

Introducing Standardized and Evidence Based Thresholds for Hip and Knee Replacement Surgery.

The Arthroplasty Candidacy Help Engine (The ACHE tool)

HTA Project: 11/63/01

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1. Synopsis

Title:	Introducing Standardized and Evidence Based Thresholds for Hip and Knee Replacement Surgery. The Arthroplasty Candidacy Help Engine (The ACHE tool).
Study Period:	September 2013 - August 2016
Overall aim of the study:	To develop a standardized NHS framework for identifying patients for hip and knee replacement surgery using safe and equitable thresholds by creating the ACHE (Arthroplasty Candidacy Help Engine) tool, based on a currently available assessment score, with thresholds that take account of patients' capacity to benefit from surgery and the cost-effectiveness of the treatment. The new system will be applicable in both Primary and Secondary Care.
Research Questions:	<p>(A) Can clinical tools for assessment of a patient's suitability for knee or hip replacement be used to set thresholds for operation?</p> <p>(B) How does the choice of threshold affect the cost effectiveness of the procedure and subsequent improvements in patient quality of life?</p>
Research Objectives:	<p>1 Create a shortlist of scoring systems potentially useful for selecting candidates for arthroplasty surgery.</p> <p>1.1 Establish from the literature the scores/instruments available. Published evidence concerning their measurement properties, and their past or projected use in setting thresholds for hip and knee replacement, will be reviewed. This will generate a shortlist of potential scoring systems.</p> <p>1.2 Using existing datasets, and guidance from users, we will refine the shortlist, by establishing the necessary measurement properties of potential scores/instruments, where not available in the literature.</p> <p>2 Identify a scoring system, and a set of threshold values, to be used to select candidates for hip and knee surgery</p> <p>2.1 For each short-listed instrument, determine score thresholds for candidacy for joint replacement surgery.</p> <p>2.2 Determine the relationship between threshold levels and cost effectiveness of hip and knee arthroplasty surgery.</p> <p>2.3 Select the most applicable single score and set of thresholds for incorporation into the ACHE tool (Arthroplasty Candidacy Help Engine).</p> <p>3 Explore the effectiveness of the ACHE tool and determine the potential acceptability of the tool and thresholds to stakeholders and patients.</p> <p>3.1 Determine the effect of using the ACHE tool on patterns of referral of hip and knee patients to secondary care.</p> <p>3.2 Evaluate user opinion: General Practitioners and Patients.</p> <p>3.3 Engage with a wider stakeholder group to assess the acceptability of the ACHE Tool.</p>

Contents

1. Synopsis	3
2. Background	5
3. Methodology	8
Pre-Work Package	8
Work Package 1 (addressing Research Objective 1).....	9
Work package 2 (addressing Research Object 2)	14
Work Package 3 (addressing Research Objective 3):	19
4. Concluding output of grant	21
5. Ethical Arrangements	21
6. Research Governance.....	21
7. Expertise:	22
8. Service Users	22
9. References.....	23
Appendix A: Study Flow Diagram.....	51

2. Background

Hip and knee osteoarthritis is a common musculoskeletal condition causing significant pain and loss of function for patients. Joint replacement treatment for end-stage disease has been shown to be an effective treatment. Each year 150,000 hip and knee replacements are performed in the UK with the majority of patients having successful outcomes (1). However, the nationally collected patient reported outcome data for hip and knee replacement have identified two striking issues with regard to the provision of joint replacement in the UK. Firstly, there is marked variation in current clinical practice in referring and undertaking surgery in patients with arthritis of the hip and knee (1). Previous studies from the UK support this observation with recent evidence showing that access to joint replacement is currently inequitable, with deprived areas associated with greater symptom severity and lower surgery rates (2, 3) (4). A previous large national survey of UK NHS patients undergoing joint surgery also concluded that there was no evidence that patients were being prioritized on the basis of the severity of their symptoms and function (5). Secondly, the national outcomes data have revealed that between 10-15% of patients undergoing hip or knee joint replacement are not satisfied with their treatment and these findings, particularly in the knee, are supported by other recent studies (6, 7). It has been suggested that selecting patients too early in their disease process may have a role in producing dissatisfaction with surgery (7). Overall, these findings suggest that there is no standardization to the process by which patients are assessed and selected for hip and knee replacement surgery. This is a particular concern given both the projected increased need for joint replacement over the next decade to accommodate an aging population and the pressure of potential reductions in NHS funding.

Given the issues of unwarranted variation and poor outcome in some patients, outlined above, there has been significant interest in trying to standardize the process of referral and selection for joint replacement. The use of certain 'priority criteria' (such as the New Zealand Score or Western Canada Waiting List Score) has been investigated as a more consistent method of selecting patients for referral and treatment (8-10). These tools identify candidates for surgery in Primary Care and are based on estimating a patient's capacity to benefit from surgery. They are generic and attempt to standardize the patient pathway for joint replacement at the entry point. The New Zealand priority criteria have been used in some regions within the NHS, but have not reached widespread acceptance and the current

evidence of their reliability and validity is minimal (11, 12). Other tools have been developed but not fully tested in clinical practice within the UK(13-15). In 2009 the DoH introduced routine collection of Patient Reported Outcome Measures (PROMs) for hip and knee surgery, to measure the outcome of surgery performed in NHS hospitals (6, 16). There has been Government support for extending the use of scoring systems pre-operatively to create thresholds for referral and candidacy for surgery (17, 18). In fact, many PCTs and NHS Trusts have already introduced PROM based severity score thresholds for surgery although the thresholds used vary widely between regions (19-26). However, evidence underpinning and endorsing the use of PROMs, or any assessment score for thresholds is scant and without validation. This creates significant risk to patients as an incorrectly set threshold may unfairly restrict access to care, or conversely, inappropriately select patients for joint replacement (27). The development of a pre-operative threshold score to identify candidates for hip and knee replacement, offers a significant opportunity to standardize the patient pathway. However this HTA call reflects the pressing need within the NHS to produce evidence to support or refute their use.

To be fit for purpose, as a screening device, any candidate score must satisfy a number of requirements. Firstly, the score must have adequate measurement properties to enable assessment of patients for joint replacement viz. adequate validity. Secondly, valid evidence based thresholds must be produced. By highlighting an individual's 'chance' of benefit following surgery (based on their pre-operative score), patients are provided with key information to help with their decision-making, particularly in secondary care. Hence, highlighting the risk to benefit may make the decision to have surgery more obvious for many patients. This type of information allows patients to participate more comprehensively in the decisions made about their care. Thirdly, we must understand how the introduction of thresholds for surgery affects the cost-effectiveness of the treatment. Lower limb joint replacement has been previously shown to be highly cost-effective, costing between €1,276 and €18,300 per quality-adjusted life-year (QALY) gained for the average patient (28-32), which is substantially lower than the £20,000–£30,000/QALY range that the National Institute for Clinical Effectiveness (NICE), consider to be cost-effective for use within the NHS(33). However, it is important for commissioners of hip and knee replacement surgery to understand how cost-effectiveness varies between patient and procedure subgroups, and how thresholds for hip and knee surgery affect the cost utility of

the interventions. It will also be important to understand whether the health economic threshold is broadly aligned with the clinically defined thresholds. Lastly, having identified and validated a clinical tool and calculated valid and evidence-based thresholds for surgery, within the NHS, it must be established whether the tools are acceptable to 'the end users'. Despite some thresholds for hip and knee having already been introduced to clinical practice in parts of the country, there has been little or no engagement with the wider stakeholders about the appropriateness of this approach or how thresholds should be used in practice. The introduction of thresholds requires the support of patients, healthcare professionals and commissioners. Their opinion and input is critical to underpin the internal validity of the tools and any chosen threshold levels, as well as to encourage subsequent implementation. Furthermore, the possibility exists for more than one instrument to be found suitable. End users, considering aspects such as ease of use and familiarity, would be pivotal in deciding which instruments are chosen.

The thresholds calculated for the identified scoring system will be incorporated into a user-friendly knee and hip replacement candidacy assessment tool - The ACHE tool (Arthroplasty Candidacy Help Engine). Although it is too early to describe the precise form that the final instrument will take, we envisage that in Primary Care the ACHE tool would consist of a questionnaire for the patient to fill out (which would include one of the existing scoring systems, and may be joint specific). The questionnaire responses would be scored and compared to reference threshold values provided for the GP. This would initially be paper based but would be easily transferable to a computer based system. The same ACHE tool would be used in Cats or referral hubs to check for continued candidacy for arthroplasty. The ACHE tool may have a knee and hip version, but keeping the same format.

Secondary Care involves more complex assessments and would need to embrace expectation, co-morbidity, age related factors and function. The ACHE tool could be used in Secondary Care in a slightly more sophisticated version incorporating the above factors. It would be used to reinforce patient knowledge about the likelihood of improvement from surgery. The process would be further supported by the use of Patient Decision Aids with the tool/score embedded within them (34, 35). This is a potentially valuable step in standardising the patient pathway. The pre-operative score could theoretically also be used to prioritise patients waiting for surgery and the assessment score may also be used at other

time-points across the pathway, to measure outcome or provide surveillance of long-term outcome of surgery.

In summary, greater standardization is required in the patient pathway leading to hip or knee joint replacement surgery. We aim to develop a new evidence based NHS Framework for patients who might be candidates for surgery, introducing valid thresholds based on scores that are already available (Figure 1). Due to our experienced team, ongoing work with related NIHR projects on predicting outcome for joint replacement (e.g. COAST) and access to pre-existing data sets we believe we can deliver this within a 3-year time frame.

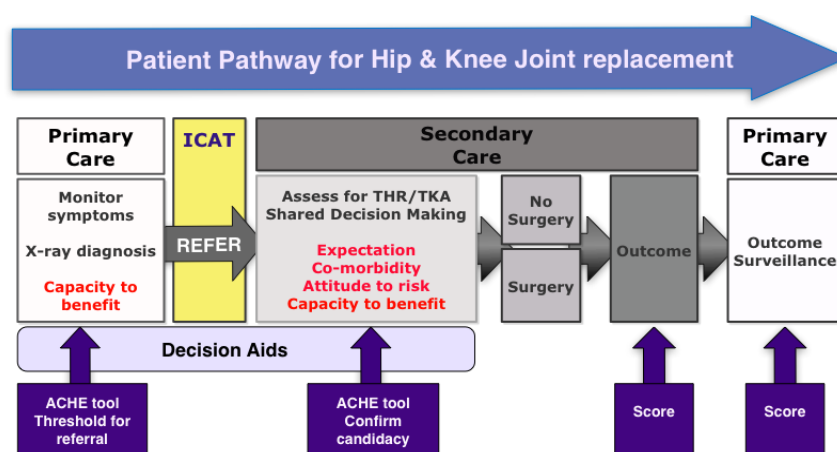


Figure 1;

A Patient Pathway Frame Work for the NHS to identify candidates for hip and knee replacement. The selected assessment score may also be used later in the pathway to measure the outcome of surgery and to offer surveillance for joint replacement post-surgery.

3. Methodology

We will use literature review, statistical analysis of existing datasets, health-economic modelling and facilitated stakeholder engagement.

Pre-Work Package

Creation of user group

The 12-person group will comprise of patient partners, general practitioners, an orthopaedic knee surgeon representing the British Association for Surgery of the Knee (BASK), an orthopaedic hip surgeon (x1) representing the British Hip Association (BHA), extended practitioner physiotherapist, and local commissioners of hip and knee surgery .

USER Group: Meeting One

Initial meeting to inform every one of the research plan, and engage them, before data collection begins.

Training and PPI Plan Development. Modifications of research protocols based on feedback.

Work Package 1 (addressing Research Objective 1)

CREATE A SHORTLIST OF SCORING SYSTEMS POTENTIALLY USEFUL FOR SELECTING CANDIDATES FOR ARTHROPLASTY SURGERY

- 1.1 Using the published literature to identify existing scoring systems and assess evidence concerning their suitability, measurement properties and feasibility.
- 1.2 Using existing datasets to calculate the measurement properties of those potential candidate tools not previously evaluated (from the literature).

1.1 PUBLISHED LITERATURE TO IDENTIFY POTENTIAL SCORING SYSTEMS AVAILABLE AND ASSESS EVIDENCE OF THEIR MEASUREMENT PROPERTIES AND FEASIBILITY.

Overview: A structured literature review will be conducted to identify and compare the measurement properties of candidate tools that have been evaluated (both in groups and on individual patient basis) for use with patients suffering from osteoarthritis/undergoing joint replacement surgery. The review will also aim to identify any previous evidence on how health outcomes, joint survival, costs or cost-effectiveness vary in relation to scores of candidate tools and any evidence-based thresholds that are already proposed in the literature.

1.1 Detailed methodology

Search sources and terms

We will use a search strategy developed by the Patient Reported Outcome Measure group at the University of Oxford that has been used in several previous reviews(36). This includes searching MEDLINE (PubMed), using a sensitive filter for finding studies on measurement properties, and further searches of EMBASE, PsycINFO, CINAHL, Oxford PROMS

bibliographic database, EuroQoL (EQ-5D) website, ProQolid, Centre for Reviews and Dissemination (CRD) and Econlit will be searched using a combination of MeSH and free-text terms. The search will be limited to the English language, and no time restrictions will be set. Hand searching of titles of the following key journals from October 2005 will be conducted: Health and Quality of Life Outcomes, Quality of Life Research, Journal of Bone and Joint Surgery (Am and Br) and Journal of Arthroplasty. Additionally, the following supplementary sources will be searched: the National Institute for Health Research: Health Technology Assessment Programme and the Cochrane library.

Inclusion criteria for literature:

We will apply the following criteria relevant to the candidate instruments and studies introducing them:

- 1 The instrument uses a standard scoring system (representing indices or scales), containing items that are either clinician or patient-reported (or a combination of these);
- 2 The instrument is already available and has been used in clinical settings or research to assess adult (>18 years old) patients prior to hip or knee replacement (e.g. NZ Score, WCWL Score, ICOAP, WOMAC, SF-12, EQ-5D, ICOAP, Oxford hip and knee Scores, KOOS, HOOS).
- 3 The instrument has been validated for the English language population.
- 4 The study design is development, concurrent re-validation or a prospective study of a score with information on its measurement properties (e.g. reliability, validity, responsiveness).
- 5 Sample size in the study was more than 50 subjects/patients.

Published titles and abstracts will be obtained relating to any tools identified at this stage and these will be scrutinized using the inclusion criteria described above. Two members of the team will conduct this task independently. Comprehensive details/articles relating to identified tools will be retrieved for all shortlisted abstracts. The same methodology will be applied on full text documents for their inclusion in the review, as well as in the case of abstracts that are identified but where initial abstract-based information leads to uncertainty or disagreement between assessors. Publications may also be identified from references obtained from the reference lists of selected articles.

Assessment of methodological quality of the included studies and each score/tool.

The methodological quality of each measure will be assessed using the appraisal framework developed by the University of Oxford, Dept. of Public Health, Patient Reported Outcome Measure group [http://phi.uhce.ox.ac.uk/inst_selcrit.php]. The checklists will be administered by one reviewer and checked by the second reviewer. Consensus or the third reviewer will resolve any disagreements.

1.2 USING EXISTING DATASETS TO CALCULATE THE MEASUREMENT PROPERTIES OF POTENTIAL SCORING SYSTEMS (NOT PREVIOUSLY EVALUATED).

Overview: We will examine data from a series of large cohorts either held locally or for which we have collaborative access. A team of two statisticians will analyze the data to further characterize the measurement properties of potential scoring systems/tools where these are not available from previous literature.

1.2 Detailed methodology

We have secured access to patient-level data from a large number of patient databases, which include data on several different relevant scoring systems for the purpose of completing this research:

KAT (The Knee Arthroplasty Trial): an NIHR HTA funded RCT that has examined the outcome of 2352 TKA over a ten-year period, including data on costs and resource use (OKS, SF-12, EQ-5D)

EPOS (The Exeter Primary Outcome Study): EPOS has collected detailed follow-up on 1500 Exeter Hip replacements up to 10-years, including data on costs and resource use (OHS, SF-36, and Patient Satisfaction)

SWLEOC: The Elective Orthopaedic Centre (EOC, London) database provides data of 4000 hip and knee replacements with follow-up of up to 2-years (OHS, OKS, EQ-5D, and Patient Satisfaction).

COAST: The COAST cohort from Oxford and Southampton of 1500 hip and 1500 knee replacement patients currently being prospectively collected in Oxford and Southampton.

Two to three year data will be available at the time of our proposed programme of work (Pain detect, ICOAP, AKSS, OKS, OHS, EQ-5D, Satisfaction, HADS, Tegner, UCLA).

BELFAST: The Belfast database, 1500 hip and 1500 knee replacements followed for 1- year (OKS, SF-12, Satisfaction, AKSS).

NATIONAL PROM HES linked Dataset: complete pre and 6 month post operation Oxford hip and knee PROM data from patients who have undergone 180,696 (85,215 hip/95,481 knee) hip and knee replacements. Our group already is analysing data from this source on another project (OKS, OHS, EQ-5D, Satisfaction, Post-op improvement) . For WP2 we will apply for a new data set for all available data (2009-present). In addition we will apply for access to the National Joint Registry data to link to HES/PROMs data so we can investigate different types of knee and hip arthroplasty (e.g. partial or total knee arthroplasty, total hip or hip resurfacing arthroplasty).

APEX: RCT of 600 patients based in Bristol of joint replacement patients (WOMAC, ICOAP, EQ-5D, HADS, Pain detect)

ADAPT: Longitudinal cohort series of 264 hip and knee replacement patients (OHS, OKS, WOMAC, SF-12, HADS)

EUROHIP: A cohort of 1051 people having primary hip replacement for primary OA - about 250 came from UK, the rest from other European countries (WOMAC, EQ-5D)

TJR-600: A cohort of 600 people having primary hip or knee OA with follow-up to 3 years (SF-36, WOMAC, HADS, Satisfaction)

NUFFIELD ORTHOPAEDIC CENTRE OA COHORT: 200 knee OA patients followed for 2 years (OKS, KOOS, ICOAP, patient/doctor data) regarding need for arthroplasty

SASH: The Somerset and Avon Survey of Health (SASH) cohort is a cross-sectional survey of 28,080 individuals aged >35 years followed for 8 years, with subgroups of patients undergoing TKR/TKR (New Zealand Score, WOMAC)

Depending on existing evidence available relating to each of the potential scoring systems and the availability of relevant variables (presenting existing or scales), validating reliability, responsiveness and interpretability (particularly relevant for proposed uses) will be evaluated:

Selection of potential instruments: Based on the following criteria:

- 2 The score is already available and has been used in clinical or research settings to assess adult (>18 years old) patients prior to hip or knee replacement.
- 3 Evidence on validity, reliability and responsiveness in individuals and groups of patients being assessed for joint replacement.
- 4 The score is practical for use in Primary Care (score/form completion time, does not require high level specialist knowledge or clinical skills).
- 5 The instrument is available in English and has been validated in an English language population (North America, UK or Australasia).
- 6 Patient-level data on pre-operative scores, resource use (e.g. length of hospital stay and numbers of revisions) and either post-operative functional status or quality of life are available to enable the analyses proposed within work package 3 and 4. If the datasets listed in WP2 provide no data on a clinical tool that would otherwise be highly suitable, we will contact other research teams to establish whether any other data can be sought.
- 7 Copyright issues addressed. The candidate instrument must be available for widespread uptake within NHS without punitive fiscal or logistic implications.

USER Group: Meeting Two (WP1)

Meeting to inform of scoring systems identified, highlight shortcomings, positive aspects, guide potential candidates. Choice of potential scoring systems (maximum of 3) carried forward to WP2.

Work-Package 1 Output

At the end of WP1 we will have identified candidate scores/tools from the literature, that are already routinely used in the assessment of patients for hip and knee joint replacement, and we will have determined for each score their relevant published measurement properties, including their appropriateness for assessing individual patients. A user group meeting will help establish a shortlist of three potential tools, based on scientific evidence and appropriateness, to take forward to Work Package 2.

Work package 2 (addressing Research Object 2)

IDENTIFY A SINGLE SCORING SYSTEM AND A SET OF THRESHOLD VALUES THAT CAN BE USED TO SELECT CANDIDATES FOR HIP AND KNEE SURGERY

- 2.1 Determine pre-operative threshold scores for surgery in each of the 3 shortlisted scoring systems.
- 2.2 Determine the relationship between threshold levels and cost effectiveness of hip and knee arthroplasty surgery for each scoring system.
- 2.3 Establish a scoring system with thresholds for the ACHE tool (Arthroplasty Candidacy Help Engine).

The outcome of this work package will be the production of two general evidence-based clinical tools (based on a scoring system and a set of thresholds) for hip and knee surgery that are based on both a patient's capacity to improve from surgery and their own perception about the need for joint replacement surgery (in relationship to the severity of the condition). These values alone will be useful and will contribute substantially to allocation of healthcare resources. A further level of sophistication will be added which accounts for the effect of pre-operative co-variables on the outcome of surgery. This information will be used to build a prediction model (regression equation) that can be easily used in routine clinical practice. The cost effectiveness implications for each threshold value will also be evaluated. The threshold values will be incorporated into a user-friendly tool, the ACHE tool. Early prototypes would be paper/spreadsheet based but future development could produce a simple online tool for GPs and surgeons. Substantial involvement of the Patient & User Consultation group is planned throughout this WP.

2.1 DETERMINING PRE-OPERATIVE THRESHOLD SCORES FOR SURGERY IN THE SHORTLISTED HIP OR KNEE SCORES.

Overview: Using a large series of established patient datasets we will establish clinical thresholds for each of the shortlisted instruments brought forward from WP1 to guide hip and knee replacement surgery. Several calculation methods will be used as consensus as to

the most appropriate method is yet to be reached. Ideally, there will be a level of consistency for thresholds generated by the different methods. The thresholds are likely to be influenced by other pre-operative co-variables such as gender, age, co-morbidities etc. We will therefore explore the influence of these co-variables and use the information to build a prognostic model. The final threshold values for clinical practice will therefore be the most representative and appropriate for the population and fully account for patients' capacity to benefit. The model and adjusted thresholds will be brought forward for incorporation of the Health Economics modeling (WP 2.2) and subsequently for final selection in WP 2.3.

2.1 Detailed methodology

Calculation of general pre-operative thresholds for surgery.

Using our established datasets we will focus on the following clinically relevant outcomes in order to create pre-operative score thresholds for surgery: 1) the patient's capacity to benefit from the surgery (in terms of improving scores beyond the MCID or scores associated with being satisfied with the results of surgery), and 2) patients' perceptions about their need and urgency for surgery. We will use descriptive statistics and ROC analysis to compute relevant pre-operative thresholds. We will then compare the consistency among the resulting thresholds.

Calculation of individual capacity to benefit after accounting for the effect of pre-operative co-variables

The analyses described above will establish general hip/knee severity threshold levels using a relatively simplistic model. Many other factors normally inform decision making for arthroplasty. Relevant pre-operative co-variables include age, obesity, co-morbidities, radiographic changes, smoking/alcohol use and psychological factors including a patient's expectations of surgical outcome(37, 38). It is unknown to what extent such factors (alone or in combination) will influence an individual patients' capacity to benefit from surgery. These should be investigated and, if necessary accounted for in any decision making model. Within the series of large cohort datasets for this project, detailed pre-operative

information on a wide range of such factors has been recorded and is available for this purpose. If required a multivariable risk prediction model that can be easily used in clinics to predict the postoperative outcome, whilst taking into account relevant individual pre-operative characteristics, will be developed.

The multivariable prognostic study will follow three phases: 1) development and internal validation of the model, 2) external validation of the model (both described in WP2), and 3) evaluation of users' opinion and impact of implementation of the prediction tool (WP 3).

Development of these statistical models will build on our existing expertise within the team in the use of computational models to combine data from large cohort studies and in the development and validation of prognostic models through the NIHR funded COAST study (Clinical Outcomes in Arthroplasty Study)(13, 39-43). Furthermore, support from Professor D Altman (CSM) who is a leading figure in prognostic modeling, will ensure strong support in the methodological quality of the study.

2.2 DETERMINE THE RELATIONSHIP BETWEEN THRESHOLD LEVELS AND COST EFFECTIVENESS OF HIP AND KNEE ARTHROPLASTY SURGERY

Overview: Having identified candidate clinical thresholds for each candidate score, 2.2 will assess how the cost-effectiveness of hip and knee replacement varies with clinical scores and the thresholds used. Two questions will be addressed for hips and for knees:

2.2.i What is the economic threshold for each clinical tool? i.e. at what score does joint replacement cease to be cost-effective at a £20,000-£30,000 per QALY ceiling ratio?

2.2ii How do the incremental costs, QALYs and cost-effectiveness of joint replacement vary depending on the threshold and clinical tool used and what is the economic benefit of making a stratified decision using each of the threshold values estimated in 2.1.?

Both questions will be addressed by modeling how the improvements in health-related

quality of life from joint surgery and the cost of surgery/subsequent management vary with clinical scores, using patient-level data.

For each of the shortlisted clinical tools, we will estimate the threshold score at which joint replacement ceases to be cost-effective, estimate the cost-effectiveness of joint replacement in the patients meeting each threshold and estimate the net health gains for each threshold and clinical tool. Such analyses will be conducted for THR and TKR; if sufficient data exist, we will also consider partial knee replacement and hip resurfacing as additional alternatives.

2.3 Choosing the scoring system, with thresholds, to incorporate into the ACHE tool (Arthroplasty Candidacy Help Engine) a clinical tool to select patients for both hip and knee replacement.

USER Group Meeting Three: (WP2.3)

Potentially the most critical user meeting to decide on the instrument to be used for ACHE. The content, format and expected output of the meeting is described in detail below.

Overview: The culmination of the tool development process will be a final selection of the best scoring system, and associated threshold values, for clinical use within a new assessment device, the ACHE tool. Arbitrary values have previously been created, often based on categories of cumulative frequency within a dataset (i.e. top centile) rather than being associated with any meaningful anchor. WP1 and more significantly, WP2.1 and WP2.2 will be assimilated and presented to the user group. Specific criteria will be used to select the most appropriate and useful scoring system and the calculated threshold values, for integration into the ACHE device.

2.3 Detailed methodology:

A two-stage process will be used. 1) The selection of the scoring system 2) The selection of threshold value(s) for the selected scoring system.

1) **Scoring System:** To choose the scoring system the user group will be presented with the

following information:

- History, original purpose, focus and derivations of the potential scoring systems.
- Ease of use.
- Validity & reliability (WP1).
- Incidental findings (any discoveries made regarding the scoring systems in the course of the project).
- Expert opinion (Healthcare Measurement).
- Example of use (within a mock ACHE tool).

A modified SWOT (Strengths, Weaknesses, Opportunities, and Threats) analysis will be performed under the guidance of a facilitator.

Threshold choice: WP2.1 and 2.2 will generate a number of different threshold choices. To choose the appropriate threshold level (for the newly selected scoring system) the user group will be presented with the following information:

- A summary of the different thresholds generated for the chosen instrument (evidence based, capacity to benefit, health economic)
- Theoretical implications for each of the thresholds will be highlighted.
- Some hypothetical examples of how each the threshold value will impact upon a) individuals and b) the NHS can be given.
- Consensus achieved by the group.

Work-package 2: Output

This will generate a single tool, the ACHE tool (each for hip and knee) that can be used to identify patients who are candidates for hip and knee replacement surgery. It is somewhat difficult to visualize the exact template for the final tool until the earlier data has been analysed. However, it is anticipated that the tool would be a multivariable predictive model, based on an established clinical score, that is easy to understand and use. At this stage the ACHE tool will consist of paper based questionnaires and reference threshold

values. The tools will pass forward to Work-Package 3 for impact and end user (Patients, GPs, secondary clinicians) evaluation.

Work Package 3 (addressing Research Objective 3):

EXPLORE THE POTENTIAL IMPACT OF THE 'ACHE' TOOL AND DETERMINE THE ACCEPTABILITY OF THIS APPROACH TO STAKEHOLDERS AND PATIENTS.

- 3.1 Determine the potential impact of using the ACHE tool in the NHS.
- 3.2 Survey evaluation of potential users' opinion of the ACHE tool; (GPs and patients)
- 3.3 Explore the potential acceptability and feasibility of the general approach and the calculated thresholds to patients, health care practitioners and commissioners.

We will assess the likely impact, acceptability and feasibility of introducing the ACHE tool within the NHS, using three different approaches. Firstly, we will assess the likely impact of using the ACHE tool on patients' referral to secondary care. A second approach will use questionnaires to ask the opinion of a large number of GP and patient USERS regarding the proposed usage of the ACHE tool. Finally we will use broad stakeholder consultation groups ('conferences'), using deliberative methods of stakeholder engagement (44, 45) to further explore acceptability and feasibility. This work-package will inform future evaluation and refinement of tools for use in primary and secondary care.

3.1 Determine the impact of the ACHE tool on referral patterns.

Overview: The potential impact of the ACHE tool on current referral practice in the NHS will be evaluated by applying the ACHE tool to a cohort of 400 patients attending the Nuffield Orthopaedic Centre (NOC) Referral Hub for assessment for hip and knee replacement.

3.2 Evaluation of the user opinion: General Practitioners and Patients.

Overview: We will determine GP and Patient opinion regarding the content and acceptability of the completed ACHE tool via questionnaires by administering a survey to evaluating GPs' opinions about the use of the clinical tool and score threshold system on 348 GPs and 271 patients .

3.3 Extended USER Group Consultation to explore the potential acceptability of the ACHE tool and calculated thresholds to patients, health care practitioners and commissioners.

Overview: The aim of this work is to consult across all stakeholders in a collaborative process to determine the acceptability of introducing the ACHE tool and the chosen threshold levels within the NHS.

The Group will meet twice, with two months between meetings. Each meeting will last four hours with a break. In chaired and facilitated discussion meetings, stakeholders will be provided with findings from earlier parts of this programme (WP2, WP3.1 & 3.2) and enabled to ask questions of the research team, who will then engage in facilitated discussion. The interactive meetings will aim to identify levels of consensus about thresholds and tools and to specify challenges and solutions to their implementation.

Work-Package 3 Output:

WP3 will have facilitated informed discussion about the introduction of a more standardized method of managing patients with hip or knee OA. This will deliver a consensus about which ACHE thresholds appear to be most acceptable to stakeholders. Although representing a small-scale consultation exercise, this will also provide suggestions about how best to implement thresholds in preparation for further future evaluation and refinement.

4. Concluding output of grant

We will produce the ACHE tool for assessing patients with hip & knee arthritis that can be used in Primary Care to identify candidates for hip and knee joint replacement, guiding referral to secondary care. The tool will be incorporated into the NHS patient pathway for hip and knee replacement surgery to standardise patient care, reducing unwarranted variation and improving patient outcome. Use of the ACHE tool will be included in the NHS Commissioning Guidance for hip & knee surgery, ensuring uptake in to NHS.

5. Ethical Arrangements

All studies included in WP 1&2 comprise analyses of existing datasets in studies that already have NHS Research Ethics (REC) approval in place. We envisage that we may need to amend these approvals in order to allow additional staff members to access the data, although the data will be anonymised. Any such amendments should be straightforward and will be in place before the study starts. WP3.1 will require ethical approval but we do not envisage any issues in obtaining this. USER and Stakeholder group meetings are not classified as research activity and would only require NHS REC approval if we conduct research about the stakeholder process or impact, which we do not intend to do.

6. Research Governance

Andrew Price (PI) will take responsibility for overall conduct and management of the study. He will also manage the study budget. David Beard will support him in these roles. The Oxford Based Study Researcher will coordinate and manage the project day-to-day: data collection, monitoring study progress, planning and supporting meetings associated with the study and dealing with all study data in accordance with ethical requirements. Professor Ashley Blom will be lead investigator in Bristol, supported by Dr Rachael Goberman-Hill in co-coordinating the link with Bristol and supervising the researcher and statistician embedded there.

A Steering Group will be set up to manage the Governance of the study. The Steering Group will meet every 12 months during the course of the study (a total of 3 times).

The sponsor for the study is the Oxford University Hospitals NHS Trust. All work and data handling will be conducted within GCP guidelines and the Declaration of Helsinki.

7. Expertise:

The study team comprises individuals with considerable clinical, academic and research expertise, who have published extensively and have already collaborated successfully on externally funded research projects in the past and present. Our application is a collaborative study from Oxford, Bristol and Peninsula and the team of researchers have expertise in all the relevant areas required to deliver this program of research; measurement tools in musculo-skeletal medicine (Fitzpatrick, Dawson, Valderas, Dieppe), Primary Care and Prioritisation of Patients for Orthopaedic surgery (Valderas), assessment of OA patients and pathways to surgery (Dieppe, Gooberman-Hill), the epidemiology of joint replacement (Arden), thresholds in orthopaedic commissioning (Barker, Price, Chivers, Wilton), design and application of Oxford PROMs (Fitzpatrick, Dawson, Carr, Murray), health economics (Gray, Dakin), orthopaedic outcome studies (Price, Beard, Carr, Murray, Judge, Arden, Blom), threshold setting and statistics support (Judge). Altman is Director of CSM (Oxford) and has substantial expertise in Diagnostic Methodology. Eight of the team have previously been NIHR/HTA principal investigators.

8. Service Users

The service users' perspectives lie at the heart of this study and we wish to maximise their involvement. To this end we have already consulted with a dedicated patient organization at the Nuffield Orthopaedic Centre: the NOC Network via Sue Woolacott, (Chair) and patient representatives who have provided us with helpful feedback during the writing of this application(46). In particular patients showed great support for being involved in the consultation process to assess the proposed threshold levels. Our USER group will include members of the public and patients from the NOC Network. To

disseminate our research findings, results will be presented to the Patient and Research Engagement Forum (PREF) at the NOC. The purpose of PREF is to involve, inform and educate patients & public about research in Oxford, improving its the relevance, quality and appropriateness from the patient's perspective. To facilitate this the NOC Network will run a 'Joint Venture' event, which is an interactive public information event focusing on our research, culminating with a discussion and Q&A session. We have involved South Central RDS who will help us provide training and support for our USER team in developing our PPI plan.

9. References

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Appendix A: Study Flow Diagram

Introducing Standardized and Evidence Based Thresholds for Hip and Knee Replacement Surgery: Study Flow Diagram: ref 11/63/01

