Assessing early postoperative recovery following lower limb joint replacement

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Abstract

Assessing early postoperative recovery following lower limb joint replacement
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Improving perioperative recovery is critical to enhance patient care, ensure timely discharge from the patient, clinician and hospital perspective and improve short and long-term outcomes after surgery.

A systematic review was performed examining tools for early post-operative recovery after elective lower limb joint replacement. It showed that no fully-validated, patient-reported tools existed. Currently used measures included pain scores, opioid usage, length of stay and surgical satisfaction.

In order to address this need, a patient-reported outcome measure (PROM) and change measure for use in the first six weeks following surgery have been developed. A five-phased, best practice, iterative approach was used.

Planning Phase - Qualitative interviews (n=22) were performed with orthopaedic healthcare professionals, ascertaining if and how clinicians would use such a PROM. These helped determine the views of potential users, and guide structure and layout.

Phase One - Qualitative patient-interviews (n=30) from the day of surgery to nine weeks postoperatively were completed. Analysis of these interviews identified important patient-reported factors in early recovery.

Phase Two - The factors provided from Phase One interviews were used to find questionnaire themes. Items were then generated and pilot questionnaires developed. Items were tested and refined in the context of cognitive debrief interviews (n=34) for potential inclusion in the final tools.

Phase Three - Final testing of questionnaire properties with item reduction (n=168). The Oxford Arthroplasty Early Recovery Score (OARS) is a 14-item PROM measuring health status at the time of testing. The Oxford Arthroplasty Early Change Score (OACS) is a 14-item measure to assess change.

Phase Four - Validation: The OARS and OACS were administered to consecutive patients (n=155) in an independent cohort. Validity and reliability were assessed. Psychometric testing showed positive results, good validity and sensitivity to change.

The OARS and OACS were then utilised in a pilot study to assess the feasibility of day case treatment. Inpatient (n=29) and day-case (n=26) unicompartmental knee arthroplasty (UKA) patients completed the two measures, and the results confirmed that day case treatment and discharge is a valid option.

The work completed in this thesis will now enable these newly developed scores to be used to define and assess an optimal-recovery protocol for lower limb joint replacement.

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Abbreviations

FS-15	15-item questionnaire after Caesarean Section
CARE	Convalescence and Recovery Evaluation
CED	Concept Elaboration Document
CI	Confidence Interval
DoH	Department of Health
EFA	Exploratory Factor Analysis
ePRO	Electronic Patient-Reported Outcomes
ERAS	Enhanced Recovery after Surgery
ERPs	Enhanced Recovery Programmes
ES	Effect Size
FDA	Food and Drug Administration
FRI	Functional Recovery Index
FSQ	Functional Status Questionnaire
GSDS	General Symptom Distress Scale
HRA	Health Research Authority
IP	Inpatient
JLA	James Lind Alliance
KMO	Kaiser-Meyer-Olkin Measure of Sampling Adequacy
LOS	Length of Stay
MCS	Mental Component Summary for the SF-36
MIC	Minimally Important Change
NHS	National Health Service
NICE	National Institute For Health And Care Excellence
NIH	National Institute of Health
NJR	National Joint Registry
OA	Osteoarthritis
OACS	Oxford Arthroplasty Early Change Score
OARS	Oxford Arthroplasty Early Recovery Score
OHS	Oxford Hip Score
OKS	Oxford Knee Score
OUI	Oxford University Innovation
PFJ	Patellofemoral Joint Arthroplasty

PCS	Physical Component Summary
PPI	Patient and Public Involvement
PROMs	Patient-Reported Outcome Measures
PASQOL	Post-anesthesia Short-term quality of life
PSR	Post-discharge surgical recovery scale
PQL	Postoperative Quality of Life Metric
PQRS	Postoperative Quality of Recovery Scale
PRP	Postoperative Recovery Profile
PCA	Principal Component Analysis
QoR-9	Quality of Recovery from Anesthesia 9-item survey
QoR-15	Quality of Recovery from Anesthesia 15-item survey
QoR-40	Quality of Recovery from Anesthesia 40-item survey
REC	Research Ethics Committee
Rev. THA	Revision Total Hip Arthroplasty
Rev. TKA	Revision Total Knee Arthroplasty
Rev. UKA	Revision Unicompartmental Knee Arthroplasty/
RCT	Randomised Controlled Trial
SDS	Same-day Surgery Discharge
SF-36	Short-form 36-question quality of life questionnaire
SD	Standard Deviation
SRM	Standardised Response Mean
SPSS	Statistical Package for the Social Sciences
SRI	Surgical Recovery Index
SRS	Surgical Recovery Scale
THA	Total Hip Arthroplasty
TKA	Total Knee Arthroplasty
TOPKAT	Total or Partial Knee Arthroplasty Trial
TA	Translatability Assessment
UK	United Kingdom
US	United States of America
USA	United States of America
VAS	Visual Analogue Scale
WHO	World Health Organisation

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1 Introduction

1.1 Overview

Patient recovery following surgery is multi-factorial. Optimising perioperative recovery is critical to enhancing patient care, ensuring timely discharge and improving short and long-term outcomes after surgery. Being able to accurately measure the quality of recovery and change in recovery during the early postoperative period would be extremely beneficial. Brief, easy-to-complete, reliable patient-reported tools could not only aid in assessment of recovery, but could also assist in evaluating the efficacy of perioperative interventions, such as drugs or surgical technique, and provide a foundation for evidence-based care.

The purpose of this thesis was to develop a patient-reported outcome measure (PROM) that can effectively measure early postoperative recovery after lower limb (hip or knee) joint replacement. In addition, a health transition questionnaire or change measure will also be developed. This work will explore and define patient-reported factors that are important in lower limb joint replacement recovery, develop a PROM and change measure for early postoperative recovery for this population and validate the score in an independent cohort. Results will directly impact clinical practice, as they will allow clinicians to assess patient recovery and stimulate research to optimise the patient journey and outcomes following surgery.

This chapter explains the concept of arthroplasty, recovery, PROMs, recovery tools, Enhanced Recovery Programmes (ERPs) and medications used in the surgical orthopaedic setting. The overall aims and objectives of the thesis will be introduced and a synopsis of thesis chapters included.

1.1.1 Arthroplasty

Arthroplasty, or joint replacement, particularly of the hip or knee, is an effective surgical treatment option for patients with moderate to severe symptomatic arthritis who have not responded to medical management (1). Arthroplasty comes from the Greek 'arthron', meaning joint, and 'plastos', meaning to mould. In these procedures, the damaged, arthritic parts of the joint are surgically removed and replaced using metal, plastic and/or ceramic prostheses.

The incidence of arthritis in the aging population has increased with the World Health Organisation (WHO) acknowledging osteoarthritis as one of the developed world's 'ten most disabling conditions' (2). Currently, it is believed that worldwide the overall international incidence is around 10% in men and 18% in women over 60 (2).

For the purpose of this thesis, lower limb arthroplasty will include hip, knee and unicompartmental or partial knee replacement surgery.

1.1.2 Background to recovery following arthroplasty

The first modern total hip replacement was performed in the early 1960's (3) and knee replacement a few years later in 1968 (4). In the early days of arthroplasty, surgical recovery involved a very prolonged period, with patients spending weeks, sometimes months, in both bed and hospital following surgery (5). In addition, they were often brought into hospital in the days prior to surgery for preparation. These prolonged periods of hospitalisation often led to complications, including respiratory infection (6), thrombosis (7, 8), pressure sores (9) and joint infection (10). It was not until the 1990's, when regional anaesthesia and alternatives to general anaesthesia were introduced, that patients began to have a more rapid recovery and decreased length of stay following surgery (11). As

surgical techniques, instrumentation and implants themselves improved, so too did the rate of recovery for patients (12).

Estimates in the United Kingdom (UK) are that around 40% of adults over 65 have osteoarthritis (13). Currently around 102,000 total knee arthroplasties (TKA) and 92,000 total hip arthroplasties (THA) are performed in England, Northern Ireland and Wales annually (1). These procedures account for around 800,000 hospital days per year, with the average length of stay (LOS) in the UK in 2013 being around five days (14). In the United States of America (USA), around 750,000 TKA (15) and 326,000 THA (16) are performed annually, with this number expected to grow exponentially by the year 2030 (17).

The main purposes of both TKA and THA surgery are to restore movement and function, improve quality of life and decrease pain (18). In patients with isolated arthritis of the knee, a unicompartmental knee replacement, or arthroplasty (UKA), might be an alternative to TKA. With this procedure only the affected part of the knee is replaced and therefore the amount of bone surgically resected is less and the recovery process for the patient is also reduced (19).

1.1.3 Perioperative period

The perioperative period is the time around surgical intervention (20). It can begin at the time when a decision is made to have a surgical intervention (21), continue through admission to the hospital or clinic, into the operating room and extends throughout the postsurgical recovery period. The exact timing before and after surgery can vary according to which reference source is used (22). Sometimes it is seen to begin on admission to the hospital and end with discharge from the hospital (23). It may also be thought to be the immediate time spent in the operating theatre and ending 48 hours later (24). The exact end of the postoperative period can be vague and is sometimes listed as ninety days (21)

and used in determining and classifying surgical complications. It has also been historically guided by the requirements of medical insurance for the follow up period and recording of morbidity and mortality up to thirty days (25). At other times it can be seen to extend until the time a patient is released from the physician's care following surgery.

1.1.4 Postoperative recovery

Similarly to the definition of the perioperative period, postoperative recovery is something that can be viewed differently and as such the exact definition is mixed and somewhat vague (21). This variation can differ from patient to patient, clinician to clinician and hospital to hospital. The period of time given to postoperative recovery and indeed its meaning are open to interpretation (26). However, it is widely regarded as a return to function, sometimes considered 'normal function', where the problematic symptoms have been resolved (26). Phases of recovery can be divided into early (from the day of surgery through the first weeks), medium (six weeks to six months) and long term (more than six months). Patients can take over one to two years to 'fully' recover (27, 28). Much research has been carried out looking at recovery over the medium to long term, but there has been a paucity of work in the early postoperative period (29). Fortunately, over the last two decades, more work is being carried out in this area.

1.1.5 Early recovery

As with other definitions regarding the period around surgery and recovery, the early recovery period itself has vast variation. In some areas it applies to the immediate minutes and hours after surgery and for others it is until the time of discharge from the surgeons care. For the purposes of this thesis, the early recovery period will be considered as the time of surgery through to approximately six weeks postoperatively (27). This period was chosen as it is when the patient is seen in clinic for discharge from the surgeons care. This

early period is believed to be of great importance in affecting patients' satisfaction, experience, short and long term recovery, and outcomes (30-33).

1.1.6 Pain management

Pain is by definition an unpleasant and subjective experience (34) affecting the individual as a whole. It has physical, emotional and psychological implications (35) and is a major cause of dissatisfaction, delay in discharge and readmission to hospital following surgery (36). Patients undergoing lower limb joint replacement typically experience moderate to severe pain due to the disease process. As such, pain has been recognised, by patients, as a top clinical priority for hip and knee arthroplasty patients in a priority research setting partnership (37). Despite advances in multi-modal techniques to reduce, pre-empt and minimise the severity of pain, as many as 40% of arthroplasty patients experience severe pain in the immediate postoperative period (38). In addition, one-in-five patients go on to experience chronic, often debilitating, pain in the long term (39). Furthermore, it is believed that poor management of acute pain can lead to the development of chronic pain (40). It is important to recognise that there may also be a genetic component to the formation of chronic pain (41).

In 1993, Kehlet and colleagues in Denmark wrote about the importance of a multi-modal approach to postoperative pain (42). The previous decade had revealed new knowledge regarding pain and the pathophysiology of pain (43). This multimodal idea involved tackling the postoperative pain issue from multiple points along the pain pathway, ideally resulting in a reduction in postoperative pain (44).

In recent years in the US, the overuse of opioid medications has become a national health emergency. In 2015 alone, over 33,000 deaths were attributed to it in the US. It is now an issue of concern in the UK, with recent NHS reports that almost 13% of adults received an

opioid prescription in the last two years. In the light of this opioid situation, finding the optimal multi-modal regimen for acute postoperative pain has never been of more importance (45, 46). However, as yet, no 'gold standard' has yet been found to treat postoperative pain (47). A 'gold standard' in any aspect of healthcare is a term originally utilised by economists, but now refers to a widely accepted best practice or best available treatment for the clinical situation or condition (48). In an attempt to define and understand what components of the multi-modal approach were effective, systematic reviews and meta-analyses of commonly used adjuncts were performed. These included gabapentinoids (49), corticosteroids (50, 51) and two Cochrane reviews on liposomal bupivacaine (52, 53). Some of the work in this section has been published in a peer-reviewed journal (54). A brief synopsis of each follows.

1.1.6.1 Gabapentinoids

This group of antiepileptic drugs includes gabapentin, which was found to be an effective anti-convulsant, and pregabalin, which has proved to be of use in chronic neuropathic pain control regimens, including diabetic and post-herpetic neuropathy (55). These have recently found a place as adjuvant non-opioid analgesics for acute postoperative pain relief and are currently used in about half of the enhanced recovery programmes in the United Kingdom (UK) (54).

A systematic review and meta-analysis (49) found no evidence to support the routine use of gabapentinoids in the management of acute postoperative pain following total knee arthroplasty. Although some analgesic efficacy and opioid-sparing effects were seen with the use of pregabalin (0.5 and 0.3 reduction in pain scores on an 11-point scale at 24 and 48 hours respectively), these were unlikely to be of clinical or meaningful subjective importance. Additionally, no beneficial effects in improving short-term function or

reducing the long-term incidence of chronic pain were detected and, although an anti-emetic effect was observed (risk ratio 0.7), there was a significant increase in the risk of sedation (risk ratio 1.4) with pregabalin.

1.1.6.2 Corticosteroids

Corticosteroids are used in healthcare for many different reasons including dermatologic, respiratory, rheumatologic, and endocrine conditions (56).

They can be used for postoperative nausea and vomiting, with as many as 80% of patients experiencing these during their hospital stay (57). This can be a major source of patient dissatisfaction and negatively affect plans for early mobilisation (58). They have also been used in recent times in an attempt to control acute pain in the postoperative period (50).

When the use of steroids following TKA was analysed (51), a mild reduction in pain was seen with systemic steroids at 12 hours (1.1 points), 24 hours (1.3 points), and 48 hours (0.4 points) postoperatively. Local corticosteroids did not reduce pain.

1.1.6.3 Liposomal bupivacaine

Liposomal bupivacaine is a local anaesthetic consisting of bupivacaine hydrochloride that is encapsulated within multiple, lipid vesicles. This encapsulation technique produces a method of sustained drug release which has the potential, if effective, of reducing opioid consumption in the acute postoperative phase (52). This drug has been used in the United States and is currently under trial in the UK. It is considered to be of potential use as a long-acting local anaesthetic due to the sustained release mechanism in the drug.

In the results of two Cochrane reviews (52, 53) however, it did not appear that the liposomal bupivacaine was superior to traditional local anaesthetics in either the nerve

block analysis or surgical site. Further large scale testing would be needed to determine its efficacy.

1.1.7 Enhanced Recovery after Surgery (ERAS)

Optimising recovery holds significant benefits for patients, healthcare professionals and health care payers. In particular, enhanced recovery protocols (ERPs), which were first proposed in bowel surgery in Denmark by Kehlet et al. in the 1990's to attempt to reduce the surgical stress response, have evolved across surgical specialities to address the many factors involved in a patient's short-term recovery from surgery (44, 59). ERPs utilise multimodal techniques, as mentioned above, ranging from pre-operative education to infiltration of the surgical site with local anaesthetic. There is evidence that ERPs significantly reduce perioperative pain and opiate consumption (47). This is associated with significant cost savings to the healthcare system as they lead to a reduced length of stay (LOS) and accompanying reduced healthcare costs. In addition, the short-term benefits seen with the use of ERPs have been reported to translate into reduced long-term patient morbidity and mortality, and improved functional outcomes (30-32). Patient experiences and satisfaction with surgery have also been found to be affected significantly in terms of improved outcomes (33).

ERPs generally encompass three time periods in relation to the patients' surgery. These are: preoperative (the time from when the patient makes the decision to consent for surgery); perioperative (the time immediately around surgery) and postoperative (the period following surgery). ERPs are patient care pathways designed to improve the surgical outcomes for the patient and maximise and expedite recovery. In addition, reduction of pain, complications and length of hospital stay have also been reported (43).

Pathways begin in the preoperative period before the patient has surgery and aim to bring a patient whose health has been optimised prior to the day of surgery. This includes evaluating and improving, wherever possible, concurrent medical conditions, providing preoperative physiotherapy and exercises, and health counselling (60).

Interestingly, as LOS decreases with the implementation of same-day discharge following joint replacement, researchers have begun to question whether measuring LOS in terms of hours spent in hospital rather than days would be more useful in clinical decision making (61).

At present, there is no gold standard protocol or consistent guidelines for ERP, with many hospitals developing and utilising their own protocols. Therefore it was determined that an audit would be undertaken of hospitals in the UK to evaluate and compare protocols and adherence to them (54).

Hospitals within the UK performing hip and knee replacement utilising an ERP were contacted for inclusion. Forty five centres reported their protocols with significant variance in both components and adherence to those protocols. The variance ranged from 40–100% for TKA and 17–94% for THA.

Reviewing published trials of ERPs in joint replacement reveals that they all use a pain score as primary outcome, with opiate usage and LOS typically used as secondary outcomes. The use of pain scores to assess patient recovery has significant disadvantages, most notably that a low pain score can be achieved by administering high dose opioids which, whilst effective, can result in significant side effects (62). In addition, LOS does not necessarily assess recovery from the patient's perspective and can also be affected by the availability of carers, convalescent establishments, and general practitioner (GP) home health services (63). These can change due to policy decisions within governing bodies.

The lack of a gold standard outcome measure for recovery has resulted in a paucity of research and evidence about the efficacy of the many factors involved in ERPs.

1.1.8 Patient-reported Outcome Measures (PROMs)

PROMs are patient-reported questionnaires that provide information directly from patients as to how they see their health at a specific point in time (64). These have usually been tested and validated for use. They can be generic or disease specific. PROMs have been routinely used since 2009 within the National Health Service (65) to measure long-term health improvement in patients undergoing hip and knee replacement (65). These PROMs are most often used at mid to long term recovery periods of six months and longer. Their use is absent in the critical early recovery period. An outcome measure assessing early postoperative recovery within the first six weeks needs to satisfy eight requirements:

- Appropriate for intended study population
- Acceptable to patients
- Feasible to perform
- Reliable
- Valid
- Sensitive to change/responsive
- Precise
- Interpretable (66)

A prior systematic review identified seven instruments for use after ambulatory surgery in general and found that only one met all eight requirements (67, 68). Ambulatory surgery is defined as a surgical procedure where the patient is admitted to and discharged from hospital on the same-day (20). However, in recent years, the types of surgery being carried out on a day-surgery basis have been increasing in terms of complexity and recovery.

Subsequent analysis, however, has revealed that only the Quality of Recovery from Anesthesia 40-item survey (QoR-40), and specifically only the QoR-40 physical domain, was valid in assessing quality of recovery in the knee replacement population and only then in the first month, not first few days, following surgery (69).

This absence of sensitivity to early recovery in current instruments means they cannot assist clinicians in planning discharge, nor can they differentiate between those patients who have a good or bad recovery. This limits benchmarking of current practice. It also restricts research aimed at improving recovery and defining evidence-based guidelines.

One of the reasons that the majority of current scores do not perform well in orthopaedic surgery is that they have been developed in predominantly general surgical populations, with under 15% of the cohorts undergoing orthopaedic surgery. The mixed populations in which the existing tools have been developed have resulted in scores being weighted heavily towards items such as bowel and bladder function which are less of concern to a patient undergoing joint replacement compared to a patient undergoing an abdominal procedure.

The US Food and Drug Administration (FDA) have issued clear guidelines for best practice in the development of outcome measures (70). These have been followed throughout the work of this thesis and will be discussed accordingly in each chapter.

1.1.9 Potential benefits of this work

This work would provide a new ‘gold standard’ for measuring patient-reported recovery following lower limb arthroplasty in the first days and weeks after surgery. The work in this thesis has created and tested a more traditional patient-reported outcome measure (PROM) for measuring recovery at a moment in time, and a change measure for patients recovering from hip or knee joint replacement. These would be first of their kind and the

only ones fully designed and developed with the exact patient population being involved from its conception through validation. These tools could positively influence the care and pathways received by patients' themselves by directly affecting both clinical research and hospital programmes. This could in turn lead to improved patient care and satisfaction, and decreased hospitalisation and facilities costs which would be of significant relevance and value to patients, carers, healthcare professionals and hospital trusts alike.

1.2 Broad Aims

The broad aims of the thesis are to:

1. To investigate the concept of quality of recovery in hip and knee joint replacement patients, particularly in early recovery, during the first six weeks (objectives 1-3).
2. To develop tools to assess quality of recovery for hip and knee joint replacement patients, particularly in early recovery, during the first six weeks (objectives 4-7).

1.3 Specific Objectives

The specific objectives of the thesis are:

1. To assess current tools used to evaluate quality of recovery.
2. To identify strategies and interventions for enhanced recovery following hip and knee joint replacement.
3. To identify current practice, including medication use in enhanced recovery programmes.
4. To explore qualitative themes in professionals and patients around early recovery from hip and knee replacement.

5. To develop a list of potential candidate items for the PROM and change measures.
6. To develop a PROM and change measure for early recovery following lower limb joint replacement.
7. To validate the PROM and test the change measure in an independent population.

1.4 Thesis Structure

Chapter 1 - Introduction

This introductory chapter explains the concept of the perioperative period, recovery tools, PROMs, ERPs and drugs in the surgical orthopaedic setting. It discusses their use in the clinical care environment. In addition, by discussing systematic reviews performed in specific areas of ERPs, a more rounded picture of the early recovery period and its treatment modalities is created. The overall aims and objectives of the thesis are introduced. A synopsis of thesis chapters is included.

Chapter 2 - Systematic review

This chapter provides findings from the systematic review performed of the available tools for use in the measurement of early recovery following joint replacement. The potential need for an early recovery PROM in orthopaedic surgery was highlighted.

Chapter 3 - Initial phases in the development of a patient-reported outcome measure (PROM)

This chapter reports the beginning phases of PROM development which consisted of qualitative interviews. The initial Planning Phase comprised 22 health care professionals who all care for lower limb joint replacement patients. In Phase One, 30 hip and knee

replacement patients were interviewed once during the perioperative period. The Planning Phase interviews provided background and clinician perspective to the possible new PROM. The interviews from Phase One, provided themes and topics of importance to patients which facilitated meaningful item generation in the next phase.

Chapter 4 - Development of two pilot questionnaires

The process of candidate item generation for the pilot questionnaires is described in this chapter. Initial testing of the questionnaires in 30 patients is also reported. These were administered once to patients in the early postoperative period during hospitalisation (days one to nine). Completion of the questionnaire was performed in the context of cognitive debriefing. Following completion of the questionnaire by the participant, an audio-recorded interview was then conducted by the researcher to determine the meaning that patients attributed to each item. This lead to the first version of the test questionnaire being developed that was then refined in the following phases.

Chapter 5 - Final questionnaire development and translatability assessment

In Phase Three of the study, the test questionnaires were administered on postoperative days 1, 2, 3, 7, 14 and again at 6 weeks to a cohort of approximately 150 consecutive hip and knee replacement patients. Exploratory factor analysis and item reduction was performed on the data. Translatability assessment of the questionnaire was also discussed. This key process includes clarification of the questionnaire, its wording and meaning for the countries and languages that would be using the questionnaire. This resulted in the final questionnaires that were tested and validated in Phase Four.

Chapter 6 - Validation of questionnaire and sensitivity to change

This chapter reports the final testing and validation of the questionnaires in Phase Four to a cohort of approximately 100 consecutive hip and knee patients. These patients received

both newly developed questionnaires at day 1, 2, 3, 7, 14 and at 6 weeks and, in addition, a widely recognised and validated generic measure, the Short Form-36 version 2 Acute (SF-36v2), United Kingdom, English version, was also used on days 7, 14 and 6 weeks. Sensitivity to change was analysed throughout. Correlations and comparisons in data were assessed and discussed. The subsequent findings and results of analysis are included in this chapter.

Chapter 7 - Substantive results from a comparison of inpatient versus same-day unicompartmental knee arthroplasty

This chapter reports and describes administration of the Oxford Arthroplasty Early Recovery Score (OARS) and the Oxford Arthroplasty Early Change Score (OACS) in a cohort of approximately 50 consecutive unicompartmental knee replacement patients. Some patients receiving same-day discharge and some traditional inpatient stays were also studied. Questionnaires took under 6 minutes to complete each day.

Chapter 8 – Conclusions and future work

This chapter includes discussion of findings and questionnaire development. The issue of generalisability of the questionnaire and challenges are addressed.

Limitations and areas for further work will be explored.

1.5 Summary

This introductory chapter has explored the background behind the work of this thesis. Important aspects of joint replacement, pain management and the perioperative period of recovery have been introduced. The next chapter contains a systematic literature review of currently available tools used in the measurement of postoperative recovery.

2 Systematic review[1]

2.1 Introduction

The early recovery period following surgery is of vital importance for every patient as well as his/her clinician undergoing any type of surgical intervention. It is known that appropriate care including pain management in the early phase can improve long term outcomes and help avoid chronic pain and other long term complications (40). This is of particular importance to patients undergoing lower limb arthroplasty who need to be able to mobilise and improve their mobility during those early postoperative days (71). This chapter will report the findings of a systematic review conducted to evaluate recovery tools and to determine if any exist for use in the care of joint replacement patients.

2.2 Introduction to Measurement Tools

Optimal patient recovery following surgery is critical to improving patient outcomes. Many factors contribute to patient recovery including: motivations , pre-morbid health status, prior operative and anaesthetic experience, type of surgery, analgesia, as well as expectations from surgery (72). Traditionally, patient recovery has been assessed by the surgeon and allied health care professionals using pain scores and analgesic consumption, together with objective measurements, including time to achieve set rehabilitation goals, such as knee flexion greater than 90°, or hospital discharge (73). Whilst these objective measurements assess a patient's recovery from the physiological perspective they fail to assess many of the

[1] Work presented in this chapter has been published in:

Strickland LH, Hamilton TW, Jenkinson CC, Murray DW, Pandit HG. Patient-Reported Outcome Measure for Early Postoperative Recovery Following Lower Limb Arthroplasty: A Systematic Review. Journal of Arthroplasty. 2016; 31(12):2933-40.

factors known to influence self-reported outcomes. Due to the limitations of objective measurements in assessing patient outcomes, interest has shifted towards the use of patient-reported outcome measures (PROMs) for assessment of surgical interventions (74). These focus on patient self-reported functioning and well-being (75). Their use is instrumental in assisting clinicians and policy makers to take important strides towards optimising the provision of care through refining modifiable factors such as indications for surgery, implant selection and surgical technique.

In orthopaedic surgery, whilst PROMs are routinely used to assess the functional outcomes of surgery at six months and beyond, their use before this time point, and in particular the immediate postoperative period is rare. Despite this, the ability to measure the multiple facets of patient recovery from their own perspective at this early time point is critical to improving patient care. From the patient perspective, improving recovery will enhance patient experience and satisfaction. From the surgical perspective, it has been demonstrated that improved perioperative patient recovery is associated with improved short and long term patient outcomes (76). From the healthcare payer perspective, in the context of increasing patient numbers, finite resources and change in patient expectations, optimising patient recovery and reducing LOS is more important than ever (59, 77).

Such are the benefits to improving the quality of patient recovery that Enhanced Recovery Programmes (ERPs) have been introduced across a wide range of surgical interventions (59). However, there remains a lack of consensus as to what represents the gold standard or indeed which components are critical to enhancing recovery. This has led to a wide range of different ERPs being used both across different specialties and also within specialties themselves. One reason behind the lack of consensus may be the inability of current methods to assess patient recovery during the early postoperative period. This argument is supported by the findings from a recent audit of UK ERPs for lower limb arthroplasty that demonstrated

that patient education was included in over three-quarters of ERPs, despite strong evidence that it does not influence standard measures of recovery, such as LOS (78). In addition, the lack of an appropriate measure to assess recovery may be why compliance to local ERPs was as low as 40% in some centres.

The aim of this systematic literature review is to determine which recovery tools can effectively measure early postoperative recovery after hip or knee arthroplasty. Part of this work has been published in a peer-reviewed journal (79).

A recognised part of the Food and Drug Administration (FDA) guidance in the development of a PROM is to conduct a literature review (70).

2.3 Materials and methods

2.3.1 Eligibility criteria

The number of early recovery tools specifically related to orthopaedic patients was anticipated to be small; therefore a systematic review of *all* recovery tools in *all* postoperative populations was carried out to assess whether they could be applied to an orthopaedic population. Studies that assessed and/or validated specific postoperative recovery tools were included in the review. Studies were selected with no time restriction up to the search date of January 13th 2016. The search was restricted to English language papers and adult respondents.

Inclusion criteria:

1. Validated postoperative outcome measurements at one week or less after surgery
2. Surgical studies
3. English language

4. Over 18 years of age

Studies were not restricted by sample size or by length of follow up. There were no exclusion criteria based on the publication status.

2.3.2 Information sources

Electronic databases (PubMed (Ovid), EMBASE (Ovid), Medline (Ovid), Web of Science (ISI Web of Knowledge), PsycINFO, Applied Social Sciences Index and Abstracts (ASSIA), The Cochrane library and SCOPUS were searched from their inception until January 13th 2016 for prospective studies reporting the development, validation and use of post-surgical quality of recovery tools. Searches were tailored to individual databases with the search strategy for MEDLINE shown below.

1. postoperative.mp.

2. recovery.mp.

3. quality.mp.

4. 1. AND 2. AND 3.

5. assessment*.mp. OR score*.mp. OR scale*.mp.

6. 4. AND 5.

The search strategy included the use of text words and MESH terms. In addition, reference lists of reviews and retrieved articles were assessed for further studies and registers of controlled clinical trials (metaRegister of controlled trials (mRCT) (www.controlled-trials.com/mrct), clinicaltrials.gov (www.clinicaltrials.gov) and the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP)

(http://apps.who.int/trialsearch/) were searched for ongoing trials. A summary of the search results is presented as a PRISMA flowchart (82) (Figure 2.1).

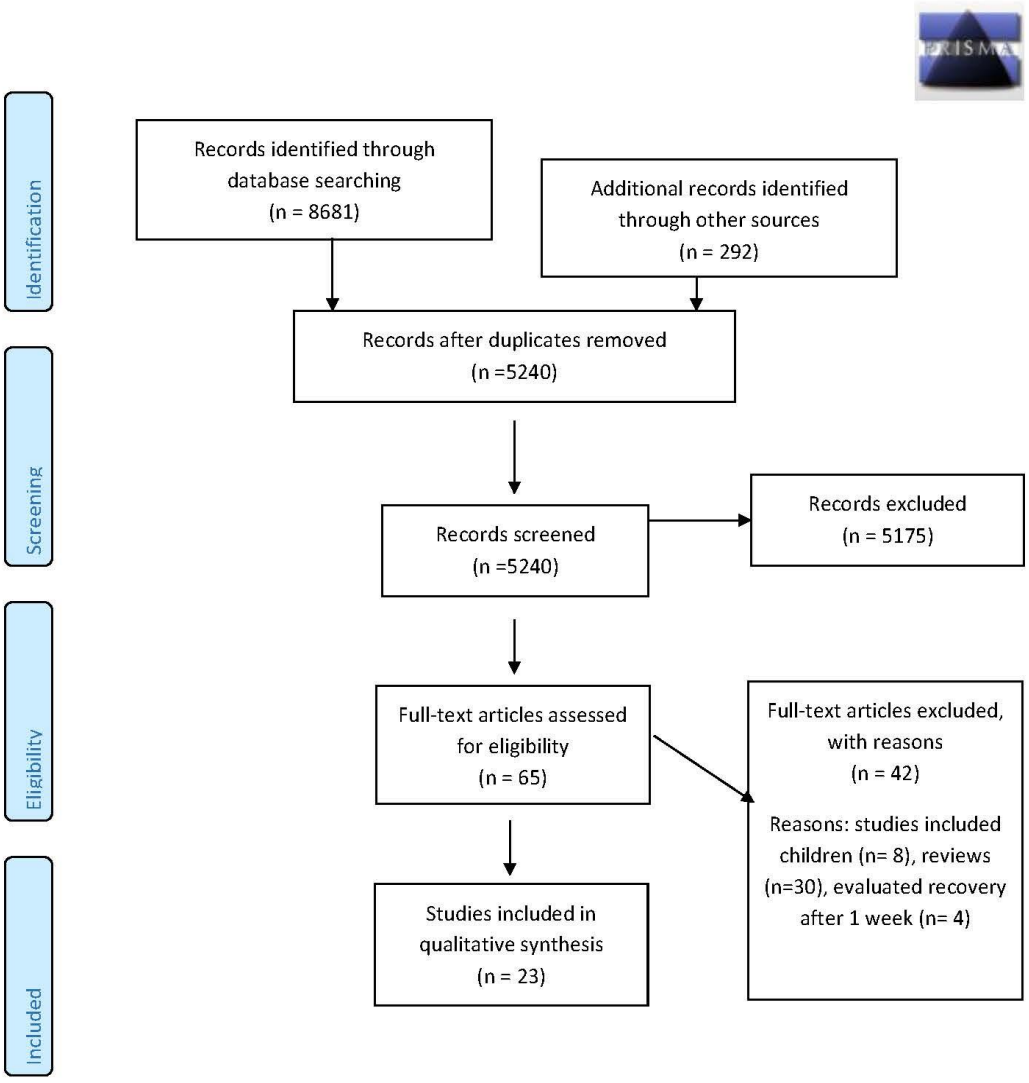


Figure 2.1: Flow Diagram of study selection (PRISMA STATEMENT) Quality of recovery PRISMA 2009

2.4 Data collection

The full texts of eligible studies were retrieved and data extracted into an electronic database. The search, appraisal and extraction processes were performed in duplicate by two independent reviewers (LS and TH). Items recorded included author; year; country; patient demographics (sex and age); surgical procedure; recovery tool; number of patients; method and timing of administration; outcomes; findings and validation methodology.

The data were extracted and appraised in line with established criteria (83).

2.4.1 Quality Criteria

For any assessment tool to be effective, one needs to establish its quality, appropriateness, acceptability, precision, reliability, validity and responsiveness to change over time (83). The tools identified were assessed against these recognised criteria.

2.5 Results

2.5.1 Study Characteristics

Twenty-three studies, relating to 15 unique recovery tools were found (Table 2.1).

Table 2.1: List of included studies

Lead Author Year Country	Name of Tool	Population	Outcomes	Number patients
Myles 1999 Australia	9-item Quality of Recovery from anesthesia (QoR 9) survey	Development stage (patients/family and staff)/ Cohort A (Mixed surgical)/ Cohort B (Minor and Major surgery patients)	Overall well-being, support especially from hospital staff, postoperative understanding, personal hygiene and toileting, breathing, pain and nausea/ vomiting	449
Myles 2000A Australia	9-item Quality of Recovery from Anesthesia (QoR 9) Survey	Surgical inpatients and ambulatory patients	To determine if quality of recovery is associated with satisfaction with anaesthesia and identify perioperative factors that influence these outcomes. To further validate the QoR tool	5672
Wu 2005 USA	9-item Quality of Recovery from Anesthesia (QoR) Survey	Elective radical retro-pubic prostatectomy	Primary outcome variable was QoR. Secondary outcomes included Brief Fatigue Inventory (BFI) and Epworth Sleepiness Scale (ESS)	100
Arnberger 2009 Switzerland	9-item Quality of Recovery from Anesthesia (QoR 9) Survey	Elective liver resection	Perceived patient physical and mental health (SF-36) baseline/7days and physical wellbeing and pain (QoR9) postoperatively	19
Stark 2013 Australia	15-item Quality of Recovery from Anesthesia (QoR 15) Survey	Mixed surgical patients receiving general anesthesia	The primary outcome was to develop the QoR15 and test its validity, reliability, responsiveness, clinical acceptability and feasibility.	127
Myles 2000B Australia	40-item Quality of Recovery from Anesthesia (QoR 40) Survey	Patients receiving general anaesthesia and surgery	Emotional state, physical comfort and independence, pain, psychological support	160
Leslie 2003 Australia	40-item Quality of Recovery from Anesthesia (QoR 40) Survey	Elective cranial and spinal neurosurgery	QoR-40 score, visual analogue scores for pain and quality of recovery, and data on complications were collected over 90 days	200
Poitras 2012 Canada	40-item Quality of Recovery from Anesthesia (QoR 40) Survey	Total hip or knee arthroplasty	Comparison of psychometric properties in QoR40 and SF12	132
Shida 2015 Japan	40-item Quality of Recovery from Anesthesia (QoR 40) Survey	Primary colorectal cancer surgery	The primary outcome was patient reported quality of recovery in each domain using the QoR40 in an enhanced recovery after surgery (ERAS) setting	94
Allvin 2009 Sweden	Postoperative Recovery Profile (PRP)	Mixed surgical patients including total hip and knee	Development and initial validation of a new brief postoperative recovery tool	40
Allvin 2011 Sweden	Postoperative Recovery Profile (PRP)	Mixed surgical patients including total hip and knee	Further validation and testing of previously designed PRP. Evaluation of items	158

Lead Author Year Country	Name of Tool	Population	Outcomes	Number patients
Bright 2009 Ireland	15-item questionnaire (FS-15)	Caesarean section	Physical functional status, ability to nurse the new-born, pain, vitality, and mental health. Overall recovery and patient satisfaction	40
Delaney 2009 USA	Postoperative Quality-of-life Metric (PQL)	Laparoscopic or open major abdominal surgery for colorectal procedures	Global QOL, nausea, pain (at rest and on maximal activity), bowel function, and return to normal health	74
Keller 2013 USA	Postoperative Quality-of-life Metric (PQL)	Laparoscopic or open Colorectal surgery via abdominal approach	Global QOL, nausea, pain (at rest and on maximal activity), bowel function, and return to normal health	88
Hogue 2000 USA	24-Hour Functional Ability Questionnaire(24hFAQ)	Surgical patients receiving two balanced general anesthesia techniques	Expectations preop, pain, nausea and vomiting, decreased alertness, satisfaction	1334
Hollenbeck 2008 USA	Convalescence and Recovery Evaluation (CARE)	Abdominal and pelvic surgery	To develop a generic instrument for measuring short-term health status in the recovery period among patients undergoing abdominal and pelvic surgery	96
Kleinbeck 2000 USA	Postdischarge surgical recovery scale (PSR)	Phase 1 Laparoscopic cholecystectomy and inguinal hernia repair/ Phase 2 Mixed surgical patients	Health status, fatigue and activity, work ability, patient expectations	242
Oakes 2002 USA	Post-anesthesia short-term quality of life (PASQOL)	Mixed surgical patients	Physical, psychological experiences and role function following surgery particularly related to anaesthesia	46
Paddison 2011 Australia and New Zealand	Surgical Recovery Scale (SRS)	Elective open or laparoscopic colonic resection	Feelings of fatigue, feelings of vigour, impacts on concentration, impacts on energy, and impacts on daily activities	150
Royse 2014 Australia	Postoperative Quality of Recovery Scale (84)	Knee arthroscopy (young and old groups) or knee arthroplasty	The primary outcome was quality of recovery in each domain over 3-month period using PQRS. Secondary outcomes included analysis of overall perspective domain of PQRS including satisfaction	135
Swann 1998 USA	General Symptom Distress Scale (GSDS) and Functional Status Questionnaire(FSQ)	Laparoscopy and incisional hernia repair	General symptom distress, Functional status	100
Talamini 2004 USA	Surgical Recovery Index (SRI)	Laparoscopic and open cholecystectomy	Pain, pain with activities, overall health, postoperative return to activities	149
Wong 2009 Canada	Functional Recovery Index (FRI)	Mixed ambulatory surgical patients	Pain and social activity, lower limb activity and general physical activity	688

The 15 tools found were:

- 9-item Quality of Recovery from Anesthesia (QoR 9) Survey (85-88)
- 15-item Quality of Recovery from Anesthesia (QoR 15) Survey (89)
- 40-item Quality of Recovery from Anesthesia (QoR 40) Survey (68, 69, 90, 91)
- Postoperative Recovery Profile (PRP) (92, 93)
- 15-item questionnaire (FS-15) (94)
- Postoperative Quality-of-life Metric (PQL) (95, 96)
- 24-hour Functional Ability Questionnaire (24hFAQ) (97)
- Convalescence and Recovery Evaluation (CARE) (98)
- Post-discharge surgical recovery scale (PSR) (99)
- Post-anesthesia short-term quality of life (PASQOL) (100)
- Surgical Recovery Scale (SRS) (101)
- Postoperative Quality of Recovery Scale (84) (102)
- General Symptom Distress Scale (GSDS)/Functional Status Questionnaire (FSQ) (103)
- Surgical Recovery Index (SRI) (104)
- Functional Recovery Index (FRI) (105)

Timing of the instruments began from the preoperative period to one year postoperatively. Most studies included at least one preoperative baseline evaluation, where others (PRP, FS-15, 24hFAQ, PASQOL and SRI) were only assessed in the postoperative phase. Important considerations in the timing of administration of questions in very early recovery are the effects of pain, anaesthetics and cognitive concerns in the elderly population (106). Timing is shown in Table 2.2. Table 2.3 shows quality measurement criteria discussed below.

Table 2.2: List of included combined studies

Name of Tool	References	Number of patients	Population	Number of items	Mean time to complete (minutes)	Timing of measurement
9-item Quality of Recovery from anesthesia (QoR 9) survey	Myles 1999, Myles 2000A, Wu 2005, Arnberger 2009	6240	Mixed surgical patients	9	2	Preoperative baseline then day 1 through 6 weeks postoperatively
15-item Quality of Recovery from Anesthesia (QoR 15) Survey	Stark 2013	127	Mixed surgical patients receiving general anesthesia	15	2.5	Preoperative baseline then day 1 through 3 months postoperatively
40-item Quality of Recovery from Anesthesia (QoR 40) Survey	Myles 2000B, Leslie 2003, Poitras 2012, Shida 2015	586	Mixed surgical patients	40	6.3	Preoperative baseline then days 1, 2, 3, 6, 30, and 90 postoperatively
Postoperative Recovery Profile (PRP)	Allvin 2009, 2011	198	Mixed surgical patients	19	9	Days 2 and 3 or 3 and 4 (2009) Discharge then days 3, 10 then monthly through 12 months postoperatively (2011)
15-item questionnaire (FS-15)	Bright 2009	40	Caesarean section	15	-	Days 1,2 and 3 postoperatively
Postoperative Quality-of-life Metric (PQL)	Delaney 2009, Keller 2013	162	Laparoscopic or open major abdominal surgery for colorectal procedures	14	-	Preoperative baseline then day 1 through day 90 postoperatively
24-Hour Functional Ability Questionnaire (24hFAQ)	Hogue 2000	1334	Surgical patients receiving two balanced general anesthesia techniques	21	10	1 day postoperatively
Convalescence and Recovery Evaluation (CARE)	Hollenbeck 2008	96	Abdominal and pelvic surgery (general, urology and gynaecology)	27	-	Preoperative baseline then weeks 1, 2, 4, 6 and 12 postoperatively
Post-discharge surgical recovery scale (PSR)	Kleinbeck 2000	230	Laparoscopic cholecystectomy and inguinal hernia repair/ Mixed surgical patients	15	7	Preoperative baseline then days 1-4 postoperatively

Name of Tool	References	Number of patients	Population	Number of items	Mean time to complete (minutes)	Timing of measurement
Postanesthesia short-term quality of life (PASQOL)	Oakes 2002	46	Mixed surgical patients	40	-	Days 1,5,6 and 7 postoperatively
Surgical Recovery Scale (SRS)	Paddison 2011	150	Elective open or laparoscopic colonic resection	13	-	Preoperative baseline then days 3, 7, 30 and 60 postoperatively
Postoperative Quality of Recovery Scale (84)	Royse 2014	135	Knee arthroscopy (young and old groups) or knee arthroplasty	18	-	Preoperative baseline then days 1, 3 and 3 months postoperatively
General Symptom Distress Scale (GSDS) and Functional Status Questionnaire(FSQ)	Swan 1998	100	Laparoscopy and incisional hernia repair	45	-	Preoperative baseline then days 1, 4 and 7 postoperatively
Surgical Recovery Index (SRI)	Talamini 2004	149	Laparoscopic and open cholecystectomy	15	-	1 week- 28 days postoperatively
Functional Recovery Index (FRI)	Wong 2009	688	Mixed ambulatory surgical patients	14	4.2-4.5	Preoperative baseline then days 1, 3, 5, and 7 postoperatively

Table 2.3: Quality measurement criteria

Name of Tool	References	Number of patients	Population	Number of items	Mean time to complete (minutes)	Timing of measurement
9-item Quality of Recovery from anesthesia (QoR 9) survey	Myles 1999, Myles 2000A, Wu 2005, Arnberger 2009	6240	Mixed surgical patients	9	2	Preoperative baseline then day 1 through 6 weeks postoperatively
15-item Quality of Recovery from Anesthesia (QoR 15) Survey	Stark 2013	127	Mixed surgical patients receiving general anesthesia	15	2.5	Preoperative baseline then day 1 through 3 months postoperatively
40-item Quality of Recovery from Anesthesia (QoR 40) Survey	Myles 2000B, Leslie 2003, Poitras 2012, Shida 2015	586	Mixed surgical patients	40	6.3	Preoperative baseline then days 1, 2, 3, 6, 30, and 90 postoperatively
Postoperative Recovery Profile (PRP)	Allvin 2009, 2011	198	Mixed surgical patients	19	9	Days 2 and 3 or 3 and 4 (2009) Discharge then days 3, 10 then monthly through 12 months postoperatively (2011)
15-item questionnaire (FS-15)	Bright 2009	40	Caesarean section	15	-	Days 1,2 and 3 postoperatively
Postoperative Quality-of-life Metric (PQL)	Delaney 2009, Keller 2013	162	Laparoscopic or open major abdominal surgery for colorectal procedures	14	-	Preoperative baseline then day 1 through day 90 postoperatively
24-Hour Functional Ability Questionnaire (24hFAQ)	Hogue 2000	1334	Surgical patients receiving two balanced general anesthesia techniques	21	10	1 day postoperatively
Convalescence and Recovery Evaluation (CARE)	Hollenbeck 2008	96	Abdominal and pelvic surgery (general, urology and gynaecology)	27	-	Preoperative baseline then weeks 1, 2, 4, 6 and 12 postoperatively
Post-discharge surgical recovery scale (PSR)	Kleinbeck 2000	230	Laparoscopic cholecystectomy and inguinal hernia repair/ Mixed surgical patients	15	7	Preoperative baseline then days 1-4 postoperatively
Postanesthesia short-term quality of life (PASQOL)	Oakes 2002	46	Mixed surgical patients	40	-	Days 1,5,6 and 7 postoperatively

Name of Tool	References	Number of patients	Population	Number of items	Mean time to complete (minutes)	Timing of measurement
Surgical Recovery Scale (SRS)	Paddison 2011	150	Elective open or laparoscopic colonic resection	13	-	Preoperative baseline then days 3, 7, 30 and 60 postoperatively
Postoperative Quality of Recovery Scale (84)	Royse 2014	135	Knee arthroscopy (young and old groups) or knee arthroplasty	18	-	Preoperative baseline then days 1, 3 and 3 months postoperatively
General Symptom Distress Scale (GSDS) and Functional Status Questionnaire(FSQ)	Swan 1998	100	Laparoscopy and incisional hernia repair	45	-	Preoperative baseline then days 1, 4 and 7 postoperatively
Surgical Recovery Index (SRI)	Talamini 2004	149	Laparoscopic and open cholecystectomy	15	-	1 week- 28 days postoperatively
Functional Recovery Index (FRI)	Wong 2009	688	Mixed ambulatory surgical patients	14	4.2-4.5	Preoperative baseline then days 1, 3, 5, and 7 postoperatively

2.5.2 Appropriateness

Table 2.4 demonstrates domains that are covered by the instruments (Table 2.4). None of the instruments were designed specifically for an orthopaedic population; with most being developed and validated in a mixed general surgical population.

Table 2.4: Domains of recovery tools

Name of Tool/Recovery Domain	Overall quality of life	Physical function and symptoms	Psychosocial and emotional support	Activity	Nociception (pain and nausea)	Cognition	Fatigue/ sleep patterns/ Vitality	Mental wellbeing
9-item Quality of Recovery from anesthesia (QoR 9) survey	+	+	+	+	+	-	-	-
15-item Quality of Recovery from Anesthesia (QoR 15) Survey	+	+	+	+	+	-	-	-
40-item Quality of Recovery from Anesthesia (QoR 40) Survey	+	+	+	+	+	-	-	-
Postoperative Recovery Profile (PRP)	+	+	+	+	+	-	+	+
15-item questionnaire (FS-15)	+	+	-	-	+	-	+	+
Postoperative Quality-of-life Metric (PQL)	+	+	-	+	+	-	-	-
24-Hour Functional Ability Questionnaire (24hFAQ)	-	+	-	-	+	+	+	-
Convalescence and Recovery Evaluation (CARE)	-	+	-	+	+	+	-	-
Post-discharge surgical recovery scale (PSR)	-	+	+	-	+	+	+	-
Post-anesthesia short-term quality of life (PASQOL)	-	+	+	-	+	+	+	+
Surgical Recovery Scale (SRS)	-	-	-	+	-	+	+	-
Postoperative Quality of Recovery Scale (PQRS)	-	+	+	+	+	+	-	+
General Symptom Distress Scale (GSDS) and Functional Status Questionnaire(FSQ)	+	+	+	+	+	+	+	+
Surgical Recovery Index (SRI)	+	+	-	+	+	-	-	-
Functional Recovery Index (FRI)	-	+	-	+	+	-	-	-

2.5.3 Acceptability to patients and feasibility

The mean time taken to complete questionnaires ranged from two minutes to ten minutes for seven of the tools. Time taken was not given for FS-15, PQL, CARE, PASQOL, SRS, PQRS, SFQ or SRI. Most instruments rated highly on acceptability with completion rates of over 77%. The lowest ranking instrument, with a completion rate of 50%, was the SRI. The next lowest instruments with 74% were PQL and PASQOL.

2.5.4 Precision

The majority of studies utilise closed questions and Likert scale (107) response option items with 3-point to 5-point or response categories. Some instruments use a visual analogue scale (VAS) as a means to elicit their response. The authors of the FS15 did not provide any information regarding the type of questions in their tool and a copy of the tool could not be obtained. Ceiling and floor effects also demonstrate a tool's precision (108). Instruments reporting ceiling and floor effects included CARE, PSR, QoR-9 and SRI.

2.5.5 Reliability

All studies except the FS-15, PQRS and PASQOL presented Cronbach's alpha statistic of reliability. Of the studies reporting Cronbach's alpha, all but GSDS FSQ and 24hFAQ were within the recommended range. CARE was at the lower end of recommended ranges with 0.7 and QoR9 ranged from 0.57-0.90. Studies reporting reliability are QoR9, QoR15, QoR40, CARE and FRI. The PRP (92) utilised a Swedish statistical programme for analysis (109, 110). These did not give traditional Intraclass Correlation or Intraclass Correlation Coefficient (ICC), but reported reliability of 80-100% using statistical methodology with rank invariant testing. The PSR reported an intra-observer testing for reliability. Sample sizes for instrument populations are listed individually in Table 2.1 and combined in Table 2.2.

2.5.6 Validity

Construct and content validity were demonstrated throughout the tools with the exception of FS-15 and GSDS FSQ.

2.5.7 Responsiveness

The timing of the test administration itself plays a pivotal part in evaluation and is shown in Table 2.2. Standardised response mean (SRM) and effect size (EF) were reported from the QoR-9, QoR-15 and QoR-40. Minimally important change (MIC) was utilised in the SRS using both anchor based and conservative distribution methods (101). Analysis of scoring across different timing of testing was used for both PRP and PQRS instruments. In assessing postoperative recovery, it is important to establish a preoperative baseline to determine how individual patients are improving in the postoperative phase. Although many of the instruments included made an evaluation at baseline, four did not (PRP, FS-15, 24hFAQ, PASQOL and SRI).

2.6 Discussion

The most important finding from this review is that whilst 15 instruments were identified to assess postoperative recovery, none were found to fulfil all quality criteria and be valid for assessing early postoperative recovery in the hip or knee arthroplasty population. Whilst the QoR-40 met all requirements for a recovery tool, analysis revealed that only the physical independence domain was valid in assessing quality of life in the knee arthroplasty population, and only then in the first month, not the first few days following surgery (67, 69). Other domains of the QoR-40, did not appear to be responsive to change for the orthopaedic population (69) This may be due to the fact it was developed in a cardiac population with differing challenges (111).

This review indicates that there is no ideal postoperative recovery specific measure for hip and knee arthroplasty. One of the reasons for this is that of the 15 patient-reported instruments identified only seven were developed in populations which involved orthopaedic patients (FRI; PQRS; PRP; PSR; QoR-9, QoR-15 and QoR-40). However, in these seven studies, only 1526 out of a total of 10,281 patients (less than 15%) were orthopaedic patients, thus limiting the applicability of these instruments. It is likely that recovery factors important to patients undergoing orthopaedic surgery are significantly different to recovery factors in patients undergoing other types of surgery. For example, bowel function and gastrointestinal recovery are highly ranked concerns in the general surgical population, whereas pain, mobility and personal hygiene were found to be the top ranking outcome concerns in the orthopaedic patient during PRP testing and analysis (112).

Furthermore, patient recovery is likely to be influenced by factors outside of the direct physiological effects of the surgery itself, including the motivations and psychological preparation for surgery. The QoR-40, which was initially developed for use in a cardiac surgery population, has been found to have potential application at one month in the physical independence domain, but not in early recovery (69). The psychological domain, however, which may be related to differences in motivations and often urgent psychological preparation for, cardiac surgery compared to joint arthroplasty was found to be not valid.

Reviewing the seven studies that included orthopaedic patients in more detail revealed that only three contained arthroplasty patients (PQRS; PRP and QoR-40), with the remainder involving arthroscopic surgery, trauma or non-specified orthopaedic cases. From the data available, it was not possible to explore the recovery profiles of patients undergoing unplanned or planned surgery for trauma to determine if they shared similar recovery profiles, and, as such, if they could be assessed using a single recovery tool. However, the

evidence suggested that recovery tools are able to differentiate between different types of surgery on the same joint, with significantly worse PQRS scores. Of particular note, this was found to be true of cognitive function, nociception, emotional recovery and daily activities, following knee arthroplasty compared to knee arthroscopy (102).

Despite acknowledging that recovery is multi-factorial, the way that patient recovery is assessed in orthopaedic surgery has not substantially changed in recent years. Reviewing published randomised controlled trials of ERPs in lower limb arthroplasty reveals that they all use pain scores as the primary outcome, with opiate usage and length of stay typically used as secondary outcomes. The use of pain scores to assess patient recovery has significant disadvantages, most notably that a low pain score can be achieved by administering high dose of pain relief, including opioids. Whilst effective for pain, these can result in significant side effects such as nausea and vomiting in over half of patients. Likewise, opiate utilisation is a poor proxy for pain as it is known that once a patient has required opiates for breakthrough pain they are significantly more likely to be given opiates, independent of their pain score. Finally, length of stay is known to be affected by many confounding factors, and does not assess recovery from the patient's perspective.

Evaluating the quality of these health measurement instruments is critical in perioperative care as they can influence and affect the interventions our patients receive (67). The absence of a validated patient reported recovery instrument to measure early recovery following hip or knee arthroplasty limits the ability to assess which interventions represent the gold standard treatment to optimise recovery in this population. From the evidence presented, it would therefore seem appropriate that a tool to assess recovery following lower limb arthroplasty is developed in an orthopaedic population. Such a tool has potential to be used to evaluate the provision of care and assess different treatment interventions, be

they physical, pharmacological or psychological. This would allow improvement of patient care pathways and lead to clinical patient centred advancement.

There are certain limitations to this review. In particular, an absolute discussion of quality of recovery is complex because, to date, no gold standard exists in terms of assessment or definition of recovery (86). Additionally, only studies carried out and reported in English were included; therefore some important work in other languages may have been missed. Finally, the studies were performed in different population groups, often with small sample size, and with differing methodologies. As such, the data obtained is heterogeneous in nature, limiting the interpretations that can be made.

2.7 Conclusions

Although traditional recovery indicators are important end points for assessing outcomes and patient safety, they provide only limited insight on the impact of surgery on patient-assessed functioning and well-being. However, at the time of writing, there is no validated PROM or change measure for use in early postoperative recovery following lower limb arthroplasty. This significantly limits research in this area. At present there is also a lack of evidence reporting patients' experience and outcomes of ERP's. Developments in the ERP pathway are driven towards improving measurable outcomes such as length of stay which do not directly represent patient experience.

2.8 Summary

By performing a systematic review of the available tools, the potential need for an early recovery PROM and health transition, or change measure, in orthopaedic surgery was highlighted. These tools were assessed as inappropriate to accurately evaluate the quality of recovery in the early postoperative period, as they are predominantly based on the

patients' signs and symptoms as perceived by the medical team looking after the patient, rather than evaluating the patient's own experience using a patient-reported outcome measure (PROM). The measures were deemed to lack precision, i.e. the ability to detect differences between groups and the individual patient (113). In addition, sensitivity to change, or responsiveness, the ability to detect change, can be of importance both clinically and to the patient (114). The potential for patient, healthcare provider and hospital trust has been explored and highlighted.

The next chapters of the thesis will describe the process of development for a PROM and measure of change. This will begin with initial qualitative work performed to facilitate concept understanding and item generation through testing and questionnaire refinement to the final validation and psychometric analysis of the finished questionnaires.

2.9 Addendum

While completing the work on this thesis, an updated literature search was performed from January 13th 2016 (when the previous searches were performed) to the present day July 12th 2019. This search was performed to ensure nothing had been omitted and to continue to monitor for updates or similar work in this field. The results found 1510 publications. However, no new published research was found that has any impact on the work undertaken for this thesis.

3 Initial phases in the development of a patient-reported outcome measure (PROM)[2]

3.1 Introduction

In general, the definition and period of recovery depends on the type of surgery and a holistic view of being returned to a pre-disease and pre-surgery state of health and recuperation (115).

The focus of this study was to look at the outcomes and experiences of the perioperative period with particular emphasis on early recovery.

Parts of this chapter have been published in two peer-reviewed journal articles (116, 117).

As previously discussed in Chapter 2, a systematic review of currently used measures for assessing recovery following lower limb joint replacement was performed (79) and it suggested that a new PROM and change score was needed for the early recovery period following joint replacement. This led to qualitative work with a view to developing an early recovery PROM and change measure.

The need for work in this area has been recognised by the James Lind Alliance (118). This patient-focussed research initiative has established a top ten of research priorities for patient groups, including hip and knee replacement patients. They reported that the number

[2] Work presented in this chapter has been published in:

Strickland LH, Kelly L, Hamilton TW, Murray DW, Pandit HG, Jenkinson C. Health Care Professionals' Perceptions of the Arthroplasty Patient Experience: Planning Phase in the Development of a Patient-Reported Outcome Measure. Journal of PeriAnesthesia Nursing. 2019; 34(2):376-85.

Strickland LH, Kelly L, Hamilton TW, Murray DW, Pandit HG, Jenkinson C. Early Recovery Following Lower Limb Arthroplasty: Qualitative Interviews with Patients Undergoing Elective Hip and Knee Replacement Surgery. Initial Phase in the Development of a Patient-Reported Outcome Measure. Journal of clinical nursing. 2017; 27(13-14):2598-608.

one priority for these groups was the identification and measurement of patient and clinical outcomes (37).

This chapter will discuss the qualitative interviews and findings of the first two phases of the development of a PROM and change measure for use in early recovery following hip or knee arthroplasty. An initial Planning Phase was performed with Orthopaedic healthcare professionals to determine their ideas on and potential uses for such tools. In Phase One, patients undergoing hip or knee replacement surgery were interviewed to determine their concerns and issues to provide potential themes and items for the pilot questionnaire.

3.1.1 Patient and Public Involvement (PPI)

In background work prior to commencing the interviews for this study, a patient and public involvement (PPI) session was conducted. This included patients, carers and members of the public and was conducted on January 13th 2015. The group consisted of ten members: five male and five female. They included one patient who had undergone hip replacement surgery, one patient who had undergone knee replacement surgery, one patient was about to have surgery, one member who had surgery and was also a caregiver for someone who had a knee replacement, a partner of someone who had recently received hip replacement surgery, as well as an orthopaedic surgeon, a clinical research fellow, a senior research physiotherapist, a junior physiotherapist and a research nurse. Patients were recruited from the Orthopaedic hospital arthroplasty and physiotherapy clinics and had expressed an interest in being involved in research. The ages of participants ranged between 25 and 82. The duration of the session was three hours and participants were offered refreshments and lunch during the meeting. The purpose of the session was to gain insight from those who have personally experienced, or are about to experience, joint replacement surgery. By speaking to family members, the perspective of those who have cared for patients

undergoing joint replacement surgery was also considered. This was carried out in order to enhance the research and ensure that the proposed studies would answer questions that really matter to patients.

Discussion during the PPI session revolved around the perioperative period from preoperative evaluation and x-rays through surgical recovery and delivery of care. Of particular note in this session was the issue of pain which was found to be significant. Some members of the group stated that it was an expected outcome in the early days following surgery. Some participants felt that it was something they knew how to deal with and not necessarily a reason for a hospital stay following surgery. Participants were keen to return home as soon as possible following surgery, particularly if they had a support network available to them.

Prior experience with either anaesthetic in general or hip and knee surgery was also seen to be a factor in how well a patient would recover postoperatively. A positive experience brought some lessened anxiety by knowing more of what to expect during recovery, for example being able to negotiate the stairs. Conversely, negative incidents (such as postoperative nausea and vomiting after anaesthetic) increased anxiety and fears that these complications may be repeated.

Patients expressed that being able to see how they were progressing over time in the recovery period would be of use, as it can difficult to see progress when receiving opioid medications and experiencing pain.

3.1.2 PROM development/ Food and Drug Administration (FDA) guidance

PROM development is a multi-phased iterative process (70). The Food and Drug Administration (FDA) have developed a guidance document for best practice in

development of outcome measures (70). This elaborates on the five stages of PROM development:

- Hypothesise Conceptual Framework
- Adjust Conceptual Framework and Draft Instrument
- Confirm Conceptual Framework and Assess Other Measurement Properties
- Collect, Analyse, and Interpret Data
- Modify Instrument

This chapter focussed on the initial phase of hypothesising the framework for the PROM. This includes defining the study group, literature review and expert consultation. The expert interviews provide the developers with potential topics, layout or structure of the measure. It is important to stress here that, after consultation with 'experts', the actual content and wording of items on the questionnaire was developed on the basis of in-depth interviews with patients' themselves, which is discussed in Chapter 4. Patients were actively involved in every phase of PROM development. This is critical to ensuring the PROM is designed from the patients' standpoint and may provide insights that were previously unknown to clinical staff or researchers (119).

3.1.3 Ethical consideration

Ethics approval was obtained for the entire project outlined in this thesis from the Health Research Authority (HRA) research ethics committee (REC) North West - Liverpool East Research Ethics Committee (Reference 16/NW/0236). If interested in possible participation, eligible participants were approached by a member of the research team, given information about the study and time to consider whether they wished to take part. Time was also given for any questions or concerns. Participants were given as much time as they required to consider participating. Written informed consent was then obtained

from all patients during their outpatient clinic appointment or when they came back into hospital for their surgery.

3.1.4 Thematic analysis

An in-depth pragmatic thematic analysis method (120) was used for the interviews in both the Planning Phase and Phase One. Thematic analysis can be utilised in qualitative research to identify themes or commonalities in interview transcripts. It helps organise and understand data. Coding is the technique by which themes are identified and organised. This method of analysis was chosen for several reasons. It was vital for this research developing a patient-reported recovery measure to fully explore and understand the themes that are of importance in postoperative arthroplasty recovery for patients and healthcare providers. As the tool was being designed for use in both clinical and home settings (the latter after discharge), the tool needed to be meaningful and effective in a real world setting (121). Following immediate exact word-for-word transcription, interviews were anonymised to remove any participant identifiable data. These transcribed interviews were then imported into NVivo software (NVivo qualitative data analysis Software; QSR International Pty Ltd. Version 11, 2015) and analysis performed. Themes that were important to patients undergoing hip or knee replacement were recorded. This process is known as coding in qualitative research (122). Initial coding of the interviews was performed independently by two reviewers, the researcher and an expert colleague in qualitative research, to ensure thorough coverage of the work. Interviews were coded based on the patients' words and context.

The interviews were analysed in an iterative ongoing basis. This technique is designed to elucidate any new themes that may emerge as the study is being performed and allows for the iterative process of interview adaptation to occur. If any new areas come to light during

the earlier interviews, they can be added into subsequent interviews as interview prompts. This too helps to ensure full coverage of the concept being explored (121).

The aims of these phases of the study are twofold:

1. To explore qualitative themes from orthopaedic healthcare professionals and patients around early recovery from hip or knee replacement surgery.

2. To analyse the qualitative interview transcripts in order to develop candidate items for an early recovery PROM and change measure.

3.2 Planning Phase: Health Care Professionals' Perceptions of the Arthroplasty Patient Experience

3.2.1 Participants and methods

These interviews ascertained whether professionals would use such a questionnaire, how they would use it and broadly what they thought it might contain. This stage of development of the measure can also inform the potential layout, scoring algorithms and topics to be explored in patient interviews. Such a procedure has been used to inform the development of other PROMs (123). This Planning Phase was completed within three months.

3.2.2 Design

The study employed a qualitative thematic analysis design. Semi-structured interviews were utilised to explore healthcare professionals' experience and perspective of early recovery for patients undergoing THA or TKA. These interviews, were guided by a list of interview prompts (Figure 3.1), which facilitated further exploration of areas of the topic that need to be covered by the interviewer (124).

- Introduction
- Explanation of why I'm speaking with you today
- What is your role?
- Length of time in career?
- What are the main concerns you see with your patients?
- What are your main concerns? Why?
- What are your discharge criteria for patients?
- What are the priorities for patients during hospitalisation from your perspective?
- Any other ideas or anything else you'd like to add?

Figure 3.1: Planning Phase interview prompts

The prompts were developed together by the research team and included discussion of participants' role within the hospital, on how or indeed if they would use a recovery questionnaire with their patients, what an early recovery questionnaire might contain, their experience with surgery, anaesthesia, hospitalisation, and recovery. Time was given for the participants to add anything else they felt was of importance but had not yet been discussed. The research team included two surgeons; one nurse; one qualitative researcher and a psychometrician with a particular interest in patient related outcomes.

3.2.3 Setting and sample

The study was conducted at a 160-bed specialist Orthopaedic hospital within the NHS, England, UK. The hospital performs elective orthopaedic surgeries. All participants were

recruited from the hospital. All participants were purposively sampled [18] healthcare professionals who care for THA or TKA patients. Participants found out about the study through word of mouth. Inclusion criteria for the study: The participant may enter the study if ALL of the following apply:

- Participant is willing and able to give informed consent for participation in the study
- Able to communicate in English
- An employee of the hospital
- Be in one of the healthcare provider groups
- Provide care for lower limb joint replacement surgery patients

Exclusion criteria for the study: The participant will be excluded from either phase of the study if ANY of the following apply:

- Aged under 18
- Lacking capacity to consent/ unable to comprehend or provide informed consent

A multidisciplinary group of healthcare professionals who provide care across the perioperative continuum were interviewed. The individuals participating represented a vast range in terms of experience to allow for the maximum possible generation of ideas. Everyone who volunteered was interviewed, with the exception of one anaesthetist who had an emergency surgical case meaning they were unable to participate. The participants included consultant surgeons and anaesthetists, nurses, physiotherapists and occupational therapists. It was anticipated that approximately 20 participants would be required for this phase of the study based on prior PROM development (123). Twenty-two participants were

recruited to the study (with years of experience caring for orthopaedic patients ranging from 1-35 years) (Table 3.1).

Table 3.1: Planning Phase participant characteristics

Parameter	
Sex Male/Female (% male)	10/12 (45.5)
Ethnicity	Arab 1 (4.5) White British 14 (63.6) African 1 (4.5) Indian 1 (4.5) Other White 4 (18.2) Irish 1 (4.5)
Employment role	Registered Nurse 5 (22.7) Orthopaedic Surgeon 5 (22.7) Anaesthetist 5 (22.7) Physical Therapist 5 (22.7) Occupational Therapist 2 (9.1)
Length of time in career (years)	16.4 (9.2) 1-35

Sub Group	Number	Sex Male/Female	Ethnicity	Length of time in career (years)
Nurses	5	0/5	White British 4 African 1	1-24
Surgeons	5	5/0	Arab 1 White British 3 Other White 1	8-21
Anaesthetists	5	5/0	White British 2 Indian 1 Other White 2	15-22
Physiotherapists	5	0/5	White British 3 Other White 2	5-33
Occupational therapists	2	0/2	White British 2	12-35

Data are n (%) or mean (SD) range. Ethnicity categories from Office for National Statistics (ONS), Census 2011.

3.2.4 Data collection

Following ethical approval and informed consent, interviews were performed with healthcare providers. These aimed to identify factors seen to be pertinent to patients in their early surgical recovery. Interviews were semi-structured in nature with prompts and

open-ended questions. These encouraged exploration of the healthcare providers' experience, role and how they viewed their patients' early surgical recovery (Figure 3.1). Interviews were audio recorded. The duration was approximately 30 minutes or under for each interview, with a range from six to 35 minutes. On completion of each interview, field notes were recorded to document particular details about the process. These notes included reflection on participant responses, the physical environment and the researcher's personal reflections. The interviews were then transcribed, and anonymised. Interviews were transcribed from the audio recordings by a member of the research team within the university. Any identifying contextual names were removed.

3.2.5 Analysis

Data were analysed using a thematic analysis method (120) and using NVivo software (NVivo qualitative data analysis Software; QSR International Pty Ltd. Version 11, 2015). Anonymised transcripts were used. At the time of transcription, all identifying details were removed. Analyses were performed on an ongoing basis and as part of an iterative process as the interviews were being undertaken. The sample size was guided by data saturation (125, 126) which is the time at which subsequent interviews did not produce any new themes. Interviews were coded based on the participants' words and context (Table 3.2).

Table 3.2: Planning Phase Coding Sheet

1. Demographics
1.1 Sex
1.2 Employment role
1.3 Length of time in career
1.4 Specialty area
2. Immediate patient recovery issues
2.1 Pain
2.2 Nausea and vomiting
2.3 Bladder and bathroom
2.4 Anxiety
2.5 Complications
2.6 Medications
2.7 Mobility and range of motion
2.8 Mental health
2.9 Expectations, motivation and goals
3.0 Discharge
3.1 Home situation: support and family at home
3.2 Other
4. Discharge criteria
4.1 Physiotherapy satisfaction
4.2 Physician satisfaction
4.3 Patient satisfaction
4.4 Patient safety and ability to resume tasks at home
5. Priorities from healthcare providers' perspective
5.1 Pain
5.2 Nausea and vomiting
5.3 Range of motion and ability to mobilise
5.4 Eating and drinking
5.5 Home environment and support networks
5.6 Patient safety
5.7 Patient expectations and education
5.8 Anaesthetic
5.9 Postoperative environment and care
6.0 Satisfaction and feeling of well being

Topics that are important to professionals in the recovery phase were documented. Themes evolved from recurring words and ideas from the participants (127). Independent analyses of the interviews were performed by the researcher. Initial coding of the first few interviews was performed independently by a second researcher to ensure thorough coverage of the work and discussed. The coding sheet was developed and refined as the analysis progressed. Any unresolved concerns were taken to a third researcher, an expert in qualitative research, for resolution.

3.3 Planning Phase Results

3.3.1 Participants and demographics

A total of 22 participants were included in the study: 12 women (55%) and 10 men (45%) (Table 3.1). The sample consisted of nurses (n=5), surgeons (n=5), anaesthetists (n=5), physiotherapists (n=5) and occupational therapists (n=2). Ethnicities of the group were predominantly White British 14 (63.6%) but also included one Arab (4.5%), one African (4.5%), one Indian (4.5%), Other White four (18.2%) and one Irish (4.5%). All have been working in the care of the arthroplasty patient for an average of 16.4 years (SD=9.2). All participants work in the same Orthopaedic hospital setting. Specifically, within the nursing participants, four were of white British and one of African (Nigerian) ethnicity. Their length of experience in Orthopaedics ranged from one year to 24 years. The surgeon group consisted of three white British, one other white (Australian) and one Arab (Iranian). Their lengths of experience varied between eight and 21 years. The anaesthetists were represented by two white British, two other white (Russian and South African) and one Indian. They ranged between 15 and 22 years of practice. The physiotherapy group consisted of three white British, one Irish and one other White (Portuguese). Their length of experience ranged from 5-33 years. The occupational therapists were both white British and had 12 and 35 years' experience respectively. The surgeon and anaesthetist group were all male. The other three groups were all female.

3.3.2 Themes

Three main themes evolved from the interviews and were mentioned by all interviewees: immediate recovery issues (n=22), discharge criteria (n=22), and priorities during hospitalisation from healthcare providers' perspective (n=22).

3.3.2.1 Immediate patient recovery issues

Within this broad overall theme, sub-themes emerged: pain and medications; nausea/vomiting; bladder/bathroom; anxiety and mental health; mobility/range of motion; expectations, motivation and goals; discharge and home situation. All participants recognised pain as the primary postoperative issue for patients. 'The main issue is pain' (Participant 4, surgeon). They expressed in detail how it affects the overall recovery and wellbeing of the patient in the early recovery period. It can limit postoperative mobilisation and physiotherapy and can lead to complications and increased length of stay for some patients, which can in turn affect patient satisfaction and their long term recovery. It was felt that patients undergoing TKA seemed 'to suffer a little bit more' than THA (Participant 3, Nurse). Another felt that 'generally they are the same across the board but obviously it varies in extent depending on the type and duration of surgery' (Participant 8, anaesthetist). Pain management was seen as something that can be 'extremely variable and can be difficult to manage particularly in people who are on a lot of strong analgesia before they come in' (Participant 10, surgeon). Medications were also viewed as being challenging for patients. Prior medication use, side effects and getting the balance right between being over medicated and being in pain were expressed. 'More so I would say that we would seem to be over giving them stuff that kind of some individuals maybe don't need as much analgesia as some of the others so it knocks them for six' (Participant 3, nurse). Medication delivery and pain management were reported to be 'very dependent upon the expertise of people who are around at the time' (Participant 10, surgeon). As a direct result of medication use, at times, patients had been seen to 'get more constipated, dehydrated and they feel worse in the whole process' (Participant 10, surgeon).

Nausea and vomiting and issues around using the bathroom were also seen as significant issues in the immediate postoperative phase.

Anxiety was reported in relation to many of the other issues discussed. Some providers reported that patients demonstrated a sense of relief that the surgery was over, but concern and some worry over just how their recovery would progress. If a patient had prior experience with surgery, this could either alleviate some of the anxiety or worsen it depending on experience. 'They worry about how their pain is going to be maintained and controlled and will they be able to have the comforts they desire' (Participant 7, nurse). A patient's mental health and appropriate allocation of care for it was considered as a concern in the early recovery period (Participant 2, nurse).

Participants described how patients face challenges with regaining postoperative mobility and range of motion. It was felt that patients are mostly 'functional goal oriented' (Participant 20, physiotherapist) and keen to know what they 'can and can't do' (Participant 14, physiotherapist) following surgery. 'Often we get the knees affected by block. You don't see patients not mobile because they are in pain' (Participant 2, nurse). Being 'able to do stairs' (Participant 16, physiotherapist) is a commonly reported goal.

Expectations, motivation and goals were found by participants to be of importance for the patient as they embarked on recovery. These were observed to affect many different aspects in the early recovery period. 'People have lives, you know. People want to go back to dancing. They want, you know--you have got youngsters wanting to rock climb. They've got their jobs. They have got their mortgage to look after. They have a life and we need to be proactive in saying this is how you manage life with a joint replacement – yes' (Participant 2, nurse).

The timing and concept of discharge home from hospital was a cause of both concern and relief for patients. Healthcare providers reported that while some patients were keen for a speedy discharge, to recover in their home environment, others were content to stay in hospital for an extended period of time. The issue of patient dissatisfaction with delay in discharge due to lack of timely drugs arriving from the pharmacy was considered. It was noted that work was being done to improve the length of time it took for medication to reach patients from the pharmacy.

A patients' home situation, including the level of support and family members at home, were also found to be relevant. Patients were reported to have concerns over 'how am I going to cope at home if they live on their own' (Participant 17, physiotherapist) or how they would manage if they are the primary 'carer for others' (Participant 21, occupational therapist).

One professional felt that as healthcare professionals it is important to maintain a holistic view of the recovery period. 'We get over obsessed about pain and not look at the other things that patients might have a better stay though' (Participant 9, anaesthetist). He explained that often the side effects of opioid medications are sometimes worse for patients than the pain itself. 'I mean often nausea and itching distress the patients more than pain' (Participant 9, anaesthetist).

3.3.2.2 Discharge criteria

As the interviews and ongoing analysis evolved, participants addressed specific criteria in relation to what they wanted to see before the patient would be discharged home. This comprised of physiotherapy satisfaction, physician satisfaction, patient satisfaction, patient safety and ability to resume tasks at home.

All participants reported that successful assessment by the physiotherapist was one of the most important criteria for discharge. 'The physio has said they can go home and the doctor is happy with them' were seen as definitive markers of a patient's readiness for discharge (Participant 3, nurse). Patient satisfaction was seen to be closely linked with discharge. 'Patient expectation is very key with regard to discharge planning' (Participant 21, occupational therapist). 'It's the thing that people care about and whether they feel like they have been supported and facilitated' (Participant 13, surgeon). It was also noted that having shared understanding of the anticipated discharge was important. 'Our expectations are the same, that you know that we are very clear' (Participant 3, nurse). 'Safety and mobility are the key things in terms of discharge for patients' (Participant 20, physiotherapist). 'We can teach them safe techniques and if you teach them correctly it empowers them' (Participant 2, nurse). 'So the main things, very much back to the basics of what we need to do as humans on a daily basis is what we look at. We scratch the surface sometimes in terms of younger patients that are wanting to return to work, but on the whole, with such a short length of stay, it is very much kind of washing, dressing, domestic mobility, transfers and that's pretty much what we look at. Obviously, if they are needing support we can look at onward referrals to care services or for rehab beds' (Participant 22, occupational therapist).

3.3.2.3 Priorities during hospitalisation from healthcare providers' perspective

This theme displayed some interesting sub-themes from the healthcare professionals' perspectives: pain; nausea/vomiting; range of motion/ability to mobilise; eating/drinking; home environment/support networks; patient safety; patient expectations/education; anaesthetic; postoperative environment/care and satisfaction/feeling of well-being.

‘The main issue is pain relief. Second I would put nausea and vomiting. Third I would put is mobility, eating and drinking and, although I am not a surgeon, most patients ask me when will I be able to go home’ (Participant 8, anaesthetist). ‘They get nauseated from the morphine and things and this can be a bit of a knock on effect’ (Participant 5, nurse).

One participant saw patients who had ‘adapted to strong pain relief so managing that is something that is very dependent upon the expertise of people who are around at the time and how well that is managed. Sometimes if you bring them an ice pack and put it over the wound that is just as effective if not more so than a big slug of an opiate analgesia that will make you feel horrible’ (Participant 10, surgeon).

Again being able to effectively negotiate the stairs was seen as essential. ‘If they need to do stairs, some people don’t have stairs and say I never come across them and don’t do them, but yes of course that’s important. Sit to stand; you have to be able to get out of a chair. It’s the whole overall picture’ (Participant 18, physiotherapist). ‘When you are in hospital you have quite a lot of time on your hands’ (Participant 5, nurse). Utilising this time was seen as important.

The home setting and being able to resume activities of daily living upon return home were also seen as a priority. ‘Where they are, what is their home environment, what support networks do they actually have, the accessibility to shopping, what community support have they already got in place. Their medical history, their activity levels now, are they already able to get out shopping and be able to drive again? Being able to do the activities of daily living—yes—I think that’s really important in assessing the patients’ (Participant 2, nurse).

Other priority issues included variability amongst the type of anaesthetic and anaesthetist. 'In the postoperative phase the thing you really notice is which anaesthetist you have' (Participant 4, surgeon). The difference in individual technique and type of anaesthetic given, general or spinal, were reported to have major impact on patients and their immediate recovery.

Many professionals described the importance of repetition and reinforcement of information given to patients and families throughout the perioperative period. 'What we do know is that patients only normally take in about 10% of the information you give them each time you see them so it is about giving them repetitive information and giving them information in different forms, not just verbally, but papers or websites and things like that to go to. It's just about reinforcing; it's very important about reinforcing the same message. I mean that's where a lot of the difficulty comes, where people start saying slightly different things' (Participant 15, surgeon).

3.4 Planning Phase Discussion

Pain has long been seen as a postoperative issue (128). Many participants in the study recognised it as the most significant factor in recovery, particularly following knee replacement. The concept of patients with TKA experiencing more severe pain has been reported in the literature (49, 129). In relation to pain management, nurses described their concern for patients receiving the correct medications. Some surgeons noted that it was important to acknowledge individual patient requirements, as one standardised programme does not work for all.

Anxiety as discussed by the participants has been identified in the early postoperative period, particularly in first few days (130, 131). This was noted to affect many different aspects of a patient's recovery journey, including independence, pain and mobility.

The anaesthetist was seen by other team members to be an important component of the multidisciplinary team. They were also reported to feature, sometimes strongly, in individual patient recovery. In discussion, participants felt, anecdotally, that this was possibly due to a combination of factors. These included regularly caring for this specific patient population, their skill as an anaesthetist and bringing a certain art to the science itself. This is in agreement with prior research looking at postoperative recovery challenges (62).

Patient satisfaction is thought to be linked to a higher quality of recovery postoperatively (129). It has also been shown that how the patient feels can be directly related to their level of satisfaction with the care received (132) as patient satisfaction and outcomes are highly correlated.

Interestingly, similarities were seen among the disciplines in terms of discharge criteria and priorities in care. Work performed by Broos and Fourneau (133) demonstrated the importance of a patient's home situation in their recovery and indeed outcomes of surgery following discharge home from hospital or rehabilitation centre. Those with strong networks and families were found to have improved recoveries. Satisfaction in the care and relationship with hospital professionals was reported to improve not only a patient's outcome, but also how able they felt to deal with things following discharge home (134). Pain has also been recognised as a cause for delay in discharge and readmission in arthroplasty patients (36).

Participants felt that patients needed reinforcement of their changing requirements to prepare for discharge and the days following. Repetition and printed instructions with specific information regarding medications, wound care and physical changes assisted with this. This coincides with previous work following arthroplasty surgery (135).

Preoperative education has long been considered to be beneficial in the recovery process and timely discharge of patients following arthroplasty surgery (136), a sentiment which was echoed in these findings. Interestingly, conflicting evidence suggesting the contrary, as discussed in Chapter 2, does exist (54).

Improvement in function and mobility are some of the key reasons for arthroplasty surgery. Having key skills such as managing the stairs and having confidence in the ability to do so were recognised. The physical recovery paired with self-efficacy that participants observed has been reported in the literature (137).

The Planning Phase of this study has shown key areas of focus for healthcare professionals in the early postoperative phase: immediate recovery issues, discharge criteria and priorities during hospitalisation from healthcare providers' perspective. A patient's immediate physical symptoms in this peri-anaesthetic phase become the healthcare providers' priority. When these immediate concerns are stabilised and under control, attention then turns to the imminent discharge and ensuring a safe transition into the home area.

3.5 Phase One: Qualitative interviews with patients undergoing elective hip and knee replacement surgery

The purpose of Phase One was to provide themes and topics of importance to patients in recovery to facilitate meaningful item generation for the potential new PROM and change measure. Phase One was completed within three months.

3.5.1 Design

The study employed a qualitative design. Open, semi-structured interviews (138) were utilised to allow a deeper understanding of the patient perspective when going through

hip or knee replacement. These interviews, guided by a list of interview prompts (Figure 3.2), facilitated exploration of areas of the topic that need to be covered by the interviewer (124).

- Introduction, confirmation of procedure
- How are you today?
- History of joint problems
- Take me back to when you first had a hip/knee problem?
- Symptoms and strategies for management
- What led you to talk to your surgeon?
- Talk me through your day of surgery?
- Tell me more about: pain, feelings around your involvement in care decisions, education you received?
- Tell me about your hospital and surgery admission
- Tell me about the anaesthetic?
- Did you experience any nausea or vomiting?
- Tell me about your pain?
- How was your wound?
- Did you have any issues with going to the bathroom?
- How did you find the physiotherapy?
- Tell me about your mobility?
- How was your hospital stay?
- How did your family at home manage?
- Tell me about what happened prior to discharge?
- What happened to you after discharge?
- Is there anything else you'd like to add?

Figure 3.2: Phase One interview prompts

The prompts were developed together by the research team and included discussion of participants' history of joint problems, coping strategies, prior experience with surgery, anaesthesia, hospitalisation, and recovery. Time was given for the participants to add anything else they felt was of importance but had not yet been discussed.

3.5.2 Setting and sample

The study was conducted at a 160-bedded specialist Orthopaedic hospital within the NHS, England, UK. The hospital performs elective orthopaedic surgeries. A purposive sampling framework was used as much as possible for interviews to ensure that patients undergoing total hip or knee replacement were recruited. Inclusion criteria for the study included being willing and able to give informed consent, being aged 18 years or above and being able to communicate in English. All participants were recruited from the orthopaedic clinic at the hospital. All participants were purposively sampled (139) as being treated with hip or knee with joint replacement surgery. Thirty patients were recruited to the study (16 women and 14 men; aged 45-92) (Table 3.3).

Table 3.3: Phase One participant characteristics

Parameter	
Age (years)	71.0 (10.3) 45-92
Sex Male/Female (% male)	14/16 (46.7)
Ethnicity	WB 28 (93.3) OW 2 (6.7)
Duration of disease (years)	4.6 (4.1) 0.67-20
Time since surgery (days)	28.5 (24.0) 0-63
Type of surgery	THA 16 (53.3) TKA 11 (36.7) UKA 2 (6.7) Rev. THA 1 (3.3)
Employment	Employed 7 (23.3) Retired 21 (70) Disabled 2 (6.7)
Living situation	Alone 6 (20) Family 24 (80)
Home situation	One level 4 (13.3) Up and down stairs 26 (86.7)

Data are n (%) or mean (SD) range. Ethnicity: WB= White British; OW= Other White. Ethnicity categories from Office for National Statistics (ONS), Census 2011. Type of surgery: THA= Total Hip Arthroplasty; TKA= Total Knee Arthroplasty; UKA= Unicompartmental Knee Arthroplasty; Rev. THA= Revision Total Hip Arthroplasty.

3.5.3 Data collection

Following ethical approval and informed consent, interviews were undertaken to identify factors that patients view as important to their surgical recovery. Patients were interviewed once during their perioperative care, either on the morning of surgery (pre-operative), within the first week after surgery (immediate postoperative) or up to nine weeks following surgery (early postoperative). Interviewing patients at different times across the perioperative continuum provided a group that could both comment on what

was acutely happening to them and also reflect back to the recent past and time of surgery to include all possible ideas. Interviews were open, semi-structured in nature with prompts (140). The prompts encouraged exploration of patients' perceptions on the history, diagnosis and progression of their arthritis (Figure 3.2). Treatment and surgical procedures were also explored. Interview prompts were informed by the clinical experience of the research team and patient input. Interviews were audio recorded. The duration was approximately 30 minutes for each interview, with a range from 10 to 36 minutes. On completion of each interview, field notes were recorded to document particular details about the process. These notes included reflection on participant responses, physical situation and the researcher's personal reflections. The interviews were then transcribed verbatim and anonymised.

3.5.4 Analysis

Data were analysed using an in-depth narrative thematic analysis method (120). Analysis was performed using NVivo software (NVivo qualitative data analysis Software; QSR International Pty Ltd. Version 11, 2015). Analysis was performed on an ongoing basis and as part of an iterative process as the interviews were being completed. The sample size was guided by the time at which subsequent interviews did not produce any new themes. From previous studies, the point of data saturation was estimated to be 30 interviews (141, 142). Independent analysis of the interviews was performed by a member of the research team. Anonymised transcripts were used. Initial coding of the interviews was performed independently by two reviewers to ensure thorough coverage of the work. Interviews were coded based on the patients' words and context (Table 3.4).

Table 3.4: Phase One coding sheet

1.1 Sex 1.2 Location of disease 1.3 Waiting time for surgery 1.4 Previous or other surgery or hospitalisation 1.5 Home situation flat or stairs 1.6 Living situation family or alone
2.1 Duration of disease 2.2 Preoperative pain and triggers for pain 2.3 Preoperative activity changes and general activities and past times 2.4 Preoperative fatigue and sleeping 2.5 Preoperative x-rays and testing
3.1 Expectations and goals 3.2 Anxiety 3.3 Attitude 3.4 Preoperative education 3.5 Preoperative GP, physiotherapy and doctors' appointments 3.6 Preoperative family and friend support 3.7 Preoperative management strategies and coping
4.1 Surgery, anaesthetic and sleep 4.2 Immediate postoperative phase, pain and medications 4.3 Urinary catheter and bathroom 4.4 Nausea and vomiting 4.5 Eating, drinking and loss of appetite 4.6 Wound, infection and other complications 4.7 Physiotherapy, discharge, education and advice 4.8 Length of stay, anticipated if preoperative
5.1 Length of time since surgery 5.2 Pain, medications and triggers for pain 5.3 Increasing physical activity, aids and devices 5.4 Home situation and family support 5.5 GP, physiotherapy and nursing follow up and community support 5.6 Fatigue and sleeping at home 5.7 Room for improvement, concerns, other comments and advice for others

Topics that are important to patients in recovery were recorded. Themes evolved from recurring words and ideas from the patients (127). This important part of the analysis was performed independently by two researchers and discussed. Any unresolved concerns were taken to a third researcher for further resolution. Best practice in qualitative analysis and reporting were referred to and used (143, 144). This includes appropriate study methodology, design, data collection, analysis and reporting.

3.6 Phase One Results

3.6.1 Participants and demographics

A total of 30 participants were included in the study: 16 women (53.3%) and 14 men (46.7%) (Table 3.3). The mean age of participants was 71.0 years (SD=10.9; range 45-92). The surgeries within the sample consisted of THA (n=16), TKA (n=11), UKA (n=2) and revision THA (n=1). The ethnic composition of the sample was predominantly White British 28 (93.3%) but also included two White - Other (6.7%). All had undergone arthroplasty surgery within the past nine weeks (mean= 28.5 days; SD=24.0). All participants were recruited in the same orthopaedic hospital. The duration of disease ranged from 0.67 years to 20 years (mean=4.6; SD=4.1). Within the group, seven were currently employed (SD=23.3), the majority, 21, were retired (SD=70) and two were unable to work due to health conditions (SD=6.7).

3.6.2 Themes

Seven main themes evolved from the interviews: ‘improving function and mobility’, ‘pain’, ‘effects of healthcare on outcomes’, ‘support from others’, ‘involvement and understanding of care decisions’, ‘behaviour and coping’ and ‘fatigue and sleeping’.

3.6.2.1 Improving function and mobility

A key area of importance for all respondents (n=30) recovering from joint replacement was that of getting back to the level of function and mobility they experienced prior to the onset of hip or knee joint arthritis. Patients referred to working towards a return to ‘normal’ function as they saw it. All participants discussed in detail how a sometimes gradual, sometimes sudden loss of mobility and limb function had been a very limiting problem in the immediate preoperative period. As a result of these preoperative challenges, participants were content when they saw improvements early in the postoperative phase:

'I was back to normal soon after it was done. I am not one to hang around' (Participant 3), 'They got me out of bed first thing on the Saturday morning and I walked with the Zimmer frame and that was it, away I went' (Participant 16) and 'I felt absolutely fine day one' (Participant 10). Other participants, however, reported a slower return of function and strength in the days following surgery: 'I gradually increased the distance and that was fine' (Participant 15) and 'I can do the stairs now. I struggle but I do it' (Participant 17).

Participants were hopeful and excited about the possibility of being able to return to activity in general and specifically to areas they had previously enjoyed but had been limited due to arthritis symptoms in recent years. These pursuits included cycling, playing with grandchildren, family vacations, walking, jobs and other sources of employment which were also negatively affected by the loss of function and inability to move around in the preoperative period.

Participants who were in the early days of recovery during hospitalisation reported varying degrees of movement, ranging from 'I couldn't at the moment stand on it and walk—say from the bed to the bathroom, which means I couldn't do that at home either' (Participant 11) to 'I am up and about and walking and can go to the loo and that's the main part' (Participant 27).

Even in the early days, participants seemed optimistic about their potential and improving function. 'Hopefully I'll start walking better and being able to do more' (Participant 18), 'I think that if I can go up the stairs I can go home then' (Participant 28) and 'I do feel a lot better and that is brilliant' (Participant 19).

Participants reported pleasure at regaining their sense of independence as mobility returned following an extended period of time being reliant on crutches or other aids. 'I now have

just one walking stick and I can manage and I like it because it makes me feel free-er' (Participant 22).

3.6.2.2 Pain

Pain was discussed by all participants (n=30) in this study. The amount of pain experienced with the disease in the preoperative phase was also discussed. Pain was reported with all activities of daily living, but especially with functional mobility. Participants discussed having to give up jobs and make lifestyle changes due to the pain. Some reported no longer being able to do anything that was enjoyable to them: gardening, getting in and out of bed, driving, going to art galleries and even sitting to read had become uncomfortable. Most participants were relieved to be having the surgery after having sometimes years of unrelenting pain. 'Excruciating pain. I don't think the operation could have caused more pain [laughs]' (Participant 5).

Pain was seen as part of the disease of arthritis and an understood part of the recovery process by respondents. 'You already have pain but you're given analgesia for it. You are bound to have some pain aren't you? I mean you have to accept some' (Participant 6).

When reporting and emphasising the amount of pain they had experienced, participants often used repetition of a phrase to reinforce and give power to their statement (120). 'Pain. I've had pain, oh god I've had pain, so much pain' (Participant 19).

Participants were used to dealing with pain and although some reported surprise at having pain in the immediate postoperative phase, the majority of patients found it to be as anticipated: 'My pain was as I expected it and I know how to manage it' (Participant 28).

Participants reported a significant reduction in pain following surgery. 'The pain I had all the time to the pain now is very good' (Participant 19) and 'It aches occasionally. It aches to walk, but normally it's OK. It's just going downstairs' (Participant 7).

3.6.2.3 Effects of healthcare on outcomes

All participants spoke about the effects of care they had received during treatment. A mix of positive and negative encounters were described. In the narratives, some participants were experiencing hospitalisation for the first time (n=7), while others drew on previous hospital and surgical experiences (n=23). When undergoing a procedure for the first time, patient concerns revolved around fear of the unknown. 'I was worried obviously for the first one because it was all so different and new but, when it came to the second one, I knew the pattern and the routine. So, yeah, more or less, yeah pleased' (Participant 3). Participants took comfort if they knew the hospital and the surroundings. Then it felt less alien to them. 'I know this hospital very well and that's why I chose it to have my surgeries' (Participant 29). Already having been through a similar procedure brought a similar sense of comfort to participants, unless a prior experience had been negative. 'I sort of knew what to expect and I have got good quads anyway and so you grit your teeth and go for it' (Participant 9). Participants felt that their individual attitude made a difference in their recovery. 'I had three cancer operations within 11 weeks of each other, two breast and bowel and I survived those because I am a very positive sort of person' (Participant 5).

Patients reported varying experiences of both surgery and the anaesthetic. 'It was such a benign proceeding that on both occasions I had a cup of tea in the recovery room' (Participant 10) and 'Perfect. It was just like a good sleep and just waking up sort of thing' (Participant 16). 'I was sick on the Tuesday because I'd been laid down for a while. They asked if I could sit up and I said I was feeling woozy and the next minute I was sick' (Participant 4).

Some participants reported a delay in being sent to theatre which made for a very uncomfortable experience (Participant 25) due to being hungry and thirsty.

Others expressed concern at being awake and numb, with a spinal anaesthetic during the surgery. ‘You could hear them banging and crashing at the end and things’ (Participant 11) and ‘it’s slightly disconcerting that you can hear the operation particularly when you can hear something that’s like a workshop. You can hear the banging of the new joint’ (Participant 21).

For some, the experience of waking up immediately after surgery in the recovery room and being numb from the waist down was frightening. ‘I woke up in recovery with a mask on and I kind of panicked. I went to lift my leg up and couldn’t because it was numb’ (Participant 30). Some participants reported feeling reassured by having confidence in the healthcare providers ‘the consultant is such a wonderful man’ (Participant 28) and ‘I certainly was looked after very well’ (Participant 22) and had concern when they did not: ‘I didn’t like the anaesthetist [Whispers]’ (Participant 28). Participants were overall happy with the care and attention they received but did acknowledge the challenges of staffing in a busy NHS hospital. ‘If you are in a ward I mean they are working really hard and I have got no complaints but you do have to take your turn’ (Participant 18).

3.6.2.4 Support from others

Participants reported a wide range of support, including: family, friends, formal and informal carers. Some reported being more concerned about how their family would cope during their hospitalisation and surgery than with their own concerns regarding surgery and recovery.

Spouses, partners, adult children and grandchildren were reported as being key supports in the perioperative period. This was particularly important in the immediate discharge phase following surgery. As time moved on and the participants were improving in recovery, some of the care and attention was not always welcome. ‘They are just there looking after

you. My husband especially asking "are you sure you should be doing that?" Can you do this, can you do that and I just say go for a walk. I'm doing it and you get on in the end. [Laughing]' (Participant 3).

Overall, participants found the process worked well—the preoperative 'joint schools' being well received. These preoperative sessions provide patients with a central location for multi-disciplinary information on all aspects of postoperative recovery. Nurses, occupational therapists and physiotherapists provide practical instruction and information as to what they can expect following surgery. 'I think the system they have got here is actually remarkably good' (Participant 10). Participants reported that going through the postoperative physiotherapy and occupational therapy requirements prior to the operation was beneficial.

Participants found the hip school quite enjoyable and a welcome dose of levity in an otherwise quite serious time. 'There's the hip school which is a bit of a giggle but I mean it goes through some little tricks which are useful' (Participant 10).

Participants were happy with their length of stay and discharge home from hospital as they knew who to contact in times of concern: 'No regrets about getting home because you could always ring physiotherapy and if there's any issue you know drop in' (Participant 10).

Participants reported liking the fact that someone could be contacted by telephone, just to talk over what was on their mind (Participant 22).

3.6.2.5 Involvement and understanding of care decisions

Participants reported mixed levels of involvement and understanding in their care decisions. Initially some patients were shocked to discover that they needed surgical intervention to fix their hip or knee. However, after accepting the idea, most were relieved

and looking forward to life with their new joint. Participants reported that they did not feel involved in their anaesthetic choice, with some expressing concern that they felt as if their wishes were not always taken into consideration. Some did accept that their choice may not have been the best from a medical standpoint.

Some expressed being happy to be looked after and not feeling the need to make any decisions as their healthcare providers 'know and I don't, so I'll let them do it' (Participant 22). One interviewee reported that 'they have been very good at giving you what they think you need' (Participant 11). Another felt that, in regards to their healthcare decisions, such as medication options or discharge planning, they did not know enough about it to make informed choices. They also felt ill-equipped to say the right things. 'I was asking for something I couldn't have' (Participant 18). One suggested that being given more printed information sheets could be beneficial to help understand their available drug combinations, therapeutic actions, dosing and timing.

Some found that the information they were given regarding the early recovery phase during hospitalisation was contradictory. This lead to confusion and uncertainty over what to expect and who to believe. 'The surgeons tell you, you can come out the next day, the nursing staff say you are not ready to go home and you can't go home till the physios say you can anyway so everybody you speak to tells you a different story. They could liaise a bit better on that I think [laughs]' (Participant 11).

Participants reported relief following discharge. They felt that once home they were more in charge of their own schedules (medication, sleep, activity) and were better able to relax and manage their recovery.

3.6.2.6 Behaviour and coping

Throughout the interviews, ways of managing the symptoms of arthritis, subsequent arthroplasty surgeries and recovery were explored. Participants reported multiple methods of coping, including altering activity and participation levels, medications, body mechanics, use of physical aids and attitudes.

Preoperatively, in terms of day-to-day coping with the changing movement ability and stiffness of the joint, participants found ways to position the leg to minimise symptoms. 'It's alright. If I keep my knee in this position too long then it hurts. I have to keep moving it so it doesn't stick in one position' (Participant 5).

Interviewees felt better equipped to deal with activity as they learned what activities they could and could not manage. 'I am getting to the point now I know what I can do and what I can't do' (Participant 1). Another explained that 'you don't realise what you can't do, you know, until you can't do it' (Participant 16) and now 'I know my capabilities' (Participant 15).

Following surgery, prior experience gave important insight into how best to conduct themselves. 'I know to take it easy the first day when you are back from surgery but the next day then hopefully I'm going to get up and start walking like I did before' (Participant 3).

The benefits of using ice and its effect on medication requirements were discussed by the participants, while in hospital and at home. 'I think the ice pack worked and I think actually it was as good a pain killer as having you know heavy drugs' (Participant 18) and 'It was painful at night. My partner had to keep going down to get frozen peas to put on it' (Participant 4).

Having a reduction in the amount of medication that was required in the postoperative phase was described as a positive change by one interviewee. 'The last few years one way or another I have been living on pain killers to take the edge off what was happening and I haven't had any pain killers for three weeks and I feel really good' (Participant 9). Participants reported that finding a happy balance between rest and activity (Participant 11) was a key coping method in the recovery period. Interestingly, the use of physical walking aids were seen as more of 'a mental crutch' (Participant 21) than anything else. 'I went out for walks with my sticks but I didn't feel I really needed them. They were there for just in case' (Participant 20). These aids provided a valuable source of confidence and belief in the user's ability while recovering from arthroplasty. 'I don't have a lot of confidence in my balance as yet and the crutches literally are a crutch. It gives you confidence' (Participant 23).

Participants' attitudes played a substantial role in how they dealt with the recovery process. A sense of humour was demonstrated to be helpful with all participants (n=30) laughing and sharing a joke during the interview sessions. Some had advice that had helped them cope that they wanted to share with others. 'Why paint a silly picture. It's painful; you have to put up with it don't you?' (Participant 9) 'Listen to what you are being told but know what you can do – yeah. Have faith in yourself that you can do it. Just set yourself that little goal each time and go for it. The physios and everything were marvellous here and they know, you know and if you think you can do it. Take a little time to do it. Go careful but take your time. Don't rush; don't jump before you can walk type of thing' (Participant 3).

3.6.2.7 Fatigue and sleeping

All participants reported perioperative changes in their sleep patterns and levels of fatigue. These were related to several different factors. In the preoperative period pain and difficulty with positioning were reported by most but not all of the interviewees. 'I was awake all hours of the night…not to be able to get any sleep at night is a horrible thing' (Participant 2) and 'Yes, it was painful it didn't stop me sleeping but it was painful' (Participant 10).

In the immediate postoperative phase, the main complaints for problems with sleeping while in hospital related to pain (Participant 17), especially the first night (Participant 26), and muscle spasms (Participant 20), snoring roommates (Participant 21) and an uncomfortable bed (Participant 30). Some participants slept quite well from the first night after surgery and seemed to take it in their stride. 'I had fairly decent night's sleep, very comfortable' (Participant 30).

On the other hand, participants that were not sleeping well or were out of their sleep routines reported the most problems from this disruption. 'Getting enough sleep and being able to sleep in the day is really important to me' (Participant 28) and 'I think the phrase was, distraught. I just basically said "I want to go home. I am not comfortable here. I am not sleeping. I want to go home" (Participant 30).

Following discharge and the subsequent recovery period at home, participants reported an increase in their ability to sleep well and that their overall fatigue was less. 'I can easily sleep at night it doesn't bother me now' (Participant 25) and 'it doesn't tire me out quite so much' (Participant 2).

3.7 Phase One Discussion

Throughout the interviews, the issues and topics raised by both hip and knee patients were very similar. Improvement in joint function and overall mobility have been reported and discussed in the literature (71). This was confirmed in the study with patients reporting progress in the early days following arthroplasty. Patients overall expressed a general feeling of heightened well-being in the postoperative period. This was particularly noted in the patients that had been symptomatic for an extended period of time. The surgery had brought a welcome relief from the debilitating pain and stiffness they had experienced previously.

As mentioned above, by the time the majority of arthroplasty patients reach the operating theatre doors, they will have dealt with increasing pain and decreasing mobility and function. This is particularly true for the TKA patient (145). In both the findings of this study and in prior PPI work, patients discussed pain in the context of both preoperative and postoperative experiences. Discussing postoperative pain in the PPI group, patients reported that it was something they knew how to deal with. This was mirrored in the study and patients felt they knew how to manage their pain. Previous work looking at reasons for delay in discharge and readmission following discharge in arthroplasty patients has identified pain as the most common factor (36).

Pain is a common postoperative complaint following arthroplasty, particularly of the knee (49, 146). It has also been recognised as a possible cause of confusion and disorientation in the immediate postoperative phase for the elderly (147). This study found patients dealing with surgical pain in combination with physiotherapy and the side effects of medications. This was a challenging combination for some, but not all. This is in agreement with both prior work (148) and current work (28).

Patients reported concern regarding having a regional anaesthetic (spinal, epidural or local block) for their surgery. These fears centred around two main areas: being awake or conscious during the procedure and not being able to move in the postoperative phase upon awakening in the recovery room. Some patients reported feelings of alarm at emerging from the anaesthetic. Previous studies have demonstrated that these feelings can be quite distressing for the patient in the perioperative phase (149-151).

A patient's prior experience impacted how they saw the current surgical setting. Respondents reported that familiarity with hospital routines helped to alleviate some of their worry. Again, in the PPI session, these findings were confirmed when patients explained that positive experiences, such as with previous joint replacement, positively influenced recovery in terms of knowing what to expect, and how to tackle challenges such as stairs. Some patients felt the whole experience of healthcare was a very positive one. Patients expressed feelings of being well cared for and given what they needed while hospitalised. A European study has shown that if a patient has positive, satisfying experience during their care, they are more likely to have a higher quality of recovery postoperatively (129).

Patient support networks and the feeling of being supported by both family and professional sources have been found to have an impact on patient recovery and outcomes (133). Study patients reported the need for increased connection with hospital professionals immediately following discharge. Patients liked knowing that they could speak to someone by telephone to talk through things instead of making a physical appointment. A Danish trial reported that patients felt more able to succeed and accomplish tasks through telephone follow up (134).

Patients reported needing help understanding their changing needs in order to make informed decisions during the early recovery period. This included changing medication needs, wound care and other transitions. This confirms previous work investigating the needs of patients and their partners following arthroplasty surgery (135). Preoperative education has been considered by some to be beneficial in the recovery process and timely discharge of patients following arthroplasty surgery (136). Certain literature contradicts this (54). However, from a patient perspective, they have reported increased feelings of confidence and trust in the surgical process through these programmes (152). This reinforces findings in the study that patients reported feeling more able and prepared to deal with things as they came along following attendance. It was also reported to be an enjoyable and uplifting process.

Patients reported using a range of psychological coping mechanisms throughout the perioperative phase. These included humour, not taking things too seriously and knowing that they were in the midst of a recovery process and that it would pass. Work by Moon and Backer (153) discusses the importance of self-efficacy in recovery. A patient's belief in their ability to cope and recover will have a direct impact on their actual recovery. This point was echoed in the study where a patient encouraged others to have faith in themselves and the process. Participants also reported that the use of physical aids, such as crutches, were often just mental crutches. They recognised that they were using it for the feeling of confidence it gave them as opposed to actually needing them for mobility. This has been previously reported in the literature (137). Rebuilding trust and confidence in a patient's own ability following arthroplasty takes time and is not just a physical issue.

Fatigue and sleep disruption in the postoperative period has been recognised over the years as detrimental to the recovery process of many types of surgery (154). Problems with sleep as a direct result of acute postoperative pain have been explored following lower limb

arthroplasty, with between 44-57% of knee patients and 21-52% of hip patients reporting pain on the first three postoperative days (155). This then returned to baseline levels by one week (156).

Patients reported being keen to return home so they would be able to have a good night's sleep. Patients reported disruption in sleeping patterns ranging from other patients snoring in their shared room, disruption from staff or equipment noise and postoperative pain. It has been reported that sleep disruption in the perioperative period following arthroplasty has long lasting effects on outcomes (157).

3.8 Strengths and Limitations

Validity and reliability are important issues to address in both qualitative and quantitative research (158). As such, acknowledging the potential for interviewer bias in this area of research is necessary. To minimise the risk of bias, the interviewer examined their own motivation prior to commencing the project. It is recognised that the prior experience and feelings of an interviewer with a clinical background may have a bias and some preconceived ideas regarding the subject matter.

Interviews in both phases were coded independently by two reviewers to ensure thorough coverage of the work and discussed. Member checking was also performed in both phases on an ongoing basis to confirm themes and ideas derived from the iterative analysis (159).

One of the strengths of this study is that patient involvement occurred at every step of its development and refinement. It is essential that from its beginnings, patients and their concerns are involved in development of a patient-reported measure. This includes defining the early surgical recovery concept with the PPI group, expert consultation and

patient interviews and identification of themes (83). In addition, qualitative guidelines for best practice and reporting were followed throughout (143, 144).

3.8.1 Planning Phase

The demographic distribution of participants was somewhat mixed. However, it is important to acknowledge that cultural differences may exist between other groups. As this study was carried out in the UK and in an NHS hospital, it may only be applicable in the NHS. The lack of open-ended questions is another limitation. In addition, all participants in the study were recruited from and employed by the same institution in the UK. This may be a limitation in terms of external validity.

3.8.2 Phase One

The demographic distribution of participants was very homogenous due to the local patient population presenting at the hospital. It is acknowledged that cultural differences may exist between other patient groups. The importance of culture and understanding of both participants and the interviewer in the qualitative process is recognised in this work (160).

Heterogeneity is recognised within the data itself. For example, the type of procedures patients received during Phase One, mostly consisted of THA and TKA. There were only two UKAs and one revision THA, which have the potential to skew findings. Care was taken to balance the number and types of procedures on both hips and knees. However, due to patients' medical conditions, willingness to participate and cancellations, this was not fully achieved. In addition, there was huge variation in both the time since surgery (0 to 63 days) and the duration of disease (a few months - 20 years) when the interviews were carried out. These were both considered and discussed during the study period.

As this study was carried out in the UK and in an NHS hospital, it may only be applicable in the NHS.

3.9 Summary

The chapter has discussed results from interviews undertaken to develop a PROM and change measure specifically for lower limb joint replacement, as this cohort of patients share similar characteristics and recovery profiles. Patient-identified issues can give vital insights into a patients' perspective through the perioperative experience. Understanding the issues that healthcare providers witness gives insight as to how best care for the patient.

Seven main themes evolved from the patient interviews: 'improving function and mobility', 'pain', 'effects of healthcare on outcomes', 'support from others', 'involvement and understanding of care decisions', 'behaviour and coping' and 'fatigue and sleeping'. In addition, three main themes evolved from the expert consultation: immediate patient recovery issues, discharge criteria, and priorities during hospitalisation from health care providers' perspectives.

With current trends in healthcare moving towards enhanced early recovery, this work shows key issues for the hip and knee patient directly from the front line. To be able to measure improvement and patient-reported change following arthroplasty could be of great benefit in clinical trials involving medication, care pathways and implant selection (161). It could also potentially work to optimise routine care by allowing provision of appropriate, safe, timely care and interventions.

To have specific patient-reported information regarding key areas of importance, such as function and mobility, pain, fatigue and sleep, is also recognised as essential to the PROM development process (162, 163). It gives awareness and understanding to this increasing patient group. This study has also served as a starting point in the development of questionnaires which may be used to assess interventions in the lower limb arthroplasty population.

The next chapter will report the process of item generation and pilot questionnaire development for both the PROM and health transition measure from the qualitative interview data.

4 Development of two pilot questionnaires

4.1 Introduction

Chapter 3 reported the methodology and findings of both the Planning Phase and Phase One interviews. As previously discussed, the gold standard for development of patient-reported outcome measures (PROMs) are the FDA guidelines (70). These provide a thorough outline by which new questionnaires should be developed. The interviews performed in both the Planning Phase and Phase One of this study adhere strictly to these guidelines. Item generation comes directly from patient statements and from the patient population the tools are being designed to serve. Throughout the entire process including item generation, selection of candidate items, wording changes and item reduction, a detailed item tracking matrix was maintained. This FDA compliant tool provides ease of identification in item modifications, direct patient sources, and a record of item deletions. This chapter will explain the process of candidate item development, selection and initial testing of the questions. This chapter will explain the process of candidate item development, selection and initial testing, including item response options, and choice of recall period.

4.2 Participants and Methods

4.2.1 Conceptual Framework

The development of a conceptual model or theoretical underpinning is essential when developing a new tool (164). This framework was developed from the qualitative work in both the Planning Phase and Phase One interview analyses. This provided a necessary framework around which the items and purpose of the questionnaire could be prepared. In the development of a PROM, or change measure, content validity is an essential

component, as it ensures that the constructs of the topic, in these aspects of recovery from joint replacement surgery, are covered by the measure (Table 4.1).

Table 4.1: Conceptual framework

Conceptual Framework	**Theme**	**Subtheme**
Recovery following lower limb arthroplasty	Pain	Swollen Pain at night Constant pain Feeling faint Feeling in general Comfort Joint pain Muscle spasms Pain killers
	Improving function and mobility	Difficulty getting into bed Not able to stand or walk Movement and mobility Going up and down stairs Strength
	Effects of healthcare on outcomes	Coping at home Appetite Mood Feeling sick or woozy Constipation Unwell Disorientated
	Fatigue and sleep	Feeling tired Not sleeping well Difficulty sleeping Not sleeping due to pain Energy level Feeling overall
	Support from others	Family Friends Worry Preoperative hip school After discharge
	Involvement in/understanding of care decisions	Knowing enough to make decisions Anaesthetic Giving you what they think you need
	Behaviour/ coping	Putting up with it Knowing my capabilities Listening to what you are being told Having faith in care providers Physical crutches Mental crutches

By utilising both patient data and an expert group of healthcare providers, this not only strengthened the robustness of the tool, but also ensured that it would make sense in the clinical setting in which it would be used. Whilst expert opinion aided the development of the semi-structured interview schedule, the items were generated solely on the basis of patient reports in Phase One of the study. Existing literature in the field was also consulted to reinforce the model.

4.2.2 Item Generation

As discussed in Chapter 3, exploratory, in-depth interviews were performed with orthopaedic, healthcare professionals (n=22) in the Planning Phase and with perioperative arthroplasty patients (n=30) in Phase One. Following thematic analysis and coding of qualitative interviews, a list of potential sample items were created for each theme.

These interviews were then analysed using a pragmatic thematic analysis technique and themes identified. The patient interviews provided statements for potential inclusion as items in the pilot questionnaires. Initially 136 statements were drafted for consideration (Appendix 1: Phase One draft statements).

These statements included items from all patient interviews and all themes from the Phase One analyses. These were reviewed by the expert and patient panel which included two surgeons, two nurses, an anaesthetist, two hip and knee arthroplasty patients, a psychometrician with a particular interest in patient related outcomes, and one patient caregiver. The purpose of this panel was to review and evaluate potential items. In addition, ideas and suggestions for layout and response options were also discussed. These draft statements were approved and constituted the measures to be evaluated in Phase Two. From this list of patient statements, between six and 12 were chosen by the panel for each thematic

area. These covered recovery topics in full and were intended to be sensitive to changes following surgery.

By discussion and exploration of the draft statements, it was determined that the items would be separated into two patient-reported questionnaires: one PROM and one change measure. Therefore the Oxford Arthroplasty Early Recovery Score (OARS) (Appendix 2: Pilot version OARS) and Oxford Arthroplasty Early Change Score (OACS) (Appendix 3: Pilot version OACS) were developed. Healthcare professionals stated that these could be of great use in the clinical area. Patients had expressed interest in seeing how things had changed, and hopefully improved, since surgery.

An item tracking matrix was used to record reasons for items being added, removed or changed throughout (70). The OARS and OACS evolved through multiple iterations prior to their completion for use in Phase Two. Careful consideration was given throughout to both the items themselves and to the answer response options. The wording rubric and instructions for completion also developed and improved through this process (Appendix 4: Evolution of questionnaires). Some themes were removed from the item selection pool because they related more to experiences than recovery and quality of life. Future work may incorporate an experiences questionnaire, but that was out with the scope of this thesis. Professional interviews were used only to guide the structure and format of these draft questionnaires (123). The items and wording came directly from patients themselves.

For the items being developed for testing in Phase Two, it was important that questions reflect how items have improved or changed as a result of the surgery. Careful consideration of question types and response options including ‘yes/ no’ versus frequency response categories (107) with multiple answer agreements were explored. These multiple answers allow patients to state to what extent they agree or disagree with a statement (107).

Previous research has indicated that responses to items can be influenced by place of completion (165). Significant attempts were made to keep responses as consistent as possible by avoiding phrasing of questions where place of completion could affect the answers.

4.2.3 Oxford Arthroplasty Early Recovery Score (OARS)

The first iteration of the OARS contained 18 items (Appendix 2: Pilot version OARS). The items in this PROM covered all aspects of the early recovery period. The items covered all the themes reported by patients (Table 4.2).

Table 4.2: Pilot OARS items and themes breakdowns

Phase Two OARS Item	**Theme**	**Participant ID**
1. I have felt unwell	Effects of healthcare on outcomes	2, 11
2. I have felt disorientated	Effects of healthcare on outcomes	11, 18
3. I have felt tired	Fatigue and sleep	14
4. I have felt faint	Pain	18
5. It has been quite painful	Pain	3, 11, 13, 25
6. I have had constant pain	Pain	13
7. I have worse pain at night	Pain	13
8. It has felt swollen	Pain	10, 13, 26
9. I have difficulty getting into bed	Improving function and mobility	8
10. I am not able to stand	Improving function and mobility	11
11. I am not able to walk	Improving function and mobility	11
12. I have not slept well	Fatigue and sleep	18, 26
Which question 13a or 13b do you prefer? 13a. I have found it quite hard to sleep or 13b. I have found it difficult to sleep	Fatigue and sleep	6, 21
14. I have not been able to sleep due to the pain	Fatigue and sleep	30
15. I have felt sick	Effects of healthcare on outcomes	2, 4, 11, 13, 17, 18, 20, 21, 23, 24, 26
16. I have felt woozy	Effects of healthcare on outcomes	4
17. I have been constipated	Effects of healthcare on outcomes	13, 23, 24
18. I have lost my appetite	Effects of healthcare on outcomes	2, 24, 25

4.2.4 Oxford Arthroplasty Early Change Score (OACS)

The first iteration of the OACS contained 25 items. (Appendix 3: Pilot version OACS). This change measure included items designed to cover the concepts of early recovery and the change that may occur during the first six weeks. The items covered all themes reported by patients (Table 4.3).

Table 4.3: Pilot OACS items and themes breakdowns

Phase Two OACS Item	**Theme**	**Participant ID**
1. Your ability to stand compared to prior to the operation?	Improving function and mobility	11
2. Your ability to move compared to prior to the operation?	Improving function and mobility	1, 3, 8, 16
3. Your movement compared to prior to the operation?	Improving function and mobility	7, 19, 30
4. Your mobility compared to prior to the operation?	Improving function and mobility	13
5. Your ability to walk compared to prior to the operation?	Improving function and mobility	3, 15, 16, 27
6. Your ability to go upstairs compared to prior to the operation?	Improving function and mobility	1, 5, 7, 17, 22, 27, 28
7. Your ability to go down stairs compared to prior to the operation?	Improving function and mobility	1, 5, 7, 17, 22, 27, 28
8. Your strength compared to prior to the operation?	Improving function and mobility	20, 30
9. Your pain compared to prior to the operation?	Pain	2, 5, 6, 9, 12, 13, 14, 15, 18, 19, 20, 21, 23, 24, 29, 30
10. How you feel today as compared to prior to the operation?	Pain	9, 10, 25, 27
11. How comfortable you feel today compared to prior to the operation?	Pain	7, 10, 30
12. Your pain when walking as compared to prior to the operation?	Pain	2, 5, 6, 8, 9, 12, 13, 14, 15, 17, 18, 19, 20, 21, 23, 24, 29, 30
13. Your pain in the joint today compared to prior to the operation?	Pain	18, 30
14. Your pain at night compared to prior to the operation?	Pain	20
15. Your pain when getting into bed compared to prior to the operation?	Pain	8
16. Your muscle spasms compared to prior to the operation?	Pain	20
17. The amount of pain killers you need to take as compared to prior to the operation?	Pain	29
18. Your ability to cope at home compared to prior to the operation?	Effects of healthcare on outcomes	21
19. Your appetite as compared to prior to the operation?	Effects of healthcare on outcomes	24, 25
20. Your mood compared to prior to the operation?	Effects of healthcare on outcomes	7, 18, 30
21. Your energy level compared to prior to the operation?	Fatigue and sleep	2
22. Your sleep as compared to prior to the operation?	Fatigue and sleep	2, 17, 21, 25, 26, 28, 30
23. How you feel overall compared to prior to the operation?	Fatigue and sleep	9, 11, 17, 19
24. Your pain when trying to sleep compared to prior to the operation?	Fatigue and sleep	17
25. Your ability to sleep through the night compared to prior to the operation?	Fatigue and sleep	30

4.3 Phase Two

4.3.1 Assessment of candidate items

Questionnaires were created using candidate items, each with five point response options. This scale allows respondents to express how much they agree or disagree with each statement (166). Patients were requested to complete the questionnaire in the context of cognitive debriefing. These techniques allow the interviewer to determine the meaning a participant gives to questions and why they selected particular response options (70, 167). All participants received both the OARS and OACS at the time of testing. These draft questionnaires were administered once to 34 patients in the early postoperative period during hospitalisation (days 0 to 8). (Table 4.4).

Table 4.4: Phase Two Participant Characteristics

Parameter	
Age (years)	67 (11.3) 50-81
Sex Male/Female (% male)	16/18 (47)
Ethnicity	WB 32 (94.1) OW 2 (5.9)
Duration of disease (years)	4.4 (4.2) 0.5-30
Time since surgery (days)	3.15 (2.83) 0-8
Type of surgery	THA 9 (26) TKA 9 (26) UKA 12 (35) Rev. THA 1 (3) Rev. TKA 3 (9)
Employment	Employed 16 (47) Retired 18 (53)
Living situation	Alone 8 (24) Family 26 (76)
Home situation	One level 6 (18) Up and down stairs 28 (82)

Data are n (%) or mean (SD) range. Ethnicity: WB= White British; OW= Other White. Ethnicity categories from Office for National Statistics (ONS), Census 2011. Type of surgery: THA= Total Hip Arthroplasty; TKA= Total Knee Arthroplasty; UKA= Unicompartmental Knee Arthroplasty; Rev. THA= Revision Total Hip Arthroplasty; Rev. TKA=Revision Total Knee Arthroplasty.

4.4 Methods and participants

The participants were recruited from the same orthopaedic hospital as the previous two phases. As with the prior phases of the study, patients were recruited from the hospital pre-assessment clinic as they were being seen prior to hip or knee replacement surgeries. Following recruitment and giving written informed consent, participants answered the newly created OARS and OACS questionnaires once postoperatively during their hospital stay. The participants were then asked to discuss the items, the reason for their answers and the meaning they attributed to them. During these interviews, participants were asked to discuss how thorough they felt coverage was of the topic of recovery after TKA or THA.

In addition, they were asked if the questions were easily understandable and if they were relevant to their particular situation. These interviews were audio recorded and transcribed verbatim. Completion of the questionnaires and the following interview took no more than 30 minutes in combination (10-15 minutes questionnaire and 10-15 minutes interview). This led to the first version of test questionnaires being developed that were refined in the following phases. Phase Two took three months to complete. The testing and interviews conducted in Phase Two were carried out in April and May 2017.

4.5 Results

A total of 34 participants were included in the study: 18 women (53%) and 16 men (47%) (Table 4.4). The mean age of participants was 67 years (SD=11.3; range 50-81). The surgeries within the sample consisted of THA (n=9), TKA (n=9), UKA (n=12), Rev. THA (n=1) and Rev. TKA (n= 3). Ethnicities of the group were predominantly White British 32 (94%) but also included Other White 2 (6%). The duration of disease ranged from 0.5 years to 30 years (mean=4.4; SD=4.2). Within the group, 16 were currently employed (47%) and

the majority, 18, were retired (53%). 26 (76%) participants lived with family and 8 (24%) lived alone. Six participants (18%) lived on one level and 28 (82%) had stairs.

4.5.1 Interviews and candidate item refinement

Cognitive debrief interviews (n=34) were used to assess items for face and content validity. Some patients felt that it was too early to ask them on the day of surgery to complete it. Timing is discussed later in this chapter.

4.5.2 Oxford Arthroplasty Early Recovery Score (OARS)

Overall patients liked the questions and layout of the OARS.

> 'It was easy to fill in and they are all questions that are relevant' (Participant 6).

> 'That was OK yeah, quite straightforward yeah' (Participant 19).

When asked if the questions made sense or if any were confusing, patients again appeared to be happy with the content and wording.

> 'They all made sense yeah' (Participant 22).

> 'I found that one quite easy, yeah that was quite easy. No, they were OK them ones (Participant 23).

> 'They were dead easy and straight forward' (Participant 30).

> 'They were OK yeah, no they're fine' (Participant 34).

Patients were asked if there were any additional questions they would like to have been asked or if they felt anything had been omitted.

> 'I might on reflection think of something else but at the moment I would have said that, that was fine' (Participant 11).

Also item 13 contained two answer options as both had been expressed by patients. Patients had a preference for 13b so that was selected for inclusion in the Phase Three OARS (Table 4.5).

Table 4.5: OARS Item 13 Option

Which question 13a or 13b do you prefer?	
13a. I have found it quite hard to sleep or 13b. I have found it difficult to sleep	Option A-12; Option B-19; Either/or-3.

4.5.3 Oxford Arthroplasty Early Change Score (OACS)

The majority of patients found the OACS straightforward and easy to use.

> 'Oh simple, yeah, simple to answer and understand' (Participant 2).

> 'I think you have covered it all haven't you' (Participant 3).

> 'I am quite enjoying it really' (Participant 5).

> 'Certainly it is quite clear that erm, I am at a very early stage of recovery in terms of being able to stand, walk etc.' (Participant 7).

Patients were asked if there were any additional questions they would like to have been asked or if they felt anything had been omitted.

> 'I think it covered most bases. The questions themselves were good questions, yes' (Participant 8).

> 'I think that's relevant' (Participant 11).

'I don't think there was anything (missing). I think you pretty well covered everything. No I don't think so' (Participant 15).

Some patients found the use of the word 'prior' in the rubric confusing (Participant 23, Participant 28). This was discussed with other patients and the expert group and changed to 'before'.

Following feedback from participants in Phase Two, four items were removed from the OACS (Table 4.6).

Table 4.6: OACS Phase Two removed items

Phase Two OACS Items Removed	Reason for removal
3. Your movement compared to prior to the operation?	Duplicate item
9. Your pain compared to prior to the operation?	Disliked by patients as seen as too similar to other questions
10. How you feel today as compared to prior to the operation?	Disliked by patients as seen as too similar to other questions
17. The amount of pain killers you need to take as compared to prior to the operation?	Too ambiguous per patients

4.5.4 Timing of administration

Considerable thought was given to the timing for administration of the tests. Initially daily testing for the first fortnight with subsequent testing at six weeks was considered. When asked about potential testing times, healthcare professionals had confirmed that testing through six weeks, when patients are routinely discharged from follow-up care would make sense clinically. Patients too had some useful ideas regarding this schedule. Testing on day 0, the day of surgery, was seen as just too early, with day one making more sense.

> ‘Too early as day zero. In fact I am just sorry I can’t fill in more because I haven’t really had any of the experiences yet like sleeping, getting out of bed and so on. I’d have more to tell you I’d have probably been out of bed and had a chance to sleep yeah. Can’t say how much pain I am getting when I am sleeping because I haven’t had a chance. Tomorrow I will probably have a better idea, better ability to fill them in.’ (Participant 12).

> ‘I would have felt different on day two.’ (Participant 30).

Day three testing just before discharge would be both pragmatic and clinically based in terms of testing. It is the typical day of discharge (within 24 hours of discharge) and clinically demonstrates that the doctors feel they are physically ready for discharge.

> ‘Fill it in on day three maybe?’(Participant 6).

> ‘It’s just interesting for me to be able to reflect in terms of where I am at.’ (Participant 7).

> ‘Maybe at one week and a week later when I am home.’ (Participant 3).

> ‘It’s going to be six weeks and then, after six weeks if all goes well, you are going to have answers down there saying, you know, I agree, or you know, yes, the response was good after six weeks, you know.’ (Participant 27).

After discussion with patients and with the expert group, it was determined that testing for the subsequent phases would be on days 1, 2, 3, 7, 14 and at six weeks. This was thought to maximise information gleaned from the testing time period but also to minimise the patient burden by reducing the number of administrations during the first fortnight from 15 to five.

It was hypothesised that the first few days following surgery were of importance to both patients and clinicians. As previously discussed, pain management is of vital importance during this time. A change was expected to be seen between weeks one and two and therefore these testing points were thought to be significant. In addition, patients are seen in the discharge clinic at around six weeks and therefore this would make sense clinically and if any problems were detected, the patient could be seen. Six weeks is also the time when many patients are permitted to resume activities such as driving, so it was anticipated that another measurable change might be observed if testing at this time point.

4.6 Discussion

The process of item generation and questionnaire development is complex and iterative (70). From the vital information derived in the qualitative interviews in both the Planning Phase and Phase One, first-hand patient reported issues and ideas were derived. Being able to effectively convey and represent the challenges and growth experienced by the arthroplasty hip and knee arthroplasty patient population was at the very centre of this task.

Patients in the midst of an experience of immediate postoperative issues were able to elicit direct responses to the pilot items in the PROM and change measure during their orthopaedic hospital stay. These ideas were confirmed by the expert panel of healthcare professionals. The opinions from patients on the timing, wording of items and the answer options, provided essential feedback which shaped the next version of both the OARS and OACS questionnaires for testing and validation in the subsequent phases.

As patients were only administered the questionnaires once during this phase, they were keen to test the OARS and OACS at different time points and see if they would answer differently. This response was positive as the measures will be tested and validated over different time points during the recovery period in the next phases.

4.7 Strengths and Limitations

This study was carried out in an NHS hospital in England, UK and as such may not be generalisable outside of the NHS. In addition, as the study was performed in one location in the UK, it may not be transferable to the rest of the country, and indeed abroad.

The demographic distribution of participants was very limited with the majority being white British (94%) and the remainder, other white (6%). The lack of diversity among the participant group in Phase Two was acknowledged and discussed by the expert and patient panel during the study.

Heterogeneity of the participant population has already been discussed within this thesis. However, it is important to note that participant demographics of patients presenting at the hospital for treatment is not representative of the local area demographics, where, in the most recent population census. around 64% were found to be white British, 14% were white non-British and 22% of the population black or minority ethnic groups (168). The largest non-white ethnicities within the local population were found by census to be Pakistani, Indian, Black African, 'other Asian' and Chinese ethnic groups.

Challenges are known to exist related to healthcare seeking behaviours of different cultures with beliefs regarding diseases, being long recognised as culturally specific (169). For example, beliefs around activity and its importance are known to be influenced at an early age during childhood, with Asian children being less active than their white counterparts (170). Similarly, physical activity above the normal levels required for daily housework and chores, has been described as not being of benefit to health and perhaps even ‘selfish’ of the individual to consider (171). Asians within the UK have been found to take health advice more from advisors within their peer group than by seeking healthcare professionals advice (171). This may in part explain some of the disparities in participant demographics.

The Department of Health (DoH) in the UK acknowledged the differing needs of joint replacement patients across the country and that there may indeed be inconsistencies in the delivery and allocation of joint replacement, regardless of disease severity, based on socio-economic factors (172). It has also been reported that people in deprived areas anticipated that they would have negative experiences and potentially worse outcomes following joint replacement than those in more affluent areas with a feeling of being blamed for their condition based on lifestyle choices, such as smoking and diet (173).

Amongst black joint replacement patients, a research group in New York has found that less patients initially seek out hip replacement than their white counterparts and are less satisfied postoperatively with their results (174). In addition, they found a slightly higher risk of revision following knee replacement (175) and poorer outcomes than their white counterparts (176). When looking at the effects of deprivation and poverty on pain and postoperative patient outcomes, they reported that university education was found to improve outcomes for patients living in poorer areas (176). Interestingly, the study found that education was not found to have any impact on the outcomes of patients living in wealthier areas.

It has also been reported that ethnic minorities are underrepresented in not only orthopaedic research and clinical trials (177), but in healthcare research in general (178). This underrepresentation is not believed to be due to a lack of willingness to participate, as research has demonstrated that minorities are as inclined as non-ethnic groups to be involved in research (179).

4.8 Summary

The iterative method of questionnaire development used provided the items and structure required for creation and evolution of the pilot questionnaires. This chapter has reported

and discussed the process of item generation, questionnaire development and refinement of the initial OARS and OACS questionnaires. Both measures were registered with Oxford University Innovation (OUI) (Oxford, England, UK). This subsidiary company of the University manages all technology transfers for the University including a number of previously developed PROMs. Chapter 5 will now report testing of the questionnaires and item reduction using exploratory factor analysis and principal component analysis.

5 Final questionnaire development and translatability assessment

5.1 Introduction

The previous chapters have discussed the development and initial testing of two questionnaires, the Oxford Arthroplasty Early Recovery Score (OARS) and Oxford Arthroplasty Early Change Score (OACS), for use in the early recovery period following joint replacement surgery. This chapter reports on the testing of these measures and reports results gained from them. Translatability assessment of both the OARS and OACS is reported and discussed. Data reduction, item selection and identification of domains are detailed. The testing and findings from the subsequent Phase Two of the study is also described.

5.1.1 Translatability Assessment

Prior to testing, a translatability assessment (TA) was performed on the two measures (Appendix 5: Translatability Assessment). TA has been recognised as an important part of the questionnaire development process (70). It provides meaningful insight into what extent the items in the questionnaires can be translated into other languages and be easily understood. It is undertaken to ensure the questionnaire can be translated into other languages and does not contain items containing words or phrases that are peculiar to the original (English) version. It can also provide useful information to avoid problems at a later stage when the measure is translated into other languages (180).

The FDA 2009 guidance recommends this be carried out for all outcome measures that are likely to be used internationally (70). This guidance has been developed from a previous draft (181). A concept elaboration document (CED) is initially created to fully define and

clarify question items and the meanings attributed to them (Appendix 6: Concept Elaboration Document). Developed in combination with the author (182) and specialist translators, this CED provides specific detail regarding the explicit line-by-line meaning of items and concepts. It can avoid potential future problems in further translations by providing clarification of each line of the questionnaire (183). The CED also helps ensure that all translators understand the questions and meaning prior to any translations being performed.

Linguistic consensus meetings and TA were then carried out prior to testing of the final questionnaire. TA was outsourced to a professional provider (Clayson Linguistic Validation Services Ltd, Northampton, England, UK) as it requires established contacts across a number of cultures so that the questionnaire can be tested internationally. This process would be challenging to coordinate independently. TA is considered to be of value in PROM design (70) and has been utilised in the development of other questionnaires (123). The review and assessment were carried out for the following languages: Afrikaans (South Africa), French (France), German (Germany), Hebrew (184), Hindi (India), Russian (Russia), Simplified Chinese (China) and Spanish (Argentina). The assumption in creating these questionnaires is that they will be used globally. As only a finite number of countries, usually between six and ten can be chosen for TA, eight countries were selected with guidance from the translator. They were chosen to provide as wide a cross section of languages as possible and to provide maximum variation.

5.1.2 Data reduction, item selection and identification of domains

Factor analysis was used to explore the dataset and determine what latent underlying constructs are being measured. Factor analysis is a series of statistical procedures used to reduce the number of items and to determine correlations between related variables within

a dataset (113). Factor analysis can reduce the number of variables in a questionnaire or item pool and indicate potential relationships between these variables (185). A statistical solution acts as a guide in the interpretation of the questionnaire structure and examines the underlying latent variables. In addition being able to understand and interpret the results is of particular significance in the clinical setting where decisions directly affecting patient care may be based on these results. Therefore, the clinical setting and statistical results can come together to give a more complete picture, for example, pain or surgical recovery (186).

5.2 Participants and Methods

5.2.1 Phase Three

The two questionnaires, OARS and OACS, were distributed to consecutive patients in a cohort of hip and knee replacement patients. They were administered on days 1, 2, 3, 7 and 14 in the early postoperative period and also at six weeks following surgery.

In participants who were discharged prior to day three, questionnaires with stamped self-addressed envelopes were provided. During development of the study protocol and ethics application, approval to contact participants for follow-up with a reminder was obtained. Participants were asked if and how they would like to be contacted should a reminder be required. Additionally, participants were asked how they preferred to be contacted by telephone, email or post. Reminders have been shown to increase completion of follow-up responses (187, 188).

As discussed in Chapter 4, the specific testing time points were chosen to maximise the information acquired from participants and also to provide thorough coverage of the early recovery period. It was initially decided to administer the questionnaires daily for the first

two weeks following surgery starting on the day of surgery, day 0 and again at 6 weeks. After speaking to patients, it was determined that day 0 was too early.

> 'I am just sorry I can't fill in more because I haven't really had any of the experiences yet like sleeping, getting out of bed and so on. Tomorrow I will probably have a better idea, better ability to fill them in' (Participant 12).

Based on the experience of both PPI participants and clinical advisors, it was assumed, and anticipated, that there would be changes within the first three days following surgery.

> 'I would have felt different on day two.'(Participant 30).

> 'Fill it in on day three maybe?' (Participant 6).

After that, change would possibly be seen at day seven, with another significant change by day 14.

> 'Maybe at 1 week and a week later when I am home?' (Participant 3).

As previously discussed in Chapter 4, testing at six weeks was seen a useful measurement time as patients are due to return for their postoperative discharge clinic appointment at around that time. Clinicians when interviewed, felt that would be useful as if there were any problems or concerns, the patient would be due in follow up anyway at around that time point and could be seen. In addition, patients themselves expected improvement around the six week mark and so felt that testing at that stage would be worthwhile.

> 'It's going to be six weeks.' (Participant 27).

Particular care and attention was given to the timing to ensure that participant burden was minimised. Initial daily questionnaire administration for the first fortnight was considered prior to study commencement. In discussion regarding minimising patient burden with PPI representatives and clinical advisors, the reduced testing time points were determined to be

equally as effective. As with the prior phases of the study, patients were recruited from the hospital pre-assessment clinic as they were being seen prior to hip or knee replacement surgeries. Phase Three took six months to complete.

5.2.2 Statistical Analysis

The plan for statistical analysis was decided upon prior to study commencement and during the time of protocol writing. The following analysis plan was executed:

- Kaiser-Meyer-Olkin Measure of Sampling Adequacy (KMO) and Bartlett's Test of Sphericity tests were performed to determine if the data was appropriate for factor analysis.
- Frequency tables were created and examined for floor and ceiling effects.
- An initial principal component analysis (PCA) was undertaken to determine if any of the items were not suitable for analysis or outliers.
- Descriptive statistics and frequency tables reported.
- Exploratory factor analysis (EFA) was carried out on the most populous time point to determine what constructs underlie the data and to determine redundancy in any of the items.
- PCA with Varimax rotation was performed on days one, seven, fourteen and at six weeks. PCA is utilised to reduce the data into a smaller number of components. Varimax rotation was selected as it facilitates data pattern interpretation.
- Item reduction reported.
- Internal consistency reported.

SPSS 25 was used for all analyses (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.).

5.2.3 Item reduction

Classic psychometric theory is widely acknowledged and accepted as a method to reveal underlying dimensions in an exploratory way within a dataset. It relates to the theory and technique of psychological measurement (185). Traditional psychometrics includes exploratory factor analysis. This process involves analysing items in a group and determining how they relate to each other within the group and which dimensions or factors they fall into. This is known as 'loading'. Correlation values are observed and ranked according to value (189). In a sample size of 150, a value of 0.45 is an acceptable cut off (189). Thresholds vary among researchers and many psychometricians consider 0.5 to be a valid loading. In this group, those with stronger factor correlations (above 0.5) are considered to have loaded on those factors. The weaker, or non-loading, items can then be considered for removal. This process is known as item reduction. After each item is removed, it is important to reanalyse the remaining items and factors to determine if any changes in pattern or factor loadings occurred as a result of the reduction. If a similar pattern in items and loadings remains, then further analysis and item removal can take place using an iterative approach.

5.2.4 Exploratory Factor Analysis

Exploratory factor analysis (EFA) is used in part to determine construct validity of the items in a questionnaire (190). It is recommended that EFA be performed on a dataset to explore underlying variables. Items that have significant floor/ceiling effects, high non-response levels or do not show internal consistency can be identified and removed prior to further testing. Prior to performing EFA, Kaiser-Meyer-Olkin Measure of Sampling Adequacy (KMO) and Bartlett's Test of Sphericity tests were performed. These important tests determine the suitability of the dataset for factor analysis (191, 192). The KMO statistic examines sampling adequacy within each variable and as an overall whole with a

result of 0.8-1 being acceptable. Bartlett's test inspects correlations and relationships within variables to ascertain the usefulness of factor analysis within the dataset with a value of less than .05. Principal Component Analysis (PCA) is used in combination with EFA to extract and define factors within the data set (193). This process sorts variables into factors and indexes the amount of variance from each. This number is called the eigenvalue and values above one are considered statistically significant and meaningful (185).

5.2.5 Internal consistency

Internal consistency is a measurement of reliability and reflects the correlations on a test (190). The alpha statistic, known as Cronbach's alpha, indicates the extent to which there is a pattern of responses to items. It is a commonly used statistical test for this purpose (194), with scores above 0.7 considered acceptable. Scores in the region of 0.9 – 1 may suggest item redundancy if the measure is designed for use at the group level. However, such high scores may be desirable for questionnaires which may be used at the level of the individual.

5.2.6 Content Validity

Content validity explores and evaluates how well items on a questionnaire address all aspects of the topic they assert to cover (195). Both the OARS and OACS have been developed with strong indicators for content validity. In speaking with both patients and orthopaedic healthcare professionals throughout the entire development process, it has been of utmost importance that the questions fully cover and represent the domain they purport to assess (196). Reviewing items with both stakeholder groups, patients and clinicians, and keeping detailed records of changes and revisions to the pilot questionnaires, provides confidence in their content validity (197). Another important aspect of content validation is the relevance of the items to the domains being measured (198). As previously

reported in Chapter 4, in depth records including an item tracking matrix, have been kept through the entire development and testing processes. These are not only useful tools for the creators of PROMs and other healthcare measures, but an essential part of a 'gold-standard' design process and a requirement by the FDA (70).

5.2.7 Sample size calculations/considerations

There are many differing approaches when calculating sample sizes required for research, with larger sample sizes often considered desirable (199). There is no consensus as to how sample sizes for the development of questionnaires should be calculated. That said, sample sizes based on five to ten times the number of respondents as items are often quoted (200, 201). The OARS and OACS questionnaires being tested in Phase Three contain 18 and 21 items respectively, so it was determined that a sample size of between 105 and 210 participants would be sufficient for this phase of testing. As this study is pragmatic in nature, recruitment deadlines were considered during the expert consultation meetings and a cut off time determined.

5.3 Results

5.3.1 Translatability assessment

The translatability assessment (TA) and concept elaboration documents (CED) (Appendices 5 and 6 respectively) brought some interesting insight from the following countries language experts: Afrikaans (South Africa), French (France), German (Germany), Hebrew (184), Hindi (India), Russian (Russia), Simplified Chinese (China) and Spanish (Argentina). As previously mentioned, these languages were chosen to provide as wide a variety of different languages as possible.

Initial comments regarding translation of the questionnaire names were discussed. The OARS and OACS did not always translate fully into all languages. The initial answering instruction rubric at the top of the OACS questionnaire was changed from the colloquial use of the word 'things' to 'the following'. Answer option orientation and layout was also changed during this process. The answer options had been slanted across the top of the OARS and OACS at an angle. Through the TA, the importance of switching to horizontal answer options was explained. Some of the more intricate languages and font styles, such as Indian or Asian scripts, become more difficult to read at an angle. In addition, some languages, such as Hebrew or Arabic, are read from right to left and the addition of being on the diagonal would make it more complicated for the end user. Finally, as the OARS and OACS may eventually be used for electronic administration, the system of delivery electronic patient reported outcomes, (202), requires a horizontal layout for many electronic devices.

Some concerns were raised regarding the tense of the specific items within the OARS questionnaire. In particular, the present perfect tense does not exist within the Afrikaans language. Also, in Argentine Spanish, the translators felt a simple past tense had a more natural feel. It was therefore decided that should translation into present perfect tense not be possible for a particular language, the simple past tense could be substituted.

Within the OARS questionnaire, Item 2 (I've felt disorientated) and item 16 (I've felt woozy) were both brought up as possible challenging items for translation. By performing both the TA and CED, allowed for discussion between the developer and language experts to allow substitutions within the questionnaire for language specific concerns, while maintaining the meaning and understanding of the questions. Some issues were raised regarding items of a similar nature (mobility or pain). These were discussed and it was determined that items may be removed following further patient input and analyses.

5.3.2 Participants

A total of 168 participants were included in the study: 97 women (58%) and 71 men (42%) (Table 5.1).

Table 5.1: Phase Three Participant Characteristics

Parameter	
Age (years)	66.1 (9.9) 38-87
Sex Male/Female (% male)	71/97 (42)
Ethnicity	WB 157 (93.5) OW 7 (4.2) WI 2 (1.2) A 1 (0.6) OA 1 (0.6)
Duration of disease (years)	6.2 (6.8) 0.5-43
Length of stay (days)	2.3 (2.5) 0-15
Type of surgery	THA 70 (41.7) TKA 26 (15.5) UKA 54 (32.1) PFJ 2 (1.2) Rev. THA 7 (4.2) Rev. UKA/TKA 9 (5.4)
Employment	Employed 67 (39.9) Retired 91 (54.2) Disabled 10 (5.9)
Living situation	Alone 41 (24.4) Family 127 (75.6)
Home situation	One level 37 (22) Up and down stairs 131 (78)

Data are n (%) or mean (SD) range. Ethnicity: WB= White British; OW= Other White; WI= White Irish; A=African; OA= Other Asian. Ethnicity categories from Office for National Statistics (ONS), Census 2011. Type of surgery: THA= Total Hip Arthroplasty; TKA= Total Knee Arthroplasty; UKA= Unicompartmental Knee Arthroplasty; PFJ=Patellofemoral Joint Replacement; Rev. THA= Revision Total Hip Arthroplasty; Rev. UKA/ TKA=Revision Unicompartmental Knee Arthroplasty/Total Knee Arthroplasty.

All respondents completed both OARS and OACS. The mean age of participants was 66.1 years (SD=9.9; range 38-87). The surgical interventions within the sample consisted of total hip arthroplasty (THA) (n=70), total knee arthroplasty (TKA) (n=26), unicompartmental knee arthroplasty (UKA) (n=54), patellofemoral joint arthroplasty (PFJ) (n=2), revision total hip arthroplasty (Rev. THA) (n=7) and revision unicompartmental/total knee arthroplasty (Rev. UKA/TKA) (n= 9). Ethnicities of the group were predominantly White British 157 (93.5%) but also included Other White 7 (4.2%), White Irish 2 (1.2%), Asian 1 (0.6%) and Other Asian 1 (Filipino) (0.6%). Mean length of hospital stay for participants was 2.3 days (SD=2.5; range 0-15). The duration of disease ranged from 0.5 years to 43 years (mean=6.2; SD=6.8). Within the group, 67 were currently employed (39.9%), 91 were retired (54.2%) and 10 were unable to work due to health conditions (5.9%). 127 (75.6%) participants lived with family and 41 (24.4%) lived alone. 37 (22%) participants lived on one level and 131 (78%) had stairs.

5.3.3 Data reduction, item selection and identification of domains

Before principle component analysis (PCA) was performed, KMO and Bartlett's test of sphericity were performed to determine the suitability of the data for factor analysis. These appeared favourable for both the OARS and OACS with KMO .835 and .936 respectively and Bartlett's test of significance .001 (Tables 5.2 and 5.3). Consequently the data from both measures appeared amenable to factor analytic techniques.

Table 5.2: OARS Kaiser-Meyer-Olkin Measure of Sampling Adequacy (KMO) and Bartlett's Test of Sphericity tests

KMO and Bartlett's Test		
Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.835
Bartlett's Test of Sphericity	Approx. Chi-Square	1486.258
	df	153
	Sig.	.001

Table 5.3: OACS Kaiser-Meyer-Olkin Measure of Sampling Adequacy (KMO) and Bartlett's Test of Sphericity tests

KMO and Bartlett's Test		
Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.936
Bartlett's Test of Sphericity	Approx. Chi-Square	3013.278
	df	210
	Sig.	.001

EFA evaluates the scale properties and aids in removing items that have a significant ceiling effect, non-response level or are not internally consistent (203, 204). EFA was performed on the most populous time point (day 1 testing) for both the 18-item OARS and 21-item OACS questionnaires. Out of 168 participants, 161 returned their questionnaires at time point one (day 1 postoperatively) (missing n=7, 4.2%).

In addition, correlation matrices were created to confirm the appropriateness of the data for analysis. Matrices displaying multiple correlations greater than 0.3 are considered suitable for factor analysis (204), with both questionnaires demonstrating appropriateness. Frequencies and frequency tables were created for both questionnaires. The results were examined for floor and ceiling effects. These are considered when answers elicit an extreme (either best or worst answer) response percentage of 40% or more for an item (190). Missing values were recorded in SPSS as '999'.

5.3.3.1 Oxford Arthroplasty Early Recovery Score (OARS)

Frequency tables were created and examined for floor and ceiling effects (known jointly as 'end effects'). End effects were found on item five 'it's been painful in the affected area' (n= 46.6%) (Table 5.4 OARS item five frequency table).

Table 5.4: OARS Item Five frequency table

It's been painful in the affected area					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Strongly disagree	75	44.6	46.6	46.6
	Disagree	59	35.1	36.6	83.2
	Neither agree nor disagree	7	4.2	4.3	87.6
	Agree	9	5.4	5.6	93.2
	Strongly agree	11	6.5	6.8	100.0
	Total	161	95.8	100.0	
Missing	999	7	4.2		
Total		168	100.0		

However, as this was day one postoperatively following a hip or knee replacement, it was considered important and an expected outcome and not cause for item reduction.

PCA indicated that over 64% of the variance could be explained by four factors. (Table 5.5)

Table 5.5: Phase Three: OARS day 1 Principal component analysis total variance

Total Variance Explained									
Component	Initial Eigenvalues			Extraction Sums of Squared Loadings			Rotation Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	6.398	35.545	35.545	6.398	35.545	35.545	3.435	19.083	19.083
2	2.238	12.433	47.978	2.238	12.433	47.978	3.380	18.778	37.861
3	1.737	9.651	57.628	1.737	9.651	57.628	2.604	14.468	52.329
4	1.188	6.598	64.226	1.188	6.598	64.226	2.142	11.897	64.226
5	1.001	5.555	69.781						
6	.815	4.525	74.306						
7	.702	3.900	78.206						
8	.668	3.709	81.915						
9	.640	3.558	85.473						
10	.506	2.811	88.284						
11	.434	2.409	90.693						
12	.399	2.216	92.908						
13	.297	1.648	94.556						
14	.262	1.455	96.011						
15	.237	1.318	97.329						
16	.202	1.123	98.452						
17	.166	.921	99.373						
18	.113	.627	100.001						
Extraction Method: Principal Component Analysis.									

Principal component analysis with Kaiser Varimax rotation provided loadings for these four factors (Table 5.6).

Table 5.6: OARS Day 1 Principal Component Analysis rotated component analysis

Rotated Component Matrix[a]				
	Component			
	1	2	3	4
OARS Item 6: I've had constant pain in the affected area	.779	.078	.257	.213
OARS Item 5: It's been painful in the affected area	.774	.021	.248	.224
OARS Item 7: I've had pain at night in the affected area	.768	.071	.276	.189
OARS Item 8: The affected area has felt swollen	.665	.159	.002	.003
OARS Item 3: I've felt tired	.576	.337	.037	-.147
OARS Item 17: I've been constipated	.317	.263	.011	.042
OARS Item 16: I've felt woozy	.027	.878	.032	.105
OARS Item 15: I've felt sick	.086	.821	.123	.146
OARS Item 4: I've felt faint	.120	.755	.063	.057
OARS Item 1: I've felt unwell	.452	.614	.195	.114
OARS Item 2: I've felt disorientated	.274	.542	.027	.170
OARS Item 18: I've lost my appetite	.100	.540	.121	.339
OARS Item 13: I've found it difficult to sleep	.114	.080	.919	.137
OARS Item 12: I've not slept well	.141	.118	.911	.174
OARS Item 14: I've not been able to sleep due to the pain in the affected area	.404	.152	.739	.169
OARS Item 10: I've not been able to stand	.199	.178	.184	.857
OARS Item 11: I've not been able to walk	-.059	.289	.264	.804
OARS Item 9: I've had difficulty getting into bed	.462	.156	.056	.579
Extraction Method: Principal Component Analysis. Rotation Method: Varimax with Kaiser Normalization.[a]				
a. Rotation converged in 6 iterations.				

Inspection of the items suggested that the factors were tapping aspects of pain, sleep, nausea and feeling unwell, and mobility respectively.

Item 17 (I've been constipated) did not load on any of the factors and was removed.

Item 2 (I've felt disorientated) and item 16 (I've felt woozy) were both brought up during TA assessment as possible challenging items for translation and disliked by patients in the previous testing phase and were removed. In addition, item 6 (I've had constant pain) was disliked by patients and removed.

Reanalysis following repeated item reduction by principal component analysis produced the same four factors resulting in similar variance (14 items) 69% (Table 5.7).

Table 5.7: OARS 14 item Principal component analysis total variance

Total Variance Explained									
Component	Initial Eigenvalues			Extraction Sums of Squared Loadings			Rotation Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	5.304	37.888	37.888	5.304	37.888	37.888	2.643	18.876	18.876
2	1.692	12.088	49.977	1.692	12.088	49.977	2.588	18.484	37.360
3	1.578	11.270	61.246	1.578	11.270	61.246	2.379	16.993	54.353
4	1.136	8.112	69.358	1.136	8.112	69.358	2.101	15.005	69.358
5	.745	5.324	74.682						
6	.697	4.978	79.660						
7	.647	4.622	84.282						
8	.515	3.677	87.959						
9	.443	3.167	91.126						
10	.395	2.820	93.946						
11	.303	2.164	96.110						
12	.229	1.633	97.743						
13	.202	1.446	99.189						
14	.114	.811	100.001						
Extraction Method: Principal Component Analysis.									

Repeat principal component analysis with Kaiser Varimax rotation on the new 14 items provided similar loadings for these four factors (Table 5.8).

Table 5.8: OARS 14 item rotated component analysis

Rotated Component Matrix[a]				
	Component			
	1	2	3	4
OARS Item 7: I've had pain at night in the affected area	.752	.296	.075	.207
OARS Item 5: It's been painful in the affected area	.749	.273	.044	.235
OARS Item 8: The affected area has felt swollen	.703	.024	.102	.028
OARS Item 3: I've felt tired	.609	.043	.341	-.129
OARS Item 13: I've found it difficult to sleep	.093	.920	.094	.134
OARS Item 12: I've not slept well	.124	.910	.125	.176
OARS Item 14: I've not been able to sleep due to the pain in the affected area	.362	.757	.148	.182
OARS Item 15: I've felt sick	.083	.100	.839	.156
OARS Item 4: I've felt faint	.132	.040	.771	.063
OARS Item 1: I've felt unwell	.439	.203	.629	.126
OARS Item 18: I've lost my appetite	.063	.112	.616	.320
OARS Item 10: I've not been able to stand	.181	.194	.156	.866
OARS Item 11: I've not been able to walk	-.091	.263	.283	.807
OARS Item 9: I've had difficulty getting into bed	.484	.059	.145	.596
Extraction Method: Principal Component Analysis. Rotation Method: Varimax with Kaiser Normalization.[a]				
a. Rotation converged in 6 iterations.				

The OARS questionnaire displayed good internal consistency and reliability with Cronbach's alpha ranging between .74-.89 (Table 5.9). Item-to-total correlations are an additional measure of test reliability and are also presented in table 5.9.

Table 5.9: Phase Three day 1 14 item OARS item to total correlations and internal reliability

Domain	Item	Corrected Item to Total Correlation	Cronbach's Alpha
Pain			.74
	3. I've felt tired	.434	
	5. It's been painful in the affected area	.647	
	7. I've had pain at night in the affected area	.629	
	8. The affected area has felt swollen	.459	
Nausea and feeling unwell			.78
	1. I've felt unwell	.586	
	4. I've felt faint	.561	
	15. I've felt sick	.695	
	18. I've lost my appetite	.499	
Fatigue and sleep			.89
	12. I've not slept well	.853	
	13. I've found it difficult to sleep	.829	
	14. I've not been able to sleep due to the pain in the affected area	.699	
Increasing function and mobility			.79
	9. I've had difficulty getting into bed	.501	
	10. I've not been able to stand	.776	
	11. I've not been able to walk	.659	

5.3.3.2 Oxford Arthroplasty Early Change Score (OACS)

Frequency tables were created and examined for floor and ceiling effects. Floor effects were found on six items (item 3 - mobility, item 4 - ability to walk, item 5 - ability to walk upstairs, item 6 - ability to walk down stairs, item 9 - pain in the affected area when walking, and item 14 - ability to cope at home) (Table 5.10).

Table 5.10: OACS frequency tables

Your mobility compared to before the operation?					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Much worse	65	38.7	40.9	40.9
	Worse	56	33.3	35.2	76.1
	The same	14	8.3	8.8	84.9
	Better	18	10.7	11.3	96.2
	Much better	6	3.6	3.8	100.0
	Total	159	94.6	100.0	
Missing	999	9	5.4		
Total		168	100.0		
Your ability to walk compared to before the operation?					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Much worse	71	42.3	44.7	44.7
	Worse	55	32.7	34.6	79.2
	The same	13	7.7	8.2	87.4
	Better	15	8.9	9.4	96.9
	Much better	5	3.0	3.1	100.0
	Total	159	94.6	100.0	
Missing	999	9	5.4		
Total		168	100.0		
Your ability to walk upstairs compared to before the operation?					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Much worse	73	43.5	50.0	50.0
	Worse	42	25.0	28.8	78.8
	The same	18	10.7	12.3	91.1
	Better	12	7.1	8.2	99.3
	Much better	1	.6	.7	100.0
	Total	146	86.9	100.0	

Missing	999	22	13.1		
Total		168	100.0		

Your ability to walk down stairs compared to before the operation?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Much worse	70	41.7	47.9	47.9
	Worse	45	26.8	30.8	78.8
	The same	19	11.3	13.0	91.8
	Better	10	6.0	6.8	98.6
	Much better	2	1.2	1.4	100.0
	Total	146	86.9	100.0	
Missing	999	22	13.1		
Total		168	100.0		

Your pain in the affected area when walking as compared to before the operation?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Much worse	63	37.5	40.4	40.4
	Worse	55	32.7	35.3	75.6
	The same	14	8.3	9.0	84.6
	Better	22	13.1	14.1	98.7
	Much better	2	1.2	1.3	100.0
	Total	156	92.9	100.0	
Missing	999	12	7.1		
Total		168	100.0		

Your ability to cope at home compared to before the operation?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Much worse	59	35.1	40.1	40.1
	Worse	46	27.4	31.3	71.4
	The same	27	16.1	18.4	89.8
	Better	14	8.3	9.5	99.3
	Much better	1	.6	.7	100.0
	Total	147	87.5	100.0	
Missing	999	21	12.5		
Total		168	100.0		

However, as this was day one postoperatively following a hip or knee replacement, some were considered important and retained as not a cause for item reduction (items 4, 5, 6, and 9).

PCA indicated that over 70% of the variance could be explained by two factors (Table 5.11).

Table 5.11: Phase Three OACS day 1 principal component analysis total variance

Total Variance Explained

Component	Initial Eigenvalues			Extraction Sums of Squared Loadings			Rotation Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	13.207	62.889	62.889	13.207	62.889	62.889	8.455	40.264	40.264
2	1.592	7.582	70.471	1.592	7.582	70.471	6.344	30.207	70.471
3	.961	4.577	75.048						
4	.721	3.434	78.482						
5	.574	2.734	81.216						
6	.495	2.359	83.575						
7	.486	2.315	85.890						
8	.418	1.989	87.879						
9	.409	1.945	89.825						
10	.362	1.723	91.548						
11	.316	1.504	93.052						
12	.279	1.327	94.379						
13	.253	1.205	95.584						
14	.221	1.054	96.638						
15	.172	.817	97.455						
16	.161	.765	98.221						
17	.131	.625	98.846						
18	.097	.464	99.310						
19	.083	.397	99.707						
20	.039	.186	99.893						
21	.022	.107	100.001						

Extraction Method: Principal Component Analysis.

Principal component analysis with Kaiser Varimax rotation provided loadings for these two factors (Table 5.12).

Table 5.12: OACS Day 1 Principal Component Analysis rotated component analysis

Rotated Component Matrix[a]		
	Component	
	1	2
OACS item 4: Your ability to walk compared to before the operation?	.888	.318
OACS item 3: Your mobility compared to before the operation?	.872	.354
OACS item 2: Your ability to move compared to before the operation?	.871	.320
OACS item 5: Your ability to walk upstairs compared to before the operation?	.865	.288
OACS item 6: Your ability to walk down stairs compared to before the operation?	.859	.284
OACS item 1: Your ability to stand compared to before the operation?	.841	.337
OACS item 9: Your pain in the affected area when walking as compared to before the operation?	.735	.387
OACS item 14: Your ability to cope at home compared to before the operation?	.684	.436
OACS item 10: Your pain in the affected area compared to before the operation?	.671	.518
OACS item 12: Your pain when getting into bed as compared to before the operation?	.668	.482
OACS item 7: Your strength compared to before the operation?	.645	.368
OACS item 8: How comfortable you feel when sitting compared to before the operation?	.588	.514
OACS item 20: Your pain when trying to sleep compared to before the operation?	.437	.766
OACS item 18: Your sleep as compared to before the operation?	.314	.755
OACS item 21: Your ability to sleep through the night as compared to before the operation?	.325	.751
OACS item 19: How you feel overall compared to before the operation?	.476	.746
OACS item 16: Your mood compared to before the operation?	.292	.728
OACS item 13: Your muscle spasms in the affected area compared to before the operation?	.147	.701

OACS item 11: Your pain in the affected area at night compared to before the operation?	.452	.678
OACS item 15: Your appetite as compared to before the operation?	.265	.629
OACS item 17: Your energy level compared to before the operation?	.535	.586
Extraction Method: Principal Component Analysis. Rotation Method: Varimax with Kaiser Normalization.[a]		
a. Rotation converged in 6 iterations.		

This questionnaire was designed to primarily assess recovery and change over time following surgery. An initial factor analysis was undertaken, and a rotated solution indicated a two factor solution. Inspection of the items suggested that the two factors were primarily addressing three separate issues of mobility, pain, and sleep. Upon analysis of the data over 63% of the variance was explained by one factor. The Eigenvalue for the second factor was very low (1.592) and the amount of variance (7.5%) that was explained by the second factor was also low. Selection and decision making on the number of factors to be retained can be determined by multiple means of testing including Eigenvalues and factor loadings (205). It did not appear to be a meaningful factor, and furthermore, inspection of the items supported that. The two separate factors did not appear to be meaningful on their own. Consequently, it was decided to determine if a single forced-factor would make the most parsimonious solution (206), and any item not loading could be deleted (Table 5.14). All items loaded on the one factor solution for the OACS, and therefore, this was not used as a method of item reduction or parsimony during these analyses. The items were all found to load highly, above .6, on the one-factor solution (145).

Table 5.13: Phase Three OACS day 1 one factor principal component analysis total variance

Total Variance Explained						
Component	Initial Eigenvalues			Extraction Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	13.207	62.889	62.889	13.207	62.889	62.889
2	1.592	7.582	70.471			
3	.961	4.577	75.048			
4	.721	3.434	78.482			
5	.574	2.734	81.216			
6	.495	2.359	83.575			
7	.486	2.315	85.890			
8	.418	1.989	87.879			
9	.409	1.945	89.825			
10	.362	1.723	91.548			
11	.316	1.504	93.052			
12	.279	1.327	94.379			
13	.253	1.205	95.584			
14	.221	1.054	96.638			
15	.172	.817	97.455			
16	.161	.765	98.221			
17	.131	.625	98.846			
18	.097	.464	99.310			
19	.083	.397	99.707			
20	.039	.186	99.893			
21	.022	.107	100.001			
Extraction Method: Principal Component Analysis.						

Factor loadings for the one factor OACS are presented below (Table 5.14).

Table 5.14: OACS Day 1 one factor 21 item Principal Component Analysis and factor loading

Component Matrix[a]	
OACS Item	**Factor loading**
OACS item 3: Your mobility compared to before the operation?	.897
OACS item 4: Your ability to walk compared to before the operation?	.886
OACS item 2: Your ability to move compared to before the operation?	.874
OACS item 1: Your ability to stand compared to before the operation?	.862
OACS item 5: Your ability to walk upstairs compared to before the operation?	.850
OACS item 10: Your pain in the affected area compared to before the operation?	.847
OACS item 19: How you feel overall compared to before the operation?	.842
OACS item 6: Your ability to walk down stairs compared to before the operation?	.842
OACS item 20: Your pain when trying to sleep compared to before the operation?	.826
OACS item 12: Your pain when getting into bed as compared to before the operation?	.822
OACS item 9: Your pain in the affected area when walking as compared to before the operation?	.813
OACS item 14: Your ability to cope at home compared to before the operation?	.805
OACS item 17: Your energy level compared to before the operation?	.786
OACS item 11: Your pain in the affected area at night compared to before the operation?	.781
OACS item 8: How comfortable you feel when sitting compared to before the operation?	.781
OACS item 7: Your strength compared to before the operation?	.731
OACS item 21: Your ability to sleep through the night as compared to before the operation?	.730
OACS item 18: Your sleep as compared to before the operation?	.724
OACS item 16: Your mood compared to before the operation?	.690
OACS item 15: Your appetite as compared to before the operation?	.606
OACS item 13: Your muscle spasms in the affected area compared to before the operation?	.561
Extraction Method: Principal Component Analysis. 1 components extracted.	

Item 2 (ability to move) had been recognised in the TA as a duplicate question and was removed. Item 3 (mobility) was seen as a duplicate question and item 14 was disliked by patients and therefore removed. Item 13 (muscle spasms) was disliked by patients in the previous phase of testing who said they had never had them and was also removed. Item 11 (pain at night) and item 12 (pain when getting into bed) were disliked by patients as seen as too similar to other questions and removed. In addition, item 21 (ability to sleep) was also disliked by patients as seen as too similar and therefore removed (Table 5.15).

Table 5.15: OACS Removed Items

Phase Three OACS Items Removed	Reason for removal
2. Your ability to move compared to before the operation?	Duplicate item in TA
3. Your mobility compared to before the operation?	Duplicate item in TA
11. Your pain in the affected area at night compared to before the operation?	Disliked by patients as seen as too similar to other questions
12. Your pain in the affected area when getting into bed compared to before the operation?	Disliked by patients as seen as too similar to other questions
13. Your muscle spasms in the affected area compared to before the operation?	Disliked by patients as never had them
14. Your ability to cope at home compared to before the operation?	Disliked by patients
21. Your ability to sleep through the night compared to before the operation?	Disliked by patients as seen as too similar to other questions

Reanalysis of the remaining 14 items was performed following item reduction and similar variance and factor loadings were found (Tables 5.16 and 5.17).

Table 5.16: Phase Three OACS day 1 14 item principal component analysis total variance

Total Variance Explained						
Component	Initial Eigenvalues			Extraction Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	8.845	63.179	63.179	8.845	63.179	63.179
2	1.214	8.673	71.851			
3	.756	5.401	77.252			
4	.569	4.065	81.318			
5	.484	3.455	84.772			
6	.383	2.733	87.505			
7	.369	2.639	90.144			
8	.299	2.138	92.282			
9	.295	2.106	94.388			
10	.253	1.805	96.193			
11	.247	1.765	97.958			
12	.137	.976	98.934			
13	.127	.907	99.841			
14	.022	.159	100.001			
Extraction Method: Principal Component Analysis.						

Table 5.17: OACS Day 1 one factor 14 item Principal Component Analysis and factor loading

Component Matrix[a]	
OACS Item	**Factor loading**
OACS item 4: Your ability to walk compared to before the operation?	.875
OACS item 5: Your ability to walk upstairs compared to before the operation?	.859
OACS item 6: Your ability to walk down stairs compared to before the operation?	.851
OACS item 19: How you feel overall compared to before the operation?	.841
OACS item 10: Your pain in the affected area compared to before the operation?	.834
OACS item 9: Your pain in the affected area when walking as compared to before the operation?	.817
OACS item 1: Your ability to stand compared to before the operation?	.813
OACS item 17: Your energy level compared to before the operation?	.805
OACS item 20: Your pain when trying to sleep compared to before the operation?	.790
OACS item 8: How comfortable you feel when sitting compared to before the operation?	.779
OACS item 7: Your strength compared to before the operation?	.757
OACS item 16: Your mood compared to before the operation?	.720
OACS item 18: Your sleep as compared to before the operation?	.706
OACS item 15: Your appetite as compared to before the operation?	.645
Extraction Method: Principal Component Analysis. 1 components extracted.	

Typically, patients expect to experience significant pain at day one postoperatively. Clinically it is understood that this pattern changes over time and that at two or six weeks later, a number will be reporting less pain.

In order to explore this concept within the context of this dataset, the one-factor solution is based on analysis at multiple time points and solutions. The data set was analysed at multiple testing time points over the six week testing period to determine whether all of the

items consistently loaded on the factor. The resulting analyses in the one-factor solution indicated high levels of internal consistency at multiple time points and have low missing data and limited floor ceiling effect. Floor effects are anticipated, and indeed expected, in the early days immediately following an operation. It would be concerning if they were not seen. This is in essence part of the construct validity for the OACS questionnaire. Initial testing showed floor/ceiling effect for items on day one; which would be expected immediately after surgery. Accordingly, data was analysed at subsequent time points (day seven, fourteen and six weeks). These end effects were reduced as time progressed and patients say they have had considerable improvement.

The OACS questionnaire displayed good internal consistency and reliability with an overall Cronbach's alpha of .95. Item-to-total correlations are an additional measure of test reliability and are also presented for the OACS in table 5.18.

These analyses resulted in the final OARS and OACS questionnaires, which now contain 14 items. Their validation will be discussed in the next chapter.

5.3.4 Internal Consistency

Internal consistency for both the OARS and OACS were good, with overall Cronbach's alpha of 0.87 and 0.95 respectively. Cronbach's Alpha reliability analysis for items loaded in each factor are presented (Tables 5.9 and 5.18). This provides evidence that items in both the OARS is measuring health status at the time of testing, and that the OACS is measuring the change.

Table 5.18: Phase Three day 1 14 item OACS item to total correlations and internal reliability

OACS Item	Corrected Item to Total Correlation	Cronbach's Alpha
		.95
1. Your ability to stand compared to before the operation?	.778	
4. Your ability to walk compared to before the operation?	.849	
5. Your ability to walk upstairs compared to before the operation?	.829	
6. Your ability to walk down stairs compared to before the operation?	.819	
7. Your strength compared to before the operation?	.714	
8. How comfortable you feel when sitting compared to before the operation?	.742	
10. Your pain in the affected area compared to before the operation?	.801	
9. Your pain in the affected area when walking as compared to before the operation?	.784	
15. Your appetite as compared to before the operation?	.597	
16. Your mood compared to before the operation?	.676	
17. Your energy level compared to before the operation?	.769	
18. Your sleep as compared to before the operation?	.661	
19. How you feel overall compared to before the operation?	.810	
20. Your pain when trying to sleep compared to before the operation?	.756	

5.3.5 Content Validity

In both the OARS and OACS, content validity appears to be good. Through item development and both expert and patient feedback, all important aspects of their respective domains have been covered.

5.4 Methodological Challenges

Many challenges present themselves in the course of patient recruitment and study participation. In this phase of the study, surgery schedules were seen to change frequently, often on a daily basis. Patients may be delayed or require further testing or interventions before being medically 'cleared' for surgery. Surgery lists can be rearranged based on how long a patient has been on the waiting list and acceptable NHS waiting times. Patients are also seen to be cancelled if a theatre list overruns due to a complicated surgery or anaesthetic or to an unexpected event arising in theatre. Hospital and theatre staffing can also affect the day of surgery plans. Almost all of the patients that were approached to participate in the study chose to do so. Three patients refused: one stated that he was happy to participate while in hospital, but that as he did not read anything at home, he would not read and complete the questionnaires following discharge. Another explained that she really did not want to help anyone with anything while she was recovering from surgery. The third stated that he was simply not interested. The process of discharge from hospital and its seeming unpredictability can be challenging when following up patients postoperatively. On two occasions, patients were discharged home prior to their anticipated dates. In delivering the questionnaires to postoperative patients, regular ward rounding and checking with nursing staff was most helpful in questionnaire completion. Patients appreciated the follow-up and continuity with visits while hospitalised.

While 168 patients were included in this study, some patients did not complete all time points for the study (n=48).

- One patient (participant 35), whilst in hospital, decided to drop out due to being 'completely stressed out and unable to cope' due to noise from her neighbours on the ward.
- Two patients (participants 138 and 143) had their questionnaires filed in medical records instead of being taken home on discharge.
- One patient (participant 61) accidently recycled his day 7 questionnaires.
- Two patients required readmission and subsequent reoperation for infection at day 15 and 5 weeks respectively (participants 19 and 142).
- An additional patient (participant 62), suffered from a dislocated hip and required revision surgery at six weeks postoperatively.

A number of questionnaires and return envelopes were not received at the research office (n=44). Many of the patients were concerned as they reported having returned them. An investigation by the post office revealed a problematic situation in their head office. They managed to retrieve three additional questionnaires, but it is unclear how many were lost. As a result of this situation, it is difficult to determine the true response rates for this phase of the study.

5.5 Discussion

Initial evaluation of the OARS and OACS' suitability for factor analysis was determined through KMO and Bartlett's testing. These tests showed favourable results in the adequacy of the OARS and OACS datasets for factor analysis. Frequency tables were performed and end effects reported and discussed. PCA explored the datasets to discover the presence of outliers or items unsuitable for factor analysis. EFA was subsequently carried out and factor

loadings observed. Four factors emerged from the OARS analysis: pain, sleep, nausea and feeling unwell, and mobility. It appeared that two factors were found initially on analysis of the OACS tapping aspects of mobility, pain and sleep. However, the majority of the variance was attributed to one factor. So a one-factor solution was explored. Items were reduced according to both statistical analysis and participant feedback. Following item reduction and retesting, similar variance was found in the factors. Cronbach's alpha statistic appeared to show high levels of reliability in all dimensions. These findings make sense in conjunction with the clinical picture of early recovery following surgery. Both the OARS and OACS indicated high levels of internal consistency, content validity and relevance to both patients and clinicians alike.

The OARS and OACS have been designed and created with patient and healthcare professional participation and input. The aim was to have short, reliable, easy to complete questionnaires for the arthroplasty patient to fill the void in early postoperative assessment and healthcare planning. In order for them to be relevant to both patients and healthcare providers, it has been of great importance to have the direct involvement of these pivotal stakeholders during their design, creation and initial testing. The content of both the OARS and OACS has been taken directly from patient and provider interviews: the item pool being generated directly from these themes and topics. The issues expressed as being significant to patients in their postoperative recovery have been addressed by the questions. Topics including pain, disorientation and nausea, sleep, and mobility were all identified as factors that are both relevant and important to the recovering patient. It is anticipated that both the OARS and OACS will facilitate important healthcare decision making in combination with other assessment modalities to continue work to improve outcomes for both hip and knee patients.

5.6 Strengths and limitations

The strengths of Phase Three include having recruited and tested an adequate sample size for the questionnaires. As previously discussed, the specific requirements for sample size calculation in PROM development is somewhat controversial as to how to calculate sample size, but this study allowed for a more than adequate number of respondents for each item with both the OARS and OACS.

The limitations for this part of the study include concerns regarding potential generalisability of the results, as the study was performed in only one NHS hospital in England. This phase of the study consisted of different types of procedures and indeed different percentages of those procedures as compared to those in the prior study phase. In any research study it is important to consider the impact of other potential confounders (207). In an often aging patient population, with sometimes multiple comorbidities and arthritic joints, these cannot be avoided, but it is important to consider and be aware of the potential for bias confounders can introduce in research.

5.7 Summary

The testing, analysis and development of the final questionnaires have been reported and discussed in this chapter. The results presented in this chapter describe and report the initial testing and item reduction for the OARS and OACS assessment measures. Both show good psychometric properties in terms of internal consistency, content validity and relevance to patients and clinicians. In addition, these measures have been shown to be acceptable to patients at different time points throughout the early recovery period with validation across the six-week period. The next chapter will report their subsequent validation and testing of sensitivity to change.

6 Validation of questionnaire and sensitivity to change

6.1 Introduction

The previous chapters have reported on the development and initial testing of two new measures, the Oxford Arthroplasty Early Recovery Score (OARS) and the Oxford Arthroplasty Early Change Score (OACS), for use in the early recovery period following hip or knee arthroplasty. This chapter reports and describes the final questionnaire validation. This is recognised as an important part in the FDA 'gold standard' development of a PROM (70). This chapter will discuss their administration in an independent cohort of consecutive hip and knee replacement patients.

6.2 Participants and Methods

6.2.1 Phase Four

The two questionnaires, OARS and OACS (Appendix 7: Final version OARS and OACS), were distributed to consecutive patients in a cohort of hip and knee replacement patients. They were administered on days 1, 2, 3, 7 and 14 in the early postoperative period and also at six weeks following surgery.

As previously discussed, the specific day timings of testing were chosen to maximise the information and coverage of the recovery period of the data retrieved and to minimise patient burden. Patients were recruited from the hospital pre-assessment clinic while being seen for either hip or knee replacement surgeries.

During the study, for those participants who were discharged prior to day three, additional questionnaires with stamped self-addressed envelopes were provided. The six week questionnaires were mailed to patients with stamped self-addressed envelopes.

6.2.2 Short Form-36 version 2 Acute Health Survey (SF-36v2 Acute)

The Short Form-36 version 2 Acute (SF-36v2), United Kingdom (English) version, is a widely used and previously validated generic health measure (208) (Appendix 8 SF-36 v2 acute). This self-administered questionnaire covers eight domains of both physical and mental health. These include physical functioning (PF); Role-Physical (RP); Bodily Pain (209); General Health (GH); Vitality (VT); Social Functioning (SF); Role-Emotional (RE) and Mental Health (MH). Two summary scores, mental component summary (MCS) and physical component summary (PCS) for the SF-36 v2, are available for use in trials. These were not used for this study as more granular results and not overall derived summary scores were desired to specify what correlations may be found to be relevant to the patient population. The SF-36 has been used in various forms during the validation of other disease specific health measures across a wide range of conditions (210, 211). The SF-36v2 Acute has a recall period of one week, as opposed to the standard version which has a recall period of four weeks, and therefore made it appropriate for use in evaluating the new OARS and OACS questionnaires for change over a period of one week. Consequently, the SF-36v2 Acute was given to participants, in addition to both the OARS and OACS, on days 7, 14 and at 6 weeks. Prior hypotheses for this study were considered. These included that the highest correlations would be found between OARS domains and SF-36 v2 Acute dimensions between the following: OARS pain with the SF-36v2 Acute bodily pain; OARS nausea and feeling unwell with SF-36v2 Acute domain of general health; OARS fatigue and sleep with SF-36v2 Acute vitality; and OARS improving function and mobility with SF-36v2 Acute physical functioning. This will also, in part, validate the new tools (210, 211).

6.2.3 Sample size calculations

As discussed in Chapter 5, recommendations for sample size calculations in this area of research vary, with some researchers stating that there should be a minimum of 100 participants, and three to five times the number of respondents to items (212). Others advise as many as ten times the number respondents as items (200). A relatively conservative (i.e. large) estimate was calculated for this study with the aim to recruit the largest sample possible given time and resource limitations. As both OARS and OACS questionnaires contain 14 items, it was determined that a sample size of 100 to 140 completed participants would be sufficient.

Phase Four was completed between February and July 2019.

6.2.4 Statistical Analysis

The plan for statistical analysis was decided upon prior to study commencement and during the time of initial protocol writing. The following analysis plan was followed:

- Scale generation and testing scale properties.
- Descriptive statistics and frequency tables reported.
- Internal consistency reported.
- External validity.
- Responsiveness and sensitivity to change.

SPSS 25 was used for analyses (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.). Recommended scoring algorithms were utilised for the SF-36v2 (Quality Metric Health Outcomes™ Scoring Software 5.0; 2016).

6.2.5 Scale generation and testing scale properties

Both the overall 14-item OARS and domains of the OARS were scored on a scale of zero to 100, with zero being poor recovery and 100 being positive and indicative of a good recovery. The OACS change measure was also scored across a scoring range of 100, with minus 50 being much worse than before surgery, to 50, being much better than before surgery. Zero indicates no change. In the presence of missing data, scores were not imputed for these participants. As it is part of a validation study, it is not appropriate to impute data when testing the measurement properties of an instrument.

Overall questionnaire scores for the OARS, OACS and domains scores for the OARS were calculated. The domain scores for the OARS were then compared for previously predicted correlations with known dimensions of the SF-36v2. Spearman rank-order correlation coefficients (213), or Spearman's rho, were measured between the dimensions of the OARS and SF-36v2 Acute. This non-parametric statistical procedure measures the association between two variables and the extent to which they increase, or decrease, together (214). Correlations over 0.3 are considered as fair (215) and between 0.4 and 0.7 are considered moderate (216).

6.2.6 Internal consistency

As discussed in Chapter 5, internal reliability assesses the consistency of results across items within a test. Items on a questionnaire intended to measure the same underlying construct should be correlated with each other (190). Cronbach's alpha indicates the extent to which there is a pattern of responses to items. It is a commonly used statistical test for this purpose (194), with scores above 0.7 considered acceptable, although scores in the region of 0.9 – 1 may suggest item redundancy if the measure is designed for use at the

group level. However, such high scores may be desirable for questionnaires which may be used at the level of the individual which may be a possibility.

6.2.7 Content validity

Content validity refers to the ability of the questionnaire to cover the conceptual framework it was created to measure (217). As discussed in Chapter 5, developing outcome measures with qualitative input from both patients and orthopaedic healthcare professionals throughout the process is critical in optimising content validity (70). Evidence based literature and statistical methods can provide guidance, but it is essential that qualitative feedback is received from the patient population.

6.2.8 Construct validity

Construct validity is the extent to which a questionnaire measures what it claims to measure (190). This may guide clinicians in their choice of measures for clinical trials or decision making based on its interpretations (218).

Comparison and correlation of the previously hypothesised dimensions of the SF-36v2 can be made in relation to a new PROM or measure to assess construct validity (190). All correlations and dimensions were considered during this process.

6.2.9 Responsiveness and sensitivity to change

The results from the OARS and OACS were evaluated for responsiveness, a measure's ability to detect clinically important changes and sensitivity to change over time, a statistical feature of a measure. These are important, closely related qualities in validating outcome measures, particularly if they are potentially being used in clinical decision making and trials (219). The initial testing time point was measured and compared with the means of additional testing points through six weeks. The OACS questionnaire was

designed to be a highly sensitive change measure and as such was utilised for the purpose of defining significant change in the OARS. As previously discussed, the OACS change measure was scored from negative 50, indicating poor recovery, to positive 50, indication a good recovery. As this change measure is designed for and by the early recovery joint replacement population, the OACS measure is designed to assess change and, as it has multiple items, it may be more granular than a single transition question (220, 221). It was determined by the expert group that the change in score would be used to calculate the minimally important change (MIC). Change from'-5' to '5' out was considered 'no change' and change of between '-15'to '-5' and '5' to '15' were considered minimal change. Participant responses were categorised at each time point and means calculated. OARS scores were tested, both in aggregate (positive and negative change together, sign corrected), as discussed by Guyatt (222, 223), and positive change only.

6.2.10 Effect size

Effect size (ES) calculations offer a measurement of the magnitude of change and can act as a guide, though Cohen remarked the standard recommendations may differ in their applicability across measures (224). This was originally designed to facilitate sample size calculations (190). It can also be used as a guide to the extent of change, with an ES of 0.2 being categorised as small, around 0.5 as medium and 0.8 as large (224). More recently an ES of above 1.2 has been acknowledged by Sawilowsky as very large(225).

6.3 Results

6.3.1 Participants

Out of the 158 approached, a total of 155 participants were included in the study: 90 women (58%) and 65 men (42%) (Table 6.1).

Table 6.1: Phase Four Participant Characteristics

Parameter	
Age (years)	68 (10.9) 20-87
Sex Male/Female (% male)	65/90 (42)
Ethnicity	WB 151 (97.4) OW 1 (0.6) I 1 (0.6) A 1 (0.6) C 1 (0.6)
Duration of disease (years)	6.2 (9.3) 0.5-74
Length of stay (days)	2.6 (2.7) 0-21
Type of surgery	THA 58 (37.4) TKA 33 (21.3) UKA 55 (35.5) Rev. THA 6 (3.9) Rev. TKA 3 (1.9)
Employment	Employed 38 (24.5) Retired 110 (71) Disabled 7 (4.5)
Living situation	Alone 27 (17.4) Family 128 (82.6)
Home situation	One level 20 (12.9) Up and down stairs 135 (87.1)

Data are n (%) or mean (SD) range. Ethnicity: WB= White British; OW= Other White; I= Indian; A=Arabic; C= Caribbean. Ethnicity categories from Office for National Statistics (ONS), Census 2011. Type of surgery: THA= Total Hip Arthroplasty; TKA= Total Knee Arthroplasty; UKA= Unicompartmental Knee Arthroplasty; Rev. THA= Revision Total Hip Arthroplasty; Rev. TKA=Revision Total Knee Arthroplasty.

The mean age of participants was 68 years (SD=10.9; range 20-87). The surgical interventions within the sample consisted of THA (n=58), TKA (n=33), UKA (n=55), Rev. THA (n=6) and Rev. TKA (n= 3). Ethnicities of the group were predominantly White British 151 (97.4%), but also included Other White 1 (0.6%), Indian (0.6%), Arabic 1 (0.6%) and Caribbean 1 (0.6%). Mean length of hospital stay for participants was 2.6 days (SD=2.7; range 0-21). The duration of disease ranged from 0.5 years to 74 years (mean=6.2; SD=9.3). Within the group, 38 were

currently employed (24.5%), 110 were retired (71%) and seven were unable to work due to health conditions (4.5%). 128 (82.6%) participants lived with family and 27 (17.4%) lived alone. Twenty (12.9%) participants lived in a property on one level and 135 (87.1%) had stairs. Response rates were 78-91%, with the mean time to complete being approximately 6 minutes.

6.3.2 Scale generation and testing scale properties

Items in both the OARS and OACS questionnaires were scored at each testing time point and with the OARS being transformed to a score out of 100 and the OACS to a score from negative 50 to 50. The mean overall scores for each surgery type (by testing time point) in both the OARS and four OARS domain scores: pain; nausea and feeling unwell; fatigue and sleep; and improving function and mobility, can be seen in Tables 6.2 and 6.3 respectively. The mean overall OACS scores for each surgery type by testing time point can be seen in Table 6.4.

Table 6.2: Mean overall scores for OARS testing time points

	OARS day 1	**OARS day 2**	**OARS day 3**	**OARS day 7**	**OARS day 14**	**OARS 6 weeks**
Mean	35.07	39.49	46.27	54.46	62.10	72.41
CI	31.47-38.67	35.96-43.03	43.36-49.17	51.66-57.27	59.13-65.07	69.32-75.49
N	141	146	143	138	134	126
SD	21.64	21.61	17.59	16.68	17.37	17.50
Range	98.21	94.64	91.07	91.07	80.36	80.36
Minimum	0.00	0.00	0.00	7.14	19.64	19.64
Maximum	98.21	94.64	91.07	98.21	100.00	100.00

CI= 95% Confidence Interval; N=number; SD= Standard deviation.

Table 6.3: Mean domain scores for OARS

Pain	**Day 1**	**Day 2**	**Day 3**	**Day 7**	**Day 14**	**6 weeks**
Mean	25.04	27.32	30.99	35.09	42.55	55.18
N	149	148	145	140	135	128
SD	20.99	21.54	17.08	19.11	21.60	26.51
Range	100	93.75	87.5	93.75	100	93.75
Minimum	0	0	0	0	0	6.25
Maximum	100	93.75	87.5	93.75	100	100
Nausea and feeling unwell	**Day 1**	**Day 2**	**Day 3**	**Day 7**	**Day 14**	**6 weeks**
Mean	44.83	46.90	55.17	68.66	78.47	86.12
N	150	149	145	140	135	127
SD	27.46	25.29	22.97	21.03	20.21	16.42
Range	100	100	100	87.5	81.25	93.75
Minimum	0	0	0	12.5	18.75	6.25
Maximum	100	100	100	100	100	100
Fatigue and sleep	**Day 1**	**Day 2**	**Day 3**	**Day 7**	**Day 14**	**6 weeks**
Mean	32.72	39.43	46.35	50.00	50.18	63.16
N	150	149	146	141	136	126
SD	31.51	31.73	28.28	27.53	30.61	28.99
Range	100	100	100	100	100	100
Minimum	0	0	0	0	0	0
Maximum	100	100	100	100	100	100
Improving Function and Mobility	**Day 1**	**Day 2**	**Day 3**	**Day 7**	**Day 14**	**6 weeks**
Mean	37.38	46.32	54.71	66.43	78.67	85.48
N	142	147	145	140	134	128
SD	30.07	26.82	23.89	21.16	17.08	16.24
Range	100	100	100	100	75	66.67
Minimum	0	0	0	0	25	33.33
Maximum	100	100	100	100	100	100

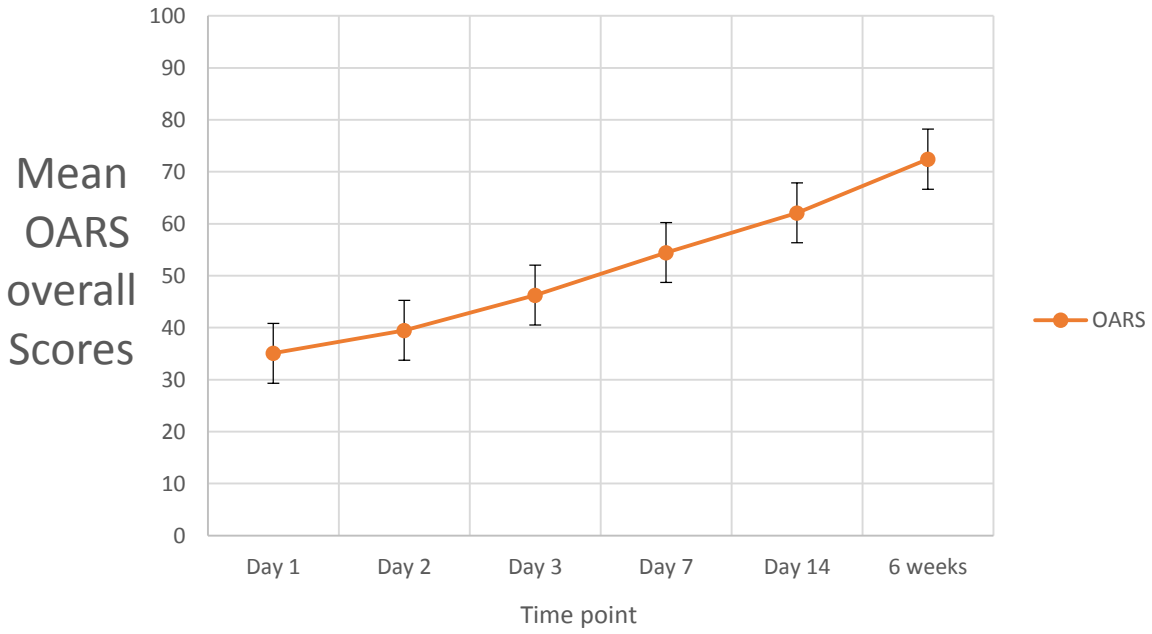
N=number; SD= Standard deviation.

Table 6.4: Mean overall scores for OACS testing time points

	OACS day 1	OACS day 2	OACS day 3	OACS day 7	OACS day 14	OACS 6 weeks
Mean	-27.07	-22.42	-18.27	-13.81	-3.98	11.51
CI	-30.02--24.13	-25.45--19.39	-20.80--15.74	-16.64--10.97	-7.40--0.57	7.78-15.24
N	125	124	131	127	121	121
SD	16.64	17.04	14.63	16.14	19.00	20.74
Range	80.36	76.79	73.21	78.57	89.29	91.07
Minimum	-50.00	-50.00	-50.00	-48.21	-44.64	-41.07
Maximum	30.36	26.79	23.21	30.36	44.64	50.00

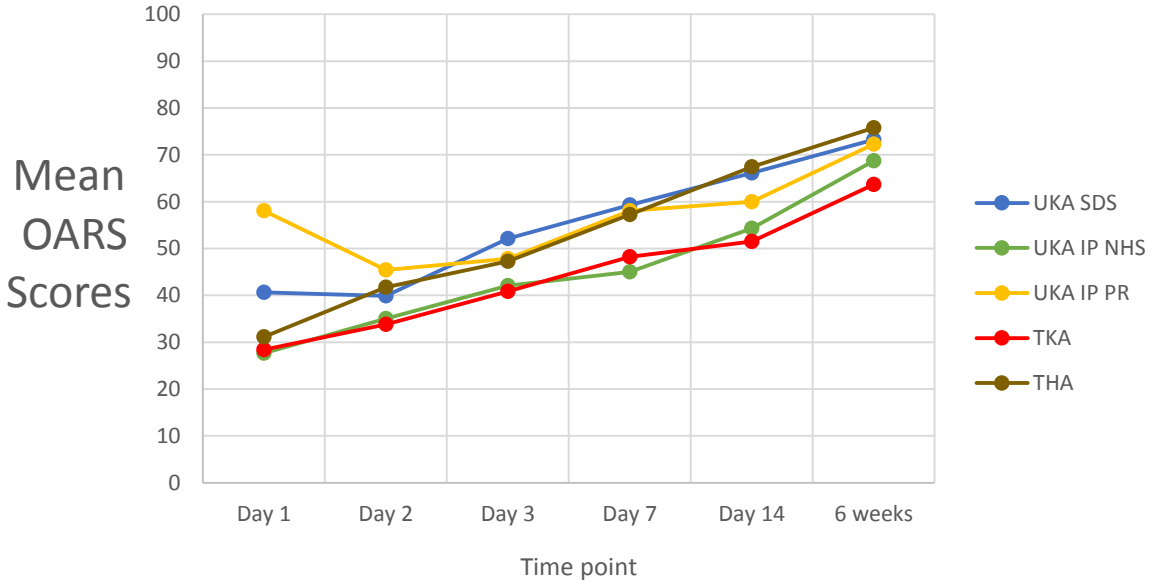
CI= 95% Confidence Interval; N=number; SD= Standard deviation.

The mean OARS and OACS scores over time and by surgery type are shown below (Figures 6.1, 6.2, 6.3 and 6.4). Revision hips and revision knees were removed from the tables due to insufficient data (n=6 and 3 respectively).



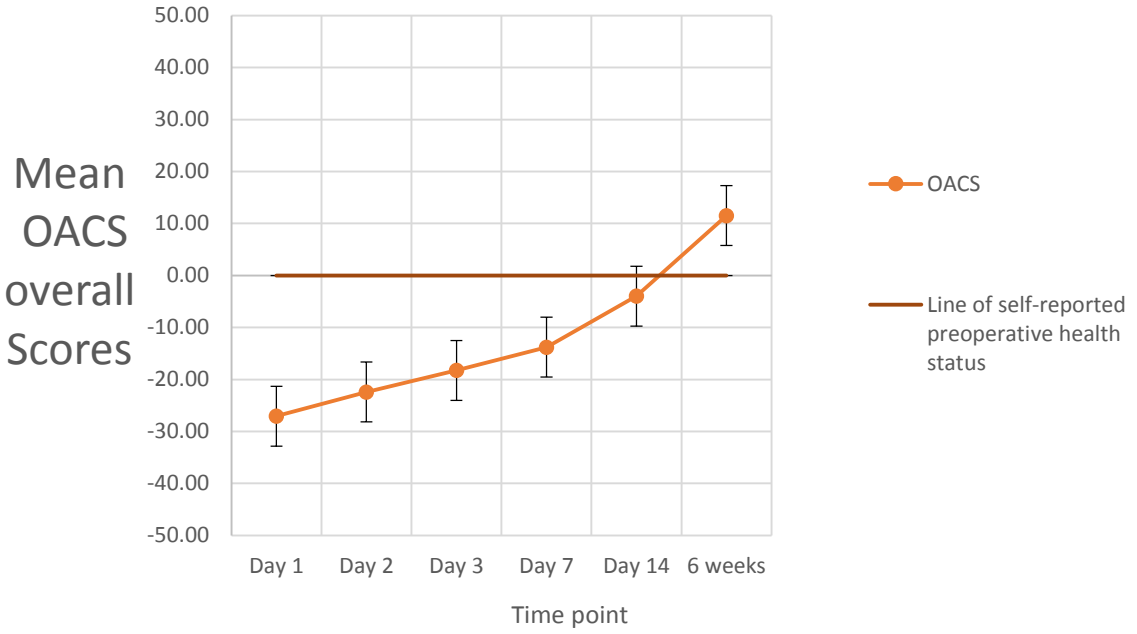
OARS= Oxford Arthroplasty Early Recovery Score.

Figure 6.1: Mean OARS overall scores over time



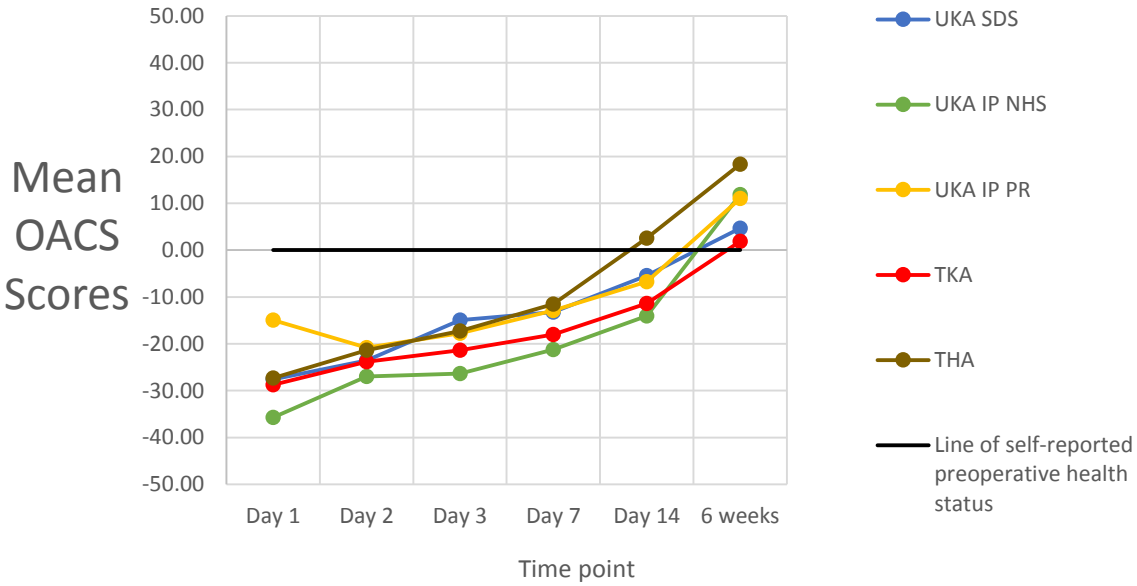
Type of surgery: UKA= Unicompartmental Knee Arthroplasty, SDS= Same-day surgery discharge; IP= inpatient; NHS=National Health Service Hospital; PR=Private hospital; TKA= Total Knee Arthroplasty; THA= Total Hip Arthroplasty.

Figure 6.2: Mean OARS scores by surgery type over time



OACS=Oxford Arthroplasty Early Change Score.

Figure 6.3: Mean OACS overall scores over time



Type of surgery: UKA= Unicompartmental Knee Arthroplasty, SDS= Same-day surgery discharge; IP= inpatient; NHS=National Health Service Hospital; PR=Private hospital; TKA= Total Knee Arthroplasty; THA= Total Hip Arthroplasty.

Figure 6.4: Mean OACS scores by surgery type over time

6.3.3 Internal Consistency Reliability

The OARS questionnaire displayed good internal consistency and reliability with Cronbach's alpha ranging between .77-.91 (Table 6.5). Similarly, the OACS questionnaire displayed an overall Cronbach's alpha of 0.93.

These results for Cronbach's alpha provide evidence that items in the OARS are measuring health status at the time of testing, and that the OACS is measuring the change. Cronbach's alpha numbers above 0.9 are of particular significance as future work may lead to these measures being investigated for use at the level of the individual (Table 6.5).

Item-to-total correlations are an additional measure of test reliability and are presented below in Table 6.5.

Table 6.5: OARS Items to total correlations and internal reliability

Domain	Item	Corrected Item to Total Correlation	Cronbach's Alpha
Pain			.77
	2. I've felt tired	.468	
	4. It's been painful in the affected area	.743	
	5. I've had pain at night in the affected area	.706	
	6. The affected area has felt swollen	.401	
Nausea and feeling unwell			.82
	1. I've felt unwell	.728	
	3. I've felt faint	.523	
	13. I've felt sick	.707	
	14. I've lost my appetite	.590	
Fatigue and sleep			.91
	10. I've not slept well	.854	
	11. I've found it difficult to sleep	.862	
	12. I've not been able to sleep due to the pain in the affected area	.744	
Increasing function and mobility			.86
	7. I've had difficulty getting into bed	.554	
	8. I've not been able to stand	.872	
	9. I've not been able to walk	.824	

6.3.4 Mean scores of OARS domains and SF-36v2 Acute

Table 6.6 shows the mean scores, standard deviation (SD) and confidence intervals (CI) for the domains and dimensions of both the OARS and SF-36v2 Acute for days 7, 14 and 6 weeks.

Table 6.6: Mean scores for the domains and dimensions of the OARS and SF-36v2 Acute

Day 7	**Mean (SD)**	**95% CI**
OARS dimensions		
Pain	35.09 (19.11)	13.90-38.28
Fatigue and sleep	50.00 (27.53)	45.42-54.58
Nausea and feeling unwell	68.66 (21.03)	65.15-72.18
Increasing function and mobility	66.43 (21.16)	62.89-69.96
SF-36v2 Acute Scales		
Physical Functioning	16.67 (16.46)	13.91-19.43
Bodily Pain	28.22 (18.80)	25.08-31.36
General Health	64.88 (18.28)	61.84-67.92
Vitality	34.33 (19.25)	31.11-37.55
Day 14	**Mean (SD)**	**95% CI**
OARS dimensions		
Pain	42.55 (21.60)	38.87-46.22
Fatigue and sleep	50.18 (30.61)	44.99-55.37
Nausea and feeling unwell	78.47 (20.21)	75.03-81.91
Increasing function and mobility	78.67 (17.08)	75.75-81.59
SF-36v2 Acute Scales		
Physical Functioning	28.64 (21.12)	25.05-32.24
Bodily Pain	43.22 (20.19)	39.78-46.66
General Health	70.03 (19.75)	66.68-73.38
Vitality	43.94 (20.19)	40.50-47.37
6 weeks	**Mean (SD)**	**95% CI**
OARS dimensions		
Pain	55.18 (26.51)	50.54-59.81
Fatigue and sleep	63.16 (28.99)	58.05-68.27
Nausea and feeling unwell	86.12 (16.42)	83.24-89.01
Increasing function and mobility	85.48 (16.24)	82.64-88.32
SF-36v2 Acute Scales		
Physical Functioning	57.88 (21.66)	48.06-55.70
Bodily Pain	59.96 (22.21)	56.06-63.86
General Health	69.43 (20.27)	65.87-72.98
Vitality	54.07 (19.09)	50.72-57.42

Mean; SD=Standard Deviation; and 95%CI=Confidence Interval.

6.3.5 Construct validity

Spearman rank-order correlation coefficients, or Spearman's rho, were measured between the dimensions of the OARS and SF-36v2 Acute (n=142 participants) (Table 6.7). Moderate to strong correlations were found between many of the previously hypothesised domains of the OARS and SF-36v2 Acute. These included correlations between OARS pain and SF-36v2 Acute bodily pain; OARS nausea and feeling unwell with SF-36v2 Acute domains of general health and vitality; OARS fatigue and sleep with SF-36v2 Acute vitality; and OARS improving function and mobility with SF-36v2 Acute physical functioning. These associations were seen between domains on all time points. As previously discussed, these relationships were anticipated and made sense within the clinical picture of early recovery after hip or knee replacement.

Table 6.7: Spearman's rho correlations for domains of the OARS and SF-36v2 Acute health domain scores at days 7, 14 and 6 weeks

Correlations Day 7			**Physical Functioning**	**Role-Physical**	**Bodily Pain**	**General Health**	**Vitality**	**Social Functioning**	**Role-Emotional**	**Mental Health**
Spearman's rho	Pain	Correlation	.388**	.285**	.505**	.407**	.443**	.349**	.410**	.453**
		Sig. (2-tailed)	.001	.001	.001	.001	.001	.001	.001	.001
	Nausea and feeling unwell	Correlation	.259**	.262**	.226**	.367**	.409**	.255**	.359**	.402**
		Sig. (2-tailed)	.002	.002	.007	.001	.001	.002	.001	.001
	Fatigue and sleep	Correlation	.269**	.355**	.454**	.249**	.420**	.368**	.368**	.358**
		Sig. (2-tailed)	.001	.001	.001	.003	.001	.001	.001	.001
	Improving function and mobility	Correlation	.413**	.295**	.369**	.272**	.271**	.263**	.207*	.289**
		Sig. (2-tailed)	.001	.001	.001	.001	.001	.002	.014	.001
Correlations Day 14			**Physical Functioning**	**Role-Physical**	**Bodily Pain**	**General Health**	**Vitality**	**Social Functioning**	**Role-Emotional**	**Mental Health**
Spearman's rho	Pain	Correlation	.426**	.412**	.556**	.331**	.497**	.458**	.460**	.479**
		Sig. (2-tailed)	.001	.001	.001	.001	.001	.001	.001	.001
	Nausea and feeling unwell	Correlation	.287**	.298**	.398**	.380**	.444**	.287**	.379**	.438**
		Sig. (2-tailed)	0.001	.001	.001	.001	.001	0.001	.001	.001
	Fatigue and sleep	Correlation	.278**	.322**	.477**	.231**	.376**	.332**	.311**	.355**
		Sig. (2-tailed)	0.001	.001	.001	0.007	.001	.001	.001	.001
	Improving function and mobility	Correlation	.542**	.335**	.409**	.439**	.390**	.310**	.360**	.409**
		Sig. (2-tailed)	0	0	0	0	0	0	0	0
Correlations 6 weeks			**Physical Functioning**	**Role-Physical**	**Bodily Pain**	**General Health**	**Vitality**	**Social Functioning**	**Role-Emotional**	**Mental Health**
Spearman's rho	Pain	Correlation	.481**	.454**	.659**	.318**	.569**	.490**	.468**	.497**
		Sig. (2-tailed)	.001	.001	.001	.001	.001	.001	.001	.001
	Nausea and feeling unwell	Correlation	.379**	.400**	.403**	.387**	.573**	.369**	.488**	.499**
		Sig. (2-tailed)	.001	.001	.001	.001	.001	.001	.001	.001
	Fatigue and sleep	Correlation	.403**	.432**	.536**	.262**	.604**	.406**	.353**	.422**
		Sig. (2-tailed)	.001	.001	.001	.003	.001	.001	.001	.001
	Improving function and mobility	Correlation	.486**	.517**	.537**	.370**	.437**	.419**	.413**	.394**
		Sig. (2-tailed)	.001	.001	.001	.001	.001	.001	.001	.001
**. Correlation is significant at the 0.01 level (2-tailed).										

6.3.6 Responsiveness and sensitivity to change

The OARS and OACS demonstrated high responsiveness and sensitivity to change. In order to estimate the minimally important change in the OARS PROM score, the OACS change measure results were reviewed by the expert group. It was determined, as previously discussed, that a change of between five and fifteen points out of 100, would indicate 'minimal change', with between five and minus five as 'no change'. OACS change scores for each patient were reviewed between each testing time point. Patients that reported a minimal change for the OACS at each change time point were then grouped together and mean change in the OARS scores calculated. Mean change on the overall OARS scores suggest that a minimal important change (MIC) of around 13 points is both significant to patients and of possible clinical significance too (Tables 6.8 and 6.9)

Table 6.8: Mean overall 'some change' aggregate OARS scores

Some change aggregate	**day 1-2**	**day 2-3**	**day 3-7**	**day 7-14**	**day 14-6 weeks**
Mean	8.53	15.21	12.05	10.16	14.23
CI	7.44-9.62	11.63-18.79	10.14-13.97	8.18-12.15	10.73-17.74
N	36	33	56	52	33
SD	3.23	10.09	7.14	7.12	9.89
Range	12.50	33.93	26.79	26.79	41.07
Minimum	1.79	0.00	1.79	0.00	0.00
Maximum	14.29	33.93	28.57	26.79	41.07

CI=95% Confidence Interval; N=number; SD= Standard deviation

Table 6.9: Mean overall 'some positive change' OARS scores

Some positive change	**day 1-2**	**day 2-3**	**day 3-7**	**day 7-14**	**day 14-6 weeks**
Mean	8.63	16.57	12.55	10.76	15.27
CI	7.36-9.90	12.33-20.81	10.12-14.97	8.36-13.16	11.44-19.10
N	24	25	38	40	29
SD	3.01	10.28	7.37	7.52	10.06
Range	8.93	33.93	26.78	26.79	41.07
Minimum	5.36	0.00	1.79	0.00	0.00
Maximum	14.29	33.93	28.57	26.79	41.07

CI=95% Confidence Interval; N=number; SD= Standard deviation

6.3.7 Effect size

Effect sizes for the OARS 'some positive change' groups and overall were calculated and are reported (Tables 6.10, 6.11 and 6.12 respectively).

Table 6.10: Effect size for 'some positive change' OARS scores

Some positive change	**day 1-2**	**day 2-3**	**day 3-7**	**day 7-14**	**day 14-6 weeks**
Mean	.40	.77	.58	.50	.71
CI	.34-.46	.57-.96	.47-.69	.39-.61	.53-.88
N	24	25	38	40	25
SD	.14	.48	.34	.35	.47
Range	.41	1.57	1.24	1.24	1.90
Minimum	.25	.00	.08	.00	.00
Maximum	.66	1.57	1.32	1.24	1.90

CI= 95% Confidence Interval; N=number; SD= Standard deviation.

Table 6.11: Effect size overall for OARS

OARS	**day 1-2**	**day 2-3**	**day 1-7**	**day 1-14**	**day 1-6 weeks**
Mean	.20	.29	.81	1.11	1.58
CI	.03-.37	.16-.43	.62-1.01	.90-1.32	1.37-1.80
N	138	140	113	113	113
SD	.98	.77	1.10	1.13	1.16
Range	7.34	5.69	6.19	5.53	5.28
Minimum	-3.14	-2.48	-1.90	-1.73	-.99
Maximum	4.21	3.22	4.29	3.80	4.29

CI=95%Confidence Interval; N=number; SD= Standard deviation

Table 6.12: Effect size overall for OACS

OACS	**day 1-2**	**day 2-3**	**day 1-7**	**Day 1-14**	**day 1-6 weeks**
Mean	.25	.26	.77	1.25	2.18
CI	.06-.41	.16-.39	.53-1.01	.99-1.51	1.89-2.47
N	113	116	93	93	93
SD	.90	.60	1.16329	1.26	1.40
Range	6.01	3.76	7.08	6.76	7.19
Minimum	-3.54	-1.50	-2.79	-2.04	-1.50
Maximum	2.47	2.25	4.29	4.72	5.69

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6.4 Discussion

In order to be considered as a valid measure, it is important that certain quality criteria are met and reported (226, 227). The OARS and OACS have been developed and assessed in accordance with these criteria (83).

The OARS and OACS are appropriate for the hip and knee replacement population. The items have been developed and created directly from patient interviews and their own words. These have been derived from the qualitative interviews and themes that were confirmed with patients following creation. The subject matter and domains of items within the questionnaires have also been confirmed with participants. Participants were generally positive in their assessment of the questionnaires and were, in most cases, willing to take part. They reported being keen to see how things had changed over time. Thus reaffirming that which the measures seek to address.

Both the OARS and OACS received response rates of 78-91%. Patients reported it was not a burden with the mean time to complete being approximately 6 minutes. Participants stated that completing the questionnaires provided a welcome distraction from their surgical recovery which was an unexpected finding as the questionnaires primary focus is recovery and change since the time of surgery. Returning the questionnaires in pre-paid envelopes was reported as giving patients a reason to get up and go to the post box during the early recovery period. In addition, postdoctoral work will include the measures being transferred onto digital electronic delivery methods (202). This will aid ease of delivery of the measures and facilitate receipt and processing of returned data.

The scores derived from both the OARS and OACS have been found to be meaningful in terms of the clinical picture of recovery for patients at the group level, and in relation to how the domain scores of the OARS correlates to the scales of a generic health measure

(SF-36v2 Acute).The minimally important change (MIC) for the OARS has been estimated and believed to be around 13 points. Future work will refine and define changes at the level of the individual level.

The precision of the OARS and OACS has been demonstrated in terms of robust psychometric testing including factor analysis and identification of items with end effects. Both the OARS and OACS have demonstrated precision in their ability to determine between groups.

Both measures display good reliability testing for internal consistency with Cronbach's alpha of between 0.77 and 0.93. An alpha of over 0.8 is desirable and it is recommended that for measures being used at the level of the individual, a higher Cronbach's alpha of 0.9 is recommended. Reproducibility, in terms of retest, is not relevant or indeed feasible because of the very nature of the work within this area of research, as patients are experiencing a sustained period of constant change and, hopefully, improvement during these six weeks.

Validity of an outcome measure is the extent to which it measures what it claims to measure. This is assessed through consideration and evaluation of several different aspects, including content and construct validity (226). In terms of content validity, as discussed above, both measures were developed, tested and created by the exact patient population they were being designed for. Construct validity has been explored and reported by examining previously hypothesised correlations between the scales of the SF-36v2 Acute and domains of the OARS. Positive correlations were found among corresponding domains across each time point during the six week early recovery period.

The OARS and OACS display good responsiveness and sensitivity to change. Both MIC and ES calculations have been reported and demonstrate the ability of the instruments to detect changes over time that matter to patients.

Table 6.13 summarises the quality findings for both the OARS and OACS that was performed in the earlier systematic review in Chapter 2.

Table 6.13: Quality criteria table for OARS and OACS

Lead Author	Strickland	Strickland	**Notes**
Year	2019	2019	
Country	England, UK	England, UK	
Name of tool	Oxford Arthroplasty Early Recovery Score (OARS)	Oxford Arthroplasty Early Change Score (OACS)	
Population	Adult total hip, unicompartmental knee and total knee replacement patients	Adult total hip, unicompartmental knee and total knee replacement patients	
Outcomes	New patient-reported outcome measure (PROM). Measures postoperative recovery during the first six weeks following surgery	New patient-reported measure of change. Measures postoperative change since surgery during the first six weeks following surgery	
Number of patients	387	387	
Number of items	14	14	
Mean time to complete	6 minutes	6 minutes	
Timing of measurement	Days 1, 2, 3, 7, 14 and 6 weeks following surgery	Days 1, 2, 3, 7, 14 and 6 weeks following surgery	
Internal consistency	Overall: 0.91; Domains: 0.77-0.91	0.93	Cronbach's alpha
Completion rate	78.1-91.6%	78.1-91.6%	Postal problem reported so may be higher.
Item selection	Experts and patients	Experts and patients	
Item generation discussed	Yes	Yes	
Construct validity	Factor analysis and variance reported	Factor analysis and variance reported	
Variance	Yes, comparisons between UKA, inpatient and same-day, UKA vs TKA and TKA vs THA reported. Between UKA groups: Day 1: p=.002; Day 7: p=.050. UKA vs TKA: Day 1: p=.004; Day 7: p=.035; Day 14: p=.015 and 6 weeks: p=.040. THA vs TKA: Day 7: p=.017; Day 14: p=.001 and 6 weeks: p=.010.	Yes, comparisons between UKA, inpatient and same-day, UKA vs TKA and TKA vs THA reported. Between UKA groups: Day 1: p=.026. UKA vs TKA: Not statistically significant. THA vs TKA: Day 14: p=.002; 6 weeks: p=.006.	Compares different groups at different times. One-way between groups analysis of variance (Anova) and independent t-test.
Responsiveness	Yes, MIC= 13; ES= Overall: 0.20-1.58.	Yes, ES= 0.25-2.18.	MIC=Minimum important change; ES=Effect size;
Convergent validity hypothesis testing	r=0.51; p<0.0011 day 7 OARS pain to BP SF-36v2 Acute r=0.56; p<0.0011 day 14 OARS pain to BP SF-36v2 Acute r=0.66; p<0.0011 6 weeks OARS pain to BP SF-36v2 Acute		OARS domains correlated with SF-36 Version 2 Acute scale scores; r=Spearman's Rank Correlation; BP=Bodily Pain SF-36v2 Acute
Domains	Pain Nausea and feeling unwell Fatigue and sleep Increasing function and mobility	Overall change score	

Testing of the OARS and OACS in Phase Four, has demonstrated good psychometric properties in terms of internal consistency reliability and sensitivity to change over time.

6.5 Strengths and Limitations

This study was carried out in one NHS hospital and one private hospital in England, UK and as such may not be externally generalisable to the rest of the country, and indeed abroad.

As is often the case in research of this nature, the demographic distribution of participants was predominantly White British (97.4%) with only a small number of people from ethnic minorities. However, there is no prior hypothesis to indicate that this should change or affect the psychometric properties for this or any other phase of the study. It is acknowledged that cultural differences may exist between other patient groups. Future research should include testing in other cultures and population groups.

There were challenges during this phase of the study. Surgery schedules were seen to change frequently, often on a daily basis. Patients were delayed and required further testing or interventions before being medically 'cleared' for surgery. Surgery lists were rearranged based on acceptable waiting times within the NHS. Patients were also cancelled when a theatre list overran due to a complicated revision surgery or an unexpected event arising in theatre. Hospital staffing also affected the surgical theatre lists.

Although 155 patients were included in this study, some patients did not complete questionnaires at all time points for the study (n=30). Three patients experienced other health events during Phase Four of the study and were unable to complete their participation. These events included infection diagnosed at day seven, a stroke at day fourteen and hip dislocation at six weeks.

A number of questionnaires and return envelopes were not received at the research office (n=27). As in Phase Three, a problem with the pre-paid return envelopes occurred in the post office, therefore, the true response rate may be higher than estimated, as patients reported returning their forms and would call the research office multiple times to confirm receipt. Further work with revision hip and knee patients would also be of interest, as the numbers of participants undergoing these procedures during this study were low.

6.6 Summary

This chapter has reported the validation and testing of sensitivity to change for the OARS and OACS questionnaires. Previously hypothesised correlations were found between the domains of the generic SF-36 v2 Acute health measure and the OARS. The next chapter will report their use in a study to evaluate and compare traditional inpatient stay following UKA with the adoption of a new, same-day discharge for UKA.

7 Preliminary results from a comparison of inpatient versus same-day unicompartmental knee arthroplasty

7.1 Introduction

The previous chapters have explored and discussed the need for and the process of development of early recovery questionnaires for the hip and knee arthroplasty population. This chapter reports the use of these instruments in a pilot study of a cohort of unicompartmental knee arthroplasty (UKA) patients. The context in which a measure can be used and possible new uses for it are both parts of the iterative best practice PROM development guidelines from the FDA (70).

7.2 Background to Same-day Surgery Discharge Unicompartmental Knee Arthroplasty

UKA is an established treatment option increasingly used for managing end-stage knee arthritis of one compartment of the knee. It has significant advantages over total knee arthroplasty (TKA), including better function, significantly lower morbidity and mortality (228) and a more rapid recovery (229, 230). Currently, a typical patient stays in hospital for two to four days after UKA, although a previous feasibility study by this research group has confirmed the ability to perform UKA as a day case surgery. Despite initial patient and service provider apprehensions, it has now been possible to implement this on a wider scale due to a variety of operational reasons. These include the shift in focus towards enhanced recovery after surgery (ERAS) for hip and knee patients (231) which has brought about newer anaesthetic and pain management options, and improved surgical techniques. As discussed earlier in this thesis, ERAS programmes, which were originally developed for colorectal surgery, have been implemented across surgical disciplines with the aim of

reducing patient length of stay, postoperative complications, pain, and improving outcomes (54, 59). These pathways include: preoperative patient education, optimisation of medical conditions, preoperative physiotherapy, early mobilisation, venous thromboembolism prophylaxis and multimodal pain regimens (47). These have been beneficial in improving the patient pathway and working towards reducing length of stay. Historically, with any knee replacement surgery, the intention was to begin physiotherapy as soon as the patient was able. The goal of this was to restore range of motion (ROM) (flexion and extension of the knee and leg) as soon as possible. Improved postoperative ROM is not only seen as important in the measurement of objective outcomes, but is also of significance to patients and closely linked to satisfaction (232). UKAs were found to have recovered good postoperative range of motions regardless of whether they had immediate or delayed exercise (233). This led surgeons and researchers to question the need for immediate activity for UKA patients. Same-day surgery discharge (SDS) UKA at the hospital began with clinical staff implementing reduced initial movement of the knee, with the patient's knee being bandaged in extension prior to discharge. This novel technique has initially showed good results (234). Until now, no standardised tools existed to assess the quality of recovery after a knee replacement.

7.3 Participants and Methods

7.3.1 UKA pilot study

Participants were divided between two hospitals: a private independent hospital and orthopaedic centre. The same surgeons were operating at both hospitals and the same instrumentation and implants used. The two questionnaires, OARS and OACS, were distributed to a cohort of 55 consecutive unicompartmental knee arthroplasty patients. They

were administered on days 1, 2, 3, 7 and 14 in the early postoperative period and also at six weeks following surgery.

7.3.2 Statistical Analysis

- Descriptive statistics and frequency tables reported.
- Effect size.
- Tests to compare groups and hypotheses.

7.3.3 Hypotheses for testing with OARS and OACS

Prior to commencing this study, many potential hypotheses were explored and discussed among the expert panel. These included differences among the surgical groups, ages of participants, duration if disease prior to surgery, ethnicity, length of hospital stay and other demographic considerations.

The following hypotheses were chosen for evaluation through this study:

- Null hypothesis: No change and recovery occur across the six week period.
- Null hypothesis: There are no differences in recovery between same-day UKA, inpatient UKA in an NHS setting or inpatient UKA in a private setting (Currently UKA patients in the private setting in this study are not offered a same-day discharge option).
- Null hypothesis: There are no differences in recovery between UKA and TKA patients
- Null hypothesis: There are no differences in recovery between THA and TKA patients

This is a pilot study investigating some hypotheses and issues using the new OARS and OACS instruments. This study may form the basis of a larger (post-doctoral) body of work

and sample size calculations will be performed in preparation for those. This data may provide useful information for those sample size calculations.

7.4 Results

7.4.1 Participants

A total of 55 participants were included in the study: 27 women (49%) and 28 men (51%) (Table 7.1).

Table 7.1: Unicompartmental Knee Participant Characteristics

Parameter	
Age (years)	67 (10.5) 42-87
Sex Male/Female (% male)	28/27 (51)
Ethnicity	WB 53 (96.4) OW 1 (1.8) I 1 (1.8)
Duration of disease (years)	6.9 (11.8) 0.5-74
Length of stay (days)	1.3 (1.5) 0-5
Type of surgery	UKA 55 (100) SDS 26 (47.3) IP 29 (52.7) • Private hospital IP 18 (62.1) • NHS hospital IP 11 (37.9)
Employment	Employed 18 (32.7) Retired 37 (67.3)
Living situation	Alone 7 (12.7) Family 48 (87.3)
Home situation	One level 9 (16.4) Up and down stairs 46 (83.6)

Data are n (%) or mean (SD) range. Ethnicity: WB= White British; OW= Other White; I= Indian. Ethnicity categories from Office for National Statistics (ONS), Census 2011. Type of surgery: UKA= Unicompartmental Knee Arthroplasty, SDS= Same-day surgery discharge; IP= inpatient.

The mean age of participants was 67 years (SD=10.5; range 42-87). All participants underwent UKA (n=55); 26 with same-day surgery discharge (SDS) and 29 having an inpatient stay. The SDS UKA were all performed in the Orthopaedic Specialty NHS hospital. The inpatient UKA surgeries were performed across both NHS (n=11) and a private hospital (n=18). The ethnic composition of the sample was predominantly White British 53 (96.4%) but also included one White – Other (1.8%) and one Indian (1.8%) respondent. Mean length of hospital stay for all participants was 1.3 days (SD=1.5; range 0-5). The duration of disease ranged from 0.5 years to 74 years (mean=6.9; SD=11.8). Within the group, 18 were currently employed (32.7%) and 37 were retired (67.3%). 48 (87.3%) participants lived with family and 7 (12.7%) lived alone. Nine (16.4%) participants lived on one level and 46 (83.6%) had stairs.

7.4.2 Mean scores for OARS and OACS

The mean overall scores for each surgery type by testing time point in both the OARS and OACS can be seen in Tables 7.2 and 7.3. In addition, the scores for TKA from the previous chapter have been included for comparative purposes.

Table 7.2: Mean overall OARS scores for UKA and TKA

Surgery		OARS day 1	OARS day 2	OARS day 3	OARS day 7	OARS day 14	OARS 6 weeks
UKA SDS	Mean	40.63	39.88	52.10	59.30	66.15	73.21
	CI	32.41-48.84	30.88-48.88	44.83-59.36	53.90-64.71	58.79-73.51	65.70-80.73
	N	24	24	23	24	23	21
	SD	19.46	21.32	16.80	12.80	17.02	16.50
	Range	67.86	75.00	66.07	58.93	66.07	51.79
	Minimum	10.71	1.79	21.43	25.00	28.57	44.64
	Maximum	78.57	76.79	87.50	83.93	94.64	96.43
UKA IP NHS	Mean	27.68	35.00	42.06	45.00	54.29	68.75
	CI	11.21-44.15	20.09-49.91	26.16-57.97	32.14-57.86	44.44-64.13	58.35-79.15
	N	10	10	9	10	10	8
	SD	23.03	20.85	20.69	17.97	13.76	12.45
	Range	55.36	62.50	53.57	53.57	42.86	39.29
	Minimum	1.79	5.36	10.71	10.71	26.79	42.86
	Maximum	57.14	67.86	64.29	64.29	69.64	82.14
UKA IP PR	Mean	58.51	45.44	47.82	58.04	59.98	72.27
	CI	46.76-70.26	32.36-58.51	38.02-57.61	48.71-67.37	50.58-69.38	64.36-80.18
	N	17	18	18	16	17	17
	SD	22.86	26.29	19.70	17.51	18.28	15.39
	Range	89.29	91.07	67.86	71.43	53.57	48.21
	Minimum	8.93	1.79	10.71	19.64	39.29	46.43
	Maximum	98.21	92.86	78.57	91.07	92.86	94.64
TKA	Mean	28.39	33.81	40.82	48.21	51.50	63.66
	CI	20.77-36.00	26.99-40.62	34.08-47.55	43.32-53.11	45.13-57.87	56.42-70.91
	N	29	29	28	25	25	23
	SD	20.02	17.91	17.37	11.87	15.44	16.75
	Range	78.57	75.00	73.21	51.79	69.64	66.07
	Minimum	0.00	0.00	0.00	17.86	19.64	30.36
	Maximum	78.57	75.00	73.21	69.64	89.29	96.43

CI= 95% Confidence Interval; N=number; SD= Standard deviation. Type of surgery: UKA= Unicompartmental Knee Arthroplasty, SDS= Same-day surgery discharge; IP= inpatient; NHS=National Health Service Hospital; PR=Private hospital; TKA= Total Knee Arthroplasty.

Table 7.3: Mean overall OACS scores for UKA and TKA

Surgery		OACS day 1	OACS day 2	OACS day 3	OACS day 7	OACS day 14	OACS 6 weeks
UKA SDS	Mean	-27.59	-23.59	-14.94	-13.27	-5.43	4.63
	CI	-35.45--19.75	-33.22--13.96	-21.87--8.02	-20.14--6.41	-13.48-2.62	-4.28-13.53
	N	22	19	19	23	23	22
	SD	17.71	19.98	14.36	15.88	18.62	20.08
	Range	80.36	66.07	60.71	71.43	76.79	69.64
	Minimum	-50.00	-50.00	-41.07	-41.07	-35.71	-30.36
	Maximum	30.36	16.07	19.64	30.36	41.07	39.29
UKA IP NHS	Mean	-35.71	-26.96	-26.34	-21.23	-14.09	11.83
	CI	-45.99--25.44	-39.67--14.25	-37.19--15.49	-35.39--7.07	-26.10--2.07	0.27-23.39
	N	9	10	8	9	9	8
	SD	13.36	17.77	12.97	18.42	15.63	13.83
	Range	33.93	57.14	37.50	58.93	44.64	37.50
	Minimum	-50.00	-50.00	-50.00	-48.21	-39.29	-7.14
	Maximum	-16.07	7.14	-12.50	10.71	5.36	30.36
UKA IP PR	Mean	-14.92	-20.83	-17.76	-12.92	-6.72	11.03
	CI	-27.01--2.83	-32.04--9.62	-26.12--9.40	-21.55--4.29	-16.18-2.74	3.14-18.92
	N	14	15	18	17	17	17
	SD	20.94	20.24	16.81	16.78	18.40	15.34
	Range	71.43	73.21	67.86	64.29	62.50	57.14
	Minimum	-46.43	-46.43	-44.64	-33.93	-28.57	-14.29
	Maximum	25.00	26.79	23.21	30.36	33.93	42.86
TKA	Mean	-28.79	-23.84	-21.35	-18.04	-11.41	1.88
	CI	-34.51--23.06	-29.71--17.97	-26.79--15.92	-24.81--11.26	-18.21--4.61	-9.33-13.09
	N	25	23	24	20	18	19
	SD	13.86	13.57	12.87	14.47	13.67	23.25
	Range	51.79	48.21	51.79	66.07	62.50	87.50
	Minimum	-48.21	-44.64	-50.00	-44.64	-44.64	-41.07
	Maximum	3.57	3.57	1.79	21.43	17.86	46.43

CI= 95% Confidence Interval; N=number; SD= Standard deviation. Type of surgery: UKA= Unicompartmental Knee Arthroplasty, SDS= Same-day surgery discharge; IP= inpatient; NHS=National Health Service Hospital; PR=Private hospital; TKA= Total Knee Arthroplasty.

7.4.3 Mean scores with domains of SF-36v2 Acute

Table 7.4 shows the mean scores, standard deviation (SD) and 95% confidence intervals (CI) for the dimensions of both the OARS and SF-36v2 Acute for days 7, 14 and 6 weeks. As discussed earlier in this thesis, prior hypotheses on correlations were made between the OARS and SF-36v2.

Table 7.4: Mean scores for the domains and dimensions of the OARS and SF-36 acute v2 for UKA and TKA

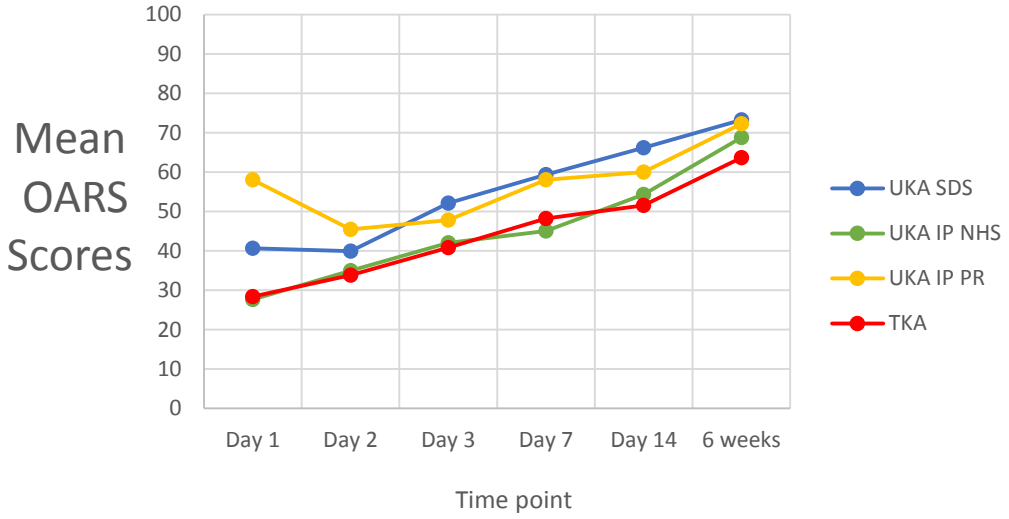
Surgery Type		Day 7	Day 14	6 weeks
	OARS dimensions			
	Pain	35.68 (11.28) 30.91-40.44	45.65 (21.36) 36.42-54.89	52.99 (25.06) 42.15-63.83
UKA SDS	Fatigue and sleep	59.33 (26.82) 48.26-70.41	60.76 (24.76) 50.31-71.22	63.89 (29.15) 50.62-77.16
	Nausea and feeling unwell	77.50 (16.24) 70.80-84.20	82.07 (17.51) 74.50-89.64	87.78 (11.33) 82.76-92.81
	Increasing function and mobility	69.67 (15.38) 63.32-76.02	78.26 (16.62) 71.08-85.45	85.15 (18.46) 77.16-93.13
	SF-36 v2 Acute Scales			
	Bodily Pain	27.25 (19.19) 19.15-35.35	46.87 (19.01) 38.65-55.09	54.95 (19.18) 46.45-63.46
	Vitality	36.46 (17.84) 28.93-43.99	47.55 (20.27) 38.79-56.32	56.16 (17.44) 48.42-63.89
	General Health	64.36 (14.53) 58.36-70.36	70.75 (14.85) 64.48-77.02	70.27 (16.78) 62.83-77.71
	Physical Functioning	18.74 (16.37) 11.83-25.65	30.73 (24.75) 20.03-41.43	49.00 (21.31) 39.56-58.45
	OARS dimensions			
	Pain	24.38 (17.54) 11.83-36.92	32.50 (11.34) 24.39-40.61	42.97 (23.00) 23.73-62.21
UKA IP NHS	Fatigue and sleep	38.33 (23.96) 21.19-55.47	38.33 (25.22) 20.30-56.37	65.63 (29.69) 40.80-90.45
	Nausea and feeling unwell	55.63 (22.72) 39.37-71.88	70.00 (21.00) 54.98-85.02	83.59 (12.47) 73.17-94.02
	Increasing function and mobility	65.00 (27.44) 45.37-84.63	78.33 (19.27) 64.23-92.44	86.46 (15.40) 73.90-99.33
	SF-36 v2 Acute Scales			
	Bodily Pain	19.60 (16.39) 7.88-31.32	32.70 (21.22) 17.52-47.88	56.50 (25.33) 35.33-77.67
	Vitality	25.00 (15.31) 14.04-35.95	38.13 (21.54) 22.72-53.53	46.09 (13.34) 34.94-57.24
	General Health	69.40 (16.65) 57.49-81.31	71.40 (20.32) 56.86-85.94	77.38 (8.60) 70.18-84.57
	Physical Functioning	13.00 (14.76) 2.44-23.56	19.50 (15.18) 8.64-30.36	39.67 (16.95) 25.50-53.84

	OARS dimensions			
	Pain	34.19 (18.63) 24.61-43.77	39.34 (20.22) 28.94-49.74	52.94 (22.76) 41.24-64.65
UKA IP PR	Fatigue and sleep	53.43 (28.42) 38.82-68.05	41.67 (33.33) 24.53-58.81	55.39 (31.45) 39.22-71.56
	Nausea and feeling unwell	69.49 (20.95) 58.71-80.26	76.47 (21.26) 65.54-87.40	89.71 (12.68) 83.19-96.23
	Increasing function and mobility	74.48 (18.38) 64.69-84.27	83.82 (15.16) 76.03-91.62	91.67 (11.79) 85.61-97.73
	SF-36v2 Acute Scales			
	Bodily Pain	29.94 (18.09) 20.64-39.24	42.35 (18.37) 32.91-51.80	59.88 (14.33) 52.52-67.25
	Vitality	41.91 (19.36) 31.96-51.87	43.75 (20.85) 33.03-54.47	55.88 (14.90) 48.22-63.54
	General Health	64.71 (16.32) 56.31-73.10	67.06 (18.78) 57.40-76.71	67.41 (16.75) 58.80-76.02
	Physical Functioning	20.00 (18.36) 10.56-29.45	35.24 (16.69) 26.66-43.82	62.13 (12.55)55.67-68.58
	OARS dimensions			
	Pain	30.25 (18.90) 22.45-38.05	32.00 (18.95) 24.18-39.82	43.75 (25.14) 32.88-54.62
TKA	Fatigue and sleep	41.67 (22.82) 32.25-51.09	39.00 (26.54) 28.05-49.96	55.44 (31.84) 41.67-69.20
	Nausea and feeling unwell	60.50 (19.07) 52.63-68.37	64.25 (23.35) 54.61-73.89	77.17 (16.17) 70.18-84.17
	Increasing function and mobility	62.33 (19.56) 54.26-70.41	73.00 (19.58) 64.92-81.08	80.44 (17.34) 72.94-87.93
	SF-36v2 Acute Scales			
	Bodily Pain	27.08 (20.35) 18.68-35.48	39.16 (22.85) 29.73-48.59	52.04 (24.41) 41.49-62.60
	Vitality	30.25 (21.17) 21.51-39.99	36.08 (17.56) 28.83-43.33	46.74 (22.99)36.80-56.68
	General Health	59.96 (22.80) 50.55-69.37	63.64 (22.39) 54.40-72.88	61.48 (22.60) 51.70-71.25
	Physical Functioning	11.94 (12.81) 6.65-17.22	18.01 (15.51) 11.61-24.41	42.13 (24.21) 31.40-52.87

Type of surgery: UKA= Unicompartmental Knee Arthroplasty, SDS= Same-day surgery discharge; IP= inpatient; NHS=National Health Service Hospital; PR=Private hospital; TKA= Total Knee Arthroplasty. Mean; SD=Standard Deviation; and 95%CI=Confidence Interval.

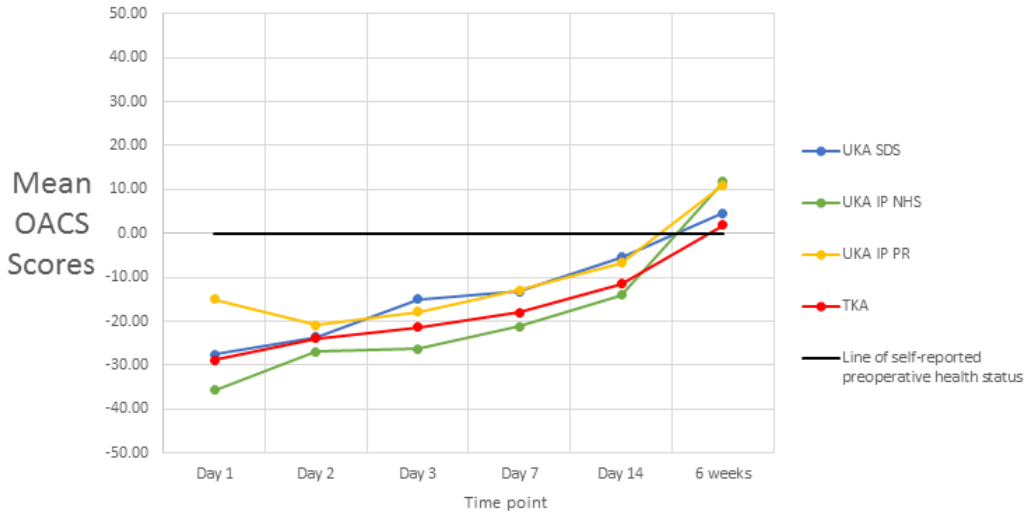
7.4.4 Comparison of UKA (same-day discharge versus inpatient) with TKA

The mean OARS and OACS scores over time and by surgery type are shown below (Figures 7.1 and 7.2).



Type of surgery: UKA= Unicompartmental Knee Arthroplasty, SDS= Same-day surgery discharge; IP= inpatient; NHS=National Health Service Hospital; PR=Private hospital; TKA= Total Knee Arthroplasty.

Figure 7.1: Mean OARS scores by knee surgery type over time

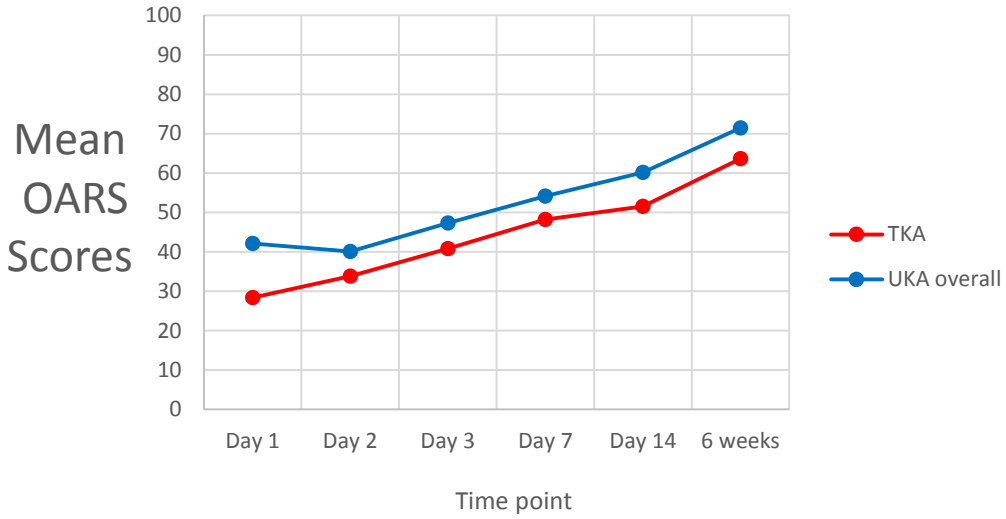


Type of surgery: UKA= Unicompartmental Knee Arthroplasty, SDS= Same-day surgery discharge; IP= inpatient; NHS=National Health Service Hospital; PR=Private hospital; TKA= Total Knee Arthroplasty.

Figure 7.2: Mean OACS scores by knee surgery type over time

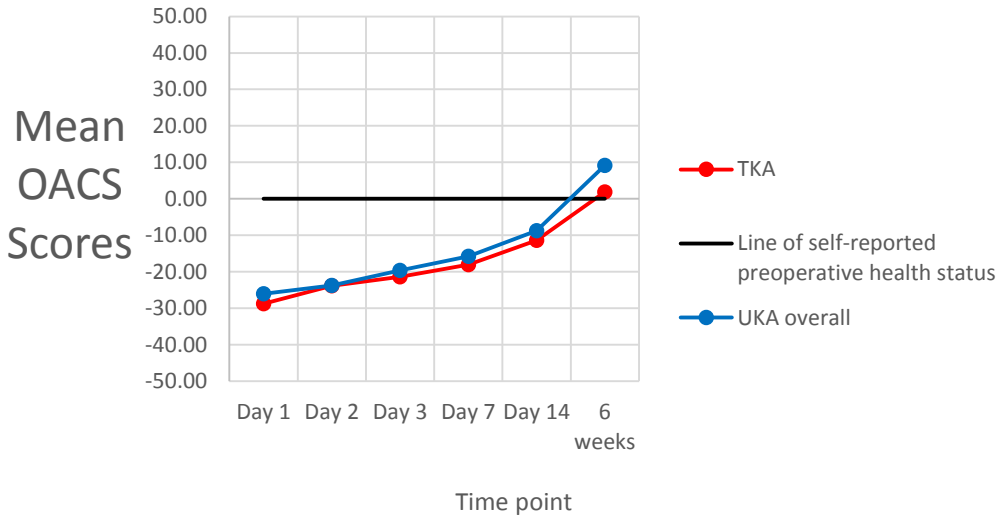
7.4.5 Comparison of UKA and TKA

The mean overall UKA and TKA OARS and OACS scores over time are shown below (Figures 7.3 and 7.4). Changes in mean scores for UKA and TKA at each testing time point are found in Tables 7.5 and 7.6 respectively.



Type of surgery: UKA= Unicompartmental Knee Arthroplasty, TKA= Total Knee Arthroplasty.

Figure 7.3: Mean OARS scores overall UKA and TKA over time



Type of surgery: UKA= Unicompartmental Knee Arthroplasty, TKA= Total Knee Arthroplasty.

Figure 7.4: Mean OACS scores overall UKA and TKA over time

Table 7.5: Mean overall OARS change scores for UKA and TKA

Surgery	OARS	day 1-2	day 2-3	day 1-7	day 1-14	day 1-6 weeks
UKA SDS	Mean	-2.23	12.05	14.73	20.63	28.93
	CI	-11.64-7.18	2.90-21.21	7.19-22.27	14.85-26.41	20.65-37.21
	N	12	12	20	20	20
	SD	14.81	14.41	16.11	12.35	17.68
	Range	44.64	55.36	71.43	51.79	64.29
	Minimum	-30.36	-3.57	-19.64	.00	1.79
	Maximum	14.29	51.79	51.79	51.79	66.07
UKA IP NHS	Mean	9.52	5.06	21.21	29.68	41.30
	CI	-2.13-21.18	-13.09-23.21	8.20-34.23	12.72-46.65	22.37-60.22
	N	6	6	8	8	8
	SD	11.10	17.29	15.58	20.29	22.64
	Range	28.57	48.21	41.07	60.71	66.07
	Minimum	-8.93	-14.29	7.14	7.14	10.71
	Maximum	19.64	33.93	48.21	67.86	76.79
UKA IP PR	Mean	-4.91	0.00	-2.98	-.48	12.62
	CI	-26.90-17.08	-12.57-12.57	-18.52-12.56	-16.78-15.82	-2.80-28.04
	N	12	12	15	15	15
	SD	34.61	19.78	28.06	29.43	27.84
	Range	103.57	67.86	103.57	105.36	103.57
	Minimum	-67.86	-25.00	-41.07	-37.50	-21.43
	Maximum	35.71	42.86	62.50	67.86	82.14
TKA	Mean	3.57	8.93	17.78	19.89	31.41
	CI	-7.60-14.74	.54-17.32	8.96-26.59	10.68-29.10	19.84-42.99
	N	13	13	22	22	22
	SD	18.50	13.89	19.88	20.75	26.10
	Range	58.93	37.50	75.00	80.36	82.14
	Minimum	-37.50	-3.57	-30.36	-33.93	-19.64
	Maximum	21.43	33.93	44.64	46.43	62.50

CI=95% Confidence Interval; N=number; SD= Standard deviation. Type of surgery: UKA= Unicompartmental Knee Arthroplasty, SDS= Same-day surgery discharge; IP= inpatient; NHS=National Health Service Hospital; PR=Private hospital; TKA= Total Knee Arthroplasty.

Table 7.6: Mean overall OACS change scores for UKA and TKA

Surgery	OACS	day 1-2	day 2-3	day 1-7	day 1-14	day 1-6 weeks
UKA SDS	Mean	6.25	3.27	12.95	19.55	30.45
	CI	-.97-13.47	-3.88-10.43	2.73-23.16	10.32-28.78	21.08-39.81
	N	12	12	20	20	20
	SD	11.36	11.26	21.83	19.72	20.00
	Range	-7.14	50.00	117.86	100.00	87.50
	Minimum	28.57	-19.64	-46.43	-21.43	-7.14
	Maximum	35.71	30.36	71.43	78.57	80.36
UKA IP NHS	Mean	4.76	3.27	13.10	21.13	43.16
	CI	-3.59-13.12	-4.35-10.90	2.99-23.20	14.70-27.56	26.93-59.38
	N	6	6	6	6	6
	SD	7.96	7.27	9.63	6.13	15.46
	Range	-7.14	17.86	25.00	16.07	44.64
	Minimum	14.29	-5.36	1.79	14.29	23.21
	Maximum	21.43	12.50	26.79	30.36	67.86
UKA IP PR	Mean	-5.66	3.87	2.06	7.97	23.35
	CI	-20.25-8.94	-3.99-11.73	-10.42-14.54	-7.52-23.45	10.38-36.32
	N	12	12	13	13	13
	SD	22.97	12.37	20.66	25.62	21.46
	Range	73.21	42.86	75.00	94.64	71.43
	Minimum	-42.86	-16.07	-26.79	-33.93	-5.36
	Maximum	30.36	26.79	48.21	60.71	66.07
TKA	Mean	2.75	1.24	9.82	13.01	25.64
	CI	-1.95-7.44	-1.56-4.04	1.58-18.07	5.16-20.86	11.59-39.69
	N	13	13	14	14	14
	SD	7.77	4.63	14.28	13.59	24.33
	Range	33.93	16.07	53.57	50.00	80.36
	Minimum	-12.50	-7.14	-12.50	-12.50	-10.71
	Maximum	21.43	8.93	41.07	37.50	69.64

CI=95% Confidence Interval; N=number; SD= Standard deviation. Type of surgery: UKA= Unicompartmental Knee Arthroplasty, SDS= Same-day surgery discharge; IP= inpatient; NHS=National Health Service Hospital; PR=Private hospital; TKA= Total Knee Arthroplasty.

7.4.6 Effect size

Effect sizes for the OARS and OACS were calculated for both UKA and TKA patients (Tables 7.7 and 7.8).

Table 7.7: Effect size for OARS for UKA and TKA

Surgery	OARS	day 1-2	day 2-3	day 1-7	day 1-14	day 1-6 weeks
UKA SDS	Mean	-.10	.56	.68	.95	1.34
	CI	-.54-.33	.13-.98	.33-1.03	.69-1.22	.95-1.72
	N	12	12	20	20	20
	SD	.68	.67	.74	.57	.82
	Range	2.06	2.56	3.30	2.39	2.97
	Minimum	-1.40	-.17	-.91	.00	.08
	Maximum	.66	2.39	2.39	2.39	3.05
UKA IP NHS	Mean	.44	.23	.98	1.37	1.91
	CI	-.10-.98	-.61-1.07	.38-1.58	.59-2.16	1.03-2.78
	N	6	6	8	8	8
	SD	.51	.80	.72	.94	1.05
	Range	1.32	2.23	1.90	2.81	3.05
	Minimum	-.41	-.66	.33	.33	.50
	Maximum	.91	1.57	2.23	3.14	3.55
UKA IP PR	Mean	-.23	.00	-.14	-.02	.58
	CI	-1.24-.79	-.58-.58	-.86-.58	-.78-.73	-.13-1.30
	N	12	12	15	15	15
	SD	1.60	.91	1.30	1.36	1.29
	Range	4.79	3.14	4.79	4.87	4.79
	Minimum	-3.14	-1.16	-1.90	-1.73	-.99
	Maximum	1.65	1.98	2.89	3.14	3.80
TKA	Mean	.17	.41	.82	.92	1.45
	CI	-.35-.68	.03-.80	.41-1.23	.49-1.34	.92-1.99
	N	13	13	22	22	22
	SD	.85	.64	.92	.96	1.21
	Range	2.72	1.73	3.47	3.71	3.80
	Minimum	-1.73	-.17	-1.40	-1.57	-.91
	Maximum	.99	1.57	2.06	2.15	2.89

CI=95% Confidence Interval; N=number; SD= Standard deviation. Type of surgery: UKA= Unicompartmental Knee Arthroplasty, SDS= Same-day surgery discharge; IP= inpatient; NHS=National Health Service Hospital; PR=Private hospital; TKA= Total Knee Arthroplasty.

Table 7.8: Effect size for OACS for UKA and TKA

Surgery	OACS	day 1-2	day 2-3	day 1-7	day 1-14	day 1-6 weeks
UKA SDS	Mean	.38	.20	.78	1.18	1.83
	CI	-.06--.81	-.23-.63	.16-1.39	.62-1.73	1.27-2.39
	N	12	12	20	20	20
	SD	.68	.68	1.31	1.19	1.20
	Range	2.15	3.00	7.08	6.01	5.26
	Minimum	-.43	-1.18	-2.79	-1.29	-.43
	Maximum	1.72	1.82	4.29	4.72	4.83
UKA IP NHS	Mean	.29	.20	.79	1.27	2.59
	CI	-.22-.79	-.26-.66	.18-1.39	.88-1.66	1.62-3.57
	N	6	6	6	6	6
	SD	.48	.44	.58	.37	.93
	Range	1.29	1.07	1.50	.97	2.68
	Minimum	-.43	-.32	.11	.86	1.40
	Maximum	.86	.75	1.61	1.82	4.08
UKA IP PR	Mean	-.34	.23	.13	.48	1.40
	CI	-1.22-.54	-.24-.71	-.62-.87	-.45-1.41	.62-2.18
	N	12	12	13	13	13
	SD	1.38	.74	1.24	1.54	1.29
	Range	4.40	2.58	4.51	5.69	4.29
	Minimum	-2.58	-.97	-1.61	-2.04	-.32
	Maximum	1.82	1.61	2.90	3.65	3.97
TKA	Mean	.16	.07	.59	.78	1.54
	CI	-.12-.45	-.09-.24	.10-1.09	.31-1.25	.70-2.39
	N	13	13	14	14	14
	SD	.47	.28	.86	.82	1.46
	Range	2.04	.97	3.22	3.00	4.83
	Minimum	-.75	-.43	-.75	-.75	-.64
	Maximum	1.29	.54	2.47	2.25	4.19

CI=95% Confidence Interval; N=number; SD= Standard deviation. Type of surgery: UKA= Unicompartmental Knee Arthroplasty, SDS= Same-day surgery discharge; IP= inpatient; NHS=National Health Service Hospital; PR=Private hospital; TKA= Total Knee Arthroplasty.

7.4.7 Hypothesis for testing

- Do recovery and change occur evenly across the six week recovery period?

  It was anticipated that no real change would occur during the first 2 days, but that from day 3 through six weeks steady observable change would be seen. Change (Tables 7.6 and 7.7) and effect size (Tables 7.8 and 7.9) were assessed across the time points. It was observed that no significant change was observed between days 1 and 2. Change was noted on day 2 to 3. From day 1 to days 7, 14 and six weeks, the substantial amount of change observed in the tables and figures above was remarkable.

- Are there differences in recovery between same-day surgery (SDS) UKA, inpatient (IP) UKA in an NHS setting or inpatient UKA in a private (PR) setting? Currently UKA patients in the private setting in this study are not offered a same-day discharge option.

  A one-way between-groups analysis of variance was conducted to explore recovery and change in health status during the six weeks following UKA, as measured by the OARS and OACS. Participants were divided into three groups according to whether they received same-day discharge following surgery, an NHS inpatient stay or private hospital inpatient stay. There were statistically significant differences at the $p<.05$ level between groups for the OARS scores on day 1 [$F(2, 48) = 7.16$, $p=.002$] and 7 [$F(2, 47) = 3.21$, $p=.050$] and for the OACS scores on day 1 [$F(2, 42) = 3.98$, $p=.026$]. The differences in mean scores between the groups was also statistically significant on those days (Table 7.9). Eta squared measures the proportion of the total variance in a dependent variable (OACS) that is associated with the membership of different groups defined by an independent variable (the three groups of patients). The effect sizes, calculated using eta squared, were .23 on

day 1 and .12 on day 7 for the OARS and .16 on day 1 for the OACS. These are considered to be suggestive of medium to large effects (224). Post-hoc comparisons, using the Tukey HSD test, indicated that the mean day 1 OARS scores were significantly different between IP PR and both SDS and IP NHS groups. Day 7 OARS scores showed statistically significant differences between SDS and IP NHS patients. On day 1, the OACS scores were significantly different between both inpatient groups (Table 7.9).

Table 7.9: UKA one-way analysis of variance test Multiple Comparisons Tukey HSD

Dependent Variable	UKA type	UKA type	Mean Difference	Std. Error	Sig.	Eta squared	95% Confidence Interval	
OARS Day 1	**SDS** (M=40.63 SD=19.46)	**IP NHS** (M=27.68, SD=23.03)	12.95	8.03	0.25	0.23	-6.47	32.37
		IP PR (M=58.51, SD=22.86)	-17.88*	6.76	0.03		-34.24	-1.53
	IP NHS (M=27.68, SD=23.03)	**SDS** (M=40.63, SD=19.46)	-12.95	8.03	0.25		-32.37	6.47
		IP PR (M=58.51, SD=22.86)	-30.83*	8.50	0.01		-51.39	-10.27
	IP PR (M=58.51, SD=22.86)	**SDS** (M=40.63, SD=19.46)	17.88*	6.76	0.03		1.53	34.24
		IP NHS (M=27.68, SD=23.03)	30.83*	8.50	0.01		10.27	51.39
OARS Day 7	**SDS** (M=59.30, SD=12.80)	**IP NHS** (M=45.00, SD=17.97)	14.30*	5.83	0.05	0.12	0.19	28.41
		IP PR (M=58.04, SD=17.51)	1.26	5.00	0.97		-10.83	13.36
	IP NHS (M=45.00, SD=17.97)	**SDS** (M=59.30, SD=12.80)	-14.30*	5.83	0.05		-28.41	-0.19
		IP PR (M=58.04, SD=17.51)	-13.04	6.24	0.10		-28.15	2.07
	IP PR (M=58.04, SD=17.51)	**SDS** (M=59.30, SD=12.80)	-1.26	5.00	0.97		-13.36	10.83
		IP NHS (M=45.00, SD=17.97)	13.04	6.24	0.10		-2.07	28.15
Dependent Variable	**UKA type**	**UKA type**	**Mean Difference**	**Std. Error**	**Sig.**	**Eta squared**	**95% Confidence Interval**	
OACS Day 1	**SDS** (M=-27.60, SD=17.71)	**IP NHS** (M=-35.71, SD=13.36)	8.12	7.15	0.50	0.16	-9.25	25.49

		IP PR (M=-14.92, SD=20.94)	-12.67	6.18	0.11		-27.68	2.33
	IP NHS (M=-35.71, SD=13.36)	**SDS** (M=-27.60, SD=17.71)	-8.12	7.15	0.50		-25.49	9.25
		IP PR (M=-14.92, SD=20.94)	-20.79*	7.72	0.03		-39.55	-2.03
	IP PR (M=-14.92, SD=20.94)	**SDS** (M=-27.60, SD=17.71)	12.67	6.18	0.11		-2.33	27.68
		IP NHS (M=-35.71, SD=13.36)	*20.79	7.72	0.03		2.03	39.55
* The mean difference is significant at the 0.05 level.								

OARS=Oxford Arthroplasty Early Recovery Score; OACS=Oxford Arthroplasty Early Change Score. Type of surgery: UKA= Unicompartmental Knee Arthroplasty; SDS= Same-day surgery; IP=Inpatient; NHS=National Health Service. M=Mean; SD= Standard deviation; CI= 95% Confidence Interval.

- Are there differences in recovery between UKA and TKA patients?

  An independent-samples t-test was conducted to compare the OARS and OACS scores between UKA patients overall and those receiving TKA. There were statistically significant differences between OARS scores for UKA vs TKA patients on day 1, day 7, day 14 and at six weeks (Table 7.10). Although differences in OACS scores were noted, there were no statistically significant differences found in the OACS scores between the UKA and TKA groups throughout any of the time points.

Table 7.10: UKA overall versus TKA Independent Samples Test

OARS	UKA overall	TKA	t-test Sig	Mean Difference	CI	Cohen's d	Effect size
Day 1	M=44.05, SD=23.81	M=28.39, SD=20.02	t(78)=2.99, p=.004	15.66	5.23-26.09	d=.71	r=.34
Day 7	M=56.04, SD=16.17	M=48.21, SD=11.87	t(73)=2.14, p=.035	7.82	0.55-15.09	d=.55	r=.27
Day 14	M=61.68, SD=17.12	M=51.50, SD=15.43	t(73)=2.50, p=.015	10.18	2.05-18.30	d=.62	r=.30
Six weeks	M=72.09, SD=15.23	M=63.66, SD=16.75	t(67)=2.10, p=.04	8.42	.40-16.45	d=.53	r=.25

OARS=Oxford Arthroplasty Early Recovery Score. Type of surgery: UKA= Unicompartmental Knee Arthroplasty; TKA= Total Knee Arthroplasty. M=Mean; SD= Standard deviation; CI= 95% Confidence Interval.

- Are there differences in recovery between THA and TKA patients?

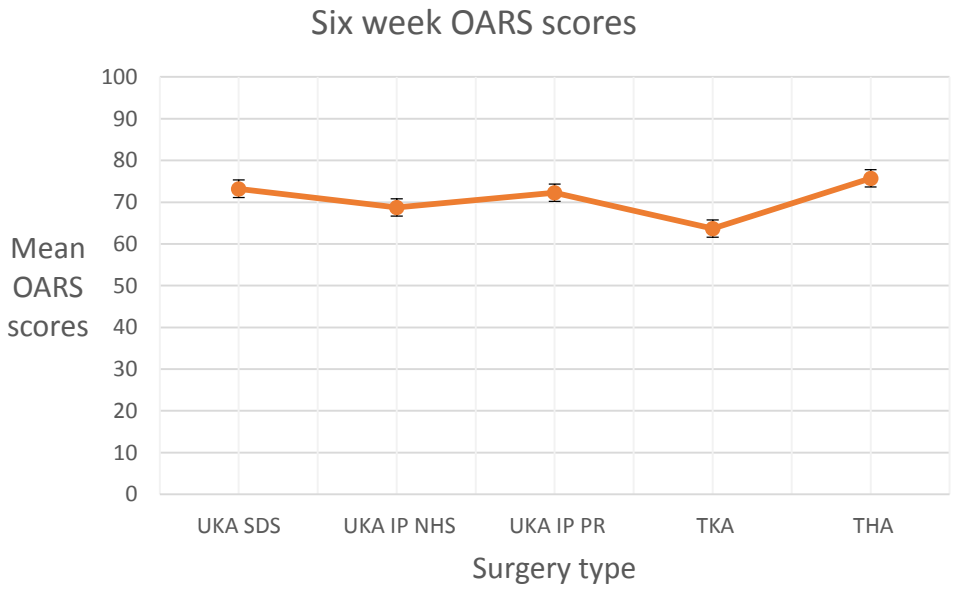
  An independent-samples t-test was conducted to compare the OARS and OACS scores between THA patients and those receiving TKA. There were statistically significant differences between OARS scores for THA vs TKA patients, with scores being statistically significant on day 7, day 14 and at six weeks (Table 7.11). In addition, statistically significant differences were found in the OACS scores between the THA and TKA groups on day 14 and at the six week time points.

Table 7.11: THA versus TKA Independent Samples Test

OARS	THA	TKA	t-test Sig	Mean Difference	CI	Cohen's d	Effect size
Day 7	M=57.24, SD=16.66	M=48.21, SD=11.87	t(77)=2.43, p=.017	9.03	1.64-16.41	d=.62	r=.30
Day 14	M=67.40, SD=16.54	M=51.50, SD=15.44	t(74)=4.02, p=.001	15.90	8.03-23.78	d=.99	r=.45
Six weeks	M=75.73, SD=18.61	M=63.66, SD=16.75	t(70)=2.65, p=.010	12.06	2.97-21.16	d=.68	r=.32
OACS							
Day 14	M=2.55, SD= 19.77	M=-11.41, SD=13.67	t(44.56)=3.23, p=.002	13.95	5.24-22.66	d=.82	r=.38
Six weeks	M=18.31, SD=20.46	M=1.88, SD=23.25	t(64)=2.84, p=.006	16.43	4.87-27.99	d=.75	r=.35

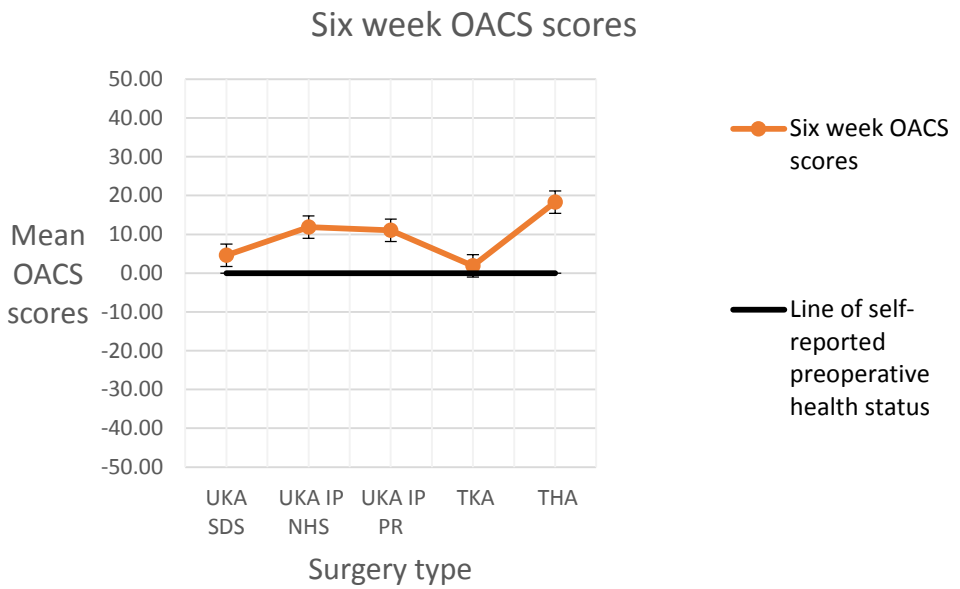
OARS=Oxford Arthroplasty Early Recovery Score; OACS=Oxford Arthroplasty Early Change Score. Type of surgery: UKA= Unicompartmental Knee Arthroplasty; TKA= Total Knee Arthroplasty. M=Mean; SD= Standard deviation; CI= 95% Confidence Interval.

Six week OARS and OACS mean scores by surgery type are presented below (Figures 7.5 and 7.6 respectively). These demonstrate the six week scores for all groups of UKA, THA and TKA patients.



Type of surgery: UKA= Unicompartmental Knee Arthroplasty, SDS= Same-day surgery discharge; IP= inpatient; NHS=National Health Service Hospital; PR=Private hospital; TKA= Total Knee Arthroplasty; THA= Total Hip Arthroplasty.

Figure 7.5: Six week mean OARS scores by surgery type



Type of surgery: UKA= Unicompartmental Knee Arthroplasty, SDS= Same-day surgery discharge; IP= inpatient; NHS=National Health Service Hospital; PR=Private hospital; TKA= Total Knee Arthroplasty; THA= Total Hip Arthroplasty.

Figure 7.6: Six week mean OACS scores by surgery type

7.5 Discussion

Of the 55 participants, 46 (84%) completed the study. Interestingly, patients in receipt of UKA surgery in the private inpatient hospital initially showed higher scores in both OARS and OACS. This could perhaps be explained by the fact that patients in the private hospital reported better early pain control, including longer lasting blocks and medications such as steroids, which are routinely used in the private sector. The private patients have also requested these elective surgeries and may also be less ill than their NHS counterparts. Patients in the private hospital are not required to do any active physiotherapy or indeed mobilise out of bed on day one.

Scores for the SF-36v2 and OARS domains can be seen to increase across the time points for the groups. The scores suggest slightly overall higher scores for each of the UKA groups versus TKA. The prior hypotheses were again considered. It is of interest to note that although initial results were higher for the inpatient private UKA patients, by six weeks the differences in recovery between the three UKA groups, same-day discharge, NHS inpatient and those performed in a private setting, were not statistically significant. The THA patients appeared to have a better recovery than TKA, and, indeed, all UKA groups displayed a better recovery than their TKA counterparts.

Although the same-day UKA patients had lower scores on day 1, these improved across the time points. In recent years, the aims of both safely decreasing hospital LOS and maximising patient recovery have been at the forefront of health debate (235). The potential for same-day discharge, where patients report being happier at home and being able to manage their own pain regimen, is now being explored for TKA patients and possibly THA patients at the NHS hospital in this study. With bed space often being an issue, this could lead to a significant reduction in inpatient costs and decrease patient waiting time. Of course, other considerations and challenges such as anaesthetist/surgeon availability and operating theatre capacity also have to be addressed. More work will be performed in this important area.

7.6 Strengths and Limitations

This study was carried out in two hospitals (one private and one NHS Orthopaedic specialist) in the same city in England, UK. The participant group consisted of a homogenous patient group, due to local population and therefore the results may not be transferrable. It is acknowledged that cultural differences may exist between other patient groups. Care was taken to balance the number of inpatient versus same-day knees by

recruiting from both hospitals. However, due to patients' medical conditions, willingness to participate and cancellations, this was not fully achieved.

The sample size for this group is small. This was an exploratory study to gather preliminary information for a potentially large scale evaluation in the future. Further analysis involving analysing the area under the curve, could give more insight into the differences in recovery between groups and may facilitate determining just what those differences are. While 55 patients were included in this study, some patients did not complete all time points for the study (n=9). None of the incomplete cases are known to be due to medical conditions or complications postoperatively. A number of questionnaires and return envelopes were not received at the research office (n=9). As in other phases, a problem with the pre-paid return envelopes through the Post Office in England affected this study.

7.7 Summary

The results and findings from this comparison of inpatient versus same-day discharge for UKA suggest that same-day discharge for UKA is not only safe and effective, but often gives better outcomes at six weeks postoperatively than the inpatient counterpart. The results show statistically significant differences in inpatient UKA between the private and NHS settings and between UKA and TKA patients. This may be due in part to improved analgesia in the private setting. However, confounders must be considered as the cohort of inpatient NHS UKA patients would have routinely been considered for discharge home if they were able. This has implications for the NHS and the greater healthcare systems, as the burden of inpatient surgery and hospital stays can be reduced effectively through this method. Currently, patients undergoing TKA are also being given a same-day discharge option in the NHS when medically fit and able.

8 Conclusions and future work

8.1 Introduction

This chapter will include discussion of findings and questionnaire development. The issue of generalisability of the questionnaires and challenges will be addressed. Limitations and areas for further work will be explored. Conclusions will be stated.

8.2 Summary of main findings of thesis and aims

Initial work for this thesis involved identifying and understanding the important aspects of joint replacement, pain management and the perioperative period of recovery. Evaluation of how recovery and change are measured during the early post-operative period was carried out by means of a systematic review of the available tools (79). This revealed the need for an early recovery PROM as well as health transition, or change measure, in orthopaedic surgery.

Previously used measures were found to be inappropriate to accurately evaluate the quality of recovery and were not designed to measure change in the early postoperative period. They were not developed in an arthroplasty population and lacked precision. This thesis has addressed important issues in the assessment of recovery after arthroplasty (236). Being able to measure improvement and patient-reported change following arthroplasty could be of great benefit in clinical trials involving medication, care pathways and implant selection. It could also potentially work to optimise routine care by allowing provision of appropriate, safe, timely care and interventions.

The process of development for a PROM and change measure was therefore begun with initial qualitative work being performed to facilitate concept understanding and item generation. Qualitative interviews were performed with patients undergoing hip or knee

replacement surgery (117). Item generation came directly from patient statements and from the patient population the tools are being designed to serve. In addition, a series of interviews was performed with orthopaedic healthcare professionals to determine how they might use an early recovery PROM and change measure (116). Patient-identified issues can give vital insights into a patients' perspective through the perioperative experience, whilst understanding the issues that healthcare providers witness gives insight as how to best care for the patient.

Seven main themes evolved from the patient interviews: 'improving function and mobility', 'pain', 'effects of healthcare on outcomes', 'support from others', 'involvement and understanding of care decisions', 'behaviour and coping' and 'fatigue and sleeping'. In addition, three main themes evolved from the healthcare provider interviews: immediate patient recovery issues, discharge criteria, and priorities during hospitalisation from health care providers' perspectives.

As previously discussed, the FDA guidelines for the development of PROMs are often cited as the gold standard for the construction of such measures (70). These provide a thorough outline by which new questionnaires should be developed. The research performed in this study adhered strictly to these guidelines. Throughout the entire process including: item generation, selection of candidate items, wording changes and item reduction, a detailed item tracking matrix was maintained. This file contains specific details of direct patient sources for items, wording changes, reasons for item deletions and modifications that occurred during each phase of PROM development.

The process of candidate item development, selection and initial testing of the questions (including item response options and choice of recall) were reported. Initial testing and questionnaire refinement through to the final validation and psychometric analyses of the

finished questionnaires was reported. Both the Oxford Arthroplasty Early Recovery Score (OARS) and Oxford Arthroplasty Early Change Score (OACS) show good psychometric properties in terms of internal consistency and sensitivity to change (114), content validity (237) and relevance to patients and clinicians (238). In addition, these measures have been shown to be acceptable to patients at different time points throughout early recovery with validation across the six week period.

The results and findings from the comparison of inpatient versus same-day discharge for UKA suggests that same-day discharge for UKA is not only safe and effective, but often gives better outcomes at six weeks postoperatively than the inpatient counterpart. In addition, UKA patients have better recovery at every time point versus patients receiving TKA. This has implications for the NHS and the greater healthcare systems, as the burden of inpatient surgery, finances and hospital stays can be reduced effectively through this method (239). Although not all patients are suitable for UKA, it is estimated that as many as 50% of TKA patients meet criteria for UKA (240). Currently, however, only 6% actually receive UKA (239).

The broad aims of this thesis were to explore the ideas around the concept of quality of recovery for hip and knee arthroplasty patients during the early recovery period of the first six weeks following surgery, and to develop a recovery and change measure to assess recovery during the first six weeks.

Optimising perioperative recovery is critical to enhance patient care, ensure timely discharge from the patient, clinician and hospital perspective and improve short and long-term outcomes after surgery (241). However, until now, it was not known how to measure recovery, particularly in the early postoperative period, with previously used measures in early recovery not patient-reported.

8.3 Limitations on study, data and findings

The specific limitations within this thesis have been previously discussed (Chapters 3 to 7).

Delay with the initial ethics approval process caused a postponement of around three months to the commencement of the study. The qualitative interviews which were planned to start in late May 2016 began in August 2016.

During both the Planning Phase and Phase One, acknowledging the potential for interviewer bias in this area of research was necessary. To minimise the risk of bias, the researcher examined their own motivations and possible bias with other members of the research team prior to commencing the project.

It is recognised that the prior experience and feelings of an interviewer with a clinical background may have a bias and some preconceived ideas regarding the subject matter.

The demographic distribution of participants in Phases One, Two, Three and Four was recognised to be very homogenous due to local patient population. It is important to note that cultural differences may exist between other patient groups.

Care was taken throughout the study phases to balance the number of hips and knees within the groups. However, due to patients' medical conditions, willingness to participate and changes to the surgery schedule including cancellations, this was not fully achieved.

In Phases Three and Four of the study, surgery schedules were seen to change frequently, often on a daily basis. Patients were delayed or required further testing or interventions before being medically cleared for surgery. Surgery lists were rearranged based on how long a patient has been on the waiting list and acceptable NHS waiting times. Patients were also cancelled if a theatre list over-ran due to a complicated surgery, anaesthetic or to

another unexpected event arising in theatre. Hospital and theatre staffing were also seen to effect the day of surgery plans.

A problem with the pre-paid return envelopes through the Post Office in England affected both Phases Three and Four. A full investigation by the Post Office led to the discovery of a problem employee in head office and to the return of three participant questionnaires after many months in Phase Three. Therefore, the true response rate may be higher than estimated as patients reported returning their forms and would call the research office multiple times to confirm receipt.

One consideration that may have improved the response rate was the patients' desire to help with research and not 'let the researcher down'. Patients were very generous and concerned that they could personally help the researcher through their responses. This has previously been discussed in the literature (242).

A nationwide government postponement of elective inpatient surgeries by the NHS led to a delay of around two months in Phase Three as no arthroplasty procedures were performed.

Initially, work was planned to explore more about the patient experience and a possible tool to assist patient discharge from hospital. However, due to time constraints, this will be explored further as post-doctoral work.

8.4 Recommendations and future work

Further testing of these questionnaires at the level of the individual in patient pathways and clinical research could bring real results to patients, healthcare providers, hospital trusts and clinical commissioning groups. As previously mentioned, both measures have been registered with Oxford University Innovation (OUI) and will be made available through

digital electronic delivery methods (202). This will aid ease of delivery of the measures and facilitate receipt and processing of returned data. The initial work and registration for these has already been performed. More work defining the operating characteristics of these new tools will include calculating the minimally clinical significant and important differences in the scores will be carried out. These questionnaires will now go on to be used in both research studies and clinical trials. The research completed in this thesis will now enable the next stage of important work using these measures to define and assess of an optimal-recovery protocol for lower limb joint replacement.

Healthcare providers and hospital bodies must continue work to progress and optimise the patient recovery pathway. Many areas could still be developed and therefore continue to make marked improvements for patients. Research using validated measures provides the opportunity, in combination with already used PROMS and patient data, to continue to make strides in recovery, patient satisfaction and outcomes.

Routine use of the new PROM and change measure could facilitate benchmarking and audit within the clinical area. In addition, potential research uses for these tools could include studies to evaluate improving post-operative pain regimens. For example, day one UKA patients in the private hospital appeared to have statistically significant less pain than their NHS counterparts. Being able to identify exactly what components are being utilised and making a difference in the private versus NHS setting could greatly improve the patient experience. This, in turn, has the potential to positively affect outcomes for the NHS patient population. Such a study could be undertaken with the tools developed in this thesis.

The good measurement properties of the OARS and OACS, their relevance to patients, clinicians and other stakeholders (as well as their established minimal important change),

make them the ideal measurement to be used in randomised controlled trials that assess the efficiency of different interventions in relevant patient population.

Another potential study, highlighted earlier in this work from a recent systematic review (50), could be the addition of steroids into the routine care of the joint replacement patient pathway. Results appear to show potential for patient analgesic and anti-emetic benefit, but suggest further studies to define this effect, which again could be undertaken using the OACS and OARS. Sample size calculations can be found in Appendix 9.10.

8.5 Conclusions

From a literature-based starting point, two early recovery tools (the Oxford Arthroplasty Early Recovery Score, a traditional PROM, and the Oxford Arthroplasty Early Change Score, a change measure) have been developed. They have been tested and validated in accordance with FDA 'gold standard' guidelines (70) and best practice through the work of this thesis. They have been validated for use in the first six weeks following UKA, TKA and THA. Psychometric testing has shown positive results, good validity and sensitivity to change. The issue of recovery following surgery has been addressed and answered in part through the work in this thesis.

The work to date has been published in peer-reviewed journals and presented at national and international conferences. Publications related to this thesis are listed in Appendix 9.

Orthopaedic surgical recovery has come a long way since the early days of Charnley and his pioneering colleagues. With significant changes in surgical techniques, technology, anaesthetics and patient population, as well as patient expectations, these will continue to be further developed.

9 Appendices

9.1 Phase One draft statements

Improving function and mobility
• I was back to normal soon after it was done (Participant 3) • I have difficulty getting into bed (Participant 8) • I feel a lot better today than I did on the day of surgery (Participant 9) • I felt absolutely fine after both operations day 1 (Participant 10) • I couldn't at the moment stand on it and walk say from the bed to the bathroom which means I couldn't do that at home either (Participant 11) • I want to be up and about (Participant 11) • I am not able to stand (Participant 11) • I am not able to walk (Participant 11) • I've got no limp I can walk really well (Participant 15) • I gradually increased the distance and I have driven this morning and that was fine (Participant 15) • They got me out of bed first thing on the Saturday morning and I walked with the Zimmer frame and that was it away I went (Participant 16) • Much better, much, much better (Participant 17) • I can do the stairs now I struggle but I do it (Participant 17) • Hopefully I'll start walking better and being able to do more (Participant 18) • I do feel it a lot better and that is brilliant (Participant 19) • I felt strong (Participant 20) • I now have just one walking stick and umm well I can manage and I like it because it makes me feel free-er (Participant 22) • I am up and about and walking and can go to the loo and that's the main part (Participant 27) • I have walked to the end of the bed (Participant 27) • I think if I can go up the stairs I can go home them (Participant 28) • I like cycling and getting fresh air and things (Participant 29)
Pain
• I have not felt much pain (Participants 1, 2, 5, 12, 16, and 29) • It has been quite painful (Participants 3, 11, 13, and 25) • Pain walking and going up and down stairs (Participant 4) • Excruciating pain. I don't think the operation could cause more pain than I've got now (laughs) (Participant 5) • It's alright if I keep my knee in this position too long then it hurts, I have to keep moving it so it doesn't stick in one position (Participant 5) • You already have pain but you're given analgesia for it, you are bound to have some pain aren't you, I mean you have to accept some (Participant 6) • It aches occasionally it aches to walk but normally it's OK it's just going downstairs (Participant 7) • The pain has been bearable (Participant 9) • The leg has felt tense (Participant 10) • I am just in agony by the end of the day. so it's having a happy balance between sitting and moving about really (Participant 11) • I have worse pain at night (Participant 13) • I have had constant pain in the joint (Participant 13) • The leg has felt swollen (Participants 13 and 26) • It was hurting to walk (Participant 17) • It is painful using the bedpan (Participant 18) • Pain. I've had pain, oh god I've had pain, so much pain (Participant 19)

- I was having pain all the way up this section here [indicates] right up into my groin (Participant 19)
- The pain I had all the time to the pain now is very good (Participant 19)
- It was just bad, a lot of severe pain with both hips sometimes I, you know, couldn't walk properly, couldn't walk any distance at all (Participant 20)
- The worst symptoms were pain in the front of the thigh. Excruciating pain at times I mean both thighs (Participant 20)
- No not really, it could be after an active day or a relatively inactive day it didn't
- really seem to make a lot of difference it was just very painful (Participant 20)
- It was sort of slightly uncomfortable but not painful in that sense (Participant 21)
- It has been tender more than painful (Participant 21)
- It didn't stop it, you know, the pain would come on when you would be walking so it wasn't. So I didn't have pain, I could sleep. I didn't have pain walking round the house, I didn't have pain walking round the office. You would get pain walking really any distance or if you were standing for a longer period but I could still do bits of exercise so long as it wasn't too impact (Participant 21)
- Getting out of bed in the morning was a bit difficult and it was a bit of a trial (Participant 24)
- There was pain and gradual loss of mobility (Participant 26)
- It was just changing my lifestyle because I couldn't do the things I wanted to do because I knew I wouldn't enjoy them because it would ache (Participant 18)
- Well it come on all of a sudden because I used to do 2 jobs, I used to by day I am a driving instructor and a job at night and then it just come on at night when I was really struggling to walk (Participant 27)
- It had started to get really sore (Participant 28)
- My pain was as I expected it and I know how to manage it (Participant 28)
- Very painful and also haven't come off crutches for about 18 months (Participant 29)

Effects of healthcare on outcomes

- A bit of A4 paper with a wound care when you get discharged you know it would be – it would have benefitted me (Participant 1)
- I have felt very well (Participant 2)
- I have had no appetite (Participant 2)
- I have felt sick (Participants 2, 4, 11, 17, 18, 20, 21, and 26)
- I was worried obviously for the first one because it was all so different and new but when it came to the second one I knew the pattern and the routine so yeah, more or less, yeah pleased (Participant 3)
- I have felt woozy (Participant 4)
- I was sick on the Tuesday because I'd been laid down for a while, they asked if I could sit up and I said I was feeling woozy and the next minute I was sick (Participant 4)
- I have been sick (Participants 4, 15, 16, 19, 20, 21, and 26)
- I had three cancer operations within 11 weeks of each other, two breast and bowel and I survived those because I am a very positive sort of person (Participant 5)
- I have not felt comfortable (Participant 7 and 30)
- Well I sort of knew what to expect and I have got good quads anyway and so you grit your teeth and go for it so it's err (Participant 9)
- It was such a benign proceeding that on both occasions I had a cup of tea in the recovery room (Participant 10)
- I think the hip school was a good one because they went through physio and what was required and the OT. It all worked very slickly (Participant 10)
- I have felt pretty awful (Participant 11 and 18)
- I have felt unwell (Participant 11)
- I have felt disorientated (Participant 11 and 18)
- I have felt rough (Participant 11)
- I have felt I have too much medication in my system, so that makes me sick (Participant 11)
- You could hear them banging and crashing at the end and things (Participant 11)
- I have been constipated which made me feel sick (Participants 13, 23, and 24)
- Perfect. It was just like a good sleep and just waking up sort of thing (Participant 16)
- I have felt very nauseous (Participant 18)
- If you are in a ward I mean they are working really hard and I have got no complaints but you do have to take your turn (Participant 18)

- I think it would have been jolly useful, whatever way they do it, at the time I thought it would be really nice if you had a sheet that told you the different drugs that were an option and what they did (Participant 18)
- I have felt faint (Participant 18)
- I have felt hopeless (Participant 18)
- It's slightly disconcerting that you can hear the operation particularly when you can hear something that's like a workshop, you can hear the banging, the new joint (Participant 21)
- I certainly was looked after very well (Participant 22)
- I have fainted (Participant 22)
- I have lost my appetite (Participant 24)
- My appetite has diminished (Participant 25)
- I didn't actually go into theatre until 4 o'clock in the afternoon and of course I didn't have anything to eat or drink so it wasn't a very comfortable experience (Participant 25)
- I didn't like the anaesthetist (Whispers) (Participant 28)
- The consultant is such a wonderful man (Participant 28)
- I know this hospital very well and that's why I chose it to have my surgeries (Participant 29)
- I woke up in recovery with a mask on erm and I kind of panicked (Participant 30

Support from others

- I think family they worry (Participant 3)
- They are just there looking after you. My husband especially asking "are you sure you should be doing that?" Can you do this can you do that and I just say go for a walk I'm doing it and you get on in the end. (Laughing) (Participant 3)
- I think the system they have got here is actually remarkably good (Participant 10)
- There's the hip school which is a bit of a giggle but I mean it goes through some little tricks which are useful (Participant 10)
- No regrets about getting home because you could always ring physiotherapy and if there's any issue you know drop in (Participant 10)
- My wife has been brilliant (Participant 15)
- I am the sort of person who is quite happy to be looked after (Participant 22)
- Luckily I had a partner, a kind woman who helped me (Participant 23)

Involvement in/understanding of care decisions

- The surgeons tell you, you can come out the next day, the nursing staff say you are not ready to go home and you can't go home till the physios say you can anyway so everybody you speak to tells you a different story. They could liaise a bit better on that I think – laughs (Participant 11)
- They have been very good at giving you what they think you need (Participant 11)
- I just felt I don't know what I am being asked to make a decision about I don't know enough about it (Participant 18)
- I think you relax more at home you can do things in your own time more at home, you are more in control of when things happen and when you want them to happen (Participant 18)
- I felt I wasn't saying the right things. I was asking for something I couldn't have (Participant 18)
- I think well they know and I don't so I'll let them do it (Participant 22)
- I don't decide on the anaesthetic. The only thing that I found uncomfortable beforehand was how the anaesthetist, he was pretty brutal (Participant 28)

Behaviour and coping

- I am getting to the point now I know what I can do and what I can't do (Participant 1)
- I am not one to hang around (Participant 3)

- I know to take it easy the first day when you are back from surgery but the next day then hopefully I'm going to get up and start walking like I did before (Participant 3)
- Listen to what you are being told but know what you can do – yeah. Have faith in yourself that you can do it and you know just set yourself that little goal each time and go for it and the physios and everything were marvellous here and they know, you know and if you think you can do it. Take a little time to do it, go careful but take your time don't rush, don't jump before you can walk type of thing (Participant 3)
- It was painful at night my partner had to keep going down to get frozen peas to put on it (Participant 4)
- Why paint a silly picture. It's painful, you have to put up with it don't you (Participant 9)
- The last few years one way or another I have been living on pain killers to take the edge off what was happening and I haven't had any pain killers for 3 weeks and I feel really good (Participant 9)
- I didn't think I would but it worked brilliantly (laughs) (Participant 10)
- I have really been struggling the last year or so because I am just in agony by the end of the day (Participant 11)
- It's a vicious circle, if you do too much you are in absolute agony and if you don't do anything you get stiff (Participant 11)
- It's having a happy balance between sitting and moving about really (Participant11)
- I know my capabilities (Participant 15)
- You don't realise you know just what you can't do you know until you can't do it (Participant 16)
- I was never in dreadful pain with it to be honest it was more that it was just changing my lifestyle because I couldn't do the things I wanted to do because I knew I wouldn't enjoy them because it would ache (Participant 18)
- I went out for walks with my sticks but I didn't feel I really needed them. They were there for just in case (Participant 20)
- It wasn't painful all the time, but when you walked a short distance it would become painful and you would have to sit down and so just walking the dog you would have to stop and you couldn't walk the dog around the park a mile or 2 miles so you would just have to sit down (Participant 21)
- I don't use the crutch other than as a mental crutch (Participant 21)
- I don't have a lot of confidence in my balance as yet and the crutches literally is a crutch, it gives you confidence (Participant 23)

Fatigue and sleep

- It doesn't tire me out quite so much (Participant 2)
- I was awake all hours of the night…not to be able to get any sleep at night is a horrible thing (Participant 2)
- I have found it quite hard to sleep (Participant 6 and 21)
- Yes, it was painful it didn't stop me sleeping but it was painful (Participant 10)
- I have felt tired (Participant 14)
- It was hurting to sleep, couldn't sleep (Participant 17)
- I have slept really well (Participant 18)
- I have not slept well (Participant 18 and 26)
- The pain in here was absolutely excruciating, sometimes it would wake me up at night and I could not get comfortable (Participant 20)
- I had several nights when I woke up with spasms and it was terrible, dreadful (Participant 20)
- I have slept slightly better (Participant 21)
- I can easily sleep at night it doesn't bother me now (Participant 25)
- The first night a bit ropey (Participant 26)
- I have not slept much (Participant 28)
- Getting enough sleep and being able to sleep in the day is really important to me (Participant 28)
- I have gone without sleep due to the pain (Participant 30)
- I had fairly decent night's sleep, very comfortable (Participant 30)
- I think the phrase was, distraught. I just basically said "I want to go home I am not comfortable here, I am not sleeping I want to go home" (Participant 30)

9.2 Pilot version of the Oxford Arthroplasty Early Recovery Score (OARS)

The following statements are about post-operative recovery. Thinking about the time since your operation, how much do you agree with these statements?

Please place a CROSS in the appropriate box.

		Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
1.	I have felt unwell	☐	☐	☐	☐	☐
2.	I have felt disorientated	☐	☐	☐	☐	☐
3.	I have felt tired	☐	☐	☐	☐	☐
4.	I have felt faint	☐	☐	☐	☐	☐
5.	It has been quite painful	☐	☐	☐	☐	☐
6.	I have had constant pain	☐	☐	☐	☐	☐
7.	I have worse pain at night	☐	☐	☐	☐	☐
8.	It has felt swollen	☐	☐	☐	☐	☐
9.	I have difficulty getting into bed	☐	☐	☐	☐	☐
10.	I am not able to stand	☐	☐	☐	☐	☐

1

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
11. I am not able to walk	☐	☐	☐	☐	☐
12. I have not slept well	☐	☐	☐	☐	☐
Which question 13a or 13b do you prefer? 13a. I have found it quite hard to sleep or 13b. I have found it difficult to sleep	☐	☐	☐	☐	☐
14. I have not been able to sleep due to the pain	☐	☐	☐	☐	☐
15. I have felt sick	☐	☐	☐	☐	☐
16. I have felt woozy	☐	☐	☐	☐	☐
17. I have been constipated	☐	☐	☐	☐	☐
18. I have lost my appetite	☐	☐	☐	☐	☐

9.3 Pilot version of the Oxford Arthroplasty Early Change Score (OACS)

The following statements are about post-operative recovery. Place a CROSS in the appropriate box.

Thinking about the state of your health before the operation, how would you rate:

		Much better	*A little better*	*The same*	*A Little worse*	*Much worse*
1.	Your ability to stand compared to prior to the operation?	☐	☐	☐	☐	☐
2.	Your ability to move compared to prior to the operation?	☐	☐	☐	☐	☐
3.	Your movement compared to prior to the operation?	☐	☐	☐	☐	☐
4.	Your mobility compared to prior to the operation?	☐	☐	☐	☐	☐
5.	Your ability to walk compared to prior to the operation?	☐	☐	☐	☐	☐
6.	Your ability to go upstairs compared to prior to the operation?	☐	☐	☐	☐	☐
7.	Your ability to go down stairs compared to prior to the operation?	☐	☐	☐	☐	☐
8.	Your strength compared to prior to the operation?	☐	☐	☐	☐	☐
9.	Your pain compared to prior to the operation?	☐	☐	☐	☐	☐
10.	How you feel today as compared to prior to the operation?	☐	☐	☐	☐	☐
11.	How comfortable you feel today compared to prior to the operation?	☐	☐	☐	☐	☐
12.	Your pain when walking as compared to prior to the operation?	☐	☐	☐	☐	☐

		Much better	A little better	The same	A little worse	Much worse
13.	Your pain in the joint today compared to prior to the operation?	☐	☐	☐	☐	☐
14.	Your pain at night compared to prior to the operation?	☐	☐	☐	☐	☐
15.	Your pain when getting into bed compared to prior to the operation?	☐	☐	☐	☐	☐
16.	Your muscle spasms compared to prior to the operation?	☐	☐	☐	☐	☐
17.	The amount of pain killers you need to take as compared to prior to the operation?	☐	☐	☐	☐	☐
18.	Your ability to cope at home compared to prior to the operation?	☐	☐	☐	☐	☐
19.	Your appetite as compared to prior to the operation?	☐	☐	☐	☐	☐
20.	Your mood compared to prior to the operation?	☐	☐	☐	☐	☐
21.	Your energy level compared to prior to the operation?	☐	☐	☐	☐	☐
22.	Your sleep as compared to prior to the operation?	☐	☐	☐	☐	☐
23.	How you feel overall compared to prior to the operation?	☐	☐	☐	☐	☐
24.	Your pain when trying to sleep compared to prior to the operation?	☐	☐	☐	☐	☐
25.	Your ability to sleep through the night compared to prior to the operation?	☐	☐	☐	☐	☐

9.4 Evolution of questionnaires

13/02/17 Thinking about the state of your health before the operation:

Response options: Much better, a little better, the same, a little worse, much worse.

Improving function/mobility

1. **How would you rate your ability to stand compared to prior to the operation** (pt11)
2. **How would you rate your ability to perform activities that you want compared to prior to the operation?** (pt19)
3. **How would you rate your ability to move the operative leg compared to prior to the operation?** (pt1, pt3, pt8, pt16)
4. **How would you rate your movement in the operative leg compared to prior to the operation?** (pt7, pt19, pt30)
5. **How would you rate your mobility compared to prior to the operation** (pt13)
6. **How would you rate your ability to walk compared to prior to the operation?** (pt3, pt15, pt16, pt27)
7. **How would you rate your ability to go upstairs compared to prior to the operation?** (pt1, pt5, pt7, pt17, pt22, pt27, pt28)
8. **How would you rate your ability to go down stairs compared to prior to the operation?** (pt1, pt5, pt7, pt17, pt22, pt27, pt28)
9. **How would you rate your ability to do physiotherapy compared to prior to the operation?** (pt13, pt21, pt22, pt23, pt26)
10. **How would you rate your limp compared to prior to the operation?** (pt15)
11. **How would rate your stiffness compared to prior to the operation?** (pt24)
12. **How would you rate your strength compared to prior to the operation?** (pt20, pt30)
13. **How would you rate your ability to do what you need to do compared to prior to the operation?** (pt20)
14. **How would you rate your ability to use the bathroom compared to prior to the operation** (pt4, pt21, pt23, pt25, pt27)

Pain

1. **How would you rate your pain compared to prior to the operation?** (pt2, pt9, pt12, pt13, pt14, pt15, pt18, pt19, pt20, pt21, pt29, pt30)
2. **How do you feel today as compared to prior to the operation?** (pt9, pt10, pt25, pt27)
3. **How comfortable do you feel today compared to prior to the operation?** (pt7, pt10, pt30)
4. **How would you rate your pain when walking as compared to prior to the operation?** (pt8, pt17)
5. **How would you rate your pain in the joint today compared to prior to the operation?** (pt18, pt30)

6. **How would rate your pain compared to prior to the operation?** (pt5, pt6, pt19, pt20, pt23, pt24, pt29)
7. **How would you rate your pain at night compared to prior to the operation?** (pt20)
8. **How would you rate your pain when getting into bed compared to prior to the operation?** (pt8)
9. **How would rate your muscle spasms compared to prior to the operation?** (pt20)
10. **How would you rate the amount of pain killers you need to take as compared to prior to the operation?** (pt29)

Experiences of healthcare

1. **How would you rate your level of optimism compared to prior to the operation?** (pt7, pt18)
2. **How would you rate your ability to cope at home compared to prior to the operation?** (pt21)
3. **How would you rate your appetite as compared to prior to the operation?** (pt24, pt25)
4. **How would you rate your mood compared to prior to the operation?** (pt30)

Fatigue/Sleep

1. **How would you rate your energy level compared to prior to the operation?** (pt2)
2. **How would you rate your ability to sleep has as compared to prior to the operation?** (pt2, pt17, pt21, pt25, pt28, pt30)
3. **How do you feel overall compared to prior to the operation?** (pt9, pt11, pt17, pt19)
4. **How would you rate your pain when trying to sleep compared to prior to the operation?** (pt17)
5. **How would you rate your sleep compared to prior to the operation?** (pt30)
6. **How would rate your ability to sleep through the night compared to prior to the operation?** (pt30)

20/02/17 Thinking about the state of your health before the operation:

Response options: Much better, a little better, the same, a little worse, much worse.

Improving function/mobility

1. **How would you rate your ability to stand compared to prior to the operation** (pt11)
2. **How would you rate your ability to move the operative leg(s) compared to prior to the operation?** (pt1, pt3, pt8, pt16)
3. **How would you rate your movement in the operative leg(s) compared to prior to the operation?** (pt7, pt19, pt30)
4. **How would you rate your mobility compared to prior to the operation** (pt13)
5. **How would you rate your ability to walk compared to prior to the operation?** (pt3, pt15, pt16, pt27)
6. **How would you rate your ability to go upstairs compared to prior to the operation?** (pt1, pt5, pt7, pt17, pt22, pt27, pt28)
7. **How would you rate your ability to go down stairs compared to prior to the operation?** (pt1, pt5, pt7, pt17, pt22, pt27, pt28)
8. **How would you rate your strength compared to prior to the operation?** (pt20, pt30)

Pain

1. **How would you rate your pain compared to prior to the operation?** (pt2, pt5, pt6, pt9, pt12, pt13, pt14, pt15, pt18, pt19, pt20, pt21, pt23, pt24, pt29, pt30)
2. **How do you feel today as compared to prior to the operation?** (pt9, pt10, pt25, pt27)
3. **How comfortable do you feel today compared to prior to the operation?** (pt7, pt10, pt30)
4. **How would you rate your pain when walking as compared to prior to the operation?** (pt8, pt17)
5. **How would you rate your pain in the joint today compared to prior to the operation?** (pt18, pt30)
6. **How would you rate your pain at night compared to prior to the operation?** (pt20)
7. **How would you rate your pain when getting into bed compared to prior to the operation?** (pt8)
8. **How would rate your muscle spasms compared to prior to the operation?** (pt4, pt20)
9. **How would you rate the amount of pain killers you need to take as compared to prior to the operation?** (pt29)

Experiences of healthcare

1. **How would you rate your ability to cope at home compared to prior to the operation?** (pt21)
2. **How would you rate your appetite as compared to prior to the operation?** (pt24, pt25)
3. **How would you rate your mood compared to prior to the operation?** (pt7, pt18, pt30)

Fatigue/Sleep

1. **How would you rate your energy level compared to prior to the operation?** (pt2)
2. **How would you rate your sleep as compared to prior to the operation?** (pt2, pt17, pt21, pt25, pt26, pt28, pt30)
3. **How do you feel overall compared to prior to the operation?** (pt9, pt11, pt17, pt19)
4. **How would you rate your pain when trying to sleep compared to prior to the operation?** (pt17)
5. **How would rate your ability to sleep through the night compared to prior to the operation?** (pt30)

27/02/17 Early recovery PROM

Thinking about the time since your operation, how much do you agree with these statements?

Strongly agree, agree, neither agree nor disagree, disagree, strongly disagree?

Overall feeling of wellbeing

Since the operation, I have felt very well (Pt2)
Since the operation, I have felt pretty awful (Pt11, Pt18)
Since the operation, I have felt unwell (Pt11)
Since the operation, I have felt disorientated (Pt11, Pt18)
Since the operation, I have felt rough (Pt11)
Since the operation, I have felt tired (Pt14)
Since the operation, I have felt hopeless (Pt18)
Since the operation, I have felt faint (Pt18)
Since the operation, I have fainted (Pt22)
Since the operation, I have not felt comfortable (Pt7, Pt30)

Pain and surgical pain

Since the operation, I have not felt much pain (Pt1, Pt2, Pt5, Pt12, Pt16, Pt29)
Since the operation, the pain has been bearable (Pt9)
Since the operation, it has been quite painful (Pt3, Pt11, Pt13, Pt25)
Since the operation, I have had constant pain in the joint (Pt13)
Since the operation, I have worse pain at night (Pt13)
Since the operation, it is painful using the bedpan (Pt18)
Since the operation, it has been tender more than painful (Pt21)

Swelling

Since the operation, the leg has felt tense (Pt10)
Since the operation, the leg has felt swollen (Pt13, Pt26)

Mobility

Since the operation, I have difficulty getting into bed (Pt8)
Since the operation, I am not able to stand (Pt11)
Since the operation, I am not able to walk (Pt11)
Since the operation, I have walked to the end of the bed (Pt27)

Sleep

Since the operation, I have not slept well (Pt18, Pt26)
Since the operation, I have slept really well (Pt18)
Since the operation, I have found it quite hard to sleep (Pt6, Pt21)
Since the operation, I have slept slightly better (Pt21)
Since the operation, I have not slept much (Pt28)
Since the operation, I have gone without sleep due to the pain (Pt30)

Nausea and vomiting

Since the operation, I have felt sick (Pt2, Pt4, Pt11, Pt17, Pt18, Pt20, Pt21, Pt26)
Since the operation, I have felt woozy (Pt4)
Since the operation, I have felt I have too much medication in my system, so that makes me sick (Pt11)
Since the operation, I have felt very nauseous (Pt18)
Since the operation, I have been sick (Pt4, Pt15, Pt16, Pt19, Pt20, Pt21, Pt26)
Since the operation, I have been constipated which made me feel sick (Pt13, Pt23, Pt24)

Eating and drinking

Since the operation, I have had no appetite (Pt2)
Since the operation, I have lost my appetite (Pt24)
Since the operation, my appetite has diminished (Pt25)

09/03/17 The following statements are about post-operative recovery. Thinking about the time since your operation, how much do you agree with these statements?

Statement	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
1. I have felt unwell					
2. I have felt disorientated					
3. I have felt tired					
4. I have felt faint					
5. The pain has been bearable					
6. It has been quite painful					
7. I have had constant pain					
8. I have worse pain at night					
9. It has felt swollen					
10. I have difficulty getting into bed					
11. I am not able to stand					
12. I am not able to walk					
13. I have not slept well					
14. I have found it quite hard to sleep					
15. I have not been able to sleep due to the pain					
16. I have felt sick					
17. I have felt woozy					
18. I have been constipated which made me feel sick					
19. I have lost my appetite					

09/03/17 The following statements are about post-operative recovery. Thinking about the state of your health before the operation, how would you rate:

Statement	Much better	A little better	The same	A little worse	Much worse
1. Your ability to stand compared to prior to the operation?					
2. Your ability to move the operative leg compared to prior to the operation?					
3. Your movement in the operative leg(s) compared to prior to the operation?					
4. Your mobility compared to prior to the operation?					
5. Your ability to walk compared to prior to the operation?					
6. Your ability to go upstairs compared to prior to the operation?					
7. Your ability to go down stairs compared to prior to the operation?					
8. Your strength compared to prior to the operation?					
9. Your pain compared to prior to the operation?					
10. How you feel today as compared to prior to the operation?					
11. How comfortable you feel today compared to prior to the operation?					
12. Your pain when walking as compared to prior to the operation?					
13. Your pain in the joint today compared to prior to the operation?					
14. Your pain at night compared to prior to the operation?					
15. Your pain when getting into bed compared to prior to the operation?					
16. Your muscle spasms compared to prior to the operation?					
17. The amount of pain killers you need to take as compared to prior to the operation?					

Statement	Much better	A little better	The same	A little worse	Much worse
18. Your ability to cope at home compared to prior to the operation?					
19. Your appetite as compared to prior to the operation?					
20. Your mood compared to prior to the operation?					
21. Your energy level compared to prior to the operation?					
22. Your sleep as compared to prior to the operation?					
23. How you feel overall compared to prior to the operation?					
24. Your pain when trying to sleep compared to prior to the operation?					
25. Your ability to sleep through the night compared to prior to the operation?					

23/03/17 The following statements are about post-operative recovery. Thinking about the time since your operation, how much do you agree with these statements?

	Strongly agree	agree	neither agree or disagree	agree	Strongly disagree
1. I have felt unwell	☐	☐	☐	☐	☐
2. I have felt disorientated					
3. I have felt tired	☐	☐	☐	☐	☐
4. I have felt faint					
5. It has been quite painful	☐	☐	☐	☐	☐
6. I have had constant pain	☐	☐	☐	☐	☐
7. I have worse pain at night					
8. It has felt swollen	☐	☐	☐	☐	☐
9. I have difficulty getting into bed					
10. I am not able to stand	☐	☐	☐	☐	☐
11. I am not able to walk	☐	☐	☐	☐	☐
12. I have not slept well					
13. I have found it quite hard to sleep	☐	☐	☐	☐	☐
14. I have not been able to sleep due to the pain	☐	☐	☐	☐	☐
15. I have felt sick	☐	☐	☐	☐	☐
16. I have felt woozy					
17. I have been constipated which made me feel sick	☐	☐	☐	☐	☐
18. I have lost my appetite	☐	☐	☐	☐	☐

23/03/17 The following statements are about post-operative recovery. Thinking about the state of your health before the operation, how would you rate:

	Much better	A little better	The same	A little worse	Much worse
1. Your ability to stand compared to prior to the operation?	☐	☐	☐	☐	☐
2. Your ability to move compared to prior to the operation?	☐	☐	☐	☐	☐
3. Your movement compared to prior to the operation?	☐	☐	☐	☐	☐
4. Your mobility compared to prior to the operation?	☐	☐	☐	☐	☐
5. Your ability to walk compared to prior to the operation?	☐	☐	☐	☐	☐
6. Your ability to go upstairs compared to prior to the operation?	☐	☐	☐	☐	☐
7. Your ability to go down stairs compared to prior to the operation?	☐	☐	☐	☐	☐
8. Your strength compared to prior to the operation?	☐	☐	☐	☐	☐
9. Your pain compared to prior to the operation?	☐	☐	☐	☐	☐
10. How you feel today as compared to prior to the operation?	☐	☐	☐	☐	☐
11. How comfortable you feel today compared to prior to the operation?	☐	☐	☐	☐	☐
12. Your pain when walking as compared to prior to the operation?	☐	☐	☐	☐	☐
13. Your pain in the joint today compared to prior to the operation?	☐	☐	☐	☐	☐
14. Your pain at night compared to prior to the operation?	☐	☐	☐	☐	☐

	Much better	A little better	The same	A little worse	Much worse
15. Your pain when getting into bed compared to prior to the operation?	☐	☐	☐	☐	☐
16. Your muscle spasms compared to prior to the operation?	☐	☐	☐	☐	☐
17. The amount of pain killers you need to take as compared to prior to the operation?	☐	☐	☐	☐	☐
18. Your ability to cope at home compared to prior to the operation?	☐	☐	☐	☐	☐
19. Your appetite as compared to prior to the operation?	☐	☐	☐	☐	☐
20. Your mood compared to prior to the operation?	☐	☐	☐	☐	☐
21. Your energy level compared to prior to the operation?	☐	☐	☐	☐	☐
22. Your sleep as compared to prior to the operation?	☐	☐	☐	☐	☐
23. How you feel overall compared to prior to the operation?	☐	☐	☐	☐	☐
24. Your pain when trying to sleep compared to prior to the operation?	☐	☐	☐	☐	☐
25. Your ability to sleep through the night compared to prior to the operation?	☐	☐	☐	☐	☐

19/04/17 Phase 2 PROM Participant # .

The following statements are about post-operative recovery. Thinking about the time since your operation, how much do you agree with these statements?

Please place a CROSS in the appropriate box.

		Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
1.	I have felt unwell	☐	☐	☐	☐	☐
2.	I have felt disorientated	☐	☐	☐	☐	☐
3.	I have felt tired	☐	☐	☐	☐	☐
4.	I have felt faint	☐	☐	☐	☐	☐
5.	It has been quite painful	☐	☐	☐	☐	☐
6.	I have had constant pain	☐	☐	☐	☐	☐
7.	I have worse pain at night	☐	☐	☐	☐	☐
8.	It has felt swollen	☐	☐	☐	☐	☐
9.	I have difficulty getting into bed	☐	☐	☐	☐	☐
10.	I am not able to stand	☐	☐	☐	☐	☐

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
11. I am not able to walk	☐	☐	☐	☐	☐
12. I have not slept well	☐	☐	☐	☐	☐
Which question 13a or 13b do you prefer? 13a. I have found it quite hard to sleep or 13b. I have found it difficult to sleep	☐	☐	☐	☐	☐
14. I have not been able to sleep due to the pain	☐	☐	☐	☐	☐
15. I have felt sick	☐	☐	☐	☐	☐
16. I have felt woozy	☐	☐	☐	☐	☐
17. I have been constipated	☐	☐	☐	☐	☐
18. I have lost my appetite	☐	☐	☐	☐	☐

19/04/17 Phase 2 PRAM Participant # .

The following statements are about post-operative recovery. Place a CROSS in the appropriate box.

Thinking about the state of your health before the operation, how would you rate:

		Much better	*A little better*	*The same*	*A Little worse*	*Much worse*
1.	Your ability to stand compared to prior to the operation?	☐	☐	☐	☐	☐
2.	Your ability to move compared to prior to the operation?	☐	☐	☐	☐	☐
3.	Your movement compared to prior to the operation?	☐	☐	☐	☐	☐
4.	Your mobility compared to prior to the operation?	☐	☐	☐	☐	☐
5.	Your ability to walk compared to prior to the operation?	☐	☐	☐	☐	☐
6.	Your ability to go upstairs compared to prior to the operation?	☐	☐	☐	☐	☐
7.	Your ability to go down stairs compared to prior to the operation?	☐	☐	☐	☐	☐
8.	Your strength compared to prior to the operation?	☐	☐	☐	☐	☐
9.	Your pain compared to prior to the operation?	☐	☐	☐	☐	☐
10.	How you feel today as compared to prior to the operation?	☐	☐	☐	☐	☐
11.	How comfortable you feel today compared to prior to the operation?	☐	☐	☐	☐	☐
12.	Your pain when walking as compared to prior to the operation?	☐	☐	☐	☐	☐

		Much better	*A little better*	*The same*	*A little worse*	*Much worse*
13.	Your pain in the joint today compared to prior to the operation?	☐	☐	☐	☐	☐
14.	Your pain at night compared to prior to the operation?	☐	☐	☐	☐	☐
15.	Your pain when getting into bed compared to prior to the operation?	☐	☐	☐	☐	☐
16.	Your muscle spasms compared to prior to the operation?	☐	☐	☐	☐	☐
17.	The amount of pain killers you need to take as compared to prior to the operation?	☐	☐	☐	☐	☐
18.	Your ability to cope at home compared to prior to the operation?	☐	☐	☐	☐	☐
19.	Your appetite as compared to prior to the operation?	☐	☐	☐	☐	☐
20.	Your mood compared to prior to the operation?	☐	☐	☐	☐	☐
21.	Your energy level compared to prior to the operation?	☐	☐	☐	☐	☐
22.	Your sleep as compared to prior to the operation?	☐	☐	☐	☐	☐
23.	How you feel overall compared to prior to the operation?	☐	☐	☐	☐	☐
24.	Your pain when trying to sleep compared to prior to the operation?	☐	☐	☐	☐	☐
25.	Your ability to sleep through the night compared to prior to the operation?	☐	☐	☐	☐	☐

9.5 Translatability assessment (TA)

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
1	Oxford Arthroplasty Early Change Score (OACS)	*Afrikaans* In Afrikaans, a compound such as this title would have to be written as one long word, which is hard to read. It is therefore necessary to use prepositions to clarify the relationship between the different concepts. It would be helpful if the title could be clarified more so as to be sure that the assumed relationships are correct. The back translation is: "Oxford score for early changes after arthroplasty (OACS)" Usually instrument abbreviations are	*German* Lay people or patients of a lower educational level might not comprehend this	*German* I was not able to find any approved translation; perhaps this should stay in English? *Russian* I recommend to explain in the Concept Elaboration that here they refer to "Oxford score" (patient survey, research, questionnaire), not to "Oxford Arthroplasty". In other words, explain that "Oxford" is associated with Score, not Arthroplasty. In other texts "Oxford" may be used as a registered trade name of a medical technology: "The Oxford® Partial Knee may be all you need."	Consideration should be given to the comments made about the title before finalising the wording and acronym	We would like to keep the title as for now. We will take the comments into consideration as we move forward.

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
		retained in English for international recognisability. However, this may be confusing to an Afrikaans reader, as the letters do not correspond to the initial letters of the translation. Consider whether there should be an instruction to include the English title in brackets for clarification. *French* The translation cannot be literal in French and should read: Oxford score for the assessment of early change in arthroplasty (OACS) *German* "Score" in medical context is generally not translated				

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
		Hebrew If I understand this correctly, I would say השינויים הראשוניים - the initial changes and not the early change in Hebrew *Hindi* Arthroplasty is difficult to translate in Hindi. It is best to transliterate the word. A common trend is to leave the name of the questionnaire in English, sometimes followed by a translation. I have translated 'Early' and 'Change' and transliterated 'Score'.				
2	Don't spend too long on any one question.	*German* Any literal translation of "spend too long" would sound stiff and formal, so I suggest here: "Don't			No issues	Agree.

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
		think too long about any one question."				
3	Your first choice of response is typically the right one.	*Afrikaans* "typically" could be correctly translated literally as "tipies" but "gewoonlik" (usually) per concept elaboration may be easier to understand for people with a lower educational level. *German* "choice" translated in a verb phrase			No issues	Agree.
4	Please answer **ALL** questions.					Agree.
5	Compared to how things were **before your operation**, in the **past 24 hours** how would you rate:	*Afrikaans* Verbs are generally placed at the end of a sentence in Afrikaans. Therefore, it would not be possible to end this segment with "how would you rate" as the			It may be best to restructure this sentence taking into account the recommendations and issues highlighted by the translators.	We would like to go back to our previous wording here. 'Thinking about the state of your heath before the operation, how would you rate:'

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
		normal structure would be "how would you [main item] rate". The intro is modified to: "Compared to how things were **before your operation**, how would you rate the following in the **past 24 hours?** *French* Par rapport à **avant l'opération**, comment évalueriez-vous votre situation au regard des critères suivants au cours des **dernières 24 heures** ? The question mark should be placed here. The following items are statements (affirmative form) The translation cannot be literal as the word			For consistency across languages the colloquial use of "things" should be changed. Recommend making this the question and the items statements without a question mark. This is also consistent with the OARS format. Compared to how you were **before the operation**, how would you rate the following in the **past 24 hours**?	PM: Okay change implemented

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
		"things" should be avoided in French. Instead, we would rather speak about "situation". The translation is therefore tricky. I would suggest something like: Compared to (the period) before the operation, how would you rate your situation with regard to the following criteria in the last 24 hours? *German* "things" should not be translated literally (considered as bad style) so I suggest "state" instead *Hebrew* בהשוואה למה שהיה **לפני הביתוח**, כיצד היית מדרג את הפעולות היום יומיות הבאות **במהלך 24 השעות האחרונות**:				

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
		Compared to how things were **before your operation**, how would you rate the following everyday activities in the **past 24 hours**: This is clearer, and it also solves the problem of having to start every question with the word את (term used to indicate a direct object) which is not ideal at the beginning of a sentence. e.g. Q1 *Hindi* There is a word for 'operation' in Hindi - 'शल्य क्रिया' - but it will be difficult for most lay persons, and 'operation' tranliterated in Hindi is now widely used. I have used 'condition' for 'things' as this conveys the meaning in a better way than literally				

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
		translating 'things'. I have added 'things' in the second part of the statement to make it idiomatically better: "in the past 24 hours how would you rate these these things:" *Simplified Chinese* The translation reads '[...] how would you rate the following areas for the past 24 hours:' to improve readability in Chinese *Spanish (Argentina)* "cómo estaban las cosas" may imply "in your country/personal life", not *their life and problems associated with their affected area* (as per concept elaboration). "things" could be replaced by a reference to the state of the respondent as in: En				

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
		comparación con su estado general **antes de su operación**, en **las últimas 24 horas** ¿cómo calificaría: (= in comparison to your general condition **before your operation**, in the **past 24 hours** how would you rate:)				
6	Please place an **X** in the appropriate box.	*French* Veuillez inscrire **une croix** dans la case qui convient. X should be spelled out			No issues	Agree.
7 R1-21	Much worse Worse The same Better Much better	*Simplified Chinese* The translation reads: Has significantly worsened Has worsened Stayed the same Has improved Has significantly improved		*Simplified Chinese* The text would be easier to read if it were horizontal	I would recommend changing the orientation of the response options to horizontal. Slanted text does not suit all languages and more complex fonts like Indian scripts and Asian scripts will become harder to read at an angle. Fonts that read right to left like Hebrew	Agree. PM: Okay change implemented

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
					and Arabic may also become more complicated to read. Furthermore, considering ePRO administration in the future, angled text isn't always appropriate for electronic devices.	
8 Q1	Your ability to stand compared to before the operation?	*German* It is more common to say "Stehfähigkeit" (standing ability) but to ensure consistency with the following items it is translated as "ability to stand"		*Hebrew* I added לאורך זמן – for a period of time, so that it will be clear what is asked here I think repeating " compared to before the operation" in every question is redundant, because it's in the heading. Although, from my experience with CI, the respondents skip the headings.	No issues See point above about removing the question mark.	We would like to keep the wording as is.
9 Q2	Your ability to move compared to before the operation?	*Hindi* There is no simple way to express 'move' in Hindi. I have translated it as "ability to walk or 'a		*German* The difference between this and next not apparent (CE basically is the same for both items)	The similarity between the next three items has already been discussed. Given that some languages translated	We would like to keep as is. We appreciate that there are some similar questions and these may be removed

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
		colloquial expression for moving the body." *Simplified Chinese* It's difficult to translate 'ability to move' and 'mobility', especially given that both refers to being able to move and walk normally according to the concept elaboration. Here 'ability to move' is translated as 'being able to move', while 'mobility' is translated as 'being able to move around'		*Hebrew* I translated this question and the next one the same. - היכולת שלך לנוע ממקום למקום – your ability to move from place to place.	this item and the mobility item in the same way at least one of these items should be removed and the remaining item should be as distinctive as possible from the wording in Q4. See point above about changing the question mark to a full stop	following patient input and analysis in the next phase of testing.
10 Q3	Your mobility compared to before the operation?	*Simplified Chinese* It's difficult to translate 'ability to move' and 'mobility', especially given that both refers to being able to move and walk normally according to the concept elaboration. Here 'ability to move' is translated as 'being able	*German* "Mobilität" means your ability to move and change position but also your ability to shift within space plus it has connotations in wider contexts, e.g. social/virtual mobility	*German* The difference between this and previous not apparent	See comments above in row 9 See point above about removing the question mark.	We would like to keep as is. We appreciate that there are some similar questions and these may be removed following patient input and analysis in the next phase of testing.

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
		to move', while 'mobility' is translated as 'being able to move around'				
11 Q4	Your ability to walk compared to before the operation?			*Hebrew* I don't see the difference in meaning of the 2 former questions and this one.	See comments above in row 9 See point above about removing the question mark.	We would like to keep as is. We appreciate that there are some similar questions and these may be removed following patient input and analysis in the next phase of testing.
12 Q5	Your ability to walk upstairs compared to before the operation?	*French* The use of the singular "escalier" (strair) still refers to a series of stairs (around 10)			No issues See point above about removing the question mark.	We would like to keep the wording as is.
13 Q6	Your ability to walk down stairs compared to before the operation?	*French* The use of the singular "escalier" (strair) still refers to a series of stairs (around 10)			No issues See point above about removing the question mark.	We would like to keep the wording as is.
14 Q7	Your strength compared to before the operation?	*French* "physical" could be added in order to be more precise, as stated in the list of concepts.			Recommend adding physical to the item to clarify that this relates to physical strength and not mental strength:	Agree.

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
		Simplified Chinese The whole term 'physical strength' as described in the elaboration is made explicit in the translation.			Your physical strength compared to before the operation	
15 Q8	How comfortable you feel when sitting compared to before the operation?	*French* In French, an object can be comfortable, like a chair, etc. but not a person. Therefore, the translation will have to read "your level of comfort" or "feeling of comfort" *German* A straight translation of "comfortable" might be misleading as it can be interpreted as "cosy"			The question appears straightforward in English – I think despite the issues this can be translated in a way which conveys the same meaning. See point above about removing the question mark.	We would like to keep the wording as is.
16 Q9	Your pain in the affected area when walking as compared to before the operation?				No issues	We would like to keep the wording as is.

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
					See point above about removing the question mark.	
17 Q10	Your pain in the affected area compared to before the operation?				No issues See point above about removing the question mark.	We would like to keep the wording as is.
18 Q11	Your pain in the affected area at night compared to before the operation?	*Simplified Chinese* 'at night' is translated as 'while sleeping at night' according to the concept elaboration		*Hebrew* I added בזמן השינה בלילה – whilst sleeping at night, so that it will be clear what is asked here	The addition of "whilst sleeping" was added here for clarity. This is incorrect as you could be awake and just lying in bed. This question would benefit from some clarification it might be better to say: Your pain in the affected area when in bed at night compared to before the operation	We would like to keep the wording as is. Please remove the 'in bed'.
19 Q12	Your pain in the affected area when getting into bed compared to before the operation?	*German* "getting into bed" is interpreted as "moving yourself into your bed" rather than "getting ready for bed"			No issues See point above about removing the question mark.	We would like to keep the wording as is.

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
20 Q13	Your muscle spasms in the affected area compared to before the operation?				No issues See point above about removing the question mark.	We would like to keep the wording as is.
21 Q14	Your ability to cope at home compared to before the operation?	*Afrikaans* "cope" does not have a literal translation. In line with the concepts, this was rendered as "manage your daily activities". *French* In order to avoid any ambiguity, the translation should read: "to take on activities of daily life" *Hindi* Translated as "ability to do your activities at home" as explained in the concepts sheet.		*Hebrew* I added להתמודד עם עבודות הבית – to cope with house chores, so that it will be clear what is asked here	Using the wording ability to cope is likely to result in different variations of this in future translation. Recommend amending the wording to say: Your ability to manage your daily activities at home compared to before the operation	We would like to keep the wording as is. We can refer to the concept elaboration document if needed.
22 Q15	Your appetite compared to before the operation?				No issues	We would like to keep the wording as is.

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
					See point above about removing the question mark.	
23 Q16	Your mood compared to before the operation?	*Hindi* A direct translation of "mood" will be a bit difficult for lay persons. Translated as "how are you feeling emotionally?"			Despite the issue with Hindi, mood is generally well understood across languages. See point above about removing the question mark.	We would like to keep the wording as is.
24 Q17	Your energy level compared to before the operation?	*German* "energy level" seems stiff in German, just "energy" is more colloquial			No issues See point above about removing the question mark.	We would like to keep the wording as is.
25 Q18	Your sleep compared to before the operation?	*German* The word "sleep" alone would sound odd, so "sleep quality" is used here as per CE *Simplified Chinese* 'sleep' is translated as 'quality of sleep', which is more fluent in Chinese and closer to the concept elaboration			Recommend adding "quality of sleep" as this is the intended meaning of the question: Your quality of sleep compared to before the operation	We would like to keep the wording as is. We feel that it is acceptable local vernacular and was not an issue in cognitive interviews.

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
26 Q19	How you feel overall compared to before the operation?	*Afrikaans* "overall" can be translated literally but an easier translation (for people with a lower educational level) is used, "in general" (per concepts).			No issues See point above about removing the question mark.	We would like to keep the wording as is.
27 Q20	Your pain when trying to sleep compared to before the operation?	*German* Translated as 'trying to fall asleep' as per CE as this is more idiomatic in German			No issues See point above about removing the question mark.	We would like to keep the wording as is.
28 Q21	Your ability to sleep through the night compared to before the operation?					We would like to keep the wording as is.
29	Oxford Arthroplasty Early Recovery Score (OARS)	*Afrikaans* See point above regarding OACS *French* The translation cannot be literal in French and should read: Oxford score for the	*German* See comment on item 1	*German* See comment on item 1 *Russian* I recommend to explain in the Concept Elaboration that here they refer to " Oxford score" (patient survey,	Consideration should be given to the comments made about the title before finalising the wording and acronym.	We would like to keep the title as for now. We will take the comments into consideration as we move forward.

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
		assessment of early recovery in arthroplasty (OARS) *German* See comment on item 1 *Hebrew* If I understand this correctly, I would say ההחלמה הראשונית - the initial recovery and not the early recovery in Hebrew		research, questionnaire), not to "Oxford Arthroplasty". In other words, explain that "Oxford" is associated with Score, not Arthroplasty. In other texts "Oxford" may be used as a registered trade name of a medical technology: "The Oxford® Partial Knee may be all you need."		
30	Thinking about the **past 24 hours**, how much do you agree or disagree with these statements?				No issues	We would like to go back to our previous wording here. 'Thinking about the time since your operation, how much do you agree with these statements?' PM: Change Implemented
31 R1-18	Strongly disagree Disagree	*French* "Neither agree nor disagree" is usually		*Simplified Chinese*	I would recommend changing the orientation of the response options	Agree.

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
	Neither agree nor disagree Agree Strongly agree	translated as "no opinion" <u>*German*</u> Only the middle option is tricky (BT: not sure) – I have used the translations that are widely used in similar questionnaires		The text would be easier to read if it were horizontal	to horizontal. Slanted text does not suit all languages and more complex fonts like Indian scripts and Asian scripts will become harder to read at an angle. Fonts that read right to left like Hebrew and Arabic may also become more complicated to read. Furthermore, considering ePRO administration in the future, angled text isn't always appropriate for electronic devices.	PM: Change Implemented
32 Q1	I've felt unwell	<u>*Afrikaans*</u> The present perfect tense does not exist in Afrikaans, so a choice has to be made between present and past. It seems more appropriate to put this in the past. For example, this item is rendered as "I felt unwell".			Consideration could be given to changing the wording to the simple past tense: I felt unwell	We would like to keep the wording as is. It is acceptable local vernacular. If other populations cannot translate into present perfect tense they can use simple past tense.

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
		Spanish (Argentina) For Arg., the simple past is more natural, i.e., Me sentí enfermo (I felt unwell)				
33 Q2	I've felt disorientated	*Afrikaans* As above for present perfect tense *German* Not usually combined with "Feel" *Hebrew* I felt the best word is מבולבל – absent minded, even *Hindi* It is difficult to capture all the things given in the concepts elaboration. The Hindi translation conveys			This question is open to interpretation and has many possible meanings which makes translation difficult. It is difficult to know how to address this issue as it is clear that different languages will have to translate this question in different ways affecting the cross-cultural validity of the item. It needs to be made more specific in some way.	We would like to keep the wording as is. This item has been marked for possible deletion.

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
		being confused and dizzy. *Spanish (Argentina)* As above for the tense: Me sentí desorientado (I felt disoriented)				
34 Q3	I've felt tired	*Afrikaans* As above for present perfect tense *German* Not usually combined with "feel" *Spanish (Argentina)* As above for the tense: Me sentí cansado (I felt tired)			Consideration could be given to changing the wording to the simple past tense: I felt tired	We would like to keep the wording as is. It is acceptable local vernacular. If other populations cannot translate into present perfect tense they can use simple past tense.
35 Q4	I've felt faint	*Afrikaans* As above for present perfect tense *German*			Consideration could be given to changing the wording to the simple past tense: I felt faint	We would like to keep the wording as is. It is acceptable local vernacular. If other populations cannot translate into present perfect tense

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
		Not usually combined with "feel" No direct equivalent to "faint", more context is given to make the meaning clearer *Spanish (Argentina)* As above for the tense: Me sentí débil (I felt faint)				they can use simple past tense.
36 Q5	It's been painful in the affected area	*Afrikaans* As above for present perfect tense *Spanish (Argentina)* As above for the tense: Sentí dolor en el área afectada (I felt pain in the affected area)			Consideration could be given to changing the wording to the simple past tense: I felt pain in the affected area	We would like to keep the wording as is. It is acceptable local vernacular. If other populations cannot translate into present perfect tense they can use simple past tense.
37 Q6	I've had constant pain in the affected area	*Afrikaans* As above for present perfect tense *Spanish (Argentina)*			Consideration could be given to changing the wording to the simple past tense:	We would like to keep the wording as is. It is acceptable local vernacular. If other populations cannot translate into

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
		As above for the tense: Sentí dolor constante en el área afectada (I felt constant pain in the affected area)			I felt constant pain in the affected area	present perfect tense they can use simple past tense.
38 Q7	I've had pain at night in the affected area	*Afrikaans* As above for present perfect tense *Simplified Chinese* Again, 'at night' is translated as 'while sleeping at night'. If this doesn't apply here, the yellow highlighted characters should be deleted. *Spanish (Argentina)* As above for the tense: Sentí dolor de noche en el área afectada (I felt pain at night in the affected area)			The addition of "whilst sleeping" was added here for clarity. This is incorrect as you could be awake and just lying in bed. This question would benefit from some clarification, it might be better to say: I felt pain when in bed at night in the affected area	We would like to keep the wording as is. It is acceptable local vernacular. If other populations cannot translate into present perfect tense they can use simple past tense. Please remove 'whilst sleeping'.

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
39 Q8	The affected area has felt swollen	*Afrikaans* As above for present perfect tense *French* In order to rend the notion of "felt", the translation should read "I've felt a swelling in the affected area" *Hebrew* The affected area was swollen (not suitable to say felt swollen in Hebrew) *Spanish (Argentina)* As above for the tense: Sentí inflamada el área afectada (I felt swollen the affected area)			May be better to reword this as: The affected area was swollen	We would like to keep the wording as is. It is acceptable local vernacular. If other populations cannot translate into present perfect tense they can use simple past tense.
40 Q9	I've had difficulty getting into bed	*Afrikaans*			Consideration could be given to changing the	We would like to keep the wording as is. It is

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
		As above for present perfect tense *German* See comment on item 19 *Spanish (Argentina)* As above for the tense: Tuve dificultades para meterme en la cama (I had difficulty getting into bed)			wording to the simple past tense: I had difficulty getting into bed	acceptable local vernacular. If other populations cannot translate into present perfect tense they can use simple past tense.
41 Q10	I've not been able to stand	*Afrikaans* As above for present perfect tense "I have not been able to" can be translated literally but is a little wordy and overly formal in Afrikaans. This item			Consideration could be given to changing the wording to the simple past tense: I was not able to stand	We would like to keep the wording as is. It is acceptable local vernacular. If other populations cannot translate into present perfect tense they can use simple past tense.

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
		was rendered as "I could not stand" *Hebrew* The same decision as above *Spanish (Argentina)* As above for the tense: No fui capaz de estar de pie (I was not able to stand)				
42 Q11	I've not been able to walk	*Afrikaans* As above for present perfect tense "I have not been able to" can be translated literally but is a little wordy and overly formal in Afrikaans. *Spanish (Argentina)*			Consideration could be given to changing the wording to the simple past tense: I was not able to walk	We would like to keep the wording as is. It is acceptable local vernacular. If other populations cannot translate into present perfect tense they can use simple past tense.

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
		As above for the tense: No fui capaz de caminar (I was not able to walk)				
43 Q12	I've not slept well	*Afrikaans* As above for present perfect tense *Hebrew* Added the word restfully *Spanish (Argentina)* As above for the tense: No dormí bien (I did not sleep well)			Consideration could be given to changing the wording to the simple past tense: I did not sleep well	We would like to keep the wording as is. It is acceptable local vernacular. If other populations cannot translate into present perfect tense they can use simple past tense.
44 Q13	I've found it difficult to sleep	*Afrikaans* As above for present perfect tense *German*			Consideration could be given to changing the wording to the simple past tense: I found it difficult to sleep	We would like to keep the wording as is. It is acceptable local vernacular. If other populations cannot translate into present perfect tense

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
		Needs more than just the word "sleep" as per CE *Hebrew* Added the word restfully *Spanish (Argentina)* As above for the tense: Me resultó difícil dormir (I found it difficult to sleep)			Although as per the German comment this is perhaps a little vague in some languages, may be better to say the following although this is very similar to the Q12 above: I found it difficult to sleep well	they can use simple past tense.
45 Q14	I've not been able to sleep due to the pain in the affected area	*Afrikaans* As above for present perfect tense "I have not been able to" can be translated literally but is a little wordy and overly formal in Afrikaans. *Spanish (Argentina)* As above for the tense: No pude dormir debido			Consideration could be given to changing the wording to the simple past tense: I could not sleep due to the pain in the affected area	We would like to keep the wording as is. It is acceptable local vernacular. If other populations cannot translate into present perfect tense they can use simple past tense.

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
		al dolor en el área afectada (I could not sleep due to the pain in the affected area)				
46 Q15	I've felt sick	*Afrikaans* As above for present perfect tense "sick" is ambiguous and could also be translated as "siek", which can mean both "nauseous" and "unwell". Since the concept elab specifies nausea, this was translated to specifically mean nausea only. *German* Not usually combined with "feel" *Spanish (Argentina)*			This question will be interpreted in different ways – in English it could mean I felt nausea or it could mean I felt poorly in general. To clarify this you could say: I had nausea But I think this is too technical and may not be understood by everyone so it may be better to say: I felt queasy This is a difficult one to convey easily	We would like to keep the wording as is. It is acceptable local vernacular. If other populations cannot translate into present perfect tense they can use simple past tense.

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
		As above for the tense: Me sentí enfermo (I felt sick)				
47 Q16	I've felt woozy	*Afrikaans* As above for present perfect tense *German* Not usually combined with "feel" *Hindi* I have translated it as feeling confused, using a wording different from Q33. *Spanish (Argentina)* As above for the tense: Me sentí mareado (I felt woozy). Translated as dizzy			This will probably need to be translated in slightly different ways as there will not be a direct translation of woozy in every language. Consideration could be given to changing the wording to the simple past tense: I felt woozy	We would like to keep the wording as is. This item has been marked for possible deletion.
48 Q17	I've been constipated	*Afrikaans*			Consideration could be given to changing the	We would like to keep the wording as is. It is

Ref	Final Wording	Linguistic Issues	Cultural Issues	General Comments	Project Manager's Recommendations	Developer's Response and Final Wording
		As above for present perfect tense *Spanish (Argentina)* As above for the tense: Estuve constipado (I was constipated)			wording to the simple past tense: I was constipated	acceptable local vernacular. If other populations cannot translate into present perfect tense they can use simple past tense.
49 Q18	I've lost my appetite	*Afrikaans* As above for present perfect tense *French* "my appetite" will read "appetite" *German* Not idiomatic to literally say "loose one's appetite" *Spanish (Argentina)* As above for the tense: Perdí el apetito (I lost my appetite)			Consideration could be given to changing the wording to the simple past tense: I lost my appetite Or to make the question less colloquial: I had a poor appetite	We would like to keep the wording as is. It is acceptable local vernacular. If other populations cannot translate into present perfect tense they can use simple past tense.

9.6 Concept elaboration document (CED)

Thank you for your feedback, you comments and suggestions have been incorporated into the report. Please can you now confirm whether you agree or disagree with the concept elaboration by entering Agree or Disagree in the Developer's Comments column for each row. If you disagree please state why and enter your prefered elaboration. For the text highlighted in yellow please can you define what is meant by the terminology in the context of these questionnaires. Thanks.

Ref	Final Wording	Concept Elaboration	Interpretation Issues & Comments/Queries	Developer's Comments
1	Title - Blank	No elaboration required		Happy for you to add our working title 'Oxford Arthroplasty Early Change Score (OACS).'
2	Don't spend too long on any one question.	No elaboration required	Do not contracted into Don't	Agree
3	Your first choice of response is typically the right one.	"typically" can be translated as usually or normally		Agree
4	Please answer **ALL** questions.	No elaboration required		Agree
5	Compared to how things were **before your operation**, in the **past 24 hours** how would you rate:	"Compared to how things were" is asking the patient to consider their life and problems associated with their leg prior to their operation		Disagree. Could we change it to problems associated with 'the affected area' prior to the operation.
6	Please place an **X** in the appropriate box.	If X is a symbol which isn't used in your language then please replace it with the most appropriate symbol for your language.		Agree
7 R1-21	Much worse Worse The same Better Much better	"Much" indicates a greater degree of improvement or deterioration than simply worse or better. If it is not possible to translate "much" directly in this context "A great deal		Agree

Ref	Final Wording	Concept Elaboration	Interpretation Issues & Comments/Queries	Developer's Comments
		worse" and "A great deal better" can be used instead.		
8 Q1	Your ability to stand compared to before the operation?	Stand in this context means standing in line or waiting for a bus rather than standing up from a sitting position.		Agree
9 Q2	Your ability to move compared to before the operation?		Please can you clarify the intended meaning of "ability to move" and specifically how it is different from "mobility" below. Thanks for you answer. For the purposes of this document please could you define what is meant by "ability to move"?	It is likely that we may remove one of the movement questions. We have used patients' words and appreciate they are similar. We will see how they answer. 'being able to move and walk normally'
10 Q3	Your mobility compared to before the operation?		Please can you clarify the intended meaning of "mobility" and specifically how it is different from "ability to move" above and "ability to walk" below. Thanks for you answer. For the purposes of this document please could you define what is meant by "mobility"?	It is likely that we may remove one of the movement questions. We have used patients' words and appreciate they are similar. We will see how they answer. 'being able to move and walk normally'
11 Q4	Your ability to walk compared to before the operation?	No elaboration required		Agree

Ref	Final Wording	Concept Elaboration	Interpretation Issues & Comments/Queries	Developer's Comments
12 Q5	Your ability to walk upstairs compared to before the operation?		Is there a number of stairs this relates to? I wonder if it would be helpful to amend this to say "walk up a flight of stairs…" which most people take to mean 10-15 stairs so the number of stairs isn't open to interpretation. It also doesn't discriminate against people who live on one floor (far more common in other countries) because it can currently be read as walk upstairs – as in walking up to the second floor in my home. Thanks for your answer. For the purposes of this document please can you define what is meant by walk upstairs e.g. is it one flight of stairs or a couple of stairs etc.	For reasons of clarity and conciseness we shall keep this as is please. 'being able to walk up several stairs'
13 Q6	Your ability to walk down stairs compared to before the operation?		See comment above – again it might be best to amend this to say "down a flight of stairs…" Thanks for your answer. For the purposes of this document please can you define what is meant by walk downstairs e.g. is it one flight of stairs or a couple of stairs etc.	For reasons of clarity and conciseness we shall keep this as is please. 'being able to walk down several stairs'

Ref	Final Wording	Concept Elaboration	Interpretation Issues & Comments/Queries	Developer's Comments
14 Q7	Your strength compared to before the operation?	Stength here refers to overall physical strength rather than mental strength		Agree
15 Q8	How comfortable you feel when sitting compared to before the operation?	"comfortable" refers in this context to feeling at ease and relaxed without pain and discomfort, when sitting down.		Agree
16 Q9	Your pain in the affected area when walking as compared to before the operation?	No elaboration required	"in the affected area" added	Agree
17 Q10	Your pain in the affected area compared to before the operation?	No elaboration required	"in the affected area" added	Agree
18 Q11	Your pain in the affected area at night compared to before the operation?	At night here should be seen as synonomous with being in bed at night, rather than at night in general i.e. out at a bar.	"in the affected area" added	Agree
19 Q12	Your pain in the affected area when getting into bed compared to before the operation?	No elaboration required	"in the affected area" added	Agree
20 Q13	Your muscle spasms in the affected area compared to before the operation?	A muscle spasm is a pain in the muscle which occurs abruptly, is painful but usually only lasts for a short period of time.	"in the affected area" added	Agree

Ref	Final Wording	Concept Elaboration	Interpretation Issues & Comments/Queries	Developer's Comments
21 Q14	Your ability to cope at home compared to before the operation?	Cope at home refers to the ability of the patient to undertake their daily activities at home.		Agree
22 Q15	Your appetite compared to before the operation?	No elaboration required	"as" removed	Agree
23 Q16	Your mood compared to before the operation?	"mood" here refers to your general sense of emotional wellbeing/how you're feeling emotionally		Agree
24 Q17	Your energy level compared to before the operation?	"energy level" refers to how much energy/vitality you have		Agree
25 Q18	Your sleep compared to before the operation?	"sleep" here refers to overall quality of sleep	"as" removed	Agree
26 Q19	How you feel overall compared to before the operation?	"Feel overall" refers to the patient's perception of their overall health (mental and physical).		Agree
27 Q20	Your pain when trying to sleep compared to before the operation?	"pain when trying to sleep" means the pain the person experiences when they're trying to fall asleep, either initially or during the night if they wake up.		Agree
28 Q21	Your ability to sleep through the night compared to before the operation?	"ability to sleep through the night" refers to being able to have an uninterrupted and undisturbed sleep from the moment you go to sleep until when you wake the next day		Agree

Ref	Final Wording	Concept Elaboration	Interpretation Issues & Comments/Queries	Developer's Comments
29	Title - Blank	No elaboration required		Happy for you to add our working title 'Oxford Arthroplasty Early Recovery Score (OARS)'
30	Thinking about the **past 24 hours**, how much do you agree or disagree with these statements?	No elaboration required		Agree
31 R1-18	Strongly disagree Disagree Neither agree nor disagree Agree Strongly agree	No elaboration required	Changed to "Neither agree nor disagree"	Agree
32 Q1	I've felt unwell	Unwell in this context refers to feeling ill	I have contracted into I've	Agree
33 Q2	I've felt disorientated	Disorientated in this context means unsure of surroundings, tired and not quite coping, raw, bleary-eyed, lacking usual self-confidence and clarity of thought, feeling woozy after operation.	I have contracted into I've	Agree
34 Q3	I've felt tired	Tired in this context includes feeling both fatigued and tired in the sense of wanting to go to be and sleep (feeling sleepy)	I have contracted into I've	Agree

Ref	Final Wording	Concept Elaboration	Interpretation Issues & Comments/Queries	Developer's Comments
35 Q4	I've felt faint	Faint means feeling weak and dizzy and close to losing consciousness	I have contracted into I've	Agree
36 Q5	It's been painful in the affected area	No elaboration required	"in the affected area" added It has contracted into It's	Agree
37 Q6	I've had constant pain in the affected area	Constant =enduring pain which doesn't subside	"in the affected area" added I have contracted into I've	Agree
38 Q7	I've had pain at night in the affected area	No elaboration required	"in the affected area" added I have contracted into I've Had added	Agree
39 Q8	My leg has felt swollen in the affected area	Swollen means inflamed	"in the affected area" added	Disagree. Could we change it to 'The affected area has felt swollen.'
40 Q9	I've had difficulty getting into bed	No elaboration required	I have contracted into I've	Agree
41 Q10	I've not been able to stand	Stand in this context means standing in line or waiting for a bus rather than standing up from a sitting position.	I have contracted into I've	Agree
42 Q11	I've not been able to walk	No elaboration required	I have contracted into I've	Agree
43 Q12	I've not slept well	Slept well means a good night's sleep/a restful sleep	I have contracted into I've	Agree
44	I've found it difficult to sleep	Difficult to sleep means the person found it difficult/hard to fall asleep,	I have contracted into I've	Agree

Ref	Final Wording	Concept Elaboration	Interpretation Issues & Comments/Queries	Developer's Comments
Q13		or they have had a restless or disturbed sleep or they woke during the night or earlier than intended.		
45 Q14	I've not been able to sleep due to the pain in the affected area	Sleep means the person found it difficult/hard to fall asleep, or they have had a restless or disturbed sleep or they woke during the night or earlier than intended.	"in the affected area" added I have contracted into I've	Agree
46 Q15	I've felt sick	"felt sick" means the person has felt like they want to vomit and that they have had a queasy feeling in their stomach. It doesn't mean they've actually vomited.	I have contracted into I've	Agree
47 Q16	I've felt woozy		Please can you define the meaning of woozy and specifically how it differs from Q4 "I have felt faint"? Thanks for your answer. Please can you define woozy? I have contracted into I've	It is likely that we may remove one of these questions. We have used patients' words and appreciate they are similar/may have potential redundancies. We will see how they answer. 'muddled, dizzy and or dazed'
48 Q17	I've been constipated	No elaboration required	I have contracted into I've	Agree
49 Q18	I've lost my appetite	"Lost my appetite" means the person feels that they don't feel as hungry as they normally do and have lost the desire to eat.	I have contracted into I've	Agree

9.7 Final versions of the Oxford Arthroplasty Early Recovery Score (OARS) and the Oxford Arthroplasty Early Change Score (OACS)

Oxford Arthroplasty Early Recovery Score (OARS)

Don't spend too long on any one question. Your first choice of response is typically the right one. Please answer **ALL** questions. This questionnaire asks about your health **TODAY.**

How much do you agree with these statements?
Please place an **X** in the appropriate box.

THINKING ABOUT YOUR HEALTH **TODAY:**		Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
1.	I've felt unwell	☐	☐	☐	☐	☐
2.	I've felt tired	☐	☐	☐	☐	☐
3.	I've felt faint	☐	☐	☐	☐	☐
4.	It's been painful in the affected area	☐	☐	☐	☐	☐
5.	I've had pain at night in the affected area	☐	☐	☐	☐	☐
6.	The affected area has felt swollen	☐	☐	☐	☐	☐
7.	I've had difficulty getting into Bed	☐	☐	☐	☐	☐
8.	I've not been able to stand	☐	☐	☐	☐	☐
9.	I've not been able to walk	☐	☐	☐	☐	☐
10.	I've not slept well	☐	☐	☐	☐	☐
11.	I've found it difficult to sleep	☐	☐	☐	☐	☐
12.	I've not been able to sleep due to the pain in the affected area	☐	☐	☐	☐	☐
13.	I've felt sick	☐	☐	☐	☐	☐
14.	I've lost my appetite	☐	☐	☐	☐	☐

Oxford Arthroplasty Early Change Score (OACS)

Don't spend too long on any one question. Your first choice of response is typically the right one. Please answer **ALL** questions. This questionnaire asks about your health **TODAY compared to before your operation.**

Thinking about the state of your health **before the operation**, how would you rate:

Please place an **X** in the appropriate box.	Much worse	Worse	The same	Better	Much better
1. Your ability to stand compared to before the operation?	☐	☐	☐	☐	☐
2. Your ability to walk compared to before the operation?	☐	☐	☐	☐	☐
3. Your ability to walk upstairs compared to before the operation?	☐	☐	☐	☐	☐
4. Your ability to walk down stairs compared to before the operation?	☐	☐	☐	☐	☐
5. Your strength compared to before the operation?	☐	☐	☐	☐	☐
6. How comfortable you feel when sitting compared to before the operation?	☐	☐	☐	☐	☐
7. Your pain in the affected area compared to before the operation?	☐	☐	☐	☐	☐
8. Your pain in the affected area when walking as compared to before the operation?	☐	☐	☐	☐	☐
9. Your appetite as compared to before the operation?	☐	☐	☐	☐	☐
10. Your mood compared to before the operation?	☐	☐	☐	☐	☐
11. Your energy level compared to before the operation?	☐	☐	☐	☐	☐
12. Your sleep as compared to before the operation?	☐	☐	☐	☐	☐
13. How you feel overall compared to before the operation?	☐	☐	☐	☐	☐
14. Your pain when trying to sleep compared to before the operation?	☐	☐	☐	☐	☐

9.8 SF-36 v2 Acute Questionnaire

Your Health and Well-Being

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. *Thank you for completing this survey!*

For each of the following questions, please tick the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. <u>Compared to one week ago</u>, how would you rate your health in general <u>now</u>?

Much better now than one week ago	Somewhat better now than one week ago	About the same as one week ago	Somewhat worse now than one week ago	Much worse now than one week ago
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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(SF-36v2® Health Survey Acute, United Kingdom (English))

3. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

		Yes, limited a lot	Yes, limited a little	No, not limited at all
a	<u>Vigorous activities</u>, such as running, lifting heavy objects, participating in strenuous sports	☐ 1	☐ 2	☐ 3
b	<u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
c	Lifting or carrying groceries	☐ 1	☐ 2	☐ 3
d	Climbing <u>several</u> flights of stairs	☐ 1	☐ 2	☐ 3
e	Climbing <u>one</u> flight of stairs	☐ 1	☐ 2	☐ 3
f	Bending, kneeling, or stooping	☐ 1	☐ 2	☐ 3
g	Walking <u>more than a mile</u>	☐ 1	☐ 2	☐ 3
h	Walking <u>several hundred yards</u>	☐ 1	☐ 2	☐ 3
i	Walking <u>one hundred yards</u>	☐ 1	☐ 2	☐ 3
j	Bathing or dressing yourself	☐ 1	☐ 2	☐ 3

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4. During the <u>past week</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Cut down on the <u>amount of time</u> you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b <u>Accomplished less</u> than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Were limited in the <u>kind</u> of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Had <u>difficulty</u> performing the work or other activities (for example, it took extra effort)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. During the <u>past week</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Cut down on the <u>amount of time</u> you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b <u>Accomplished less</u> than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Did work or other activities <u>less carefully than usual</u>	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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6. **During the <u>past week</u>, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?**

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. **How much <u>bodily</u> pain have you had during the <u>past week</u>?**

None	Very mild	Mild	Moderate	Severe	Very severe
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

8. **During the <u>past week</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?**

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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9. These questions are about how you feel and how things have been with you during the past week. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past week…

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Did you feel full of life?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Have you been very nervous?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Have you felt so down in the dumps that nothing could cheer you up?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
e Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
f Have you felt downhearted and low?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
g Did you feel worn out?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
h Have you been happy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
i Did you feel tired?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

10. During the past week, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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11. How TRUE or FALSE is <u>each</u> of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a I seem to get ill more easily than other people	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b I am as healthy as anybody I know	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c I expect my health to get worse	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d My health is excellent	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Thank you for completing these questions!

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9.9 Publications associated with this thesis

The Journal of Arthroplasty 31 (2016) 2933–2940

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The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

Review

Patient-Reported Outcome Measure for Early Postoperative Recovery Following Lower Limb Arthroplasty: A Systematic Review

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ABSTRACT

Background: Lower limb arthroplasty is an effective surgical treatment option for patients with moderate to severe arthritis who have not responded to medical management. However, surgical interventions can lead to postoperative consequences such as limited mobility, pain, and infection. Consequently, improving postoperative recovery holds significant benefits for patients, health care professionals, and health care payers. The purpose of this review is to determine if any recovery tools exist that can effectively measure early postoperative recovery after hip or knee arthroplasty.
Methods: The following databases were searched; PubMed (Ovid), EMBASE (Ovid), Medline (Ovid), Web of Science (ISI Web of Knowledge), PsycINFO, Applied Social Sciences Index and Abstracts, Cochrane library, and SCOPUS. We restricted our search to English language articles and adult respondents. Data were extracted by 2 independent reviewers using a proforma spreadsheet, and existing quality criteria were applied.
Results: Our literature search identified 23 articles relating to development, assessment, and validation of 15 tools. Not all instruments demonstrated the same levels of quality. None of the tools found were specific to both the orthopedic arthroplasty population and early recovery periods.
Conclusion: At the present time, there are no fully validated tools to assess early postoperative recovery during the first week following lower limb arthroplasty. A brief, easy-to-complete, reliable patient-reported tool could be of great use. It could not only aid in assessment of recovery but could also evaluate the efficacy of perioperative interventions such as drugs or surgical technique and provide a foundation for evidence-based care.

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Optimal patient recovery following surgery is critical to improving patient outcomes. Many factors contribute to patient recovery including: motivations, premorbid health status, prior operative and anesthetic experience, type of surgery, analgesia, as well as expectations from surgery [1]. Traditionally, patient recovery has been assessed by the surgeon and allied health care professionals using pain scores and analgesic consumption together with objective measurements including time to achieve set rehabilitation goals, such as knee flexion greater than 90° or hospital discharge [2]. While these objective measurements assess a patient's recovery from the physiological perspective, they fail to assess many of the factors known to influence self-reported outcomes. Due to the limitations of objective measurements in assessing patient outcomes, interest has shifted toward the use of patient-reported outcome measures (PROMs) for assessment of surgical interventions [3]. These focus on patient self-reported functioning and well-being [4]. Their use is instrumental in assisting clinicians and policymakers to take important strides towards optimizing the provision of care through refining modifiable

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A Meta-Analysis on the Use of Gabapentinoids for the Treatment of Acute Postoperative Pain Following Total Knee Arthroplasty

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Investigation performed at the Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, United Kingdom

Background: Total knee arthroplasty is a painful procedure, with approximately half of patients reporting severe pain during the early postoperative period. Gabapentinoids are used as an adjunct for the management of acute pain in approximately half of enhanced recovery programs. We performed a meta-analysis to assess the effectiveness and safety of gabapentinoids for the treatment of acute postoperative pain following total knee arthroplasty.

Methods: Randomized controlled trials of patients undergoing elective primary total knee arthroplasty that compared the use of the gabapentinoid class of drugs (gabapentin [Neurontin; Pfizer]) or pregabalin [Lyrica; Pfizer]) with that of placebo were retrieved, with 12 studies meeting inclusion criteria. The primary outcome was pain intensity with activity at 48 hours following the surgical procedure. The secondary outcomes included pain intensity at other time points, opioid consumption, knee function, incidence of chronic pain, and adverse events.

Results: No difference in pain score at 12, 24, 48, or 72 hours following the surgical procedure was seen between gabapentin and placebo. Although pregabalin was associated with reduced pain scores at 24 and 48 hours, this corresponded to a reduction of 0.5 point (95% confidence interval, 0 to 1.0 point) at 24 hours and 0.3 point (95% confidence interval, 0 to 0.6 point) at 48 hours on an 11-point numeric rating scale, which was assessed as not clinically important. Overall, no clinically relevant reduction in pain scores was associated with the use of gabapentinoids. Likewise, gabapentinoids were associated with a small, but not clinically important, reduction in cumulative opioid consumption at 48 hours (mean difference, −23.2 mg [95% confidence interval, −40.9 to −5.4 mg]). There was no difference in knee flexion at 48 hours ($p = 0.63$) or in the incidence of chronic pain at 3 months ($p = 0.31$) or 6 months ($p = 0.54$) associated with the use of gabapentinoids. Although gabapentinoids were associated with a significant reduction in the incidence of nausea (risk ratio, 0.7 [95% confidence interval, 0.6 to 0.9]; $p < 0.001$), pregabalin was also associated with a significant, clinically relevant increase in the risk of sedation (risk ratio, 1.4 [95% confidence interval, 1.1 to 1.9]; $p = 0.02$).

Conclusions: On the basis of this meta-analysis, we found no evidence to support the routine use of gabapentinoids in the management of acute pain following total knee arthroplasty.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

Peer Review: This article was reviewed by the Editor-in-Chief and one Deputy Editor, and it underwent blinded review by two or more outside experts. It was also reviewed by an expert in methodology and statistics. The Deputy Editor reviewed each revision of the article, and it underwent a final review by the Editor-in-Chief prior to publication. Final corrections and clarifications occurred during one or more exchanges between the author(s) and copyeditors.

Approximately half of all patients undergoing total knee arthroplasty experience severe postoperative pain, despite multimodal analgesia[1]. Pain is the most common reason for delayed discharge as well as a common cause of readmission[2]. Improving a patient's perioperative recovery through multimodal enhanced recovery programs has substantial benefits for the patient, surgeon, and health-care payer. Enhanced recovery programs have been demonstrated to reduce short and long-term

Disclosure: One author of this study (T.W.H.) received a grant from the National Institute for Health Research (NIHR) Biomedical Research Unit into Musculoskeletal Disease, Nuffield Orthopaedic Centre and the University of Oxford; funds were used to pay for his time to complete this work. The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article.

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[Intervention Review]

Liposomal bupivacaine peripheral nerve block for the management of postoperative pain

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ABSTRACT

Background

Postoperative pain remains a significant issue with poor perioperative pain management associated with an increased risk of morbidity and mortality. Liposomal bupivacaine is an analgesic consisting of bupivacaine hydrochloride encapsulated within multiple, non-concentric lipid bi-layers offering a novel method of sustained release.

Objectives

To assess the analgesic efficacy and adverse effects of liposomal bupivacaine infiltration peripheral nerve block for the management of postoperative pain.

Search methods

We identified randomised trials of liposomal bupivacaine peripheral nerve block for the management of postoperative pain. We searched the Cochrane Central Register of Controlled Trials (CENTRAL) (2016, Issue 1), Ovid MEDLINE (1946 to January Week 1 2016), Ovid MEDLINE In-Process (14 January 2016), EMBASE (1974 to 13 January 2016), ISI Web of Science (1945 to 14 January 2016), and reference lists of retrieved articles. We sought unpublished studies from Internet sources, and searched clinical trials databases for ongoing trials. The date of the most recent search was 15 January 2016.

Selection criteria

Randomised, double-blind, placebo- or active-controlled clinical trials of a single dose of liposomal bupivacaine administered as a peripheral nerve block in adults aged 18 years or over undergoing elective surgery at any surgical site. We included trials if they had at least two comparison groups for liposomal bupivacaine peripheral nerve block compared with placebo or other types of analgesia.

Data collection and analysis

Two review authors independently considered trials for inclusion in the review, assessed risk of bias, and extracted data. We performed analyses using standard statistical techniques as described in the *Cochrane Handbook for Systematic Reviews of Interventions*, using Review Manager 5. We planned to perform a meta-analysis, however there were insufficient data to ensure a clinically meaningful answer: as such we have produced a 'Summary of findings' table in a narrative format, and where possible we assessed the evidence using GRADE (Grading of Recommendations Assessment, Development and Evaluation).

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ORIGINAL ARTICLE

WILEY Journal of Clinical Nursing

Early recovery following lower limb arthroplasty: Qualitative interviews with patients undergoing elective hip and knee replacement surgery. Initial phase in the development of a patient-reported outcome measure

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Funding information
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Aims and objectives: To explore the patients' perspective of surgery and early recovery when undergoing lower limb (hip or knee) arthroplasty.

Background: Lower limb arthroplasty is a commonly performed procedure for symptomatic arthritis, which has not responded to conservative medical treatment. Each patient's perspective of the surgical process and early recovery period impacts on their quality of life.

Design: Open, semistructured qualitative interviews were used to allow for a deeper understanding of the patient perspective when undergoing a hip or knee arthroplasty.

Methods: Following ethical approval, 30 patients were interviewed between August and November 2016 during the perioperative period while undergoing an elective hip or knee arthroplasty (n = 30). The interviews were performed between the day of surgery and a nine-week postoperative clinic appointment. Data were analysed using an in-depth narrative thematic analysis method. NVivo qualitative data analysis software was used.

Results: Seven main themes evolved from the interviews: "improving function and mobility", "pain", "experiences of health care", "support from others", "involvement and understanding of care decisions", "behaviour and coping" and "fatigue and sleeping".

Conclusions: The early postoperative recovery period is of vital importance to all surgical patients. This is no different for the orthopaedic patient. However, identifying key self-reported areas of importance from patients can guide clinical focus for healthcare professionals.

Mohammad et al. Systematic Reviews (2017) 6:92
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Systematic Reviews

PROTOCOL Open Access

Perioperative adjuvant corticosteroids for post-operative analgesia in elective knee surgery – A systematic review

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Abstract

Background: Elective knee surgery is performed to reduce chronic pain and improve function in degenerate knees. Treatment of acute post-operative pain is suboptimal in 75% of patients despite multimodal analgesic approaches resulting in higher post-operative opiate consumption. The effect of corticosteroids as an adjunct for post-operative pain control remains undefined.

Methods: The databases MEDLINE, EMBASE and CENTRAL (Cochrane library) will be searched from their inception to present using broad search criteria for eligible randomised/quasi-randomised controlled trials investigating perioperative corticosteroid adjunctive use in elective knee surgery. Meta-analyses will be conducted according to the recommendations from the Cochrane Handbook for Systematic Reviews of Interventions.

Discussion: This systematic review of the perioperative adjunctive use of corticosteroids will assess the analgesic effects, post-operative nausea and vomiting, opiate consumption, infection rates and time till discharge and assess whether adjunctive corticosteroids should be encouraged in elective knee surgery.

Systematic review registration: PROPSERO CRD42016049336

Keywords: Analgesia, Corticosteroids, Knee, Perioperative, Surgery

Background

Description of the condition

Treatment of acute post-operative pain following elective surgery is suboptimal with reports of up to 75% of patients having inadequate pain relief in the immediate post-operative period [1, 2].

Elective knee surgery is commonly performed to reduce chronic pain and improve function in degenerate knees. Approximately 160,000 knee and hip replacements are conducted annually with demand on the rise [3]. This is evidenced by the greater numbers of patients having to wait beyond the 18-week target for elective surgery. In 2014, 51,388 patients waited excess of this period compared to 92,739 in 2015 [4].

Effective analgesia is therefore paramount to early rehabilitation, deconditioning prevention and timely discharge to free up resources. By the year 2030, the demand for total knee arthroplasty alone is predicted to grow sixfold placing emphasis on post-operative pain optimization as a priority [5].

Traditionally, pain control following surgery heavily relied on oral opiates and patient-controlled analgesia. However unfortunately, opiates are associated with various side effects, some of which include respiratory depression, confusion, sedation, vomiting, pruritus and urinary retention with evidence suggesting longer hospital stays and higher socioeconomic costs. Furthermore, the light sedation, muscle weakness and dizziness opiates cause may have an impact on post-operative rehabilitation delaying it or even predisposing to increased risk of injuries [6, 7].

There is also evidence that optimization of immediate post-operative analgesia reduces chronic post-surgical pain occurrences and improves functional outcomes significantly [8].

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[Intervention Review]

Liposomal bupivacaine infiltration at the surgical site for the management of postoperative pain

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ABSTRACT

Background

Despite multi-modal analgesic techniques, acute postoperative pain remains an unmet health need, with up to three quarters of people undergoing surgery reporting significant pain. Liposomal bupivacaine is an analgesic consisting of bupivacaine hydrochloride encapsulated within multiple, non-concentric lipid bi-layers offering a novel method of sustained-release analgesia.

Objectives

To assess the analgesic efficacy and adverse effects of liposomal bupivacaine infiltration at the surgical site for the management of postoperative pain.

Search methods

On 13 January 2016 we searched CENTRAL, MEDLINE, MEDLINE In-Process, Embase, ISI Web of Science and reference lists of retrieved articles. We obtained clinical trial reports and synopses of published and unpublished studies from Internet sources, and searched clinical trials databases for ongoing trials.

Selection criteria

Randomised, double-blind, placebo- or active-controlled clinical trials in people aged 18 years or over undergoing elective surgery, at any surgical site, were included if they compared liposomal bupivacaine infiltration at the surgical site with placebo or other type of analgesia.

Data collection and analysis

Two review authors independently considered trials for inclusion, assessed risk of bias, and extracted data. We performed data analysis using standard statistical techniques as described in the Cochrane Handbook for Systematic Reviews of Interventions, using Review Manager 5.3. We planned to perform a meta-analysis and produce a 'Summary of findings' table for each comparison however there were insufficient data to ensure a clinically meaningful answer. As such we have produced two 'Summary of findings' tables in a narrative format. Where possible we assessed the quality of evidence using GRADE.

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Enhanced recovery programmes for lower limb arthroplasty in the UK

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ABSTRACT

INTRODUCTION Enhanced recovery programmes (ERPs) reduce patient morbidity and mortality, and provide significant cost savings by reducing length of stay. Currently, no uniform ERP guidelines exist for lower limb arthroplasty in the UK. The aim of this study was to identify variations in ERPs and determine adherence to local policy.

METHODS Hospitals offering elective total knee arthroplasty (TKA) and total hip arthroplasty (THA) (23 and 22 centres respectively) contributed details of their ERPs, and performed an audit (15 patients per centre) to assess compliance.

RESULTS Contrasting content and detail of ERPs was noted across centres. Adherence to ERPs varied significantly (40–100% for TKA, 17–94% for THA). Analysis identified perioperative use of dexamethasone, tranexamic acid and early mobilisation for TKA, and procedures performed in teaching hospitals for THA as being associated with a reduced length of stay.

CONCLUSIONS This study highlights variation in practice and poor compliance with local ERPs. Given the proven benefits of ERPs, evidence-based guidelines in the context of local skillsets should be established to optimise the patient care pathway.

KEYWORDS
Enhanced recovery programme – Total knee arthroplasty – Total hip arthroplasty – Length of stay

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Total knee and hip arthroplasty (TKA and THA respectively) are widely recognised as being among the most clinically effective and cost-effective procedures for end-stage, symptomatic osteoarthritis. Over 145,000 National Health Service (NHS) knee and hip arthroplasty procedures are performed annually in the UK.[1] There has been significant interest in factors that the surgeon and healthcare provider can optimise to improve patient outcomes and reduce length of stay (LOS).[2,3]

Enhanced recovery programmes (ERPs) were first proposed in 1997 by Kehlet as a means to reduce the surgical stress response.[4] By using multimodal techniques, ERPs can reduce patient morbidity and mortality; they are therefore associated with significant cost savings through reduced LOS and healthcare associated costs.[5–10] Furthermore, there is emerging evidence that in addition to the short-term benefits, ERPs may be associated with reduced mortality in the longer term as well as superior long-term functional outcomes.[4,11] Two decades on, the complexity of ERPs has increased, with interventions implemented pre, intra and postoperatively.[2,3] While there is strong evidence behind certain components of ERPs, the evidence behind others is lacking and as such, what constitutes the gold standard ERP has yet to be defined.[2,3]

This study had two aims. The first was to assess the variation in current practice in the NHS with regard to local ERPs. The second was to determine compliance with these protocols within individual trusts.

Methods

A national, multicentre audit of ERPs in knee and hip arthroplasty was conducted between October 2014 and April 2015 at 57 NHS hospitals. The study was conceived and led by the

*Collaborators: A Alloush, O Ayodele, P Baker, A Behbahani, C Bretherton, M Brodermann, C Chan, M Cox, M Donaghy, J Edwards, A Ghosh, J Holton, J Jackson, A Jamshed, S Kahane, S Khan, T Knapper, A Kumar, N Kumar, T Lee, H Nuttall, B Marson, W Matthews, R Mayahi, D Mohandas, R Morgan, K Oh, O Pearce, W Pettit, M Reidy, M Shah, E Street, G Suliman, S Trowbridge, B van Herwijnen, R Whitham, W Wilson

OPEN ACCESS

Acta Orthopaedica 2018; 89 (1): 101–107 101

Long-term outcomes of over 8,000 medial Oxford Phase 3 Unicompartmental Knees—a systematic review

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Background and purpose — There is debate as to the relative merits of unicompartmental and total knee arthroplasty (UKA, TKA). Although the designer surgeons have achieved good results with the Oxford UKA there is concern over the reproducibility of these outcomes. Therefore, we evaluated published long-term outcomes of the Oxford Phase 3 UKA.

Patients and methods — We searched databases to identify studies reporting ≥ 10 year outcomes of the medial Oxford Phase 3 UKA. Revision, non-revision, and re-operation rates were calculated per 100 component years (% pa).

Results — 15 studies with 8,658 knees were included. The annual revision rate was 0.74% pa (95% CI 0.67–0.81, n = 8,406) corresponding to a 10-year survival of 93% and 15-year survival of 89%. The non-revision re-operation rate was 0.19% pa (95% CI 0.13–0.25, n = 3,482). The re-operation rate was 0.89% pa (95% CI 0.77–1.02, n = 3,482). The most common causes of revision were lateral disease progression (1.42%), aseptic loosening (1.25%), bearing dislocation (0.58%), and pain (0.57%) (n = 8,658). Average OKS scores were 40 at 10 years (n = 3,417). The incidence of medical complications was 0.83% (n = 1,443).

Interpretation — Very good outcomes were achieved by both designer and non-designer surgeons. The PROMs, medical complication rate, and non-revision re-operation rate were better than those found in meta-analyses and publications for TKA but the revision rate was higher. However, if failure is considered to be all re-operations and not just revisions, then the failure rate of UKA was less than that of TKA.

Abbreviations

AMOA – anteromedial osteoarthritis
AKSS-O – American Knee Society Score (objective)
AKSS-F – American Knee Society Score (functional)
DVT – Deep vein thrombosis
HSS – Hospital for Special and Surgery Knee Score
OKS – Oxford Knee Score
pa – Per annum
PE – Pulmonary embolism
PROM – Patient-reported outcome measure
SONK – Spontaneous osteonecrosis of the knee
TKA – Total knee arthroplasty
UKA – Unicompartmental knee arthroplasty

Over 100,000 primary knee arthroplasties are conducted annually in the United Kingdom and demand is predicted to increase 6-fold by 2030 (UK National Joint Registry 2014). The 2 main treatments for severe knee osteoarthritis that has failed non-operative management are total knee arthroplasty (TKA) and unicompartmental knee arthroplasty (UKA). UKA in appropriate patients has significant benefits over TKA including faster recovery, better patient-reported outcome measures (PROMs), and reduced risk of major complications, but has also been reported to have a higher revision rate (Liddle et al. 2014). There is therefore debate as to which is the most clinically effective.

The most commonly used UKA prosthesis in the United Kingdom is the Oxford Knee (Biomet, Swindon, UK) (UK National Joint Registry 2011). The primary indication for the Oxford Knee is anteromedial osteoarthritis (AMOA) with spontaneous osteonecrosis of the knee (SONK) being another rarer indication. In AMOA the patient should have bone-on-bone arthritis in the medial compartment, full -thickness lateral compartment cartilage, functionally normal medial collateral and anterior cruciate ligament, and a patellofemoral joint without lateral bone loss and grooving (Goodfellow et al. 1988, Beard et al. 2007). Other factors such as site of the pain, age, weight, activity, and chondrocalcinosis have been

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Perioperative adjuvant corticosteroids for postoperative analgesia in knee arthroplasty

A meta-analysis of 1,396 knees

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Background and purpose — **Immediate postoperative pain management offered in knee arthroplasty is suboptimal in up to one-third of patients resulting in high opiate consumption and delayed discharge. In this meta-analysis we investigate the analgesic effect and safety of perioperative adjuvant corticosteroids in knee arthroplasty.**

Methods — **Databases Medline, Embase, and Central were searched for randomized studies comparing the analgesic effect of adjuvant perioperative corticosteroids in knee arthroplasty. Our primary outcome was pain score at 24 hours postoperatively. Secondary outcomes included pain at 12, 48, and 72 hours, opiate consumption, postoperative nausea and vomiting, infection, and discharge time. Systemic (intravenous) and local (intra-articular) corticosteroids were analyzed separately.**

Results — **14 randomized controlled trials (1,396 knees) were included. Mean corticosteroid dosages were predominantly 50–75mg oral prednisolone equivalents for both systemic and local routes. Systemic corticosteroids demonstrated statistically significant and clinically modest reductions in pain at 12 hours by –1.1 points (95% CI –2.2 to 0.02), 24 hours by –1.3 points (CI –2.3 to –0.26) and 48 hours by –0.4 points (CI –0.67 to –0.04). Local corticosteroids did not reduce pain. Opiate consumption, postoperative nausea and vomiting, infection, or time till discharge were similar between groups.**

Interpretation — **Corticosteroids modestly reduce pain postoperatively at 12 and 24 hours when used systemically without any increase in associated risks for dosages between 50 and 75 mg oral prednisolone equivalents.**

Pain is one of the main reasons for hospital stay after knee arthroplasty; finding the best pain control regime postoperatively is therefore important (Husted et al. 2011, James Lind Alliance 2017).

Traditionally pain control following surgery heavily relied on the use of systemic opiates, which are associated with multiple side effects including muscle weakness, light sedation, and hypotensive effects, directly impacting postoperative rehabilitation (Barletta 2012, Oderda 2012). Optimization of perioperative opiate analgesia has been shown to reduce length of stay and often improves patient satisfaction as well as reducing the incidence of chronic pain and functional outcomes after surgery (Halawi et al. 2015, Meissner et al. 2015).

At present, there is no consensus regarding the use of corticosteroids in the perioperative period following knee arthroplasty. It is not known whether they should be used as part of an enhanced recovery program, and if so, whether to administer them systemically or locally. The objective of this systematic review is to assess the effect of adjunctive perioperative corticosteroids on postoperative pain in adult patients undergoing knee arthroplasty.

Methods

The prospectively registered protocol (PROPSERO - CRD42016049336) has been published (Mohammad et al. 2017). The work follows the PRISMA guidelines.

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Health Care Professionals' Perceptions of the Arthroplasty Patient Experience: Planning Phase in the Development of a Patient-Reported Outcome Measure

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Purpose: *The aim of this study was to explore health care professionals' perceptions and perspectives of surgery and early recovery for patients undergoing lower limb arthroplasty.*
Design: *Thematic analysis with semi-structured qualitative interviews.*
Methods: *Following ethical approval, interviews were performed with recovery room nurses (n=3), ward nurses (n=2), surgeons (n=5), anesthesiologists (n=5), physiotherapists (n=5), and occupational therapists (n=2). Data were analyzed using an in-depth narrative thematic analysis method. NVivo qualitative data analysis software was used.*
Findings: *Three main themes evolved from the interviews: immediate patient recovery issues, discharge criteria, and priorities during hospitalization from health care providers' perspectives.*
Conclusions: *The early postoperative recovery period can be a challenging time for health care providers and patients alike. However, identifying key areas of importance can provide insight and guide focus in clinical practice, thus improving patient recovery.*

Keywords: *orthopaedics, patient care team, qualitative nursing research, perioperative period.*
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9.10 Sample size calculations for future studies

The following paragraph lines out the principle considerations in a sample size calculation for trials, using both the OARS and the OACS as the primary outcome measure.

Study One: Potential research uses for these tools could include studies to evaluate improving post-operative pain regimens. For example, day one UKA patients in the private hospital appeared to have statistically significant less pain than their NHS counterparts.

Using a two-sided t-test, 90% power to detect a difference in the OARS of 13 points (SD 16.75) with a two-sided 5% level of significance (α), a sample size of 36 participants would be needed in each group. Accounting for dropouts and loss to follow-up of up to 15%, 43 participants would be required in each group, bringing the total sample size for a two-arm parallel group trial to 86.

If an 80% power calculation was used, the numbers required per group would be 28. Accounting for dropouts and loss to follow-up of up to 15%, 33 participants would be required in each group. The standard deviations used were obtained from the UKA patients reported in Chapter 7.

Study Two: A study to assess the addition of steroids into the routine care of the joint replacement patient pathway could be undertaken using the OACS and OARS.

Using a two-sided t-test, 90% power to detect a difference in the OARS of 13 points (SD 17.50) with a two-sided 5% level of significance (α), a sample size of 40 participants would be needed in each group. Accounting for dropouts and loss to follow-up of up to 15%, 47 participants would be required in each group, bringing the total sample size for a two-arm parallel group trial to 94.

If an 80% power calculation was used, the numbers required per group would be 30. Accounting for dropouts and loss to follow-up of up to 15%, 35 participants would be required in each group. The standard deviations used were obtained from the patients reported in Chapter 6.

These sample sizes were calculated using Stata/SE version 15.1 (StataCorp, Released 2018, College Station, Texas 77845 USA).

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