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HIP

Economic evaluation plan of a RCT of hydroxyapatite-coated uncemented hemiarthroplasty versus cemented hemiarthroplasty for the treatment of displaced intracapsular hip fractures

THE WHITE5 TRIAL

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Aim

This paper describes the methods applied to assess the cost-effectiveness of cemented versus uncemented hemiarthroplasty among hip fracture patients in the World Hip Trauma Evaluation Five (WHiTE5) trial.

Methods

A within-trial cost-utility analysis (CUA) will be conducted at four months postinjury from a health system (National Health Service and personal social services) perspective. Resource use pertaining to healthcare utilization (i.e. inpatient care, physiotherapy, social care, and home adaptations), and utility measures (quality-adjusted life years) will be collected at one and four months (primary outcome endpoint) postinjury; only treatment of complications will be captured at 12 months. Sensitivity analysis will be conducted to assess the robustness of the results.

Conclusion

The planned analysis strategy described here records our intent to conduct a within-trial CUA alongside the WHiTE5 trial.

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Introduction

In the UK, hip fractures impose a large health and social care cost burden on society; with total hospital costs amounting to around £1 billion annually.[1] This annual expenditure is projected to increase as the annual incidence of hip fractures in the UK is projected to rise to 101,000 in 2020.[2] Displaced intracapsular fractures constitute almost half of all hip fractures, and are commonly treated with a partial hip arthroplasty, or 'hemiarthroplasty', whereby the broken head of the femur is removed and replaced. The current National Institute for Health and Care Excellence (NICE) guidelines for the management of hip fractures recommends the use of a cemented hip hemiarthroplasty.[3] Much of the evidence for this recommendation is based on trials comparing cemented implants with first generation uncemented implants. However, a Cochrane review[4] has reported a lack of evidence for more contemporary uncemented implants.

There were no cost-effectiveness analyses of cemented versus uncemented hemiarthroplasty according to a systematic literature review undertaken in 2010 by NICE for the management of hip fracture.[3] The only studies identified were cost-consequences analyses, a type of economic evaluation with disaggregated costs and health outcomes for each intervention. An updated review of

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the literature shows that there have been no new cost-effectiveness analyses reported since publication of the NICE guidelines.

This paper describes the planned health economic methods for a cost-effectiveness analysis resulting from an ongoing randomized clinical trial (RCT) of contemporary uncemented versus cemented implants for older adults with a hip fracture treated with a hemiarthroplasty.[5]

The WHiTE5 trial. World Hip Trauma Evaluation Five (WHiTE5) is a two-arm parallel group multicentre randomized controlled trial that aims to recruit a minimum of 1,128 participants aged 60 years and older with a displaced intracapsular hip fracture treated with a hemiarthroplasty.[5] The trial was approved by Wales Research Ethics Committee 5 (feasibility phase: 16/WA/0351 and main phase: 17/WA/0383) and registered (ISRCTN18393176). A detailed description of the study design is available in the published protocol.[5] In brief, participants will be recruited from at least seven trial centres over a period of 18 months and randomly allocated in a 1:1 ratio to cemented hemiarthroplasty (control) or contemporary uncemented hemiarthroplasty. Participants who are treated with a total hip arthroplasty are excluded.

The primary objective of the WHiTE5 trial is to quantify and draw inferences on the observed differences in participants' health-related quality of life (HRQoL) receiving either contemporary uncemented hemiarthroplasty or the standard-of-care cemented hemiarthroplasty at four months post-injury. Secondary clinical objectives of the trial include quantifying the HRQoL at one and 12 months postinjury as well as the mortality, revision surgery, and complications at one, four, and 12 months postinjury.

Methods

The objective of the economic evaluation conducted in this study is to compare the cost-effectiveness of uncemented hemiarthroplasty versus contemporary cemented hemiarthroplasty at four months from the NHS and personal social services (PSS) perspective.

Collection of health resource data. The length of follow-up will be 12 months postinjury. Outcomes, via case report forms (CRFs) and participant-reported questionnaires, will be collected at baseline, four months, and 12 months postinjury. For participants with cognitive impairment, their main carer will complete the participant-reported questionnaires. The research team will attempt to contact the participants via telephone on three to four occasions in order to improve the response rate of the questionnaires, after which a postal questionnaire with a prepaid return envelope will be sent. Depending on the type of consent given (personal consultee or nominated consultee), the participant's carer will be contacted to complete the questionnaire on behalf of the participant. Finally, the general practitioner of those participants who are deemed "lost to follow-up" will be contacted in order to complete a record of complications related to the hip fracture and subsequent surgery.

Resource use for the initial hospital treatment will be recorded by the research team in the trial CRFs. Data for the economic evaluation will be collected via trial questionnaires given to participants at baseline (four months before baseline until baseline), four months (from baseline to four months postinjury) and 12 months after injury. Baseline here refers to the orthopaedic ward at the time of consent where preinjury data will be collected. At 12 months postinjury, the questionnaire will only capture resource use from the NHS perspective between four and 12 months postinjury, as only treatment for complications will be recorded at this timepoint.

The CRFs will capture type of implant (manufacturer and model) used and the duration of surgery at baseline. The questionnaires will capture resource use from both NHS and PSS perspectives due to hip fracture, such as the frequency of use of inpatient care, physiotherapy, home adaptations, and formal (or paid) care, as well as informal (or unpaid) care received by the participants that would be relevant from the societal perspective.

Cost estimation: WHiTE5 direct medical cost. Unit cost for each resource item associated with the trial (Table I) will be sourced from the latest national resources such as the British National Formulary (BNF),[6] NHS Electronic Drug Tariff,[7] NHS Supply Chain catalogue,[8] NHS Reference Cost,[9] and Personal Social Services Research Unit (PSSRU) Costs of Health and Social Care.[10]

General intraoperative resource use between the treatment arms (e.g. staffing) is expected to be the same except for the resources associated with the interventions (e.g. implants, cement and mixing disposables). In the cemented group, the cost of the bone cement and disposables used to mix the cement will be included in the cost of the intervention. The unit cost of implants, cement and mixing disposables will be sourced from the latest NHS Supply Chain Catalogue.[8] Unit costs for staff will not be collected as the number and type of staff is expected to be the same in both trial arms. However, the duration of surgery will be recorded and included in the analysis as a unit cost per minute of theatre time. According to an operating theatre benchmarking study in 2013, the cost of each theatre hour was on average £561, with 65% of it being staff cost.[14]

Since we did not collect any comorbidity information that would allow us to specify each participant's HRG level, the unit cost of hospitalization will be obtained from NHS Reference Cost by computing the weighted average of unit costs of relevant HRG codes (HT13 Major Hip Procedures for Trauma) based on the operation performed.

Other direct medical cost. Direct medical costs not part of the trial interventions include: inpatient care (further treatment due to wound infection or complications);

Table I. Unit costs of health and social care items due to hip fracture.

Resource item	Unit	Source
WHiTE5 direct medical cost		
Surgery		
Implant*		
Exeter cemented system†	Each	NHS supply chain catalogue[8]
Accolade II‡	Each	NHS supply chain catalogue[8]
VerSys‡	Each	NHS supply chain catalogue[8]
Corail Cathcart§	Each	NHS supply chain catalogue[8]
Metafix¶	Each	NHS supply chain catalogue[8]
Bone cement	Each	NHS supply chain catalogue[8]
Bone cement mixing disposables	Each	NHS supply chain catalogue[8]
Index hospitalization		
Acute orthopaedic ward	Bed day	NHS reference cost[9]
Rehabilitation unit	Bed day	NHS reference cost[9]
Acute hospital (acute ward)	Bed day	NHS reference cost[9]
Other direct medical cost		
Further treatment due to wound infections/ complications		
Antibiotics	Average	BNF[6] or NHS Electronic Drug Tariff[7]
Surgery	Visit	NHS reference cost[9]
Outpatient care		
Physiotherapy	Visit	NHS reference cost[9]
Community care		
Physiotherapy	Visit	PSSRU[10]
Direct nonmedical cost		
Personal social services		
Residential care facilities		
Residential home	Week	PSSRU[10]
Nursing home	Week	PSSRU[10]
Formal home care		
Full-time	Hour	UKHCA, 2019[11]
Part-time	Hour	PSSRU[10]
Home adaptations		
Bathroom	Each	Garrett et al[12]
Fixed hoist	Each	Garrett et al[12]
Grab rails	Each	PSSRU[10]
Level-access shower	Each	PSSRU[10]
Outdoor rails	Each	PSSRU[10]
Ramp	Each	PSSRU[10]
Stair lift	Each	PSSRU[10]
Informal care		
Median wage	Day	Office for National Statistics[13]

*The list of implants will be updated after all data has been collected.
†Stryker, Kalamazoo, Michigan, USA.
‡Zimmer Biomet, Warsaw, Indiana, USA.
§DePuy Synthes, Raynham, Massachusetts, USA.
¶Corin Medical, Cirencester, UK.
BNF, British National Formulary; PSSRU, Personal Social Service Research Unit; UKHCA, United Kingdom Home Care Association.

outpatient care (physiotherapy); and community care (physiotherapy). These will be sourced from the latest available NHS Reference Cost[9] and PSSRU.[10] Inpatient care is the main cost driver of hip fractures based on the systematic review by Williamson et al.[15] Collecting large amounts of post-discharge recourse use data in this frail and elderly population is difficult. Therefore, in order to increase the completion rate of the health resource use questionnaire, we concentrated on collecting information on rehabilitation, which is the second highest category of care after inpatient care.[15]

Complications related to hip fracture and subsequent surgery are important drivers of the inpatient resource use, such as a postoperative wound infection requiring antibiotics and further surgery. The unit cost of antibiotics will be obtained from the BNF[6] or NHS Electronic Drug Tariff[7] by taking the average unit cost of the commonly prescribed antibiotics. Unit cost of further surgery will be derived from the latest NHS HRG Reference Cost Grouper[16] and the NHS Reference Cost based on the procedures the participants received.

Direct nonmedical cost. The unit cost of outpatient physiotherapy will be obtained from NHS Reference Cost while the unit cost of community physiotherapy will be obtained from the PSSRU. Unit cost of social services such as residential care facilities and formal home care will be obtained from publicly available information and the PSSRU. The daily median wage, obtained from the Office for National Statistics, will be used in the computation of the cost of informal care. Unit cost of home adaptations will be obtained from the PSSRU and literature.

Cost per participant. The cost of health resource use per participant will be computed by multiplying the frequency of health resource utilization rate reported by the participant with the unit cost of each resource item. The base currency of all costs will be the year that the data analysis was performed and in UK pounds (£). Cost will not be discounted as follow-up is within a year.

Cost of index hospitalization per participant will be computed by multiplying the length of stay in the hospital when the intervention was implemented (which will be collected in the baseline CRF) with the unit cost of hospitalization for each participant. In order to compute the cost of antibiotics per participant, we assume that participants will be taking the dose of antibiotics for an average of seven days for participants treated for a wound complication not diagnosed as infection and six weeks for those diagnosed with a deep surgical site infection.

Participant-facing questionnaire were kept short in order to reduce respondent fatigue, which is likely in this frail and elderly population. The following assumptions will be made to compute the cost of health resource per participant: 1) participants who reported staying in residential care facilities since discharge will not have any home adaptations; 2) participants who reported having formal full-time care will not have any informal care; 3) participants who reported staying in residential care facilities/hospitals or had formal full-time care will not have any physiotherapy; and 4) physiotherapy duration will be an hour per session.

Outcome measure. The participant-facing questionnaire will include the EuroQol five-dimension five-level questionnaire[17] (EQ-5D-5L), a measure of health-related quality of life, for self-completion at baseline (retrospectively assessed preinjury), four months, and 12 months postinjury. The EQ-5D instrument facilitates the generation of a utility score, which refers to the preference that individuals have for any particular set of health outcomes. The EQ-5D-5L consists of five health state dimensions (mobility, self-care, usual activity, pain/discomfort, and anxiety/depression) and five levels of health status (no problems, slight problems, moderate problems, severe problems, and extreme problems). Participants will report their health before hip fracture at the date of baseline questionnaire completion and their present health at the date of follow-up questionnaire completion. Participants will also complete a Visual Analogue Scale (VAS), which will provide a non-preference-based measure of the participant's self-rated health. For those patients lacking mental capacity, the information will be collected from an approximate proxy.

Responses to the EQ-5D-5L will be converted to multi-attribute utility scores using the cross-walked algorithm developed by van Hout et al[18] to generate supplementary utility values comparable with those derived from the EQ-5D-3L instrument, if 5 L value sets that are recommended by NICE are not available at the time of the analysis. Utilities will be set to zero from the date of death for participants who died.[19] Quality-adjusted life years (QALYs) will be calculated as the area under the baseline-adjusted utility curve of EQ-5D-3L utility scores from baseline, four month, and 12 month data using the trapezoidal rule.[20] QALYs will not be discounted as follow-up duration is within one year.

Statistical analysis. Completion rate of each cost category at each timepoint will be computed by treatment arm. Utilization of resource use items will be summarized by trial allocation group and follow-up period and differences between groups will be analyzed using paired *t*-tests for continuous variables and Pearson chi-squared tests for categorical variables. Means and standard deviations for values of each cost category will be estimated by treatment allocation and follow-up period. Differences in mean costs will be assessed using paired *t*-tests and the bootstrap 95% confidence interval will be computed based on 1,000 replications. Results using both the available and complete cases will be presented for the aforementioned descriptive analysis.

Cost-utility analysis. For the base case (or primary) analysis, a within-trial cost-utility analysis will be conducted from an NHS and PSS perspective, where the cost of self-funded home adaptations and informal care will be excluded, using the multiple imputed trial data over a period of four months. The analysis will adopt an intention-to-treat ('as randomized' with imputation of missing data) approach and an incremental cost-effectiveness ratio (ICER) will be calculated as the difference in mean costs divided by the difference in mean QALYs between the interventions. There are no planned subgroup analyses, as per the statistical analysis plan.

The NICE cost-effectiveness threshold of £20,000 to £30,000 per additional QALY[21] will be used to determine the cost-effectiveness of cemented versus contemporary uncemented hemiarthroplasty. An intervention with an ICER below this threshold will generally be considered as cost-effective.

Findings of this economic evaluation will be reported in accordance with the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement for the reporting of health economic evaluations.[22]

Missing data. Before carrying out the within-trial analysis, the pattern of missing data will be assessed. Where possible, the reasons for missing data will be ascertained and reported. The nature and pattern of missingness will be carefully considered; in particular, whether data can be treated as missing at random.

The same procedures used in the main statistical analysis will be adopted for the cost-effectiveness analysis. If data are missing at random, multiple imputation analysis will be performed where QALYs will be imputed at the score level, whereas costs will be imputed at the total cost level at each follow-up timepoint.[23] This will involve multiple imputation of missing data using specified regression equations from the observed covariates (observed participant's responses) and the creation of multiple datasets containing possible values for missing observations. These would then be combined using Rubin's rules[24] to obtain estimates of missing values.

Sensitivity and uncertainty analyses. Deterministic sensitivity analysis will be performed to explore the effects of a) extending the study perspective (i.e. societal perspective where the cost of self-funded home adaptations and informal care will be included), b) extending the time horizon from four months postinjury to 12 months postinjury, c) assessing the impact of missing data (i.e. using complete case analysis) on the ICERs, and d) including an additional £15,000 per QALY threshold[25] to reflect recent trends in healthcare decision-making.

In order to assess sampling (or stochastic) uncertainty on the ICERs and varying levels of willingness-to-pay for an additional QALY, probabilistic sensitivity analysis (PSA) will be performed by computing the net monetary benefit (NMB). Results from this PSA will be presented in cost-effectiveness acceptability curves (CEACs), which will be generated via non-parametric bootstrapping. More specifically, CEACs show the probability that contemporary uncemented hemiarthroplasty is cost-effective relative to cemented hemiarthroplasty across a range of cost-effectiveness thresholds that are generated based on the proportion of bootstrap replicates that

have negative incremental costs or positive incremental health benefits.

Statistical packages. All analysis will be carried out using STATA[26] or R[27] statistical software. The relevant package and version number used for analysis will be recorded and reported.

Discussion

This paper describes the health economics analysis plan for WHITE5. It will be the first randomized controlled trial with a within-trial economic evaluation that compares the cost-effectiveness of cemented versus contemporary uncemented hemiarthroplasty among older adults with hip fractures.

Strengths of this trial include the advantage of being tailored to collect specific cost data as it is undertaken prospectively alongside a trial. The base case economic analysis will be performed at 120 days postinjury which is the same timepoint used by the National Hip Fracture Database (NHFD). This potentially makes it easier for other studies that use NHFD to compare their results.

This economic evaluation has some methodological limitations. In order to increase the completion rate of health resource use in a frail and elderly cohort, we decided to keep the length of the health economics questionnaire short. This resulted in collection of only those resources that might be the main cost drivers and making assumptions on the collected resources to compute costs. However, we have selected the resource items based on the literature and piloting the health resource questionnaire between May 2017 and April 2018.[28] The assumptions made could underestimate or overestimate the cost of the examined health resources. For example, the cost of physiotherapy could be underestimated as we assume participants who reported staying in residential care facilities/hospitals or had formal full-time care will not have any physiotherapy. However, the cost of physiotherapy could be overestimated when we assume physiotherapy to be an hour per session every week, as the duration of physiotherapy might reduce as the participant recovers.

Results from this study will provide evidence on the resources and costs related to treatment and management of hip fracture participants who undergo cemented hemiarthroplasty compared to the contemporary uncemented hemiarthroplasty treatment and help decision makers update the model of care in hip fracture. Any changes or deviations from the analysis outlined in this paper will be described and justified fully in the final report. The results are expected to be disseminated in spring 2021.

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- M. E. Png: Developed the economic evaluation plan, Reviewed and approved the final manuscript.
- M. A. Fernandez: Obtained grant funding, Wrote the manuscript, Reviewed and approved the final manuscript.
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Ethical review statement:
- Wales Research Ethics Committee 5 granted ethical approval for the feasibility phase on 2 December 2016 (16/WA/0351) and the definitive trial on 22 November 2017 (17/WA/0383).