Safety of disinvestment in mid- to late-term follow-up post primary hip and knee replacement: the UK SAFE evidence synthesis and recommendations

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Scientific summary

The UK SAFE evidence synthesis and recommendations

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Scientific summary

Background

Hip and knee replacement surgery is one of the great successes of twentieth-century medicine and has revolutionised management of degenerative joint disease. In 2018–19, a total of 95,677 primary total hip replacements (THRs), 106,617 total knee replacements (TKRs), 12,261 unicompartmental knee replacements (UKRs), 1790 revision hip procedures and 6708 revision knee procedures were carried out in the UK, an increase of 25% in only 4 years and of 300% over the past 20 years. With a rapidly ageing and increasingly obese population, and medical advances that mean less stringent criteria for surgery eligibility, there is no sign that demand will recede in coming years.

The burden on NHS orthopaedic services does not stop postoperatively. However, in the current economic climate there is increasing pressure to identify cost-saving measures. Our previous work suggested that many centres were curtailing primary total joint replacement (TJR) follow-up to deal with growing pressure on their services. However, such disinvestment is without evidence base and raises questions of the consequences to patients. Identification of problem patients in a timely fashion is important to avoid complex revision surgery, which is more traumatic to the patient, carries higher complication risk and is considerably more costly in terms of surgical and subsequent rehabilitation costs. Urgent work is, therefore, required to determine the most cost-effective follow-up pathway to minimise potential harm to patients. This project aimed to examine whether it is safe to completely disinvest in TJR follow-up or whether this will expose people to unnecessary harm.

Research question

Is it safe to disinvest in mid- to late-term follow-up of hip and knee replacement?

Objectives

- To identify which patients need follow-up and when this should occur for primary TJR by making use of routine data.
- To understand the patient journey (in primary and secondary care) to revision surgery by recruiting patients admitted for elective and emergency hip and knee revision surgery.
- To establish how and when patients are identified for revision surgery and to understand why some patients are missed from regular follow-up and present acutely with fracture around the implant [i.e. periprosthetic fracture (PPF)] by using prospective and retrospective data.
- To identify the most appropriate and cost-effective follow-up pathway to minimise potential harm to patients by undertaking cost-effectiveness modelling.
- To provide evidence- and consensus-based recommendations on how follow-up of primary TJR should be conducted.

Methods

The study comprised three complementary evidence synthesis work packages to inform a final consensus process.

Work package 1

Work package 1 was a systematic literature review that aimed to evaluate the existing evidence on the clinical effectiveness and cost-effectiveness of follow-up care pathways for hip and knee joint replacement. Specific research questions were:

- What is the clinical evidence base for current and emerging follow-up care pathways for TJR and the consequences for patients?
- What are the main follow-up care pathways for primary TJR?
- What is the cost-effective evidence for models of delivering follow-up to these patients?
- What are the barriers to and facilitators of follow-up after TJR?

The systematic review was conducted in accordance with the criteria of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). Searches were run between May and June 2017, and updated in June 2019 and April 2020. The protocol was registered on PROSPERO (reference CRD42017053017).

Work package 2

Work package 2 used routine data from five national electronic health record data sets to understand which patients present for revision surgery and when, together with prospective data collected on patients presenting for revision surgery, to understand how they are currently identified.

Work package 2a

Work package 2a was an analysis of linked national data sets from primary care [i.e. Clinical Practice Research Datalink (CPRD)–Hospital Episode Statistics (HES)] and secondary care [i.e. National Joint Registry (NJR)–HES–patient-reported outcome measures (PROMs)]. Participants were aged $\geq$ 18 years and had undergone a primary elective hip and knee replacement. The primary outcome was revision surgery $\geq$ 5 years after primary hip or knee replacement. Cox regression modelling was used to ascertain risk factors for mid- to late-term revision. Hazard ratios (HRs) and 95% confidence intervals (CIs) were used to assess the association of sociodemographic factors, comorbidities, medication, surgical variables and PROMs with mid- to late-term revision. Separate models were fitted for hip and knee joints.

Work package 2b

Work package 2b was a prospective cohort study of patients presenting for revision of a THR, TKR or UKR. This cohort was used to understand current routes to revision surgery and to explore differences in symptoms, health-care use, reason for revision and the revision surgery (e.g. surgical time, components and length of stay) between patients having and those not having regular follow-up. Included participants were aged $\geq$ 18 years with elective or emergency presentation for THR, TKR or UKR. Participants were excluded from the study for previous revision surgery, metal-on-metal primary hip replacement or hip hemiarthroplasty. Patient-reported and medical record data were collected for the 12 months prior to revision. Participants were retrospectively classified as 'follow-up' or 'no follow-up'. Multilevel regression and propensity score matching were used to compare the two groups.

Work package 3

Work package 3 used a Markov model to simulate the survival, health-related quality of life and NHS costs of patients, starting at the fifth anniversary of their hip or knee replacement and continuing for the remainder of their lifetime. In the model, a simulated cohort of patients transitioned through a series of health states at yearly intervals, with each year spent in a health state associated with a cost to the NHS and a level of quality of life. Analyses were conducted separately for each joint and for two age groups ($<$ 70 years and $\geq$ 70 years) at the time of primary operation. Model parameters were derived mainly from linked primary (CPRD) and hospital care (HES) medical records, as well as from NHS PROMs and mortality (i.e. Office for National Statistics). Transitions between health states were simulated according to parametric models built based on the observed incidence of the corresponding events. Patients were classified as having had long-term follow-up or not based on recorded attendances to hospital outpatient 'trauma and orthopaedics' consultations. The impact of the uncertainty surrounding model parameter values was assessed by a probabilistic sensitivity analysis.

Work package 4

Evidence from work packages 1–3 was fed into a face-to-face consensus panel using the National Institute for Health and Care Excellence (NICE) guidelines development model. The meeting involved 32 stakeholders, including representatives from all key orthopaedic bodies, patients, general practitioners, and industry and clinical commissioners. The purpose of this face-to-face meeting was to review the complete work packages data and obtain agreement for future care pathways, supported by evidence of their clinical effectiveness and cost-effectiveness, to be recommended and adopted across the NHS.

Results

Work package 1

The search strategy identified 21,058 articles. After the removal of duplicates, there remained a total of 15,858 articles, of which 73 met the inclusion criteria and were subject to detailed review. Seventeen articles were included in the final analysis. Synthesis of findings found that both pain and functional ability at follow-up in individuals who have undergone primary hip or knee arthroplasty serve as important indicators for detecting emerging signs of implant failure, and that the use of patient-specific outcome scores, such as Short Form questionnaire-36 items and EuroQol-5 Dimensions, three-level version, during routine follow-up might prove cost-effective. However, the evidence refuted the suggestion that adequate surveillance can be achieved with the use of PROMs alone and emphasised the importance of including a radiographic review in the follow-up of hip arthroplasty. Factors such as age, education and geographical locality, as well as socioeconomic circumstances, were identified as significant barriers to patient follow-up. There was a paucity of literature correlating quality of life with follow-up after arthroplasty of the hip and knee, and there is a need for further work in this area.

Work package 2a

NJR–HES–PROMs data were available from 2008 to 2011 on 188,509 knee replacements and 142,275 THRs. CPRD–HES data were available from 1995 to 2011, during which time 17,378 knee replacements and 17,047 THRs were recorded. Patients were a minimum of 5 years post primary surgery at the end of 2016. Age and sex distributions were similar across data sets. In the NJR, there were 8607 (4.6%) revisions for knee surgery and 3582 (2.5%) revisions for hip surgery; the median time to revision after the primary surgery was 1.8 (range 0–8.8) years and 1.9 (range 0.01–8.7) years, respectively, and there were 1055 (0.6%) mid-term revisions and 598 (0.4%) late-term revisions. In the CPRD, there were 877 (5.1%) revisions for knee surgery and 982 (5.8%) revisions for hip surgery, and the median time to revision after the primary surgery was 4.2 (range 0.02–18.3) years and 5.3 (range 0–20) years, respectively, with 352 (2.0%) mid-term revisions and 520 (3.1%) late-term revisions.

Sociodemographic factors

Increasing age was associated with reduced risk of revision for THR (HR 0.96, 95% CI 0.95 to 0.96) and TKR (HR 0.95, 95% CI 0.95 to 0.96). Obesity (obese vs. normal HR 0.70, 95% CI 0.56 to 0.88), deprivation (most deprived vs. least deprived HR 0.71, 95% CI 0.58 to 0.87), non-white ethnicity (HR 0.58, 95% CI 0.43 to 0.78), better preoperative and 6-month postoperative pain/function [Oxford Knee Score (OKS) 25–48 points preoperative HR 0.42, 95% CI 0.33 to 0.53; postoperative HR 0.33, 95% CI 0.26 to 0.41] and moderate preoperative anxiety/depression (HR 0.73, 95% CI 0.63 to 0.83) were associated with a lower TKR revision risk, and male sex (HR 1.32, 95% CI 1.04 to 1.67) was associated with an increased TKR revision risk. A better 6-month postoperative Oxford Hip Score for pain/function (24–48 vs. 0–9 points) was associated with reduced THR revision risk (HR 0.34, 95% CI 0.26 to 0.45). There was no effect on American Society of Anesthesiologists grade, smoking status or drinking risk for either hip or knee revision. Effects of comorbidity were seen only in the hip revision for primary care-recorded malabsorption (HR 3.97, 95% CI 1.13 to 13.94) and previous fracture (HR 1.76, 95% CI 1.10 to 2.82) (i.e. an increased risk) and hypertension (HR 0.76, 95% CI 0.60 to 0.95) (i.e. a reduced risk).

Surgical and operative factors

For the hip revision group, compared with metal-on-polyethylene bearing surfaces, reduced risk was seen in ceramic-on-ceramic bearing surfaces (HR 0.73, 95% CI 0.56 to 0.94) and ceramic-on-polyethylene bearing surfaces (HR 0.75, 95% CI 0.57 to 0.99). The risk of revision was greater with larger head sizes ($\geq$ 44 vs. $\leq$ 28 mm, HR 2.63, 95% CI 1.12 to 6.19). No effects were observed in the knee revision group.

Medication use

In the hip revision group, antidepressant use (HR 1.65, 95% CI 1.22 to 2.24) and steroid injections (HR 2.28, 95% CI 1.14 to 4.54) were associated with an increased risk of revision. In the knee revision group, oral glucocorticosteroid therapy was associated with a reduced risk of revision (HR 0.72, 95% CI 0.50 to 0.94) and higher doses of opioids were associated with an increased risk of revision (HR 1.67, 95% CI 1.08 to 2.59).

Work package 2b

Data from 568 patients who were recruited in 38 UK secondary care sites between October 2017 and October 2018 [43.5% male; mean age 71.86 (standard deviation 9.93) years] were analysed. There were 208 patients in the follow-up group (hips, $n = 106$; knees, $n = 102$) and 360 in the no follow-up group (hips, $n = 199$; knees, $n = 161$). No significant inclusion differences were identified between the two groups. For the hip revision group, male sex [odds ratio (OR) 1.975, 95%CI 1.083 to 3.602; $p = 0.026$], time to revision > 10 years (OR 3.804, 95% CI 1.353 to 10.694; $p = 0.011$), PPF (OR 20.309, 95% CI 4.574 to 90.179; $p < 0.001$) and dislocation (OR 12.953, 95% CI 4.014 to 41.794; $p = 0.000$) were associated with no follow-up. For the knee revision group, time to revision > 10 years (OR 2.337, 95% CI 1.007 to 5.419; $p = 0.048$) and infection (OR 2.946, 95% CI 1.046 to 8.298; $p = 0.041$) were associated with no follow-up. No other significant differences in cost outcomes, duration of surgery or access to a health professional in the year prior to revision were found between the two groups. When PPFs, dislocations and infections were excluded, health-care utilisation and use of revision implants were significantly higher in the no follow-up group.

Work package 3

We identified 9856 patients with primary TKRs and 10,837 with primary THRs in the CPRD–HES data set. After identifying attended outpatient appointments, 4349 (44%) patients with a TKR and 4870 (47%) patients with a THR were included in the follow-up group. Revision rates were higher for the follow-up group than for the no follow-up group for both age groups and for both joints. The average patient having long-term follow-up was found to be associated with higher costs and lower quality-adjusted life-years (QALYs) over their lifetime than the average patient not having long-term follow-up. The main drivers of cost differences between follow-up and no follow-up were those associated with outpatient visits (i.e. follow-up costs). This varied slightly by joint and by age group at the time of primary surgery, but did not affect final comparative results. Parameter uncertainty affected THR analyses more than TKR analyses, and the younger patient groups more than the older patient groups.

Work package 4

Following the NICE consensus model, all participants received summaries of the main research findings in advance of the meeting. At the meeting, detailed presentations were given and consensus discussions took place until agreement was reached on the final recommendation statements. It was agreed that these should be grouped as overarching statements (to place the recommendations in context) and the recommendations themselves.

Overarching statements

- These recommendations apply to post-primary hip and knee replacement follow-up.
- The 10-year time point in these recommendations is based on a lack of robust evidence beyond 10 years.
- In these recommendations, the term ‘complex cases’ refers to individual patient and surgical factors that may increase the risk for replacement failure.

Recommendations

- For Orthopaedic Data Evaluation Panel 10A* (ODEP-10A*) minimum implants, it is safe to disinvest in routine follow-up from 1 to 10 years post non-complex hip and knee replacement provided that there is rapid access to orthopaedic review.
- For ODEP-10A* minimum implants in complex cases or non-ODEP-10A* minimum implants, periodic follow-up post hip and knee replacement may be required from 1 to 10 years.
- At 10 years post hip and knee replacement, clinical and radiographic evaluation is recommended.
- After 10 years post hip and knee replacement, frequency of further follow-up should be based on the 10-year assessment (note that ongoing rapid access to orthopaedic review is still required) [Stone M, Smith L, Kingsbury S, Czoski-Murray C, Judge A, Pinedo-Villanueva R, *et al.* Evidence-based follow-up recommendations following primary hip and knee arthroplasty (UK SAFE). *Orthop Proc* 2020;**102**–**B**:13. https://doi.org/10.1302/1358-992X.2020.5.013].

Conclusions

Our analysis of routine data found that the risk of a mid- to late-term revision operation 5 years after the primary THR and TKR was very low. Interestingly, the predictors of revision were different for hips and knees, suggesting that the organisation of follow-up services may need to consider different factors when defining complex cases. The patient factors we identified were most likely markers of inequalities in access to revision surgery and these need to be addressed. In our prospective study, route to revision appeared to make minimal difference in terms of participant characteristics and we could not identify specific subgroups that would benefit from targeted follow-up. Our health economic modelling found that follow-up was associated with higher lifetime health-care costs and lower QALYs than no follow-up for both primary knee and primary hip replacement. Revisions were rare, but they were more common for patients in the follow-up group than for patients in the no follow-up group.

Summary

The UK SAFE programme demonstrated that for ODEP-10A* prostheses, it is safe to disinvest in routine follow-up in the 1- to 10-year period after non-complex hip and knee replacements. At 10 years after index surgery, clinical and radiographic review is recommended. Complex cases, implants not meeting the 10A* criteria, metal-on-metal implants and follow-up after revision surgery are not covered by this recommendation.

Recommendations for future research

- Establish the most effective model of delivering a rapid access service.
- Explore inequalities in access to follow-up services and revision surgery.
- Improve and evaluate the evidence base to enable recommendations for follow-up after 10 years.
- Evaluate alternative models of delivery of follow-up services, such as virtual clinics, and the role of patient-specific outcome scores as indicators for emerging joint failure.
- Explore extrapolation and evaluation of these recommendations for other joints.

Study registration

This study is registered as PROSPERO CRD42017053017.

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