinmann test II | Joint line palpation in varying degrees of flexion. Positive test is reproduction of pain with zone of tenderness moving more posteriorly with increasing knee flexion |
| Thessaly test | Patient weight bearing on test leg, examiner provides hands/ arms for balance. Patient flexes knee to 20 degrees and rotates. Positive test pain or catching or locking in the knee. Can also be repeated in 5 degrees flexion. |
| PATELLOFEMORAL JOINT TESTS | |
| Accessory movements | Patient supine knee in full extension. Examiner notes degree of movement compared to unaffected side. |
| Apprehension test | Patient supine knee flexed to 30 degrees. Examiner applies a lateral and distally directed pressure to the patella. Positive test apprehension |

# Appendix IX: Item level CVR values obtained following second round consideration by panel members.

Table 1. Table showing number of experts agreeing essential item and corresponding CVR values for subjective examination items:

| **Item** | **Number of experts agreeing essential** | **Content validity ratio (CVR)** |
|---|---|---|
| Clicking (knee-establish presence of) | 8 | 0 |
| Congenital problems with lower limb | 8 | 0 |
| Contact/non-contact injury | 15 | 0.875* |
| Depth of pain | 7 | -0.125 |
| Family history of knee problems | 2 | -0.75 |
| Functional level needed to return to | 12 | 0.5* |
| Giving way (establish presence of) | 16 | 1* |
| Giving way (how often) | 16 | 1* |
| Giving way (which direction/ activity) | 15 | 0.875* |
| If sporting injury, inability to continue playing immediately after injury causing event | 12 | 0.5* |
| Locking (position of leg- flexed/extended) | 15 | 0.875* |
| Locking (presence of) | 16 | 1* |
| Locking (question whether pseudo/true) | 16 | 1* |
| Mechanism of injury | 15 | 0.875* |
| Pain level (e.g. mild/moderate/severe) | 11 | 0.375 |
| Pain location (area of pain) | 13 | 0.625* |
| Pain (establish whether present at rest) | 12 | 0.5* |
| Pain (establish whether pain experienced immediately after injury) | 13 | 0.625* |
| Presence of neurological symptoms (e.g. numbness, tingling, weakness) | 13 | 0.625* |
| Presenting complaint (main problem) | 16 | 1* |
| Response to previous treatment | 11 | 0.375 |
| Sound/ pop at time of injury (establish whether present) | 13 | 0.625* |
| Swelling/effusion (presence) | 16 | 1* |
| Swelling/effusion (time to onset post initial injury event | 15 | 0.875* |
| Trust/confidence in knee | 9 | 0.125 |
| Where injury took place (location) | 4 | -0.5 |

* item accepted onto final checklist

CVR values for the individual objective checklist items are reported in tables 2 to 12 below.

# Appendix IX: Item level CVR values obtained following second round consideration by panel members.

Table 2: Table showing number of experts agreeing essential item and corresponding CVR values for general objective examination test items:

| **Item** | **Number of experts agreeing essential** | **CVR** |
|---|---|---|
| Active straight leg raise | 8 | 0 |
| All tests compared to unaffected side | 12 | 0.5* |
| Apley's distraction test (general ligament test) | 3 | -0.625 |
| Effusion tests (e.g. patellar tap/ ballottement/sweep/brush test ) | 13 | 0.625* |
| Hip joint range of movement | 10 | 0.25 |
| Knee joint movement- extension | 16 | 1* |
| Knee joint movement-flexion | 16 | 1* |
| Knee joint movement- lateral rotation | 12 | 0.5* |
| Knee joint movement-medial rotation | 12 | 0.5* |
| Losee 'disco' test | 0 | -1 |
| Neurological testing (reflexes, dermatomes, myotomes) | 2 | -0.75 |
| Strength testing- hamstrings | 8 | 0 |
| Strength testing- quadriceps | 8 | 0 |
| Swain test (medial complex injury) | 2 | -0.75 |
| Wilson test (for Osteochondritis Dissecans) | 0 | -1 |

* item accepted onto final checklist

Table 3: Table showing number of experts agreeing essential item and corresponding CVR values for single plane tests of anterior instability test items:

| Item | Number of experts agreeing essential | Content validity ratio (CVR) |
|---|---|---|
| Anterior drawer test | 13 | 0.625* |
| Anterior drawer test (modified- active drawer test) | 2 | -0.75 |
| Anterior drawer test (modified- Jakob maximum anterior drawer) | 1 | -0.875 |
| Anterior drawer test (modified- sitting anterior drawer) | 1 | -0.875 |
| Anterior drawer test (modified- 90-90 anterior drawer) | 1 | -0.875 |
| Lachman test | 15 | 0.875* |
| Lachman test (modified- drop leg) | 1 | -0.875 |
| Lachman test (modified- including visual observation eyes level with knee) | 0 | -1 |
| Lachman test (modified- maximum quadriceps) | 0 | -1 |
| Lachman test (modified- no touch/active) | 0 | -1 |
| Lachman test (modified- patient sitting over edge of plinth) | 0 | -1 |
| Lachman test (modified- prone) | 1 | -0.875 |
| Lachman test (modified- stable) | 1 | -0.875 |

* item accepted onto final checklist

# Appendix IX: Item level CVR values obtained following second round consideration by panel members.

Table 4: Table showing number of experts agreeing essential item and corresponding CVR values for single plane posterior instability test items:

| **Item** | **Number of experts agreeing essential** | **Content validity ratio (CVR)** |
|---|---|---|
| Genu recurvatum test | 10 | 0.25 |
| Godfrey (gravity) test | 1 | -0.875 |
| Posterior drawer test | 13 | 0.625* |
| Posterior sag sign | 14 | 0.75* |
| Quadriceps active test | 3 | -0.625 |
| Reverse Lachman test | 1 | -0.875 |
| Step-off test | 4 | -0.5 |

* item accepted onto final checklist

Table 5: Table showing number of experts agreeing essential item and corresponding CVR values for valgus instability test items:

| **Item** | **Number of experts agreeing essential** | **Content validity ratio (CVR)** |
|---|---|---|
| Abduction (valgus) stress test 0 degrees | 15 | 0.875* |
| Abduction (valgus) stress test 30 degrees | 16 | 1* |
| Hughston's valgus stress test | 0 | -1 |

* item accepted onto final checklist

Table 6: Table showing number of experts agreeing essential item and corresponding CVR values for varus instability test items:

| **Item** | **Number of experts agreeing essential** | **Content validity ratio (CVR)** |
|---|---|---|
| Adduction (varus) stress test 0 degrees | 15 | 0.875* |
| Adduction (varus) stress test 30 degrees | 16 | 1* |
| Hughston's varus stress test | 0 | -1 |

* item accepted onto final checklist

# Appendix IX: Item level CVR values obtained following second round consideration by panel members.

Table 7: Table showing number of experts agreeing essential item and corresponding CVR values for anterolateral rotational instability test items:

| **Item** | **Number of experts agreeing essential** | **Content validity ratio (CVR)** |
|---|---|---|
| Crossover test (Arnold) | 1 | -0.875 |
| Giving way test (Jakob) | 0 | -1 |
| Hughston's jerk test | 0 | -1 |
| Lemaire's jolt test | 0 | -1 |
| Losee test | 0 | -1 |
| Martens test | 0 | -1 |
| Nakajima test | 0 | -1 |
| Noyes flexion-rotation drawer test | 0 | -1 |
| Pivot shift test (McIntiosh) | 10 | 0.25 |
| Pivot shift test (modified- active pivot shift) | 1 | -0.875 |
| Pivot shift test (modified- graded pivot shift) | 0 | -1 |
| Pivot shift test- (modified- soft pivot shift) | 3 | -0.625 |
| Slocum test (for anterolateral instability) | 2 | -0.75 |
| Slocum ALRI test | 0 | -1 |

Table 8: Table showing number of experts agreeing essential item and corresponding CVR values for anteromedial instability test items:

| **Item** | **Number of experts agreeing essential** | **Content validity ratio (CVR)** |
|---|---|---|
| Dejour test | 1 | -0.875 |
| Lemaire's T drawer test | 0 | -1 |
| Slocum test (for anteromedial instability) | 3 | -0.625 |

Table 9: Table showing number of experts agreeing essential item and corresponding CVR values for posterolateral instability test items:

| **Item** | **Number of experts agreeing essential** | **Content validity ratio (CVR)** |
|---|---|---|
| Active posterolateral drawer sign | 3 | -0.625 |
| Arcuate spin test | 0 | -1 |
| Dial test | 10 | 0.25 |
| Dynamic posterior shift test | 2 | -0.75 |
| External rotation recurvatum test (Hughston) | 3 | -0.625 |
| Posterolateral drawer sign (Hughston) | 6 | -0.25 |
| Posterolateral rotary instability test (Loomer) | 0 | -1 |
| Reverse pivot shift test (Jakob) | 2 | -0.75 |
| Standing apprehension test | 0 | -1 |

# Appendix IX: Item level CVR values obtained following second round consideration by panel members.

Table 10: Table showing number of experts agreeing essential item and corresponding CVR values for posteromedial instability test items:

| **Item** | **Number of experts agreeing essential** | **Content validity ratio (CVR)** |
|---|---|---|
| Posteromedial drawer (Hughston) | 4 | -0.5 |
| Posteromedial pivot shift test | 1 | -0.875 |

Table 11: Table showing number of experts agreeing essential item and corresponding CVR values for meniscal test items:

| **Item** | **Number of experts agreeing essential** | **Content validity ratio (CVR)** |
|---|---|---|
| Anderson medial and lateral grind test | 0 | -1 |
| Apley compression test | 2 | -0.75 |
| Boehler-Kroemer test | 0 | -1 |
| Bounce home test | 1 | -0.875 |
| Cabot test (popliteus sign) | 0 | -1 |
| Childress sign (duck walking) | 2 | -0.75 |
| Ege's test | 2 | -0.75 |
| Joint line tenderness (palpation) | 14 | 0.75* |
| Knee compression-rotation test | 5 | -0.375 |
| McMurray test | 12 | 0.5* |
| Merke's sign | 0 | -1 |
| Modified Helfet test | 0 | -1 |
| Passler's rotational compression test | 0 | -1 |
| Payr test | 0 | -1 |
| Payr test (in cross legged sitting) | 0 | -1 |
| Steinmann test I | 0 | -1 |
| Steinmann test II | 0 | -1 |
| Thessaly test | 6 | -0.25 |

* item accepted onto final checklist

Table 12: Table showing number of experts agreeing essential item and corresponding CVR values for patellofemoral joint test items:

| **Item** | **Number of experts agreeing essential** | **Content validity ratio (CVR)** |
|---|---|---|
| Accessory movements | 8 | 0 |
| Apprehension test | 9 | 0.125 |

# Appendix X: Direct observation checklist

**Grade of clinician:** _____

**Encounter time: Clinical history: minutes seconds**

**Clinical history items**

| | Tick if observed |
|---|---|
| Contact/non-contact injury | |
| Functional level needed to return to | |
| Giving way (establish presence of) | |
| Giving way (how often) | |
| Giving way (which direction/ activity) | |
| If sporting injury, inability to continue playing immediately after injury causing event | |
| Locking (establish presence of) | |
| Locking (position of leg- flexed/extended) | |
| Locking (question whether pseudo/true) | |
| Mechanism of injury | |
| Pain location (area of pain) | |
| Pain (establish whether present at rest) | |
| Pain (establish whether pain experienced immediately after injury) | |
| Presence of neurological symptoms (e.g. numbness, tingling, weakness) | |
| Presenting complaint (main problem) | |
| Sound/ pop at time of injury (establish whether present) | |
| Swelling/effusion (establish presence of) | |
| Swelling/effusion (time to onset post initial injury event | |
| Other (please mark on additional items sheet) | |

**Please state whether each of the following is present in regards to the knee complaint. Do *not* answer unless the item has been observed**

| | Yes | No |
|---|---|---|
| Locking | | |
| Giving way | | |
| Sporting injury | | |
| Pain | | |

# Appendix X: Direct observation checklist

## Clinical examination test items

**Encounter time: Physical examination: minutes seconds**

| | Tick if observed |
|---|---|
| GENERAL TESTS | |
| All tests compared to unaffected side | |
| Effusion test (e.g. patellar tap/ ballottement/sweep/brush test) | |
| Knee joint movement- extension | |
| Knee joint movement-flexion | |
| Knee joint movement- lateral rotation | |
| Knee joint movement-medial rotation | |
| LIGAMENT/ INSTABILITY TESTS- | |
| Anterior drawer test | |
| Lachman test | |
| Posterior drawer test | |
| Posterior sag sign | |
| Abduction (valgus) stress test 0 degrees | |
| Abduction (valgus) stress test 30 degrees | |
| Adduction (varus) stress test 0 degrees | |
| Adduction (varus) stress test 30 degrees | |
| MENISCAL TESTS | |
| Joint line tenderness (palpation) | |
| McMurray test | |
| ANY ADDITIONAL TESTS | |
| Other (mark all other observed additional tests on additional items sheet) | |

# Appendix X: Direct observation checklist

**Additional items (clinical history items)**

| | Tick if observed |
|---|---|
| Clicking (knee-establish presence of) | |
| Congenital problems with lower limb | |
| Depth of pain | |
| Family history of knee problems | |
| Pain level (e.g. mild/moderate/severe) | |
| Response to previous treatment | |
| Trust/confidence in knee | |
| Where injury took place (location) | |

**Additional items (clinical examination test items)**

| | Tick if observed |
|---|---|
| Active straight leg raise | |
| Apley's distraction test (general ligament test) | |
| Hip joint range of movement | |
| Losee 'disco' test | |
| Neurological testing (reflexes, dermatomes, myotomes) | |
| Strength testing- hamstrings | |
| Strength testing- quadriceps | |
| Swain test (medial complex injury) | |
| Wilson test (for Osteochondritis Dissecans) | |
| LIGAMENT TESTS- Anterior instability tests- single plane | |
| Anterior drawer test (modified- active drawer test) | |
| Anterior drawer test (modified- Jakob maximum anterior drawer) | |
| Anterior drawer test (modified- sitting anterior drawer) | |
| Anterior drawer test (modified- 90-90 anterior drawer) | |
| Lachman test (modified- drop leg) | |
| Lachman test (modified- including visual observation eyes level with knee) | |
| Lachman test (modified- maximum quadriceps) | |
| Lachman test (modified- no touch/active) | |
| Lachman test (modified- patient sitting over edge of plinth) | |
| Lachman test (modified- prone) | |
| Lachman test (modified- stable) | |
| | |

# Appendix X: Direct observation checklist

| LIGAMENT TESTS- Posterior instability tests- single plane | |
|---|---|
| Genu recurvatum test | |
| Godfrey (gravity) test | |
| Quadriceps active test | |
| Reverse Lachman test | |
| Step-off test | |
| LIGAMENT TESTS- Medial (valgus) instability | |
| Hughston's valgus stress test | |
| LIGAMENT TESTS- Lateral (varus) instability | |
| Hughston's varus stress test | |
| LIGAMENT TESTS- Anterolateral rotatory instability | |
| Crossover test (Arnold) | |
| Giving way test (Jakob) | |
| Hughston's jerk test | |
| Lemaire's jolt test | |
| Losee test | |
| Martens test | |
| Nakajima test | |
| Noyes flexion-rotation drawer test | |
| Pivot shift test (McIntiosh) | |
| Pivot shift test (modified- active pivot shift) | |
| Pivot shift test (modified- graded pivot shift) | |
| Pivot shift test- (modified- soft pivot shift) | |
| Slocum test (for anterolateral instability) | |
| Slocum ALRI test | |
| LIGAMENT TESTS- Anteromedial rotatory instability | |
| Dejour test | |
| Lemaire's T drawer test | |
| Slocum test (for anteromedial instability) | |
| LIGAMENT TESTS- Posterolateral rotatory instability | |
| Active posterolateral drawer sign | |
| Arcuate spin test | |
| Dial test | |
| Dynamic posterior shift test | |
| External rotation recurvatum test (Hughston) | |
| Posterolateral drawer sign (Hughston) | |
| Posterolateral rotary instability test (Loomer) | |
| Reverse pivot shift test (Jakob) | |
| Standing apprehension test | |
| | |

# Appendix X: Direct observation checklist

| LIGAMENT TESTS- Posteromedial rotatory instability | |
|---|---|
| Posteromedial drawer (Hughston) | |
| Posteromedial pivot shift test | |
| MENISCAL TESTS | |
| Anderson medial and lateral grind test | |
| Apley compression test | |
| Boehler-Kroemer test | |
| Bounce home test | |
| Cabot test (popliteus sign) | |
| Childress sign (duck walking) | |
| Ege's test | |
| Knee compression-rotation test | |
| Merke's sign | |
| Modified Helfet test | |
| Passler's rotational compression test | |
| Payr test | |
| Payr test (in cross legged sitting) | |
| Steinmann test I | |
| Steinmann test II | |
| Thessaly test | |
| PATELLOFEMORAL JOINT TESTS | |
| Accessory movements | |
| Apprehension test | |

# Appendix XI: Pre-assessment data collection form

**Study ID number _____**

**Information about you**

What is your age in years? (please tick the category that applies)

| | Please tick |
|---|---|
| 16-19 | |
| 20-24 | |
| 25-29 | |
| 30-34 | |
| 35-39 | |
| 40-49 | |
| 50-59 | |
| 60 or above | |

What is your gender? (please tick the category that applies)

| | Please tick |
|---|---|
| Male | |
| Female | |

How long ago (in days) was your most recent knee injury?_____days

# Appendix XI: Pre-assessment data collection form

**About your pain.**

What is your current level of pain? (please mark with a X on the line)

No pain ——————————————————————— Worst imaginable pain

We also wish to know about you level of pain during the past day (24 hours):

During the last ***24 hours*** please answer each of the following about your pain:

What was your level of pain when moving around? (please mark with a X on the line)

No pain ——————————————————————— Worst imaginable pain

What was your level of pain when resting (lying or sitting down)? (please mark with a X on the line)

No pain ——————————————————————— Worst imaginable pain

# Appendix XI: Pre-assessment data collection form

## Knee Outcome Survey Activities of Daily Living Scale

**Symptoms: During the past day to what degree does each of the following symptoms affect your level of activity? (mark one answer for each symptom)**

| | I do not have the symptom | I have the symptom, but it does not affect my activity | The symptom affects my activity slightly | The symptom affects my activity moderately | The symptom affects my activity severely | The symptom prevents me from all daily activity |
|---|---|---|---|---|---|---|
| **Pain** | | | | | | |
| **Stiffness** | | | | | | |
| **Swelling** | | | | | | |
| **Giving way, buckling, or shifting of the knee** | | | | | | |
| **Weakness** | | | | | | |
| **Limping** | | | | | | |

# Appendix XI: Pre-assessment data collection form

## Knee Outcome Survey Activities of Daily Living Scale

**Functional limitations with activities of daily living: During the past day how has your knee complaint affected your ability to: (mark one answer for each activity)**

| | Activity is not difficult | Activity is minimally difficult | Activity is somewhat difficult | Activity is fairly difficult | Activity is very difficult | I am unable to do the activity |
|---|---|---|---|---|---|---|
| **Walk** | | | | | | |
| **Go up stairs** | | | | | | |
| **Go down stairs** | | | | | | |
| **Stand** | | | | | | |
| **Kneel on the front of your knee** | | | | | | |
| **Squat** | | | | | | |
| **Sit with your knee bent** | | | | | | |
| **Rise from a chair** | | | | | | |

# Appendix XII: Post-assessment data collection form

**Study ID number _____**

**Please complete all questions on this form. All of the answers you give will be treated confidentially. The clinician you have seen today will not be named on the form.**

**About your pain following the assessment of your knee injury.**

What is your current level of pain? (please mark with a X on the line)

No pain ——————————————————————————— Worst imaginable pain

# Appendix XII: Post-assessment data collection form

Please rate the following statements about ***today's*** consultation regarding your knee injury. Please tick one box for each statement and answer every statement. All of your answers are confidential and the doctor who has seen you will not be identified on the form.

| **How was the doctor at….** | **Poor** | **Fair** | **Good** | **Very good** | **Excellent** | **Does not apply** |
|---|---|---|---|---|---|---|
| **Making you feel at ease….** *(being friendly and warm towards you, treating you with respect; not cold or abrupt)* | | | | | | |
| **Letting you tell your "story"….** *(giving you time to fully describe your knee condition in your own words; not interrupting or diverting you)* | | | | | | |
| **Really listening….** *(paying close attention to what you were saying; not looking at notes/computer as you were talking)* | | | | | | |
| **Understanding important information about your knee injury….** *(asking/knowing relevant details about your knee injury)* | | | | | | |
| **Being interested in you as a whole person…** *(asking/ knowing relevant details about your life, your situation; not treating you as just a number)* | | | | | | |
| **Fully understanding your concerns….** *(communicating that he/she had accurately understood your concerns; not overlooking or dismissing anything)* | | | | | | |
| **Showing care and compassion….** *(seeming genuinely concerned, connecting with you on a human level; not being indifferent or "detached")* | | | | | | |
| **Being positive….** *(having a positive approach and a positive attitude; being honest but not negative about your problems)* | | | | | | |

Patient satisfaction questionnaire V1.0
01/10/2013

# Appendix XII: Post-assessment data collection form

| **How was the doctor at….** | **Poor** | **Fair** | **Good** | **Very good** | **Excellent** | **Does not apply** |
|---|---|---|---|---|---|---|
| **Explaining things clearly….** *(fully answering your questions; explaining clearly, giving you adequate information; not being vague)* | | | | | | |
| **Helping you take control….** *(exploring with you what you can do to improve your knee condition; encouraging you rather than lecturing you)* | | | | | | |
| **Making a plan of action with you….** *(discussing the options, involving you in decisions as much as you want to be involved; not ignoring your views)* | | | | | | |
| **Keeping the level of discomfort to a minimum….** *(making the examination of your knee as comfortable as possible)* | | | | | | |
| **Assessing your knee injury….** (being thorough, careful and competent) | | | | | | |
| **Helping you understand your knee condition….** *(explaining/giving information about your knee condition; making it clear what the problem is with your knee)* | | | | | | |
| **Having adequate time to assess your knee injury….** *(not being rushed; able to complete the examination of your knee)* | | | | | | |
| **Assessing your knee injury, taking everything into account….** | | | | | | |

Any further comments:

_____

_____

_____

Thank you for your time. Please return the form in the box provided.

Patient satisfaction questionnaire V1.0
01/10/2013

Business Services Organisation
Providing Support to Health and Social Care

# Office for Research Ethics Committees Northern Ireland (ORECNI)

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**HSC REC 1**

14 November 2013

Mr Colin Ayre
Advanced Physiotherapist
School of Health Studies
University of Bradford
Richmond Road
Bradford
West Yorkshire
BD7 1DP

Dear Mr Ayre

| | |
|---|---|
| **Study title:** | **Direct observation study comparing specialist and non-specialist clinical assessment of acute knee injuries** |
| **REC reference:** | **13/NI/0193** |
| **IRAS project ID:** | **112650** |

The Proportionate Review Sub-committee of the HSC REC 1 reviewed the above application on 13 November 2013.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator: Kathryn Taylor, Kathryn.Taylor@hscni.net.

**Ethical opinion**

Members present agreed that the application was suitable for Proportionate Review.

On behalf of the Committee, the sub-committee 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).

# Appendix XIII: Ethics approval

**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.

*Management permission ("R&D approval") should be sought from all NHS organisations involved in the study 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 a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.*

*For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.*

*Sponsors are not required to notify the Committee of approvals from host organisations.*

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

**You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.**

**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).**

# Appendix XIII: Ethics approval

**Approved documents**

The documents reviewed and approved were:

| *Document* | *Version* | *Date* |
|---|---|---|
| Evidence of insurance or indemnity: University of Bradford (Zurich Municipal) | | 24 June 2013 |
| Investigator CV: Mr CA Ayre; Prof M Hardy | | |
| Participant Consent Form: Patient | 1.0 | 01 October 2013 |
| Participant Consent Form: Staff | 1.0 | 01 October 2013 |
| Participant Information Sheet: Patient | 1.0 | 01 October 2013 |
| Participant Information Sheet: Staff | 1.0 | 01 October 2013 |
| Protocol | 1 | 29 October 2013 |
| Questionnaire: Background Information | 1.0 | 01 October 2013 |
| Questionnaire: Direct Observation Checklist | 1.0 | 29 October 2013 |
| Questionnaire: Patient Satisfaction Questionnaire | 1.0 | 01 October 2013 |
| REC application | IRAS 3.5 | 05 November 2013 |

**Membership of the Proportionate Review Sub-Committee**

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

There were no declarations of interest, and all members remained present during the review.

**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

**After ethical review**

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known

please use the feedback form available on the website.
information is available at National Research Ethics Service website > After Review

**13/NI/0193** **Please quote this number on all correspondence**

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

Yours sincerely

pp **Mr Mark Nelson**
**Chair**
Email: Kathryn.Taylor@hscni.net

*Enclosures:* *List of names and professions of members who took part in the review*

*"After ethical review – guidance for researchers"*

*Copy to:* *Ms Jenny Bellamy*
*Research & Knowledge Transfer Support*
*University of Bradford*
*Richmond Road*
*Bradford*
*BD7 1DP*

*Mrs Jane Dennison*
*Bradford Institute for Health Research*
*Bradford Royal Infirmary*
*Duckworth Lane*
*Bradford*
*BD9 6RJ*

Business Services Organisation
Providing Support to Health and Social Care

**Office for Research Ethics Committees Northern Ireland (ORECNI)**

**Customer Care & Performance Directorate**
Office Suite 3
Lisburn Square House
Haslem's Lane
Lisburn
Co. Antrim BT28 1TW
Tel: + 44 (0) 28 9260 3107
Fax: + 44 (0) 28 9260 3619
*www.orecni.hscni.net*

**HSC REC 1**

29 November 2013

Mr Colin Ayre
Advanced Physiotherapist
School of Health Studies
University of Bradford
Richmond Road
Bradford
West Yorkshire
BD7 1DP

Dear Mr Ayre

| | |
|---|---|
| **Study title:** | **Direct observation study comparing specialist and non-specialist clinical assessment of acute knee injuries** |
| **REC reference:** | **13/NI/0193** |
| **Amendment number:** | **Minor Amendment - Clarification re destruction of paper records** |
| **Amendment date:** | **28 November 2013** |
| **IRAS project ID:** | **112650** |

Thank you for your email of 28 November 2013, notifying the Committee of the above amendment.

The amendment has been considered by the Chair.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

**Documents received**

The documents received were as follows:

| Document | Version | Date |
|---|---|---|
| Notification of a Minor Amendment (Email from C Ayre) | Minor Amendment - Clarification re destruction of paper records | 28 November 2013 |

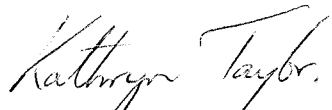
**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

# Appendix XIII: Ethics approval

| 13/NI/0193: | Please quote this number on all correspondence |
|---|---|

Yours sincerely



**Kathryn Taylor**
**Committee Administrator**
E-mail: Kathryn.Taylor@hscni.net

*Copy to:* *Ms Jenny Bellamy*
*Research & Knowledge Transfer Support*
*University of Bradford*
*Richmond Road*
*Bradford*
*BD7 1DP*

*Mrs Jane Dennison*
*Bradford Institute for Health Research*
*Bradford Royal Infirmary*
*Duckworth Lane*
*Bradford*
*BD9 6RJ*

Bradford Teaching Hospitals NHS
NHS Foundation Trust

**Enquiries on this matter should be made to:**

The Research Management & Support Office
Bradford Institute for Health Research (BIHR)
Bradford Royal Infirmary
Duckworth Lane
BRADFORD
BD9 6RJ
Email: BradfordResearch.Applications@bthft.nhs.uk
Tel: 01274 36 (6808)/(4687)
Fax: 01274 38(2640)

Research Support & Governance Manager
Mrs Jane Dennison
Email: jane.dennison@bthft.nhs.uk
Tel: 01274 382575 (Direct)

Director of Research/BIHR
Professor John Wright
Email: john.wright@bthft.nhs.uk
Tel: 01274 364279 (Direct)

24th January 2014

Mr Colin Ayre
University of Bradford School of Health Studies
Richmond Road
Bradford
West Yorkshire
BD7 1DP

Dear Mr Ayre,

**NHS Permission Letter for Research at Bradford Teaching Hospitals NHS Foundation Trust**

| | |
|---|---|
| **Re:** | **Direct observation study comparing specialist and non-specialist clinical assessment of acute knee injuries** |
| **Sponsor:** | **University of Bradford** |
| **REC Ref No:** | **13/NI/0193** |
| **R&D Ref No:** | **1641** |
| **CSP Reference:** | **N/A** |

Following submission of your Site-Specific Information form and supporting documentation seeking permission to conduct the above study at Bradford Teaching Hospitals NHS Foundation Trust (the "Foundation Trust"), I am pleased to inform you that your application has successfully completed an internal review process appropriate for this type of study and has satisfied our research governance checks. A project record has been created on the Foundation Trust's research database. You may commence research activities at the Foundation Trust in the locations specified in your Site-Specific Information (SSI) form subject to the terms of this letter. The effective date of NHS permission for research is the date of this letter and this is the earliest commencement date for research activities at the Foundation Trust. This letter supersedes all previous letters you have received from us with regard to permission to proceed with this

research at Bradford Teaching Hospitals NHS Foundation Trust.

NHS permission for the above research has been granted on the basis described in the application forms, protocol and supporting documentation. The documents reviewed were:

**Reviewed Documents –**

**SSI form** 112650/543591/6/809/168709/288114
**NHS R&D** 112650/543529/14/742
**Protocol** Version 1.0 dated 29/10/13
**Participant Information Sheet: Patient** Version 1.0 dated 01/10/13
**Participant Information Sheet: Staff** Version 1.0 dated 01/10/13
**Participant Consent Form: Patient** Version 1.0 dated 01/10/13
**Participant Consent Form: Staff** Version 1.0 dated 01/10/13
**REC Favourable Opinion Letter dated** 14/11/13
**REC Letter dated** 29/11/13
**Minor Amendment dated** 28/11/13

**The site for which NHS permission for research is given is -**

Bradford Teaching Hospitals NHS Foundation Trust

**The terms referred to are:**

1. You are the Principal Investigator or Local Collaborator for this Study and you are responsible for the conduct of this Study at this site.

2. NHS Indemnity applies to this Study with respect to negligent harm. However, NHS Indemnity does not provide compensation in the event of non-negligent harm.

3. *This Study is a non-CTIMP (ie, **not** a clinical trial that involves an investigational medicinal product) and you may commence recruitment on receipt of this letter if you are ready to start.*

4. Ongoing permission is subject to you adhering to the Trust's standard conditions of NHS Permission for research (attached).

5. You comply with the R&D Office's Oversight Plan as detailed below.

The approach taken for each Study shall be proportionate to the risks associated with the Study and the level of monitoring and support being undertaken by the Sponsor. The R&D Office's Oversight Plan for this study is as follows –

**1 Study Tracking**
Please provide the R&D Office with –

a. Completed initial project status enquiry report sent to you directly from the R&D Office following the NHS Permission Letter.
b. Completed Principal Investigator (PI) Annual Progress Report available from the Downloads section of the Bradford Institute for Health Research website at www.bradfordresearch.nhs.uk due every year for the life of the Study on the anniversary of the date of this letter.

c. Completed PI end of study declaration report (as defined in the protocol) (together with final recruitment figures for the Foundation Trust) available from the Downloads section of the Bradford Institute for Health Research website at www.bradfordresearch.nhs.uk

d. Copy of amendment documentation and a copy of the REC and MHRA (if applicable) approval letters prior to implementing the changes at the Foundation Trust.

**2 Issue Management –**

a. Managing External Agreements.
b. Managing Internal Agreements.
c. Managing Study Processes.
d. Managing Research Passports

If an issue arises during the Study, please ensure you have a process in place to escalate this and seek support from the R&D Office.

**3 Audit -**

The R&D Office performs a risk assessment prior to issuing this letter which provides the Foundation Trust with a risk-based approach to audit activities. The R&D Office undertakes to audit at least 10% of its research projects each year. Priority will be given to studies with the higher risk scores, clinical trials involving an investigational medicinal product(s) (CTIMPs), NIHR portfolio studies, and studies sponsored by the Foundation Trust. Some low risk studies may not be subject to scheduled audit at all. You will be informed by the R&D Office if a scheduled audit of this research study is planned in plenty of time (ie, at least six weeks' notice).

The R&D Office always has the option to conduct specific oversight activities at any time as the result of any exceptional activity / events identified during the Study and failure to comply with these terms may lead to suspension or termination of NHS Permission for research.

Please inform the R&D Office immediately should you have any concerns about patient safety or wellbeing with regard to research at the Foundation Trust.

If you have any queries during the conduct of your research, please do not hesitate to contact the Research Governance Manager using the contact details provided at the top of this letter. May I take this opportunity to wish you well with your research Study.

Please help us to improve our service by completing the feedback form emailed previously to you and returning it to the R&D Office as soon as possible.

Yours sincerely

PROFESSOR JOHN WRIGHT
Director of Research/BIHR

Encs

cc CI/Sponsor/study co-ordinator

HSC Business Services Organisation

***Office for Research Ethics Committees Northern Ireland (ORECNI)***

**Customer Care & Performance Directorate**
Office Suite 3
Lisburn Square House
Haslem's Lane
Lisburn
Co. Antrim BT28 1TW
Tel:+44 (0) 28 9260 3107
*www.orecni.hscni.net*
**HSC REC A**

03 October 2014

Mr Colin Ayre
Advanced Physiotherapist/ Honorary Lecturer
Bradford Teaching Hospitals NHS Foundation Trust
School of Health Studies
University of Bradford, Richmond Road
Bradford, West Yorkshire
BD7 1DP

Dear Mr Ayre

| | |
|---|---|
| **Study title:** | **Direct observation study comparing specialist and non-specialist clinical assessment of acute knee injuries** |
| **REC reference:** | **13/NI/0193** |
| **Amendment number:** | **Amendment 2 - 19/08/2014** |
| **Amendment date:** | **09 September 2014** |
| **IRAS project ID:** | **112650** |

The above amendment was reviewed at the meeting of the Sub-Committee held on 30 September 2014.

**Ethical opinion**

The members of the Committee taking part in the review gave a **favourable ethical opinion** of the amendment on the basis described in the notice of amendment form and supporting documentation.

**Approved documents**

The documents reviewed and approved at the meeting were:

| *Document* | *Version* | *Date* |
|---|---|---|
| Notice of Substantial Amendment (non-CTIMP) | Amendment 2 - 19/08/2014 | 09 September 2014 |
| Research protocol or project proposal | 2 | 19 August 2014 |

**Membership of the Committee**

The members of the Committee who took part in the review are listed on the attached sheet.

# Appendix XV: REC amendment approval

**R&D approval**

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

| **13/NI/0193:** | **Please quote this number on all correspondence** |
|---|---|

Yours sincerely

pp **Dr Catherine Hack**
**Chair**
E-mail: RECA@hscni.net

*Enclosures:* *List of names and professions of members who took part in the review*

*Copy to:* *Mrs Jane Dennison, Bradford Institute for Health Research*
*Ms Jenny Bellamy, Research & Knowledge Transfer Support, University of Bradford*

Bradford Teaching Hospitals NHS
NHS Foundation Trust

**Enquiries on this matter should be made to:**

The Research Management & Support Office
Bradford Institute for Health Research (BIHR)
Bradford Royal Infirmary
Duckworth Lane
BRADFORD
BD9 6RJ
Email: BradfordResearch.Applications@bthft.nhs.uk
Tel: 01274 36 (6808)/ (4687)
Fax: 01274 38(2640)

Research Governance Manager
Jane Dennison
Email: jane.dennison@bthft.nhs.uk
Tel: 01274 382575 (Direct)

Director of Research/BIHR
Professor John Wright
Email: john.wright@bthft.nhs.uk
Tel: 01274 364279 (Direct)

19th November 2014

Mr Colin Ayre
Bradford Teaching Hospitals NHS Foundation Trust
School of Health Studies
University of Bradford, Richmond Road
Bradford, West Yorks
BD7 1DP

Dear Mr Ayre,

**Re: Study Title: Direct observation study comparing specialist and non-specialist clinical assessment of acute knee injuries**
**REC Ref Number: 13/NI/0193**
**ReDA Number: 1641**

**Notification of Bradford Teaching Hospitals Foundation Trust Acceptance of Amendment**

***Amendment date: 09/09/2014***

***Amendment number: 2***

We were notified of this amendment on 06/10/2014 and we have reviewed the summary of changes provided to us. This letter confirms that NHS Permission at Bradford Teaching Hospitals NHS Foundation ("the Foundation Trust) remains in place subject to the conditions below.

If this amendment is rejected by the review bodies, then this letter does not provide you with the authority to implement the changes. If this amendment is re-submitted as a modified amendment, then only the changes approved in the modified submission should be implemented at site.

# Appendix XVI: Site approval amendment

You are responsible for ensuring you receive the 'approved' version of the amendment documentation from the Chief Investigator or Sponsor for your records including the approval letter from the Research Ethics Committee (REC) or letter of acceptance from the Medicines and Healthcare Products Regulatory Agency (MHRA), if required, or other regulatory body.

Continued NHS Permission for the project is subject to the following conditions:

- Research Ethics Committee (REC) approval, if required, is in place prior to implementing the changes at the Foundation Trust and only the changes approved are implemented (as described in the amendment notice or letter).
- Medicines and Healthcare Products Regulatory Agency (MHRA) acceptance, if required, or other regulatory body approval is in place prior to implementing the changes at the Foundation Trust and only the changes approved are implemented (as described in the amendment notice or letter).
- Any contractual arrangements relating to this change have been addressed prior to implementing the changes at the Foundation Trust.
- The Divisional General Manager where the research is located has approved any resource implications for the Division prior to implementing the changes at the Foundation Trust.
- The service support departments are informed of the changes as they affect them.

**Reviewed Documents:**

| *Document* | *Version* | *Date of document* |
|---|---|---|
| *Notification email* | | *06/10/2014* |
| *Ethics Approval Letter* | | *03/10/2014* |
| *Notice of Substantial Amendment (non-CTIMP)* | *Amendment 2- 19/08/2014* | *09/09/2014* |
| *Research protocol or project proposal* | *2* | *19/08/2014* |

If you have any concerns about the changes or concerns are raised by the General Manager or the service support departments that prevents you from implementing this amendment, you should notify the Chief Investigator and Sponsor immediately and also inform the R&D Office using the contact details above.

If you have any queries about this letter please do not hesitate to contact us using the contact details above.

Yours sincerely

Professor John Wright
Director of Research/BIHR

# Appendix XVII: Participant information sheet (staff)

## PARTICIPANT INFORMATION SHEET (STAFF)

OBSERVATION OF ACUTE KNEE INJURY ASSESSMENT

Version No: 1.0

Version Date: October 1st 2013

You are invited to take part in a research project. To help you decide whether to participate, I would like to explain why the research is being done, and what will be involved.
Please take time to understand the information, and talk to others for advice if you need to.

### What is the reason for the study?

This study aims to understand what occurs during the clinical assessment of acute (recent) knee injuries. Assessment of acute knee injuries is complex and it is hoped that research will help understand how we can improve the assessment of knee injuries. As part of the research a series of observations will be undertaken on different clinical staff that assess knee injuries.

### Why have I been chosen?

You have been asked to participate as you are involved in the assessment of acute knee injuries as part of your role.

### Do I have to take part?

There is no obligation to take part. It is up to you. Even if you initially agree to take part, you are free to withdraw without giving a reason. The study will be described to you, and we will go through this information sheet with you, which you can then keep.

### What will happen if I take part?

The research involves the lead researcher observing your assessment of acute knee injuries. The researcher will be recording details of the assessment process as a non-participant and therefore will not be involved in the assessment process. In addition you will be asked to complete a short questionnaire following the assessment. It is expected this will take less than 5 minutes to complete.

# Appendix XVII: Participant information sheet (staff)

**Benefits of being involved:**

There will be no tangible short term benefits to participation. However, we hope in the long-term it will show us how it is best to assess other people with acute knee injuries more effectively in the future.

**Drawbacks of being involved:**

There are no anticipated drawbacks to being involved as the research will not involve any time commitment. There will not be any follow up investigation.

**Confidentiality:**

We do not need to know your personal details to conduct this study and no personal identifiable data will be recorded at any time. It is hoped that in the future the results of the study will be published, but there will only be data about the assessment process. There will be nothing included in this to identify you. The data generated will be stored for 15 years

**What will happen to the results of the study?**

It is hoped the results of the study will be published in a peer-reviewed medical journal.

**Who has assessed the study:**

As this is research as part of a doctoral research project, specialist research tutors at the University of Bradford have assessed the quality of the proposed research, and given it a favourable opinion. Ethical approval has been gained from the local NHS research ethics committee (REC). In addition the research has been approved by a number of orthopaedic consultants working within the hospital.

**If I have questions regarding the research:** The researcher will be present intermittently in the orthopaedic outpatient clinic. Alternatively the lead researcher can be contacted from the details below:

Colin Ayre
School of Health Studies
University of Bradford
Richmond Road
Bradford
BD7 1DP
Tel: 01274 (236376)
Email: c.a.ayre1@bradford.ac.uk

# Appendix XVII: Participant information sheet (staff)

If you wish to discuss the research with someone outside the research team please contact your line manager.

**If I have a complaint:**

In the first instance the lead researcher will be available to discuss any complaints. Contact details for the lead researcher are given above.

If you would prefer to discuss a complaint with someone independent of the research project you can also contact the University of Bradford Research and Knowledge Transfer Support Unit:

Research and Knowledge Transfer Support Unit
University of Bradford
Bradford
West Yorkshire
BD7 1DP
Tel: (01274) 236000
Email: rkts@bradford.ac.uk

# Appendix XVIII: Staff consent form

## CONSENT FORM (STAFF)

Observation of acute knee injury assessment

Researcher: Colin Ayre
Version: 1.0
Version Date: October 1st 2013

1. I confirm that I have read and understand the staff participant information sheet dated ..... (version.....) 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 staff member | Date | Signature |
| _____ | _____ | _____ |
| Name of person taking consent | Date | Signature |

If you wish to receive a summary sheet detailing the results of the study once complete please provide a postal or email address where this should be sent below:

_____
_____
_____
_____
_____
_____

# Appendix XIX: Participant information sheet

## PARTICIPANT INFORMATION SHEET

OBSERVATION OF ACUTE KNEE INJURY ASSESSMENT

Version No: 1.0
Version Date: October 1st 2013

You are invited to take part in a research project. To help you decide whether to participate, I would like to explain why the research is being done, and what will be involved.
Please take time to understand the information, and talk to others for advice if you need to.

### What is the reason for the study?

This study aims to understand what occurs during the clinical assessment of acute (recent) knee injuries. Assessment of acute knee injuries is complex and it is hoped that research will help understand how we can improve the assessment of knee injuries in the future.

### Why have I been chosen?

You have been asked to participate as you have had a recent knee injury and are having an assessment of this within the hospital.

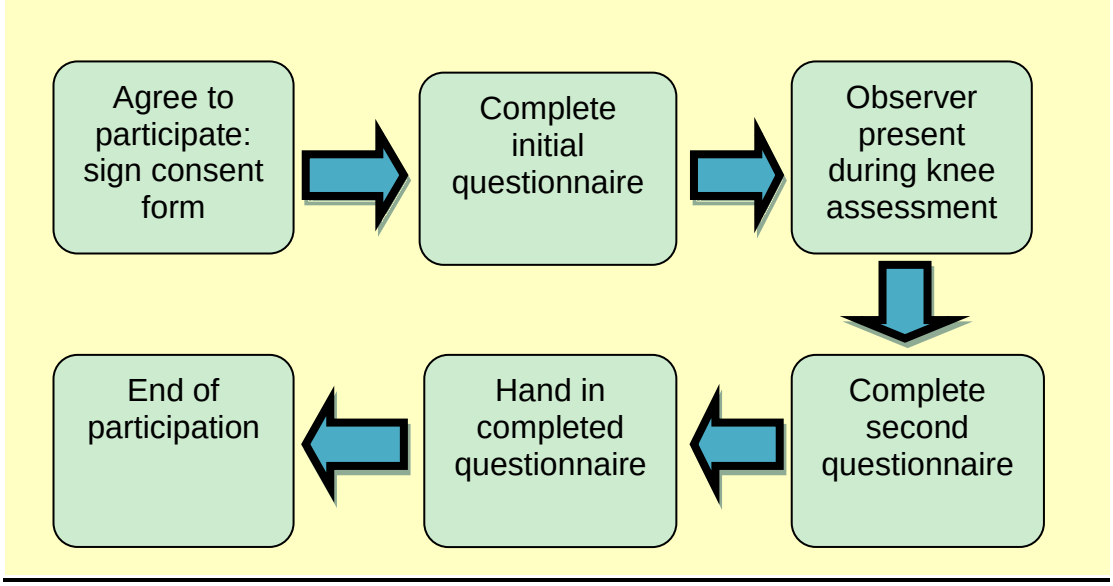
### Do I have to take part?

There is no obligation to take part. It is up to you. Even if you initially agree to take part, you are free to withdraw at any time without giving a reason. Any data collected on your involvement will be removed from the project. This does not affect any part of your ongoing treatment. The study will be described to you, and we will go through this information sheet with you, which you can then keep.

### What will happen if I take part?

The research involves someone else being present during the assessment of your knee injury. The researcher will be recording details of the assessment process but will not be involved in the assessment of your injury. Your involvement will include the completion of two questionnaires (one prior to and one following your assessment) each of which should take less than 5 minutes to complete. Participation will not affect your treatment in any way.
The procedure of your involvement is shown below.

# Appendix XIX: Participant information sheet




**Benefits of being involved:**

There will be no tangible short term benefits to participation, as the research will not involve any changes to your normal care. However, we hope in the future it will allow us to manage other people with acute knee injuries more effectively.

**Drawbacks of being involved:**

As the research does **not** involve any change to your care there are no anticipated drawbacks of being involved. The only burden is the time taken to complete the questionnaires prior to and following your appointment. Each is expected to take less than 5 minutes.

**Confidentiality:**

We do not need to know your personal details to conduct this study. It is hoped that in the future the results of the study will be published, but there will only be data about the assessment process. There will be nothing included in this to identify you.

Normally only the medical staff directly responsible for assessing you will have access to medical notes however if you agree to participate the researcher will also have access to your medical notes in order to ensure you are suitable to participate in the research. The researcher is a health professional and bounded by confidentiality.
Sometimes research is audited to ensure its quality. These auditors will be specialists from the authorities who are also bound by confidentiality.
As the study does not involve any change in your care we will not inform your GP of your involvement. The data generated from the study will be stored for 15 years

**What will happen to the results of the study?**

It is hoped the results of the study will be published in a peer-reviewed medical journal.

# Appendix XIX: Participant information sheet

**Who has assessed the study:**

As this is research as part of a doctoral research project, specialist research tutors at the University of Bradford have assessed the quality of the proposed research, and given it a favourable opinion. Also, as this research will take place within the NHS, a panel of specialists, known as a Research Ethics Committee (REC) have reviewed the research.

**If I have a complaint:** The researcher will be present at the time of your appointment to discuss any complaints you have regarding the research. Alternatively the lead researcher can be contacted from the details below:

Colin Ayre
School of Health Studies
University of Bradford
Richmond Road
Bradford
BD7 1DP
Tel: (01274) 236376
Email: c.a.ayre1@bradford.ac.uk

If you would prefer to discuss a complaint with someone independent of the research project you can also contact the University of Bradford Research and Knowledge Transfer Support Unit:

Research and Knowledge Transfer Support Unit
University of Bradford
Bradford
West Yorkshire
BD7 1DP
Tel: (01274) 236000
Email: rkts@bradford.ac.uk

If you would like more general information about participation in research you can contact the patient advice and liaison service (PALS).

Patient advice and liaison service (PALS) contact details:

Address:

Extension Block
St Luke's Hospital
Little Horton Lane
Bradford
West Yorkshire
BD5 0NA

Tel: (01274) 365853

Email: pals@bradfordhospitals.nhs.uk

# Appendix XX: Patient consent form

## PATIENT CONSENT FORM

Observation of acute knee injury assessment

Researcher: Colin Ayre
Version: 1.0
Version Date: October 1st 2013

Study ID no_____

1. I confirm that I have read and understand the information sheet dated ..... (version.....) 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, without my medical care or legal rights being affected. ☐
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
4. I understand that the researcher will have access to relevant sections of my medical records for the purpose of research. ☐
5. I agree to take part in the above study. ☐

| _____ | _____ | _____ |
|---|---|---|
| Name of patient | Date | Signature |
| _____ | _____ | _____ |
| Name of person taking consent | Date | Signature |

If you wish to receive a summary sheet detailing the results of the study once complete please provide a postal or email address where this should be sent below:

_____
_____
_____
_____
_____