



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Health Technology Assessment of Scheduled Procedures

Arthroplasty for osteoarthritis of the knee

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Safer Better Care

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1 Knee arthroplasty

1.1 Scope of this health technology assessment

This health technology assessment (HTA) evaluates the appropriateness and potential impact of introducing clinical referral and or treatment thresholds for selected scheduled knee arthroplasty (including total and partial knee replacement) procedures for adults with end-stage arthritis of the knee. These are routine scheduled surgical procedures provided within the publicly-funded healthcare system in Ireland. The effectiveness of knee arthroplasty may be limited unless undertaken within strict clinical criteria. This report is one of a series of HTAs of scheduled procedures. Details of the background to the request by the Director General of the Health Service Executive (HSE) Tony O'Brien, and the general methodology are included in the separate 'Background and Methods' document.⁽¹⁾

The scope of this HTA is to recommend clinical referral and treatment thresholds to be used in the assessment, referral and surgical management of patients for whom hip or knee arthroplasty is being considered. Input from an expert advisory group as well as a review of international guidelines, international policy documents and thresholds, and economic evaluations were used to inform the referral criteria. In addition, the resource and budget impact were assessed where appropriate.

1.2 Surgical indications

According to Arthritis Ireland, there are some 915,000 people living with arthritis in Ireland, making it the single biggest cause of disability.⁽²⁾ Osteoarthritis is the most common form of arthritis. Also known as degenerative joint disease and osteoarthrosis, osteoarthritis is a chronic joint disease characterised by joint pain, and varying degrees of functional limitation and reduced quality of life.⁽³⁾ All tissues of the joint are involved, although loss of articular cartilage and changes in adjacent bone are the most striking features. To this extent, osteoarthritis represents failure of the joint as an organ, analogous to cardiac or renal failure.⁽⁴⁾ Osteoarthritis may occur in any joint, but is most common in the hip, knee, and the joints of the hand, foot, and spine.

Osteoarthritis may be classified as primary/idiopathic or secondary. The former occurs in the absence of an identifiable prior condition or event, whilst secondary osteoarthritis occurs on a background of preceding trauma, pre-existing disease or deformity.⁽⁵⁾ Postulated risk factors have been divided into systemic (increasing age, female gender, genetics, diet) and local (previous injury to a joint, occupation, involvement in sports, joint laxity or malalignment).⁽⁶⁾ Obesity has been strongly linked with onset and progression of knee osteoarthritis.⁽⁷⁾ In 1990, Fehring et al.

reported that 31% of patients undergoing total joint arthroplasties at their institution were obese.⁽⁸⁾ In 2005, the same authors reported that the proportion of obese patients had increased to 52%; this compared to an overall population prevalence of obesity in the same year of 24%.⁽⁹⁾

The Guideline Development Group for National Institute for Health and Care Excellence Guideline 177 on osteoarthritis published in 2014 noted three factors which it felt represented a clinician's working criteria for a diagnosis of peripheral joint osteoarthritis:

- age 45 years old and over
- has activity-related joint pain
- has either no morning joint-related stiffness or morning stiffness that lasts no longer than 30 minutes.⁽¹⁰⁾

The European League Against Rheumatism (EULAR), meanwhile, published guidelines for the diagnosis of knee osteoarthritis in 2010. This suggests that a confident diagnosis of knee osteoarthritis can be made based on the presence of six clinical signs (crepitus, restricted movement, and bony enlargement) and symptoms (persistent knee pain, limited knee stiffness [less than (<)30mins], and reduced function).⁽¹¹⁾

Diagnosis depends on a combination of clinical and radiologic features; nearly half of patients with radiological features of osteoarthritis have no symptoms and vice versa,⁽¹²⁾ although concordance appears stronger in more advanced disease.⁽¹³⁾ The radiographic features conventionally used to define osteoarthritis include joint space narrowing, osteophyte formation, subchondral sclerosis, cyst formation, and abnormalities of bone contour.⁽⁴⁾ The scoring system most commonly used to assess for these changes is the Empire Rheumatism Council system, developed by Kellgren and Lawrence in 1957.⁽¹⁴⁾ This system assigns one of five grades (0–4) to osteoarthritis at various joint sites by comparison with a radiographic atlas. Scoring of joint space narrowing and osteophytosis are most closely correlated with hip and knee pain, respectively.⁽⁴⁾

Worldwide estimates are that 9.6% of men and 18% of women aged greater than or equal to (\geq)60 years have symptomatic osteoarthritis.⁽¹⁵⁾ Incidence and prevalence data for osteoarthritis is difficult to establish because of its gradual progressive development, the fact that structural changes may not be accompanied by symptoms and because of problems associated with defining a new case. Figures may be skewed depending on whether clinical and radiographic criteria are used in combination or whether radiographic data alone are employed. In addition, data will depend on whether only moderate and severe X-ray changes are counted, or

whether mild changes are also included.⁽¹⁶⁾ It has been estimated that in Ireland approximately 140,000 adults require medical attention in relation to osteoarthritis each year. This figure excludes undiagnosed osteoarthritis and is likely to be a significant underestimate of overall disease burden.⁽¹⁷⁾ A 2013 report which examined the impact of osteoarthritis on general practice in the UK, meanwhile, suggested that 18% of the population ≥ 45 years have sought treatment for osteoarthritis of the knee, with this rising to 25% of women and 23% of men aged ≥ 75 . In total, some 4.71 million people in the UK have sought treatment for osteoarthritis of the knee.⁽¹⁸⁾ Based on data from the National Joint Registry in the UK, osteoarthritis was the underlying diagnosis in 98% of patients who were scheduled for knee arthroplasty in 2012.⁽¹⁹⁾

Other surgical indications for knee arthroplasty, beyond osteoarthritis, include avascular necrosis, inflammatory arthropathy, previous infection, rheumatoid arthritis and previous trauma (combined less than 2% of all knee arthroplasties performed across England, Wales and Northern Ireland in 2012).⁽¹⁹⁾

1.3 Surgical procedures, potential complications and alternative treatments

Knee arthroplasty is an umbrella term for a number of surgical options, namely total knee replacement (TKR) – where the whole joint is replaced – and partial knee replacement, where only the most affected parts of the joint are replaced. This can be done in the medial, lateral or patella-femoral compartments.⁽²⁰⁾ There are a range of surgical approaches and implant options, in addition to a choice of bearing types (fixed versus mobile tibial component) and methods of fixation (cemented versus uncemented versus hybrid). Data from the National Joint Registry across England, Wales and Northern Ireland reported that, of 81,534 primary knee arthroplasties performed in 2012, 90.6% were TKRs and, of these, 70,853 were fully cemented.⁽¹⁹⁾

There are a number of risks associated with knee arthroplasty. Meta-analysis has demonstrated in-hospital incidence rates of symptomatic postoperative venous thromboembolism (VTE) of approximately 1% after knee arthroplasty.⁽²¹⁾ Factors which predict the development of post-operative complications include an American Society of Anaesthesiologists (ASA) classification of ≥ 3 , increased operative time, increased age, and greater body mass.⁽²²⁾ An institutional review (Mayo Clinic Total Joint Registry) of 12,727 patients who had undergone elective (planned) TKR between 1994 and 2008, reported all-cause mortality rates at 7, 30, and 90-days of 0.1%, 0.2%, and 0.4%, respectively.⁽²³⁾ It should be noted that studies have consistently demonstrated that knee arthroplasty in those who are obese is associated with higher complication rates.^(24;25) Finally, it has been suggested that,

regardless of weight, up to 20% of patients may continue to suffer knee discomfort or have problems following TKR.⁽²⁰⁾

A potential alternative surgical option to knee arthroplasty, for patients with a unicompartamental medial or lateral pathology, is that of correction osteotomy. This involves addition or removal of a portion of bone, the goal being to transfer the mechanical axis and load bearing from the pathologic to the normal compartment.⁽²⁶⁾ Knee arthroscopy is a further surgical option in patients with knee pathology. Referral guidelines for knee arthroscopy are addressed in a separate HTA report.⁽²⁷⁾

Alternative treatments

Most clinical guidelines for arthritis recommend optimal multi-modal medical and non-pharmacological treatments for the initial management of pain and dysfunction secondary to arthritis, with recommendations that such options should be exhausted prior to surgical intervention being considered. A detailed review of what constitutes optimal conservative management is beyond the scope of this HTA, but a summary table of the recommendations from some of the internationally recognised guidelines is attached as an appendix (see Appendix 1.1). These recommendations include making a holistic assessment of the patient, followed by the institution of non-pharmacological and medical treatment modalities.

Non-pharmacological measures can include patient education, the establishment of an exercise programme, and support for potentially beneficial lifestyle adjustments, including smoking cessation and weight loss programmes. Non-pharmacological treatment options include heat or cool packs as appropriate; shock absorbing footwear; the use of aids and appliances, such as walking sticks or grabbers; acupuncture or trans-electrical nerve stimulation (TENS) which may be helpful for some people.

Concurrent medical therapies include the adoption of a stepwise approach to pain management. Options may include topical and oral analgesia (painkillers), with gastroprotection as required, and the addition of adjunctive medications (for example, intra-articular injections of corticosteroid) as indicated.

1.4 Current practice in Ireland

Potential candidates for knee arthroplasty are generally referred by their general practitioner (GP) or by another hospital specialist to an orthopaedic surgeon. Referral or treatment thresholds (similar to those discussed in Section 2 below) may be used by GPs and surgeons in Ireland to identify eligible candidates for referral or

treatment. However, it is unclear if such thresholds are being used, or how consistently they are being applied.

Knee arthroplasty is a routine, scheduled surgical procedure within the publicly-funded healthcare system in Ireland. The Hospital In-Patient Enquiry (HIPE) system was employed to assess activity levels in relation to both procedures. Knee arthroplasty may be coded as the principal procedure or as a secondary procedure. For consistency and completeness, data are reported to include the principal and secondary procedures (that is, 'all procedures') with all data presented on this basis. The International Classification of Diseases (ICD) intervention codes used to retrieve this data are listed in Appendix 1.2.

The HIPE system reports that there were approximately 2,185 patients who underwent knee arthroplasty in 2012. Of these, 2,149 (98.4%) patients were admitted for their procedure on an elective (pre-planned) basis; 15 (0.7%) were admitted on an emergency basis, with the remaining 21 (1.0%) patients admitted as elective readmissions.

Knee arthroplasty routinely warrants an inpatient stay. The average length of stay (ALOS) for the 2,149 procedures carried out in the pure elective setting was 6.4 days. The target set by the National Clinical Programme in Surgery states an ALOS target of seven days for patients undergoing elective knee arthroplasty.⁽²⁸⁾ It is noted that the average length of stay for patients undergoing knee arthroplasty in public hospitals decreased from 12.1 days in 2005 to 6.4 days in 2012 (Figure 1.1 on page 12). The average age of patients undergoing elective knee arthroplasty in 2012 was 67.5 years.

In 2012, the most common procedure was unilateral total arthroplasty of the knee, which accounted for 97.6% of cases. This was followed in frequency by bilateral total arthroplasty of the knee (1.0%), hemiarthroplasty of the knee (0.7%), and total replacement arthroplasty of the patellofemoral joint of the knee (0.5%).

All patients who undergo a surgical procedure in Irish public hospitals have an operative diagnosis coded as part of the HIPE coding process. This is recorded as the principal diagnosis at the time of operation, and may not be synonymous with the preoperative diagnosis. In 2012, the principal diagnosis – at the time of the knee arthroplasty – was coded as 'other primary gonarthrosis' in 78.4%; the next most frequently coded diagnoses were 'gonarthrosis unspecified' (11.8%), and 'primary gonarthrosis, bilateral' (4.1%).

The 2,149 elective knee arthroplasties recorded within the HIPE system in 2012 were performed across 19 different hospital sites (range 3-469 procedures per site); seven

hospitals performed 10 or fewer elective procedures. These institutions are categorised according to their hospital groups in Table 1.1. Any variation may be explained by differing catchment sizes or the availability of an orthopaedic surgery service, hospital size or specialisation. It should also be noted that patient comorbidity may occasionally mandate that knee arthroplasty is performed in a tertiary level institution in which this procedure would not normally be undertaken.

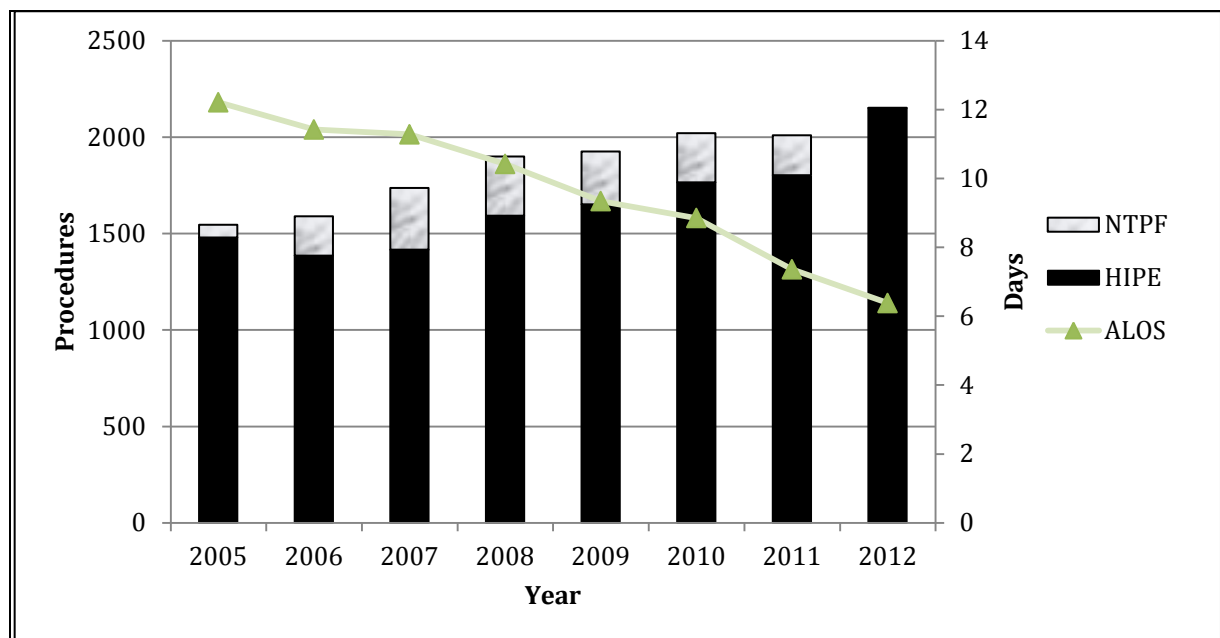
Table 1.1 HIPE data for elective knee arthroplasty procedures per proposed HSE hospital group* (2012)⁽²⁹⁾

Hospital group	Number	ALOS (days)	Inpatient bed days	Average age
	(%) (Range)			(years)
Dublin North East	18 (0.8%) (9-9)	13.2	238	69.0
Dublin Midlands	396 (18.4%) (5-223)	6.0	2,376	66.6
Dublin East	630 (29.3%) (5-469)	6.7	4,212	67.0
South/South West	591 (27.5%) (3-274)	6.0	3,515	67.4
West/North West	287 (13.4%) (34-96)	6.4	1,839	69.4
Midwest	227 (10.6%) (4-223)	6.7	1,520	68.0
Total	2,149	6.4	13,700	67.5

*Key: ALOS – average length of stay; Range – the range in terms of number of procedures performed in individual institutions within the hospital group. *See Appendix 1.2 for HIPE codes; HIPE data includes all activity in publicly-funded hospitals, including procedures in patients that used private health insurance.*

In addition to the activity levels in public hospitals, additional procedures have been funded by the public healthcare system via the National Treatment Purchase Fund (NTPF). Between 2005 and 2012, an additional 1,634 procedures were procured from the private hospitals. Data on the total number of procedures undertaken in the publicly funded system, including the additional procedures funded by the NTPF, are shown in Figure 1.1. The number of elective knee arthroplasties undertaken in the publicly-funded healthcare system has increased by 39.2% from 1,545 in 2005 to 2,151 in 2012.

Figure 1.1 Number and average length of stay (days) for knee arthroplasties provided through the publicly-funded healthcare system in Ireland, 2005-2012⁽²⁹⁾



Key: HIPE (Hospital In-Patient Enquiry Scheme) data; NTPF (National Treatment Purchase Fund) funded procedures. HIPE data includes all activity in publicly funded hospitals, including procedures in patients that used private health insurance. ALOS – average length of stay.

The length of time a patient must wait to be reviewed varies according to the referral pathway and the individual hospital and consultant to which a patient is referred. At the end of April 2014, it was reported that there were 338,943 patients on the outpatient waiting list database collated by the NTPF, 34.2% of whom were waiting longer than six months, with 6.7% on the list for longer than 12 months. Orthopaedic referrals constituted 12.4% (n=41,975) of the total waiting list; 42.0% of these patients had been waiting greater than six months for an outpatient appointment in secondary care.⁽³⁰⁾ Initiatives are underway by the HSE to

standardise the management of outpatient services and to ensure that there are consistent management processes across all publicly-funded healthcare facilities that provide outpatient services. This includes the publication of a protocol for the management of these services by the NTPF in January 2013 which provides the core guidance of the Outpatient Services Performance Improvement Programme.⁽³¹⁾ The protocol specifies that patients should be treated based on clinical urgency, with urgent referrals seen and treated first. It is intended by the HSE that the definition of clinical urgency and associated maximum wait times is to be developed at speciality or condition level and agreed by the clinical programmes.

In January 2013, the NTPF published a national waiting list management policy that outlines the standardised approach to managing scheduled care treatment for inpatient, day case and planned procedures in all publicly-funded hospitals.⁽³²⁾ It outlines a consistent structured approach that must be adopted to the management of the waiting list. Monitoring of the implementation of the policy will be routinely undertaken by the NTPF in the form of annual quality assurance reviews.

In relation to orthopaedic procedures specifically, it should be noted that a combined initiative, aimed at reducing waiting lists for outpatient appointments, was launched by the National Orthopaedic and Rheumatology Clinical Programmes in 2010. Under this initiative, 24 clinical specialist musculoskeletal (MSK) physiotherapists were employed across Ireland (six per region) to work alongside orthopaedic and rheumatology consultants, with these consultants performing the initial triage based on the referral letter. The process aimed to identify patients for whom conservative management may be a more appropriate treatment.

An audit of practice, between January and July 2012, at St. Vincent's University Hospital (SVUH) in Dublin has reported that of 763 patients allocated an appointment under this system, 49 (6%) did not attend or cancelled their appointment. At the time of the audit, 140 (20%) patients were awaiting review with the MSK team as return patients (for example, for follow-up after medical investigations). Of the remaining 574 patients, whose outcome was known, 76% were independently managed by the MSK physiotherapists without need for orthopaedic consultation; 39% of whom were discharged to physiotherapy (63% within SVUH and 37% to a primary care service) and 37% back to their general practitioner. Twenty four percent of patients (n=137) were referred on to a surgical or medical specialty, 92% (n=126) of those for an orthopaedic surgical opinion, 4% to the department of pain medicine, 1% to rheumatology and 2% to another specialty (for example, neurology, vascular surgery).⁽³³⁾

In the primary care setting, meanwhile, there were 175,926 referrals to physiotherapy services in 2013; this was 2.1% above expected activity for the year.

Overall activity levels were also 1.9% higher than expected, with 733,613 physiotherapy treatment episodes provided in 2013. This included 145,213 patients who were referred for first-time assessments (an increase of 4.4% above expected activity).⁽³⁴⁾ Despite increased activity levels, demand continues to exceed available capacity. At the end of April 2014, there were 6,377 patients waiting over 12 weeks for a physiotherapy assessment in primary care.⁽³⁵⁾

2 Clinical referral/treatment threshold

2.1 Review of the literature

A comprehensive review of the literature was conducted during March 2014 to identify international clinical guidelines and health policy documents describing treatment thresholds that are in place in other healthcare systems. It also considered systematic reviews and economic evaluations examining the effect of the introduction of those thresholds. The approach and general search terms are described in Appendix 1 in the 'Background and Methods' document; a summary of the results is included in Table 2.1. A summary of the clinical guidelines identified from the search and thresholds in use elsewhere are provided in Appendices 1.5-1.7.

Table 2.1. Summary of literature search results

Publication Type	Number	References
Clinical Guidelines	14	(36-49)
Reviews	1	(50)
Cost-effectiveness studies	8	(51-58)

2.2 Clinical evidence

International guidelines

As discussed in Section 1.4, HIPE data indicates that the majority of elective knee arthroplasties are undertaken in those with osteoarthritis of the knee.⁽⁵⁹⁾ The most recent and comprehensive guideline retrieved regarding management of osteoarthritis is that entitled 'Osteoarthritis, Care and Management in Adults', published by the UK's National Institute for Health and Care Excellence (NICE) in February 2014.⁽⁶⁰⁾ This guideline addresses management of osteoarthritis as a single clinical entity and does not provide joint-specific recommendations. As noted in Section 1.2, this guideline suggests that a clinical diagnosis of osteoarthritis can be made without investigations if the person:

- is 45 years old or over **and**
- has activity-related joint pain **and**
- has either no morning joint-related stiffness or morning stiffness that lasts no longer than 30 minutes.

The guideline suggests that a holistic approach needs to be taken to assessment and management, with core treatments based on access to appropriate information, activity and exercise, and interventions to achieve weight loss if the person is overweight or obese. A full NICE review on the pharmacological management of OA is to follow. The guideline made a number of specific recommendations in relation to consideration for referral for joint surgery:

- Prior to referral, the referring clinician should ensure that the person has been offered at least the aforementioned core (non-surgical) treatment options; this should apply to all with clinical osteoarthritis, regardless of whether or not they are symptomatic.
- Decisions regarding referral thresholds should be based on discussions between patient representatives, referring clinicians and surgeons, rather than using scoring tools for prioritisation.
- Consider referral for joint surgery for people with osteoarthritis who experience joint symptoms (pain, stiffness and reduced function) that have a substantial impact on their quality of life and are refractory to non-surgical treatment.
- Refer for consideration of joint surgery before there is prolonged and established functional limitation and severe pain.
- Patient-specific factors (including age, sex, smoking, obesity and comorbidities) should not be barriers to referral for joint surgery.
- When discussing the possibility of joint surgery, check that the person has been offered at least the core treatments for OA, and give them information about
 - the benefits and risks of surgery and the potential consequences of not having surgery
 - recovery and rehabilitation after surgery
 - how having a prosthesis might affect them
 - how care pathways are organised in their local area.

The American Academy of Orthopaedic Surgeons published its guidelines on treatment of knee osteoarthritis in 2013 (Appendix 1.1).⁽³⁷⁾ Specifically in relation to

surgery, while the guideline suggested that a valgus-producing proximal tibial osteotomy might be indicated in patients with symptomatic medial compartment osteoarthritis of the knee, it did not make specific recommendations about who should or should not be referred for consideration for knee arthroplasty.

In 2009, Australia's National Health and Medical Research Council (NHMRC) published its guideline for the Non-Surgical Management of Hip and Knee OA.⁽³⁸⁾ This guideline suggests that, for those with osteoarthritis of the knee, there is good evidence of benefit from land-based exercise for all patients and from weight reduction for those who are obese. There is some evidence of benefit from aquatic therapy, up to three months of multimodal physical therapy, thermotherapy, TENS, acupuncture, tai chi and self-management education programmes. The guideline stressed the importance of comprehensive assessment of the patient with hip or knee osteoarthritis, including their signs and symptoms, comorbidities, psychosocial and falls risk, medications and non-steroid anti-inflammatory drugs (NSAIDs) risk. Emphasis was also placed on the importance of individualisation of decisions regarding the need for multidisciplinary care, and suggested that referral to a rheumatologist should be considered for elderly patients, patients with significant comorbidity, those with extensive disease or when the diagnosis is uncertain. The guideline did not deal specifically with indications for referral for surgical intervention. Instead it referred users to a guideline developed by the Royal Australian College of General Practitioners in 2007 (see section 2.3).⁽³⁹⁾

In 2008 the Osteoarthritis Research Society International (OARSI) published its guideline, for the management of both hip and knee osteoarthritis, based on a systematic review of articles published between 1945 and 2005, inclusive.⁽⁴¹⁾ This process resulted in 25 recommendations, a sample of which are included in Appendix 1.1. Specifically in relation to referral for arthroplasty, the guideline states that:

- Patients with hip or knee osteoarthritis who are not obtaining adequate pain relief and functional improvement from a combination of non-pharmacological and pharmacological treatment should be considered for joint replacement surgery. Replacement arthroplasties are effective, and cost-effective interventions for patients with significant symptoms, and/or functional limitations associated with a reduced health-related quality of life, despite conservative therapy.
- Unicompartmental knee replacement is effective in patients with knee osteoarthritis restricted to a single compartment.

- For the young and physically active patient with significant symptoms from unicompartmental knee osteoarthritis, high tibial osteotomy may offer an alternative intervention that delays the need for joint replacement some 10 years.

It should be noted that the evidence included in this review was updated in 2010 to include published studies up to the end of 2009. While effect sizes changed in relation to some of the individual treatment strategies under study, there was no suggestion that the recommendations above required alteration.⁽⁴²⁾ In addition, OARSI published updated guidelines on the non-surgical treatment of knee osteoarthritis in 2014; key recommendations from this update are included in Appendix 1.1.⁽⁴⁰⁾

In 2010, March et al. reviewed the earlier version of the aforementioned NICE guideline (2008),⁽³⁾ together with the NHMRC and OARSI (2008) publications, and proposed a 'core set' of interventions that should be offered to all patients with osteoarthritis of the hip and/or knee.⁽⁵⁰⁾ The paper made eight recommendations (see Appendix 1.1), specifically stating that access to assessment for arthroplasty should be offered to those with severe symptomatic osteoarthritis not responding to conservative therapy.

The Ministry for Health in British Columbia, Canada, published its guideline for diagnosis and treatment of osteoarthritis in peripheral joints in 2008.⁽⁴³⁾ It suggested that one needs to consider four treatment pillars, namely patient education, rehabilitation, medications and referrals (surgical and non-surgical). Its indications for non-surgical referral were as follows:

- Refer to rheumatology or appropriate internal medicine specialist for: red flag conditions (alternative diagnosis), unexpected/unusual disease progression or complications.
- Refer to physiotherapy or occupational therapy for education on self-management or on the disease process; specific exercises for range of motion, strengthening, or joint protection; gait training; knee bracing; pain management education and techniques; mobility aids; and education for dealing with functional difficulties (home, work or leisure).
- Refer to dietician for education on weight management.
- If the patient has significant disease progression but is not a surgical candidate, for example, because of significant comorbidities, consider referral to occupational therapy for assistance with activities of daily living (ADLs).

Indications for surgical referral, meanwhile, were failure of a non-operative programme (inadequate pain control, increasing need for narcotic medications, significant pain on motion; resting pain; presence of night pain), increasing functional restriction (inability to walk without significant pain; significantly modified ADLs: that is, putting on shoes, climbing stairs, squatting and bending; increasing threat to patient's ability to work or live independently), significant abnormal findings on examination (decreasing range of motion of the hip and/or notable leg length discrepancy), and/or progression of disease on X-ray (evidence of increasing acetabular protrusion or femoral head collapse).⁽⁴³⁾

In 2005, the Ontario's Medical Advisory Secretariat published a full health technology assessment (HTA) on knee replacement.⁽⁴⁴⁾ Its primary aim, however, was to examine the effectiveness or otherwise of arthroplasty in decreasing pain and improving function – it did not suggest guidelines that might be used for referral purposes. Whilst concluding that the procedure is effective, the report noted that up to 70% of the variance in outcomes following arthroplasty is unexplained. It further stated that severity of osteoarthritis is not a predictor of outcome, but noted that one study had found that higher functioning patients had better functional outcomes up to two years after surgery compared to lower functioning patients.⁽⁴⁴⁾

Finally, in 2003, the National Institute for Health (NIH) in the United States published its consensus statement on knee arthroplasty. This suggested that those being considered for elective replacement should have radiographic evidence of joint damage, moderate to severe persistent pain that is not adequately relieved by an extended course of non-surgical management, and clinically significant functional limitation resulting in diminished quality of life. In patients with rheumatoid arthritis and other inflammatory arthropathies, additional disease-specific therapies may be needed to achieve control of disease activity before proceeding with the surgical procedure.⁽⁴⁵⁾

In summary, then, there is clear consensus across international guidelines that patients with knee osteoarthritis should be managed conservatively in the first instance, with this management plan instituted following holistic assessment of individual patient need. Patients with severe symptomatic osteoarthritis, not responding to conservative measures, should be referred to secondary care for an opinion in relation to the need for arthroplasty. The following paragraphs outline international thresholds that have integrated this evidence into their prioritisation and referral criteria.

Prioritisation and referral criteria

Prioritisation criteria, based on scoring systems, have been developed for knee arthroplasty in New Zealand,⁽⁶¹⁾ Canada⁽⁶²⁾ and Australia. The New Zealand system was introduced in 1998 and calculates a score based on pain (maximum score 40 points), physical disability (20 points), movement and deformity (20 points) and other features, including work and social issues (20 points).⁽⁶¹⁾ Its correlation with validated measures of disability and function – the Western Ontario and McMasters Universities Arthritis Index (WOMAC) and the Musculoskeletal Function Assessment (MFA) – has been questioned. however,⁽⁶³⁾ and it has been used to a varying degree across New Zealand.⁽⁶⁴⁾ In addition, the good practice guidelines published by the New Zealand Orthopaedic Association do not mention prioritisation criteria, simply stating that

“severe pain and disability with accompanying radiological changes in the knee are almost always the indications for the operation, in patients where conservative treatment has failed or is futile. Occasionally there may be an indication to replace a knee because of progressive deformity and/or instability, and pain may not necessarily be the most significant factor. Where comorbidities exist, risk benefit considerations may rule out the operation in an individual patient”.⁽⁴⁶⁾

The initial Canadian prioritisation criteria, meanwhile, used an algorithm based on rest pain, problems in work or care giving, and functional limitation, with different scores for prioritisation being assigned to different states.^(62;65) Meanwhile, the Western Canada Waiting List (WCWL) project was established in 1998. This established prioritisation criteria for both hip and knee arthroplasty, with individual criteria summing to a maximum score of 100 points for the most urgent cases (Appendix 1.3).⁽⁶⁶⁾ It, or a modified version, has been rolled out in a number of Canadian provinces.⁽⁶⁷⁾ Finally, the Orthopaedic Waiting List Project in Victoria, Australia, developed a Multi-Attribute Prioritisation Tool (MAPT); it contains 11 questions about pain, psychological and economic impact, limitations to activities, and deterioration.⁽⁶⁷⁾ It has been built into the Victorian Osteoarthritis Hip and Knee Service, an improved service model for management of patients requiring joint replacement, piloted at several Victorian hospitals. In this service model, patients are initially assessed by a specialist physiotherapist and or nurse. The MAPT score is to triage patients to the orthopaedic outpatient clinics for further assessment by a surgeon. Based on the clinical assessment of the patient, the surgeon then prioritises the appropriate patient for surgery and, hence, clinical assessment by the orthopaedic surgeon in the clinic rather than a MAPT score is the basis of prioritisation for a surgery.⁽⁶⁸⁾ One small study has examined the MAPT against

clinical and radiographic assessment of disease severity – its results suggested that no relationship exists between the two.⁽⁶⁸⁾

Over the past 20 years a large number of patient-reported outcome measures (PROMS) have been developed to evaluate the efficacy of both hip and knee arthroplasty, from the patient's perspective. These may be classified as (1) disease-specific (or OA-specific) measures (Hip Dysfunction and Osteoarthritis Outcome Score [HOOS], HOOS physical function short form [HOOS-PS], Knee Injury and Osteoarthritis Outcome Score [KOOS], KOOS physical function short form [KOOS-PS], Western Ontario and McMaster Universities Osteoarthritis Index [WOMAC]); (2) arthroplasty-specific measures (Harris Hip Score, Oxford Hip Score, Oxford Knee Score); and (3) generic measures (EQ-5D, Short Form-12 [SF-12], Short Form-36 [SF-36]).⁽⁶⁹⁾ In the UK, the PROMS of choice have been the Oxford Hip and Knee Scores (see Appendix 1.4). In some cases, there have been attempts to use these scores as a method of prioritising patients for surgery (Appendix 1.5); this has been despite the fact that these measures were not designed to be used in this way, and that there is little data to suggest that they can predict the outcome of surgery.⁽⁷⁰⁾

The use of referral thresholds by primary care trusts (PCT) in the English NHS has been common practice for several years. As part of the changes to the NHS brought about by the Health and Social Care Act 2012, PCTs and strategic health authorities (SHAs) ceased to exist on 31 March 2013. Their responsibilities were taken over by clinical commissioning groups and the NHS Trust Development Authority. However, the thresholds that were previously developed by these trusts are likely to represent ongoing practice at a local level while new commissioning guides are being established. A summary of specific thresholds from a sample of three NHS PCT areas is provided in Appendix 1.5.

The most recent national commissioning guide published relating to management of the symptomatic knee is that entitled 'Commissioning Guide – Painful osteoarthritis of the knee'.⁽⁴⁷⁾ Published in 2013, this report is sponsored by the British Orthopaedic Association (BOA), the British Association of Knee Surgery (BASK) and the Royal College of Surgeons of England (RCSEng), and NICE has accredited the process used to produce it. It makes a number of recommendations for GPs who are considering the appropriateness of referral (Appendix 1.6), including that the decision to undergo surgery is based on symptom pattern, with the type of surgery determined by the pattern of joint damage and the patient's preference, and that all patients must have engaged in a shared decision-making process about alternatives. Specifically in relation to total knee arthroplasty, it suggests that this should be considered in patients with:

- Moderate or severe knee pain not adequately controlled by three months of non-surgical management, following NICE guidance.
- Evidence of exposed bone present in at least one of the knee joint compartments (Kellgren-Lawrence [KL] Grade III and above).

It also suggests that, in patients without pain, the procedure can be considered in those who present with functional disability in the presence of end-stage cartilage disease, or progressive deformity of the knee (varus/valgus) with functional disability.

In relation to partial knee arthroplasty, meanwhile, the guidelines states it should be considered in those with:

- Moderate or severe knee pain not adequately controlled by three months of non-surgical management, following NICE guidance.
- Grade III and above arthritis confined to a single joint compartment.

Finally, in relation to high tibial osteotomy, the guideline states that it may be considered in patients with one of the following:

- Moderate to severe knee pain not adequately controlled by three months of non-surgical management.
- Varus misalignment in medial unicompartmental knee osteoarthritis and this is the main indication for high tibial osteotomy (HTO).
- Diagnosis of knee osteoarthritis (Kellgren-Lawrence grade 1-3) isolated to one compartment, usually the medial side.
- In younger patients as the outcome for partial or total knee replacement is not as successful as in older patients.

The guideline also notes that the decision as to whether patients should have high tibial osteotomy rather than unicompartmental knee replacement (UKR) or total knee replacement (TKR) remains a clinical one as good comparative evidence is not available.

A referral guideline for patients with knee pain was published in Scotland in 2011.⁽⁴⁸⁾ This segregates those with chronic knee pain (greater than [$>$] one month) by patient age and disease severity. Those older than 45 years, and considered to have moderate or advanced osteoarthritis are referred to secondary care for orthopaedic assessment; primary care initial management and physiotherapy is recommended for all others; with referral to secondary care only if they fail to have an adequate response to three months conservative management (Appendix 1.7).⁽⁴⁸⁾

In 2007, the Royal Australian College of General Practitioners (RACGP) published its guidelines regarding referral for joint replacement.⁽³⁹⁾ This states that:

- Surgery should be considered when there is confirmation of advanced disease and a continuation of severe symptoms despite optimal conservative (non-surgical) treatment.
- When referral for orthopaedic assessment and possible joint replacement surgery is indicated there should be provision of information and support to enable the patient to make an informed decision in conjunction with family members and carers as appropriate.
- The surgeon has ultimate responsibility for determining a patient's fitness to proceed with surgery and to explain to the patient the potential risks and gains of the procedure. Thus, the existence of comorbidities should not preclude referral. The general practitioner does, however, have an important role in the detection and management of comorbidities that may affect fitness for surgery.
- When making a referral for orthopaedic assessment:
 - identify and develop a plan for appropriate stabilisation of comorbidities;
 - seek specialist advice as required; and
 - consider referral for allied health assessment.

In 2013, the American Association of Hip and Knee Surgeons (AAHKS) issued guidance on joint arthroplasty for those who are obese.⁽⁴⁹⁾ Based on evaluation of the literature and consensus, the following statements were made in relation to knee arthroplasty:

- All obese patients (BMI >30kg/m²) undergoing total joint arthroplasty are at increased risk for perioperative complications and this needs to be discussed with every patient prior to considering total joint arthroplasty
- For total knee arthroplasty, based on the current literature, it appears that the morbidly obese patients, defined as a BMI ≥40kg/m², are the threshold for which the majority of perioperative complications, including infection and revision rates, appear to increase considerably. This needs to be discussed with every patient prior to surgery and strong consideration should be given to reducing weight (BMI <40kg/m²) and minimising associated comorbidities.⁽⁴⁹⁾

International referral thresholds thus uniformly suggest the need for conservative management in the first instance, prior to referral for consideration for arthroplasty. It is clear that while some organisations have adopted scoring tools or patient reported outcome measures to aid in the surgical prioritisation process, at present these are neither uniformly employed nor sufficiently evidence based to warrant implementation in Ireland. There thus remains a subjective element to the referral

process, but a number of factors which are common across thresholds, and which were enumerated in the international guidelines outlined earlier, have been identified, and these are reflected in the final threshold.

2.3 Cost-effectiveness evidence

In 2012 Dakin et al. published a cost-effectiveness analysis of total knee replacement, based on data from the Knee Arthroplasty Trial (KAT) in the UK.⁽⁵¹⁾ The authors assessed the cost-effectiveness of surgery versus no surgery, and took a provider (NHS) perspective, with a five-year timeline post surgery. A conservative approach was taken with assumptions made that those not having surgery would incur no knee-related costs and would remain at baseline utility without total knee replacement (TKR). On average, each admission for primary TKR cost £6,363 British Pounds (£GBP) (standard deviation (SD): GBP£1,702), rising to an average cost of GBP£7,458 (SD: £4,058) per patient over the following five years. TKR cost GBP£5,623 per quality adjusted life year (QALY) gained for the average patient. Patients were analysed according to Oxford Knee Score subgroups to see if this might identify a group in which surgery was not effective; TKR cost less than GBP£11,000 per QALY gained across all Oxford Knee Score deciles. Regression analysis, however, demonstrated that Oxford Knee Score had a significant effect on cost-effectiveness. That said, the authors reported that TKR was cost-effective for the vast majority of patients, and suggested that proposed guidelines by some PCTs to restrict TKRs to those with Oxford Knee Score scores of 26 or less (on the 0-48 system) would deny a highly cost-effective treatment to >10,000 patients per year.

Using 2009 US Medicare claims data, Mather et al. published (2014) a cost-utility analysis that used a Markov decision model to compare (1) TKR without delay; (2) a two-year waiting period with no non-operative treatment; and (3) a non-operative treatment bridge during that two-year waiting period in a cohort of 60 year-old patients with end-stage osteoarthritis.⁽⁵³⁾ They concluded that TKR without delay dominates (that is, it is less expensive and more effective than) delaying surgery and providing continued non-operative treatment when using either a payer or societal perspective and suggested that policies aimed at increasing the supply of TKR should be considered, as savings exist that could indirectly fund those strategies.

Waimann et al. conducted a six-month prospective cohort study of 212 patients with knee osteoarthritis, who underwent TKR in Houston, Texas.⁽⁵⁵⁾ Pain and functional outcomes were measured using the Western Ontario McMaster (WOMAC) questionnaire, with direct and indirect costs calculated (2007 values) and a societal perspective taken. Cost-effectiveness ratios for TKR ranged from approximately \$25,000 United States Dollars (USD) to USD\$57,000 for a 20% to 70% relative

improvement, leading the authors to conclude that 'TKR is an effective intervention for reducing pain and improving functional status among patients with knee OA [osteoarthritis]'.⁽⁵⁵⁾ In 2013, meanwhile, Ruiz et al. published their results from running a Markov model framework, based on 2009 costs, and again taking a societal perspective.⁽⁵⁴⁾ They demonstrated an overall QALY gain of 2.4 associated with surgical intervention, ranging from 3.4 in the 40-44 year old age group to 1.8 in those aged 80 or older. Net societal savings overall were valued at USD\$18,930, ranging from USD\$158,110 in the 40-44 year old age group to USD\$19,362 in those aged 80 or older; an incremental cost-effectiveness ratio (ICER) of USD\$5,656 was calculated for the entire cohort, with an ICER of USD\$12,410 calculated for those aged 80 years or older. The authors concluded that their results demonstrated the potential for substantial negative societal effects if TKR is unduly restricted.⁽⁵⁴⁾

Finally, Losina et al. performed a Markov Model based on Medicare data (2006 costs), and examined cost-effectiveness of TKR in low-, medium- and high-volume hospitals (1–25, 26–200, and >200 TKRs/year), and in low-, medium- and high-risk patient cohorts.⁽⁵²⁾ Lifetime costs varied from USD\$37,100 per person for no TKR to \$57,900 per person undergoing TKA. The incremental cost effectiveness ratio (ICER) of TKR was USD\$18,300 per QALY; ICER estimates ranged from \$9,700 per QALY in the low-risk group to USD\$28,100 per QALY in the high-risk group. In relation to hospital volume, the authors concluded that 'hospital volume above 25 TKR per year is sufficient to assure cost-effective delivery of TKR in the situations where there is a choice among different hospital settings'.

A summary of data from other papers is included in Table 2.2.

Table 2.2. Summary of other cost-effectiveness data

Author	Country (Currency)	Year Costed (Discount rate)	Perspective	QALY gain	Cost per QALY*	Cost per DALY*	DALY averted
Dakin ⁽⁵¹⁾	UK (GBP)	2007-2008 (3.5%)	Payer	1.33	€6,702		
Ruiz ⁽⁵⁴⁾	United States (USD)	2009 (3%)	Societal	2.4	€7,793		
Losina ⁽⁵²⁾	United States (USD)	2006 (3%)	Payer	1.14	€26,863		
Higashi ⁽⁵⁶⁾	Australia (AUD)	2003 (3%)	Payer	-	-	€14,305- €30,994	1.1
Rasanen ⁽⁵⁷⁾	Finland (EURO)	2003 (5%)	Payer	0.82-0.34	€11,062- €26,915	-	-
Tso ⁽⁵⁸⁾	Canada (CD)	2009 (3%)	Payer	1.27	€13,189- €32,208	-	-

Key: AUD – Australian dollars; CD – Canadian dollars; USD – United States dollars; QALY – quality-adjusted life year; DALY – disability-adjusted life year.

*Costs have been inflated to 2014 values and converted to euro.

Historically, the threshold at which a given technology is considered to be cost-effective has varied between €20,000 and €45,000 per QALY gained. While there are potential issues with the generalisability of cost data across healthcare systems, currencies, and time frames, all of the studies concur that knee arthroplasty is a cost-effective procedure. In particular, it is noted that it is more cost-effective to provide arthroplasty promptly in patients with severe disease once the decision to proceed to surgery has been taken for an individual patient, with evidence also to suggest that using a minimum threshold of at least 25 procedures per institution per year may be required to ensure cost-effective delivery of care.

2.4 Budget impact and resource implications

The number of knee arthroplasty procedures in Ireland has increased by 40% since 2005. As noted in Section 1.4, almost all of the procedures were undertaken as inpatient cases in 2012. The estimated annual national cost, at the time of this report, of knee arthroplasty procedures is €25.6 million, with an average weighted cost per case of €11,925, based on the latest Casemix costs (Table 2.3).

Table 2.3. HSE inpatient and day case acute hospital activity and costs for elective knee arthroplasty summarised by diagnosis-related group (based on 2011 costs and 2012 activity)⁽⁷¹⁾

DRG code	Description	Number carried out	% of knee arthroplasty procedures	Cost/ inpatient (€)
I04B	Knee replacement W/O catastrophic or severe CC	1,839	86%	11,461
I04A	Knee replacement W catastrophic or severe CC	288	13%	14,651
I01B	Bilateral/multiple major joint Pr of lower extremity W/O revision W/O Cat CC	22	1%	15,734

Key: DRG – diagnostic-related group; W – with; W/O – without; CC – complication or comorbidity; CAT – catastrophic. Data summary from HSE National Casemix Programme Ready Reckoner, 2013 based on the 2011 inpatient and day case costs reported by 38 hospitals participating in the programme that year. Activity is based on the latest 2012 HIPE data.

Despite increases in the number of knee arthroplasty procedures provided by the publicly-funded system in recent years, demand for care is anticipated to increase further due to changing demographics and rising levels of obesity. Increasing levels of obesity may also contribute to increases in the cost per episode of care. As noted in section 1.2, studies have consistently reported higher complication rates following

knee arthroplasty in those who are obese (BMI >30kg/m²), potentially delaying hospital discharge or necessitating return to surgery. Cost of care may also be increased due to the need to acquire or adapt mobility aids and other equipment and the need for additional therapy staff to safely mobilise obese patients.⁽⁷²⁾

3 Advice on clinical referral/treatment threshold

Taking account of the available evidence that exists in relation to osteoarthritis of the knee and its management with arthroplasty, the following threshold criteria are advised for referral and treatment within the publicly-funded healthcare system in Ireland:

These criteria are designed to distinguish between patients who would derive additional benefit from elective knee arthroplasty over conservative management in the primary care setting. Patients who present with 'red flag' signs or symptoms, suggestive of, for example, septic arthritis or malignancy, should continue to be referred for emergency or urgent assessment in secondary care.

All patients should have timely access to routine radiological investigations via primary care services. For those suspected of having knee osteoarthritis, plain film X-ray should be performed within three months.

The majority of patients with knee osteoarthritis should be managed conservatively in the first instance.

Where conservative management is indicated, this should be made available to patients at a time when they are most likely to derive benefit from this management.

The conservative management plan should be individualised following holistic assessment of individual patient need, and should include both pharmacologic and non-pharmacologic components.

Referral for opinion regarding the need for knee arthroplasty should be considered for patients:

- whose condition has not improved sufficiently following at least three months of conservative management in the primary care setting
- AND who have moderate or severe symptoms
- AND OR moderate to severe functional limitation, significantly affecting their quality of life

- AND who have a BMI less than ($<$) 40kg/m^2
- AND who are considered likely surgical candidates based on assessment of patient comorbidities
- AND who express a desire to proceed to surgery following discussion of the implications of undergoing knee arthroplasty.

If patients are symptomatic despite optimal conservative management in the primary care setting, and meet the other criteria above, referral should be made for review in secondary care even if X-rays suggest that there is only mild disease present.

Where patients have severe symptoms but where comorbidity / BMI / lack of desire for surgery mean that surgical referral is not currently appropriate, consideration should be given to the need for referral to a rheumatologist, geriatrician, or pain management consultant as appropriate.

All patients with a BMI of equal to or greater than (\geq) 40kg/m^2 should be referred for participation in a formal weight reduction programme, with onward referral to a bariatric surgical service where this is deemed appropriate.

Patients who do not meet these criteria should remain under the care of the general practitioner who will manage conservative treatment of the patient.

Whilst the exact nature of what constitutes optimal conservative management is beyond the scope of this assessment, options may include analgesia (pain killers), weight reduction and activity programmes, physiotherapy, shoe wear modification, and or advice in relation to activities of daily living.

4 Discussion

Referral thresholds have been developed based on a comprehensive review of the literature and international referral guidelines. The aim of these thresholds is to ensure that the right patients receive referral and treatment at the right time, and to avoid unnecessary interventions, particularly in those who are unlikely to derive additional benefit from surgery over conservative management. While referral thresholds may currently be used on an informal basis within the Irish system, this has not been done consistently. The thresholds developed here aim to provide primary care practitioners, surgeons and other clinicians involved in the care of these patients with a template upon which decision-making can be standardised. This requirement for standardisation is increasingly relevant as changing demographics and the increasing prevalence of both obesity and chronic disease place additional strain on the publicly-funded healthcare system. In this context, it is important to note that the introduction of the threshold above is not expected to impact on the number of surgeries undertaken. Rather, based on rising demand for health services, the need for knee arthroplasty (which has already increased by nearly 40% since 2005) will continue to grow, necessitating appropriate allocation of resources. This reflects international trends in terms of the growth in arthroplasty surgeries in other countries. It is also noted that the international literature suggests that total knee arthroplasty is a cost-effective use of resources in patients with severe disease, and may be cost-saving compared to delaying surgery.

One caveat to the effective implementation of referral thresholds in Ireland is the limited access to conservative treatment in the primary care setting. The provision of specialist musculoskeletal (MSK) services through the Orthopaedic and Rheumatology Clinical Programmes has clearly impacted on waiting lists for outpatient appointments in secondary care. At present, however, access to these services remains via referral into the secondary care system, where patients are then triaged according to need. Implementation of an MSK programme to support general practitioners and community physiotherapists in the primary care setting may provide one solution to the need for increased access to timely and appropriate conservative management in this setting. In addition, implementation of this threshold will require additional resources to be directed towards physiotherapists working in the primary care setting, such that patients can be assured timely access to a holistic, multidisciplinary programme of conservative management where appropriate.

It is acknowledged, in addition, that while the thresholds identified in this report suggest the need for optimal conservative management in the first instance, what constitutes optimal care remains open to question. Unfortunately, analysis of the related evidence base is beyond the scope of this present report.

It is further acknowledged that where a patient's BMI precludes them from being a candidate for arthroplasty, resources should be in place to ensure that those patients are offered formal weight reduction programmes and, where appropriate, access to a bariatric surgical service.

A key point noted in the international literature is the need for holistic assessment of the patient in the first instance. The literature also outlines the requirement that patients are not referred for a surgical opinion until there has been a discussion in relation to the pros and cons of surgical intervention and that they will be happy to proceed with surgery if considered suitable following assessment in secondary care. Both of these processes will require additional time over and above a routine appointment in primary care, and thus a further caveat to implementation of these guidelines is that this service is adequately resourced. In addition, the extent to which patients must wait for their arthroplasty once they have been listed for this procedure is currently unclear. While efficiencies have been achieved in terms of length of stay and the total number of procedures carried out, it is likely that waiting lists for surgical intervention remain substantial.

It is noted that while development of this threshold should aid in defining who should be referred for arthroplasty, the mechanisms around its practical implementation remain to be fully clarified. It is clear that the National Healthlink Project, which permits the secure transmission of clinical patient information between GPs and hospitals, has facilitated improved communication of referrals between primary and secondary care. It is thus suggested that one mechanism through which this referral threshold might be implemented would be through its integration in the form of a standardised referral form into this project. Of note, initiatives are underway by the orthopaedic and rheumatology clinical care programmes in the Health Service Executive (HSE) to develop interface clinics and consultations between primary and secondary care services in Ireland and to implement agreed national referral guidelines for all patients with musculoskeletal disease.

In conclusion, the thresholds outlined above are consistent with well established clinical guidelines and published evidence. Hence, they are unlikely to represent a major change from current practice, but rather a standardisation of referral and treatment criteria across all areas of the publicly-funded healthcare system. As with all thresholds, it is imperative that there are opportunities for appeal mechanisms to ensure good governance. In addition, while these thresholds represent best practice, their implementation will depend on timely access to both the full range of conservative treatment options and to radiology services, at the primary care level.

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Appendices

Appendix 1.1 – Examples of guidelines for the conservative management of osteoarthritis

Guideline	Recommendations
NICE ^{(73)*}	<pre> graph LR Root([Holistic assessment of person with OA]) --- Social Root --- HealthBeliefs[Health beliefs including concerns, expectations and current knowledge of OA] Root --- Occupational Root --- Mood Root --- QualityOfSleep[Quality of sleep] Root --- SupportNetwork[Support network] Root --- OtherPain[Other Musculo-skeletal pain] Root --- AttitudesToExercise[Attitudes to exercise] Root --- InfluenceOfComorbidity[Influence of comorbidity] Root --- PainAssessment[Pain assessment] Social --- EffectOnLife[Effect on life] Social --- LifestyleExpectations[Lifestyle expectations] EffectOnLife --- ADL[Activities of daily living] EffectOnLife --- FamilyDuties[Family duties] EffectOnLife --- Hobbies[Hobbies] Occupational --- AbilityToPerformJob[Ability to perform job] Occupational --- AdjustmentsToHomeOrWorkplace[Adjustments to home or workplace] AbilityToPerformJob --- ShortTerm[Short term] AbilityToPerformJob --- LongTerm[Long term] Mood --- ScreenForDepression[Screen for depression] Mood --- OtherCurrentStresses[Other current stresses in life] SupportNetwork --- IdeasConcerns[Ideas, concerns and expectations of main carer] SupportNetwork --- HowCarerCoping[How carer is coping] SupportNetwork --- Isolation[Isolation] OtherPain --- EvidenceOfChronicPain[Evidence of a chronic pain syndrome] OtherPain --- OtherTreatableSource[Other treatable source of pain] AttitudesToExercise --- InteractionOfMorbidities[Interaction of two or more morbidities] AttitudesToExercise --- Falls[Falls] InfluenceOfComorbidity --- AssessmentOfDrugTherapy[Assessment of most appropriate drug therapy] InfluenceOfComorbidity --- UnderstandingOfSurgicalOptions[Understanding of surgical options] InfluenceOfComorbidity --- FitnessForSurgery[Fitness for surgery] PainAssessment --- SelfHelpStrategies[Self-help strategies] PainAssessment --- Analgesics Analgesics --- DrugsDoses[Drugs, doses, frequency, timing] Analgesics --- SideEffects[Side effects] </pre>

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Guideline	Recommendations
BOA⁽⁴⁷⁾	<p>Core initial management for the majority of patients diagnosed with osteoarthritis:</p> <p>Access to appropriate information regarding the condition, advice to encourage activity and exercise and interventions to achieve weight loss if the patient is overweight.</p> <p>If further treatment is required then consideration should be given to the following additional non-pharmacological and pharmacological treatments, in light of the individuals person's needs and preferences: manual therapy (e.g. physiotherapy), supports and braces, shock absorbing shoes or insoles, local heat and cold therapy, non-steroidal anti-inflammatory medication (topical or oral) or COX-2 inhibitors (with a proton pump inhibitor), opioid medication.</p> <p>Patients should be encouraged to refer to the NHS shared decision-making tool for osteoarthritis of the knee.</p> <p>Patients with symptomatic knee osteoarthritis require regular long-term review of symptoms.</p>
Guideline	Recommendations
AAOS⁽³⁷⁾	<p>We recommend that patients with symptomatic osteoarthritis of the knee participate in self-management programmes, strengthening, low-impact aerobic exercises, and neuromuscular education; and engage in physical activity consistent with national guidelines.</p> <p>We suggest weight loss for patients with symptomatic osteoarthritis of the knee and a BMI ≥ 25.</p> <p>We cannot recommend using acupuncture in patients with symptomatic osteoarthritis of the knee.</p> <p>We are unable to recommend for or against the use of physical agents (including electrotherapeutic modalities) in patients with symptomatic osteoarthritis of the knee.</p> <p>We are unable to recommend for or against manual therapy in patients with osteoarthritis osteoarthritis of the knee.</p> <p>We are unable to recommend for or against the use of a valgus directing force brace (medial compartment unloader) for patients with symptomatic osteoarthritis of the knee.</p> <p>We cannot suggest that lateral wedge insoles be used for patients with symptomatic medial compartment osteoarthritis of the knee.</p> <p>We cannot recommend using glucosamine and chondroitin for patients with symptomatic osteoarthritis of the knee.</p> <p>Pharmacologic Treatments: We recommend non-steroidal anti-inflammatory drugs (NSAIDs; oral or topical) or tramadol for patients with symptomatic osteoarthritis of the knee.</p> <p>We are unable to recommend for or against the use of acetaminophen, opioids, or pain patches for patients with symptomatic osteoarthritis of the knee.</p>

	<p>Procedural Treatments: We are unable to recommend for or against the use of intra-articular (IA) corticosteroids for patients with symptomatic osteoarthritis of the knee.</p> <p>We cannot recommend using hyaluronic acid for patients with symptomatic osteoarthritis of the knee.</p> <p>We are unable to recommend for or against growth factor injections and/or platelet rich plasma for patients with symptomatic osteoarthritis of the knee.</p> <p>We cannot suggest that the practitioner use needle lavage for patients with symptomatic osteoarthritis of the knee.</p>
Guideline	Recommendations
<p>OARSI, 2008⁽⁴¹⁾ (Sample of Recommendations)</p>	<p>Optimal management of osteoarthritis requires a combination of non-pharmacological and pharmacological modalities.</p> <p>Patients with symptomatic hip and knee osteoarthritis may benefit from referral to a physical therapist for evaluation and instruction in appropriate exercises to reduce pain and improve functional capacity.</p> <p>Patients with hip and knee osteoarthritis should be encouraged to undertake, and continue to undertake, regular aerobic, muscle strengthening and range of motion exercises.</p> <p>Patients with hip and knee osteoarthritis, who are overweight, should be encouraged to lose weight and maintain their weight at a lower level.</p> <p>In patients with knee osteoarthritis and mild/moderate varus or valgus instability, a knee brace can reduce pain, improve stability and diminish the risk of falling</p>
Guideline	Recommendations
<p>OARSI, 2014⁽⁴⁰⁾ (Key updates)</p>	<p>Topical NSAIDs are recommended as appropriate for all patients with knee-only osteoarthritis and in a scientific review, were found overall to be safer and better tolerated compared to oral NSAIDs.</p> <p>The prescription drug duloxetine was evaluated for the first time and found to be an appropriate treatment for knee-only osteoarthritis patients without comorbidities and all multi-joint osteoarthritis patients.</p> <p>Due to increased safety concerns about toxicity, acetaminophen or paracetamol was given an 'uncertain' recommendation for all patients with comorbidities.</p> <p>Oral and transdermal opioid painkillers were given an 'uncertain' recommendation for all patient groups due to concerns about increased risks for adverse and serious adverse events.</p> <p>Glucosamine and chondroitin were both found to be 'not appropriate' for all patients when used for disease modification and 'uncertain' for all patients when used for symptom relief.</p> <p>Balneotherapy, defined as using baths containing thermal mineral waters, was</p>

	<p>evaluated for the first time and found to be an appropriate therapy for patients with multi-joint osteoarthritis and comorbidities, as this group has few other treatment options.</p>
<p>March et al, 2008⁽³⁾ (Key recommendations)</p>	<p>Provide advice about, and offer access to appropriate information for OA self-management and lifestyle change.</p> <p>Provide advice about weight loss if patient is overweight or obese and refer to services as required.</p> <p>Provide advice for land-based exercises incorporating aerobic and strengthening components and refer to services as required.</p> <p>Recommend adequate paracetamol for pain relief.</p> <p>Make patients aware that non-steroid anti-inflammatory drugs (NSAIDs) or coxibs can improve symptoms in majority but this comes with potential for harm and that risk potential varies – be aware of and minimise the individual’s risk potential.</p> <p>Offer intra-articular steroids for short-term relief of a flare or acute deterioration in symptoms.</p> <p>Offer stronger analgesic relief if prolonged severe symptoms.</p> <p>Offer access to assessment for arthroplasty for consumers with severe symptomatic osteoarthritis not responding to conservative therapy.</p>

Appendix 1.2 – HIPE ICD-10AM/ACHI list of intervention codes for knee arthroplasty procedures

Intervention code	Description
49517-00	Hemiarthroplasty of knee (partial joint/unicompartmental joint replacement)
49518-00	Total arthroplasty of knee, unilateral
49519--00	Total arthroplasty of knee, bilateral
49534-01	Total replacement arthroplasty of patellofemoral joint
49521-00	Arthroplasty of knee with bone graft to femur, unilateral
49521-01	Arthroplasty of knee with bone graft to femur, bilateral
49521-02	Arthroplasty of knee with bone graft to tibia, unilateral
49521-03	Arthroplasty of knee with bone graft to tibia, bilateral
49524-00	Arthroplasty of knee with bone graft to femur and tibia, unilateral
49524-01	Arthroplasty of knee with bone graft to femur and tibia, bilateral

Appendix 1.3 – Western Canada Waiting List Project – Hip and Knee Replacement Surgery, Priority Criteria Tool⁽⁶⁶⁾

Patients must be on appropriate non-surgical treatment prior to evaluation (e.g. medications, walking aids, shoe inserts)

Please check the box that most accurately describes the patient's current situation

1. Pain on motion (e.g. walking, bending): *

- None/mild (0)
- Moderate (6)
- Severe (13)

2. Pain at rest (e.g. while sitting, lying down, or causing sleep disturbance): *

- None (0)
- Mild (3)
- Moderate (8)
- Severe (11)

* Take into account usual duration, intensity, and frequency of pain, including need for narcotic vs. non-narcotic medication.

3. Ability to walk without significant pain :

- Over 5 blocks (0)
- 1-5 blocks (0)
- <1 block (4)
- Household ambulator (7)

4. Other functional limitations (e.g. putting on shoes, managing stairs, sitting to standing, sexual activity, bathing, cooking, recreation or hobbies):

- No limitations (0)
- Mild limitations - able to do most activities with minor modifications or difficulty (4)
- Moderate limitations - able to do most activities with modification or assistance (11)
- Severe limitations - unable to perform most activities (19)

5. Abnormal findings on physical exam related to affected joint (e.g. deformity, instability, leg length difference, restriction of range of motion on examination):

- None/mild (0)
- Moderate (5)
- Severe (10)

6. Potential for progression of disease documented by radiographic findings (e.g. recurrent dislocation, X-ray evidence of protrusion, significant bone loss, component wear, impending fracture):**

- None (0)
- Mild (4)
- Moderate (11)
- Severe (20)

** Predominantly applies to revisions, use in primary cases only in special circumstances (e.g. ligament instability, bone loss)

7. Threat to patient role and independence in society (i.e. ability to work, give care to dependants, live independently (difficulty must be related to affected joint)):

- Not threatened but more difficult (0)
- Threatened but not immediately (10)
- Immediately threatened or unable (20)

8. All things considered, how would you rate the urgency or relative priority of this patient?
(Draw a line across the scale.)

Not Urgent at all _____ Extremely Urgent
(just short of an emergency)

Appendix 1.4 – The Oxford Knee Score⁽⁷⁴⁾

On which side of your body is the affected joint, for which you are receiving treatment.

Left • Right • Both •

If you said 'both', please complete the first questionnaire thinking about the right side. A second questionnaire, for the left side, will follow.

PROBLEMS WITH YOUR KNEE

Tick (•) one box for every question.

1. During the past 4 weeks...

How would you describe the pain you usually have from your knee?

None Very mild Mild Moderate Severe

2. During the past 4 weeks...

Have you had any trouble with washing and drying yourself (all over) because of your knee?

No trouble at all Very little trouble Moderate trouble Extreme difficulty Impossible to do

3. During the past 4 weeks...

Have you had any trouble getting in and out of a car or using public transport because of your knee? (whichever you would tend to use)

No trouble at all Very little trouble Moderate trouble Extreme difficulty Impossible to do

4. During the past 4 weeks...

For how long have you been able to walk before pain from your knee becomes severe? (with or without a stick)

No pain/More than 30 minutes 16 to 30 minutes 5 to 15 minutes Around the house only

Not at all/pain severe when walking

5. During the past 4 weeks...

After a meal (sat at a table), how painful has it been for you to stand up from a chair because of your knee?

Not at all painful Slightly painful Moderately painful Very painful Unbearable

6. During the past 4 weeks...

Have you been limping when walking, because of your knee?

Rarely/never Sometimes, or just at first Often, not just at first Most of the time All of the time

7. During the past 4 weeks...

Could you kneel down and get up again afterwards?

Yes, easily With little difficulty With moderate difficulty With extreme difficulty No, impossible

8. During the past 4 weeks...

Have you been troubled by pain from your knee in bed at night?

No nights Only 1 or 2 nights Some nights Most nights Every night

9. During the past 4 weeks...

How much has pain from your knee interfered with your usual work (including housework)?

Not at all A little bit Moderately Greatly Totally

10. During the past 4 weeks...

Have you felt that your knee might suddenly 'give way' or let you down?

Rarely/never Sometimes, or just at first Often, not just at first Most of the time All of the time

time

11. During the past 4 weeks...

Could you do the household shopping on your own?

Yes, easily With little difficulty With moderate difficulty With extreme difficulty No, impossible

12. During the past 4 weeks...

Could you walk down one flight of stairs?

Yes, easily With little difficulty With moderate difficulty With extreme difficulty No, impossible

Each question is scored from 1 to 5, with 1 representing the best outcome/least symptoms. The scores from each question were added so that the overall figure lies between 12 and 60, with 12 being the best outcome. An alternative scoring system scores each question between 0 and 4, with 4 being the best outcome, producing overall scores running from 0 to 48, with 48 being the best outcome.⁽⁷⁵⁾

Appendix 1.5 – Primary Care Trust Thresholds for Knee Arthroplasty

Primary Care Trust	Threshold
<p>NHS Black Country Cluster, 2012</p>	<p>As per NICE guidance, prosthesis should only be used if the evidence shows they require revision at a rate of less than 1 in 10 (10%) in 10 years.</p> <p>For patients with a BMI (body mass index) of 40 and above, documented participation in a comprehensive weight management programme of at least six months' duration is required prior to surgery. Minimum Eligibility Criteria:</p> <p>The patient has a BMI below 40 supported by a primary care referral.</p> <p>AND Conservative means (e.g. Analgesics [painkillers], NSAIDs, physiotherapy, advice on walking aids, home adaptations, curtailment of inappropriate activities and general counselling as regards to the potential benefits of joint replacement) have failed to alleviate the patients pain and disability</p> <p>AND Pain and disability should be sufficiently significant to interfere with the patient's daily life and or ability to sleep/patients whose pain is so severe</p> <p>AND Underlying medical conditions should have been investigated and the patient's condition optimised before referral</p> <p>AND Patient must accept and want surgery</p> <p>Or Mobility is so compromised that they are in immediate danger of losing their independence and that joint replacement would relieve this threat</p> <p>Or Patients in whom the destruction of their joint is of such severity that delaying surgical correction would increase technical difficulty of the procedure.</p>
<p>Worcestershire, 2011</p>	<p>Patients should only be considered for joint replacement surgery if there is evidence to suggest:</p> <p>Their symptoms* have failed to respond to the conservative treatments undertaken within primary care, that is, analgesia, non-steroidal anti-inflammatory drugs and physiotherapy.</p> <p>* Should include pain and disability that is sufficiently significant to interfere with the patient' daily life and or ability to sleep.</p> <p>The referral has been endorsed by ICATS/Orthopaedic Practitioner Service (OPS).</p> <p>The patient has an Oxford Hip or Knee Score of less than 30 (see note 1 below).</p> <p>A score of less than 30 is considered to be a guide only and if, following assessment by an orthopaedic surgeon, surgery is considered to be clinically necessary in a patient with a score of more than 30, THR/TKR will be supported.</p> <p>The patient has been assessed as fit, ready and willing to undergo surgery if required.</p>

	<table border="1"> <thead> <tr> <th data-bbox="461 257 595 324">Score</th> <th data-bbox="595 257 967 324">Hip</th> <th data-bbox="967 257 1358 324">Knee</th> </tr> </thead> <tbody> <tr> <td data-bbox="461 324 595 613">0 to 19</td> <td data-bbox="595 324 967 613">May indicate severe hip arthritis. It is highly likely that you may well require some form of surgical intervention, contact your family physician for a consult with an orthopaedic surgeon.</td> <td data-bbox="967 324 1358 613">May indicate severe knee arthritis. It is highly likely that you may well require some form of surgical intervention, contact your family physician for a consult with an orthopaedic surgeon.</td> </tr> <tr> <td data-bbox="461 613 595 860">20 to 29</td> <td data-bbox="595 613 967 860">May indicate moderate to severe hip arthritis. See your family physician for an assessment and X-ray. Consider a consult with an orthopaedic surgeon.</td> <td data-bbox="967 613 1358 860">May indicate moderate to severe knee arthritis. See your family physician for an assessment and X-ray. Consider a consult with an orthopaedic surgeon.</td> </tr> </tbody> </table> <p data-bbox="446 864 1382 1021">Note: Only ONE routine follow-up to be offered following the six-week review. Note 1: TKR is cost-effective for all ASA grade 1-2 patients with baseline OKS <40 and for ASA grade 3 patients with OKS <35 and patients should be considered for surgery on this basis. (Dakin H, Gray A, Fitzpatrick R, et al. BMJ Open 2012;2:e000332. doi:10.1136/bmjopen-2011-000332.)</p>	Score	Hip	Knee	0 to 19	May indicate severe hip arthritis. It is highly likely that you may well require some form of surgical intervention, contact your family physician for a consult with an orthopaedic surgeon.	May indicate severe knee arthritis. It is highly likely that you may well require some form of surgical intervention, contact your family physician for a consult with an orthopaedic surgeon.	20 to 29	May indicate moderate to severe hip arthritis. See your family physician for an assessment and X-ray. Consider a consult with an orthopaedic surgeon.	May indicate moderate to severe knee arthritis. See your family physician for an assessment and X-ray. Consider a consult with an orthopaedic surgeon.
Score	Hip	Knee								
0 to 19	May indicate severe hip arthritis. It is highly likely that you may well require some form of surgical intervention, contact your family physician for a consult with an orthopaedic surgeon.	May indicate severe knee arthritis. It is highly likely that you may well require some form of surgical intervention, contact your family physician for a consult with an orthopaedic surgeon.								
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Swindon, 2012	<p data-bbox="432 1025 1035 1057">Criteria for routine referral to orthopaedic services:</p> <p data-bbox="432 1097 1398 1223">Moderate to severe persistent pain not adequately relieved by an extended course of non-surgical management AND clinically significant functional limitation resulting in a diminished quality of life AND radiographic evidence of joint damage.</p> <p data-bbox="432 1263 927 1294">Thresholds for knee replacement surgery:</p> <ol data-bbox="432 1335 1402 1861" style="list-style-type: none"> 1. Where the patient complains of: <ol style="list-style-type: none"> a. Intense or severe symptomatology. b. AND has radiological features of severe disease. c. AND has demonstrated disease within all three compartments of the knee (tri-compartmental) or localised to one compartment plus patello-femoral disease (bi-compartmental). 2. Where the patient complains of: <ol style="list-style-type: none"> a. Intense or severe symptomatology. b. AND has radiological features of moderate disease. c. AND is troubled by limited mobility or stability of the knee joint. 3. Where the patient complains of: <ol style="list-style-type: none"> a. Severe symptomatology. b. AND has radiological features of slight disease. c. AND is troubled by limited mobility or stability of the knee joint. <p data-bbox="432 1895 1386 1926">OR Oxford score is ≤ 20 on the 0 to 48 system, or ≥ 40 on the 60 to 12 system.</p> <p data-bbox="432 1960 1386 2016">Note that all reasonable weight management attempts should have been tried if BMI is > 30.</p>									

Appendix 1.6 – Commissioning Guide, BOA/RCSEng/BASK⁽⁴⁷⁾

Emergency referral to secondary care (same day)

Knee pain in association with a red warm joint, with acute restriction in range of movement and fever, leading to suspicion of septic arthritis.

Urgent referral to secondary care

If a patient presents with knee pain in association with any red flag symptoms or signs (<2/52):

- History of previous malignancy.
- Localised hard mass adjacent to the knee.
- Unexplained weight loss.
- Severe night pain not controlled by analgesia.
- New symptoms of inflammation in several joints suggesting systemic inflammatory joint disease (rheumatology referral).

If the patient's history includes trauma or an injury, then the patient should progress down your local knee injury pathway.

Referral for consideration of knee surgery (joint replacement or joint preserving surgery).

- Refer patients with moderate or severe symptoms that are refractory for up to three months of non-surgical treatment.
- When considering referral for surgery use NICE guidance on management of patients with OA. Patients should have received core and at least one additional non-operative therapy.
- Consider referral for joint replacement surgery for people with osteoarthritis who experience joint symptoms (pain, stiffness and reduced function) that have a substantial impact on their quality of life and are refractory to non-surgical treatment.
- Decisions on referral thresholds should be based on discussions between patient representatives, referring clinicians and surgeons, rather than using current scoring tools for prioritisation.
- Refer patients before there is prolonged and established functional limitation and severe pain.
- Patient specific factors such as age, gender, smoking, obesity and comorbidity should not be barriers to referral.
- Consider optimisation of modifiable systemic or local risk factors that may delay surgical treatment prior to referral (e.g. investigation and treatment of anaemia or leg ulcers).
- Refer patients with osteoarthritis of the knee who are refractory to non-operative treatment regardless of the radiographic grade of disease.
- Referral can be made to an intermediate care service or direct to secondary care.

The Guideline adopts a definition of 'Intermediate Care' as those services that do not require the resources of a general hospital, but are beyond the scope of the traditional primary care team. Those services provided by intermediate care can include assessment, non-surgical treatment programmes,

referral to secondary care and postoperative care. The Guideline notes that interventions should only be introduced in the intermediate care setting if the likelihood of helping patients is high. If not, referral should be considered such that delay in diagnosis or treatment can be avoided. It also encourages the use of decision aids to foster shared decision making.

Referral to secondary care, from intermediate care, is suggested:

- Where there is persistent pain and disability not responding to three months of evidence-based non-surgical treatment.
- Referral to secondary care should follow NICE guidance as laid out above for primary care.

The decision to undergo surgery is based on symptom pattern, with the type of surgery determined by the pattern of joint damage and the patient's preference. All patients must have engaged in a shared decision-making process about alternatives.

The Guideline then breaks down surgical indications into four categories, namely TKR, partial knee replacement, high tibial osteotomy and knee arthroscopy, the latter being recommended only for those with mechanical symptoms (see separate HIQA HTA entitled Knee Arthroscopy). Total and partial knee replacement, and high tibial osteotomy are recommended in specific instances, but none are recommended unless there persists moderate or severe knee pain not adequately controlled by three months of non-surgical management, following NICE guidance. Specific indications for each procedure are given in Appendix 1.6.⁽⁴⁷⁾

Surgical option: Total knee replacement

Total knee replacement is highly clinically effective and cost effective. Joint survival is 95% at seven years. It should be considered for patients with:

Moderate or severe knee pain not adequately controlled by three months of non-surgical management, following NICE guidance.

Evidence of exposed bone present in at least one of the knee joint compartments (Kellgren-Lawrence [KL] Grade III and above).

Patients outside these criteria may still be considered for surgery but a second opinion/recorded case discussion is advised. Cases focus on patients without pain (the primary indication) but who present with:

Functional disability in the presence of end-stage cartilage disease.

Progressive deformity of the knee (varus/valgus) with functional disability.

Surgical option: *Partial knee replacement*

In this procedure only one compartment of the arthritic knee is replaced. It can be considered for patients with:

Moderate or severe knee pain not adequately controlled by three months of non-surgical

management, following NICE guidance.

Grade III and above arthritis confined to a single joint compartment.

Partial joint replacement can also provide good outcome but the survival is lower than total knee replacement. Advantages are faster recovery, reduced morbidity, and reduced 90-day mortality. As partial knee replacement is less common it is more appropriately commissioned and delivered by more specialised units, with experienced surgeons, performing around 20 such procedures within a unit per year.

Surgical option: *High tibial osteotomy*

High tibial osteotomy involves removing or adding bone to realign the limb and offload the knee. It is effective and can provide functional outcomes similar to those seen after joint replacement. The post-operative failure-rate at 10 years is around 30%. There is no published cost-effectiveness data. It can be technically demanding and not all providers will be able to offer this service. It should be considered for patients with:

Moderate to severe knee pain not adequately controlled by three months of non-surgical management, following NICE guidance.

Varus misalignment in medial unicompartmental knee osteoarthritis and this is the main indication for high tibial osteotomy (HTO).

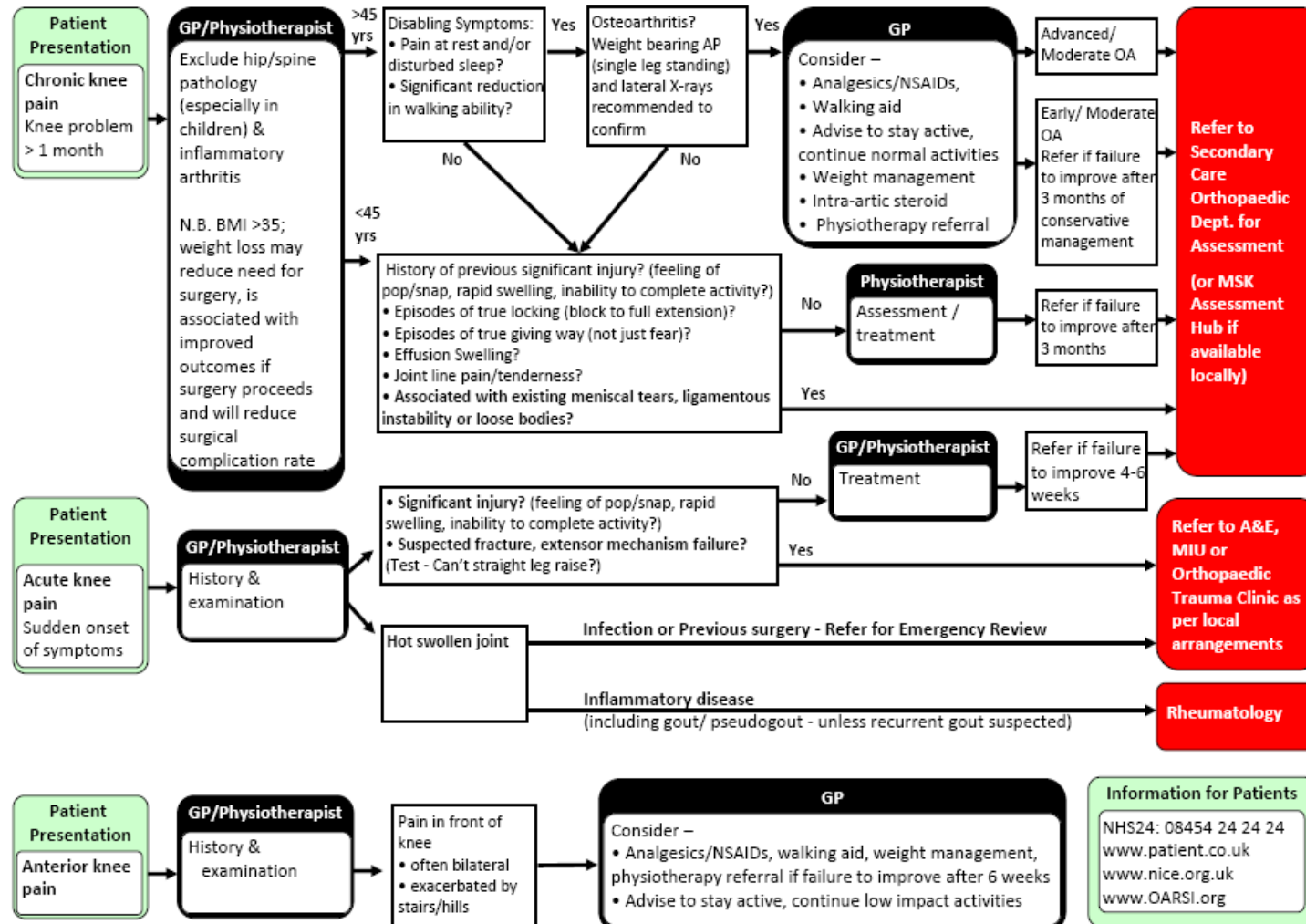
Diagnosis of knee osteoarthritis (Kellgren-Lawrence grade 1-3) isolated to one compartment, usually the medial side.

In younger patients as the outcome for partial or total knee replacement is not as successful as in older patients.

The decision as to whether patients should have high tibial osteotomy rather than UKR or TKR remains a clinical one as good comparative evidence is not available.

Appendix 1.7 – Scottish Knee Pain Referral and Management Pathway⁽⁴⁸⁾

Musculoskeletal – Knee Pain Referral and Management Pathway – Update March 2013



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