British Orthopaedic Association PATRON: H.R.H. THE PRINCE OF WALES

PRIMARY TOTAL HIP REPLACEMENT: A GUIDE TO GOOD PRACTICE

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PREFACE

Total hip replacement has been one of the most spectacularly successful innovations in modern medicine and in the United Kingdom over 80,000 such operations was carried out in 2011 and the number continues to rise¹⁻³.

This is the revised version of the original document produced under the leadership of Hugh Phillips in October 1999, and subsequently revised under the stewardship of James Nixon in 2006⁴.

We know that the first two editions of this document have been of help to clinicians in setting standards of patient care and have led the way in development of other good practice guidelines in orthopaedics.

The first version acknowledged that it was an interim statement, and thirteen years later we are addressing the changes in practice and environment that have occurred. The object of this guide is to ensure the best possible care for patients undergoing primary total hip replacement in the United Kingdom.

As with the first two editions, it is hoped that this guide will inform surgeons, primary and secondary healthcare providers and commissioners. It is not designed to inform patients but it may form the basis for patient-focussed information. This edition of the guide will also require revision in time; we suggest a review every 7 years.

Primary total hip replacement as described in this document includes any procedure on the hip joint that entails the insertion of artificial bearing surfaces. This includes both the 'classical' total hip replacement and hip resurfacing.

The standards laid down in this document apply to the practice of primary hip replacement in any setting, be it the National Health Service (NHS), Private Practice or elsewhere.

The creation of such a consensus document involves help from many experts. We acknowledge and thank those who have made this task possible. Their names are recorded in the appendices.

Gordon Bannister and BHS Executive 2012

DISCLAIMER

This good practice guidance is of a general nature and is not intended to be a substitute for professional medical advice, diagnosis, treatment or care. This guidance is intended for suitably qualified medical practitioners. The British Orthopaedic Association and the British Hip Society disclaim any and all liability from any injury, loss, or damage or any kind resulting from actions taken or omissions made by any person relying on this guidance.

PROBITY

Surgeons and the service within which they work may receive external financial support for education or research. In many cases this support takes the form of training visits or courses on new or developing techniques. In other situations support may be given for research or audit within a department which would not be possible within existing NHS resources. An innovative surgeon may develop a technique, implant or instrument that is unique; while it is appropriate that they should be able to receive some recompense for this in proportion to the time spent, it is important that all such dealings are transparent and declared to patients in receipt of such innovations as part of informed consent.

It is recommended that, where such support, either financial or in kind (travelling expenses, lecture fees, accommodation, research or audit support, either directly or indirectly through separate trusts or charities) exceeds a total of £500, this be declared in writing. It is not necessary to declare the exact amount, but the sources and amount of each sum received should be noted as part of the appraisal process to ensure that the surgeon's employers are aware of and have recorded the declaration.

Where there appears to be doubt about the relevance of declaration it is good practice to declare.

All monies received personally by the surgeon should be declared.

Surgeons should also be aware of their responsibilities regarding financial interest when conducting clinical research which has received proper ethical approval.

1. **<u>THE INTRODUCTION</u>**

- 1.1 This document is a statement of current best practice in primary total hip replacement (THR) and metal-on-metal hip resurfacing (MOMR) in the United Kingdom (UK) in all settings. It has been approved by the Council of the British Orthopaedic Association (BOA) and by the Executive and Members of the British Hip Society (BHS).
- 1.2 Many studies of THR identify the cost-effectiveness and high levels of patient satisfaction rates in the short term. Most patients are relieved of pain and disability, which has often compromised their quality of life and independence^{3,5-7}.
- 1.3 Data regarding the outcomes of MOMR are of shorter duration but they suggest that it is an effective procedure for young male patients^{5,7}. Concerns have been raised about the results in female patients; particularly those over 50 years of age, and some implant designs have demonstrated poorer results than others⁸⁻¹¹. Where MOMR is to be performed, use of a well-proven design is recommended¹¹.
- 1.4 There is variation in the types of implants used for THR and MOMR (the Operation). Surgical techniques employed and post-operative follow-up techniques vary. There remains considerable variation in length of stay and nursing practice, although the development of Integrated Care Pathways (ICPs) has been helpful^{6,12}.
- 1.5 This document attempts to identify best practice in general terms, using available evidence. It does not claim to apply to all patients and in all circumstances. Each consultant, or those within a surgical team, must continue to take into account the individual requirements of a patient. There remains a lack of standards for the operation and associated care, but the development of ICPs and the creation of the National Joint Register (NJR)⁸ and the Scottish Arthroplasty Project (SAP)¹³ is helping to address this.
- 1.6 This document should be read in conjunction with the BOA Advisory Book on Consultant Trauma and Orthopaedic Services, 2007¹⁴.
- 1.7 The patient's treatment should be in a setting wherein satisfactory standards of Clinical Governance are applied¹⁵.

2. <u>THE INDICATIONS FOR REFERRAL FOR THE OPERATION</u>

- 2.1 Pain and disability arising from degenerative (osteoarthritis) or inflammatory arthritis in the hip joint are the indications for the operation. In most cases other non-operative treatment will have failed or proved to be futile.
- 2.2 The incidence of the condition varies throughout the regions of the UK^{16,17}. Factors predisposing to the development of joint failure due to osteoarthritis are many and include genetic factors, inflammatory arthritis, occupation, injury and lifestyle.
- 2.3 The capacity of the local orthopaedic service to perform these procedures may influence referral patterns to that service. It is recommended that local referral pathways are developed with Commissioners of secondary care, possibly as part of Integrated Care Pathways (ICPs)¹². Some centres use scoring systems such as those developed in New Zealand¹⁸ to help general practitioners assess whether a patient has reached a stage that would justify referral for surgical intervention but subjective scoring systems and reliance on radiographs are of limited value and inferior to clinical assessment¹⁹. Even if such scoring systems are employed, referral for a consultant orthopaedic opinion is recommended for patients with significant symptoms (pain and disability), or where there are concerns.
- 2.4 Some patients deteriorate very rapidly and referral guidelines should be developed to help identify these patients and arrange for more rapid referral to the orthopaedic service.
- 2.5 The general practitioner (GP) should be aware of the general health of any patient and their willingness to undergo surgery before referring to the local orthopaedic service, and any significant health problems should be corrected as far as possible before that referral is made.
- 2.6 Increasingly, fracture of the proximal femur (particularly of the intra-capsular part of the neck) is an indication for the operation^{20,21}. These standards apply equally to the care of such patients.

3. <u>THE OUTPATIENT CONSULTATION</u>

- 3.1 Usually the patient will have attended their GP who will seek the opinion of a consultant orthopaedic surgeon. Waiting time for an outpatient consultation is variable throughout the UK, although should be within the 18 week guidelines, and is a reflection of many factors including the number of orthopaedic surgeons serving the local population^{22,23}.
- 3.2 The consultation with the orthopaedic surgeon should include history taking, examination, and provision of good quality X-rays films or images. As well as a routine anterior-posterior view, the surgeon may also require a lateral view. The BOA regards 20-30 minutes as the minimum time allowable for a first consultation¹⁴. The patient must feel that adequate time has been allowed for this consultation.
- 3.3 A suitable environment for discussion with the patient and relatives should be provided, and all relevant notes and investigations, including imaging, should be available.
- 3.4 Whilst the initial discussions and assessment regarding the possibility of operative management of the hip disease may be undertaken by an orthopaedic trainee, arthroplasty care practitioner or other member of the orthopaedic multidisciplinary team, the final decision should always involve a consultant who has a Certificate of Completion of Specialist Training (CCST in Trauma and Orthopaedics) and is on the General Medical Council (GMC) specialist register. The discussion should take place before the patient is offered the operation and with the patient's agreement their name is placed on the waiting list for operation.
- 3.5 Patients should have the risks and benefits of the operation explained in understandable language. An individual patient may have added risk factors present (such as cardio-vascular disease, obesity, predisposition to venous thromboembolism, neurological disease or diabetes) and should be made aware of the added risks when these factors are present. The surgeon should try to verify that the patient has understood the information.
- 3.6 Patients should be aware that they make the decision whether or not to undergo surgery. Failure of the hip joint as a result of arthritis is not a life or limb-threatening disease, but patients should appreciate that the operation generally carries a 30 day mortality rate of about 0.2% and a 90 day mortality of 0.5% and that these rates vary by age and gender.^{1,24,25} Furthermore, the observed medium and long-term mortality is significantly higher in patients who are older than 80 years at the time of surgery when compared to younger counterparts¹. It is however difficult to determine how much of this excess mortality in octogenarians is associated specifically with undergoing surgery since these patients generally have a higher risk of death nevertheless.
- 3.7 The patient should be made aware that there is the option of not having an operation, and some other procedures may be possible in appropriate cases. [See 5.3]
- 3.8 Some centres have a process whereby other practitioners may place a patient's name on the waiting list for operation. Such an arrangement should involve a team approach and it is essential that a consultant orthopaedic surgeon meeting the standards in 3.4 is involved in the process. This process should be reviewed regularly.
- 3.9 Although the consenting process commences at the initial outpatient consultation, the patient should also be encouraged to read information leaflets, ask questions and review on line information at www.boa.ac.uk and the British Hip Society at www.britishhipsociety.com

4. WAITING FOR THE OPERATION

- 4.1 Consultants and their managers are expected to manage their waiting lists ethically^{26,27}, and patients should be admitted for operation according to clinical priority and length of time on the waiting list. Social circumstances may occasionally be a factor to be borne in mind in assessing priority.
- 4.2 Procedures have been developed to identify patients deserving priority for earlier admission¹⁸. These have achieved mixed results and are not agreed or applied generally. It is the aim of all NHS Trusts that the process of referral, assessment, discussion, decision and surgery takes place within the 18 week target in a 'medically fit' patient with primary osteoarthritis of the hip. It is recognized however that not all patients will fall within the 'medically fit' category and will require additional assessment which should be provided expeditiously to avoid cumulative delay.

5. <u>PRE-ADMISSION ASSESSMENT</u>

- 5.1 A managed system of pre-admission assessment is best practice²⁸. This assessment should take place within six weeks of the operation.
- 5.2 Pre-admission clinics should be staffed by doctors and other clinicians (usually nurses) working to agreed protocols. The presence of anaesthetists at the assessment may help to prevent cancellations, through identification of co-morbidities and anaesthetic risk factors [See 3.5]. Attendance by Allied Health Professionals (AHPs), such as physiotherapists, occupational therapists, pharmacists and social workers may improve the efficiency of hospital admission, rehabilitation and discharge planning. There is also an opportunity for patient education, particularly with regard to the risks and benefits of the operation. At this stage identification of goals for that patient can be discussed.
- 5.3 Fully-informed consent for the procedure and the collection of patient details for local or national registries is best obtained at this stage by the surgeon or a senior member of the team trained to do so^{29,30}.
- 5.4 Routine investigations of blood, urine (including mid-stream specimen), blood pressure and relevant microbiological assessment (including detection of organisms such as MRSA) are best carried out at this assessment. The patient should be made aware of local policy regarding blood transfusion following the operation.
- 5.5 General health screening by the general practitioner will help to detect significant clinical problems before the pre-admission assessment and will help to identify those patients that may require additional investigation at that time.
- 5.6 Provisional discharge planning should take place. This takes into consideration age, comorbidities, home circumstances and availability of carers after discharge from hospital. To avoid last minute cancellations, patients should be telephoned shortly before admission to exclude factors that may prevent surgery such as change of mind, colds, infections or failure to receive letters from the hospital.
- 5.7 As same-day admission and early discharge has become the norm, all these arrangements become vital for the safe passage of the patient through the service.
- 5.8 Information about the operation may be given to the patient or relatives in leaflet or pamphlet form. It should be constructed in language that is understandable to the patient^{31,32}.
- 5.9 A process should be in place to ensure that all patient-related information is available at the time of admission. This applies especially to any investigations that may have been deemed necessary at the pre-admission assessment.
- 5.10 Patients considered unfit to undergo the operation and requiring further treatment or investigation should be suspended from the active surgical waiting list according to agreed national guidelines³³.

6. HOSPITAL ADMISSION

- 6.1 Patients should be admitted to hospital with adequate time before operation to allow routine pre-operative and pre-anaesthetic procedures to be completed.
- 6.2 The limb on the operation side should be indelibly marked by the surgeon, or a member of the surgical team, in an area which should be visible during preparation in the operating theatre.
- 6.3 A pre-operative visit by a member of the anaesthetic team may be appropriate in order to explain details of this part of the process to the patient, although a large part of this may have been covered in pre-assessment.
- 6.4 The patient must give written consent to the operating surgeon or senior medical member of the team and this consent is best given at the preadmission assessment. The Royal College of Surgeons of England gives guidance for surgeons in this process³⁴. [See 5.3]
- 6.5 The World Health Organisation (WHO) checklist should be utilised at the beginning of all cases

7. <u>HOSPITAL STAFF AND IN-PATIENT FACILITIES</u>

- 7.1 The operation is most safely carried out in hospitals where consultant support from other medical and surgical disciplines is readily available.
- 7.2 Access to a high dependency unit (HDU) or intensive care unit (ICU) is desirable. Such units should have nursing staff trained in the management of orthopaedic patients.
- 7.3 Adequate numbers of trained orthopaedic nurses and members of AHPs, especially physiotherapists, must be available. There must be adequate social services support.
- 7.4 Patients should be nursed in dedicated elective orthopaedic wards away from potential sources of cross-contamination from patients with infections and staffed by a team experienced in the management of patients with musculoskeletal disease.

7.5 Nursing staff will explain the process to the patient as part of an ICP10.

- 7.6 The risk of cross-infection in hospital should be reduced to a minimum. Facilities must be available for isolating patients known to be infected with, or carrying, pathogenic organisms³⁵. [See 5.4]
- 7.7 Pre- and post-operative group therapy 'classes' permit efficient use of physiotherapy and other AHP staff. The patient may benefit from the contact with others who have had a similar experience.

8. <u>OPERATING THEATRE RESOURCES</u>

- 8.1 Infection following operation is catastrophic for the patient and expensive to the Health Care provider.
- 8.2 Compared with conventional plenum ventilated theatres, ultra-clean air reduces the rate of deep infection by 2.8³⁶. Wherever possible, THR should be performed in ultra-clean air theatres.
- 8.3 In ultra-clean air theatres, interposition of theatre personnel between the air source and wound can increase rates of infection^{37,38} so provision of efficient occlusive clothing is critical
- 8.4 A combination of ultraclean air theatres, systemic antibiotics active against coagulase negative staphylococci³⁹ and, where applicable antibiotic impregnated cement⁴⁰ with either body exhaust suits³⁶ or occlusive theatre clothing⁴¹ provides the most effective prophylaxis against infection. These reduce the rate of deep infection by a factor of 18 compared to conventional theatres without additional prophylactic measures. A combination of all three of these prophylactic measures is recommended.
- 8.5 The quality of ultra-clean air should be checked regularly.
- 8.6 Theatre clothing becomes permeable to bacteria after multiple washing. The number of laundry cycles should be recorded and clothing replaced after 70 cycles.
- 8.7 Conventional operating theatres should be dedicated to elective orthopaedic surgery as far as possible. Ninety-five per cent of bacteria are cleared from a conventional theatre within 11 minutes. If the theatre has been used for a dirty case, at least that period of time should pass before a THR is undertaken.
- 8.8 Sharing theatre facilities with other elective clean surgical disciplines is acceptable, particularly in ultra-clean air theatres.
- 8.9 There should be a clear and agreed sterile technique protocol in the orthopaedic theatre, adherence to which should be mandatory.
- 8.10 Where the surgeon is identified as a responsible clinician for audit of infection, that surgeon should decide the theatre protocol in collaboration with theatre personnel, microbiology input and allied health staff.
- 8.11 The surgeon must have trained 'scrubbed' assistants during the operation, trained scrub personnel and a 'runner' fully familiar with the instrumentation and prostheses.
- 8.12 In the absence of junior medical staff, additional assistance must be available. Sometimes more than one assistant is required. Specific training should be received by any assistant.
- 8.13 A full range of implants and instruments to address intraoperative complications such as fracture must be readily available. Non orthopaedic emergencies such as vascular injury may occasionally occur and specialized instrumentation should be available to manage such situations.
- 8.14 Impenetrable sheets/drapes are essential.
- 8.15 A Hospital Sterile Supply Department (HSSD) should be near the operating theatre. It must be able to process used instruments and provide packs in an efficient and timely manner. Tracking mechanisms should be in place to ensure efficient and accountable sterilisation procedures.
- 8.16 Any instrument that is not duplicated in the theatre suite should be capable of re-sterilisation within one hour if it is found to be non-sterile during the procedure.

9. <u>THE SURGEON AND THE SURGICAL TEAM</u>

- 9.1 Consultant surgeons within the team should possess the CCST and be enrolled on the Specialist Register of the GMC, or hold another acceptable international qualification⁴². [See 3.4]
- 9.2 The surgical team will practice in accordance with the ethical standards defined by the General Medical Council⁴³.
- 9.3 All patients should receive hospital treatment under a named consultant orthopaedic surgeon who is ultimately responsible for defining the quality of clinical care provided on his/her service.
- 9.4 The consultant surgeon is responsible for defining the clinical pathways for joint replacement for patients admitted under his/her care. This will be done in collaboration with the anaesthetising clinician. [See Section 10: Enhanced Recovery Programmes].
- 9.5 The knowledge and practical skills of a consultant orthopaedic surgeon and the team performing the operation must be maintained by Continuing Professional Development⁴⁴ and by annual appraisal. The required credits for revalidation will be available through membership of the British Orthopaedic Association and the British Hip Society.
- 9.6 The competence of an operating surgeon should be assessed by the consultant under whose name the patient is admitted. More inexperienced surgeons should always be supervised by surgeons on the team who are themselves competent to perform the surgery unsupervised by a consultant. In the absence of consultant supervision in theatre, arrangements should be made for on-site consultant cover.
- 9.7 All operating surgeons must register with the National Joint Register (NJR) for England and Wales⁸. The surgeon must ensure that data for all patients is collected for entry onto the NJR.
- 9.8 Each surgeon should interrogate the NJR website for his/her own results periodically to see how they compare with standards nationally. In the event that results are poorer than anticipated or deteriorating an audit of the results should be undertaken by the clinician to establish the cause and subsequently make changes to rectify any problem identified.
- 9.9 The operating surgeon must be assisted by an appropriately skilled member of the surgical team. This person may be a surgical trainee, Surgical Care Practitioner⁴⁵ or Advanced Scrub Practitioner⁴⁶.
- 9.10 Operating theatre time must be made available in institutions where surgical training is carried out as part of a Higher Surgical Training (HST) programme. During the later years of HST some trainees receive advanced training in hip surgery. This will include the surgical management, under supervision, of more complex cases and secondary (revision) operations. Extended operating time will need to be designated for these cases.
- 9.11 Appropriately trained trainees will be appointed as consultants into NHS posts in which hip surgery is a major component of their elective work. Such surgeons will be required increasingly to meet the anticipated increase in the volume of complex hip reconstruction and revision procedures arising from the increasing numbers of primary procedures.
- 9.12 The surgical team should be able to inform the patient about outcomes of operations in that Hospital. NJR data is available for this purpose.

10. THE ANAESTHETIST AND THE ANAESTHETIC TECHNIQUE

- 10.1 The Royal College of Anaesthetists and associated groups have developed standards of training and practice in this specialty⁴⁷. These should be followed in relation to all types of hip arthroplasty. All staff should update their skills and knowledge regularly through Continuing medical education (CME) and Continuing professional development (CPD).
- 10.2 The activity of the consultant anaesthetist may include supervision of extended role practitioners such as nurse anaesthetists. This should follow nationally agreed standards
- 10.3 The surgeon and anaesthetic team should collaborate to define the most appropriate local clinical protocol for patients including prophylactic antibiotic policy and policies for venous thromboembolism prevention. [See Sections 14 and 15]
- 10.4 There is evidence that enhanced recovery programmes confer benefit to patients^{48,49}. Most patients undergoing hip replacement surgery will be appropriate to enter an Enhanced Recovery Pathway (ERP)⁵⁰. An example of such a pathway is given below (Figure 1):



- 10.5 The involvement of the anaesthetic team is helpful in the pre-admission assessment. The team should as far as possible help to identify and assess increased medical risk factors and advise on reduction of risk where possible. The team may therefore be involved in the process of informed consent [See 5.3]
- 10.6 The WHO surgical safety checklist should be used before the commencement of surgery in all cases (Figure 2)⁵¹.
- 10.7 The surgical and anaesthetic team may elect to change some details of the time-out process to better reflect local circumstances. Any adaptations should be undertaken in accordance with the local organisation's governance scrutiny process.
- 10.8 The choice of anaesthetic technique is based on the following factors:
 - i. Preference of anaesthetist and surgeon.
 - ii. Duration and associated problems of surgery.
 - iii. Patient preference.
 - iv. Associated medication and medical conditions.

SIGN IN (To be read out loud)	TIME OUT (To be read out loud)	SIGN OUT (To be read out loud)
Before induction of anaesthesia	Before start of surgical intervention	Before any member of the team leaves the operating room
Has the patient confirmed his/her identity, site, procedure and consent?	Have all team members introduced themselves by name and role?	Registered Practitioner verbally confirms with the team: Registered Practitioner verbally confirms with the team: Has the name of the procedure been recorded? Has the team confirmed that intrimunents, avoid and sharps counts are complete for not applicable? How the operformers been isolated
ts the surgical site marked?	Surgeon, Anaesthetist and Registered Practitioner verbolly confirm: What is the patient's name?	
Is the anaesthesia machine and medication check complete?	What procedure, site and position are planned?	Have any equipment problems been identified that need to be addressed?
Does the patient have a: Known allergy?	pretent have e. Anticipated critical events Surgeon: Surgeon: lergy? Are these ary specific explorest requirements or specific explorest requirements: arway/rapiration mkr Are these ary specific explorest requirements: and equipment/satisfance available Meet these ary specific explorest required. Stemulation is equipment. As 6 grade? Weak the prateint specific explorest required. and edeputer IV access/liuch planned Meet she staffly of the instrumentation bean confirmed including indicator reactions Meet she staffly of the instrumentation.	Surgeon, Anaesthetist and Registered Practitioner:
No. No. No. No.		This checklist contains the core content for England and Wales
PATIENT DETAILS	Has the surgical site infection (550) bundle been undertaken? Yeshnot opplicable • Annthacking prophysics within the last 60 minutes • Patient warming • Hair removal • Glycaemic control	
First name:	Has VTE prophylazis been undertaken?	www.nnsa.nhs.uk/nrls
Date of birth: NHS Number:*	is essential imaging displayed?	

Figure 2. The World Health Organisation (WHO) Surgical Safety Checklist for use in any operating theatre environment (Issued 26 January 2009)⁵¹

- 10.9 It is unrealistic to suggest that an ideal anaesthetic exists for hip arthroplasty. The central neuraxial blocks, i.e. spinal and epidural block, are the only blocks that can be consistently expected to provide surgical anaesthesia. The practice of having the patient awake may be safer for patients with certain types of medical problems. Many anaesthetists include sedation or general anaesthesia as part of the anaesthetic technique for hip arthroplasty.
- 10.10 Choice of regional block, including provision of post-operative analgesia. The following local anaesthesia blocks are used for hip arthroplasty:
 - i. Spinal (subarachnoid) anaesthesia
 - ii. Epidural anaesthesia
 - iii. Psoas compartment lumbar plexus block
 - iv. Femoral/sciatic/lateral cutaneous nerve or thigh blocks
- 10.11 Single shot spinal anaesthesia is the most common block performed for primary arthroplasty in the UK, and is considered by many to be the quickest and easiest to perform^{52,53}. Patients undergoing elective THR under neuraxial anaesthesia seem to have better outcomes than those under general anaesthesia⁵⁴. The choice of agent(s) has been the subject of much debate, and there are remarkably few prospective randomised trials on the subject. A review article⁵⁵ has suggested that a mixture of local anaesthetic and opioid was better at reducing pain post-operatively, when compared to spinal local anaesthetic alone. The meta-analysis of six studies showed that there was conclusive proof of reduced post-operative analgesic use and improved pain scores up to 16 hours post-surgery. In addition, quantitative analysis suggested a prolongation of the time to first analgesic request by 499.30 minutes (95% CI 334-664).
- 10.12 The choice of long duration local anaesthetic appears to be unimportant, in that there was no difference between levobupivacaine and bupivacaine with respect to pain score reduction or analgesic consumption. Spinal (intrathecal) blocks have the benefit of inducing hypotension, and also increasing pelvic venous blood flow. This results in lower operative blood loss⁵⁶. Further, the incidence of DVT and PE is reduced, although this benefit may not be as great as previously described⁵⁷.

- 10.13 Epidural analgesia infusions should be reserved for patients with high-risk cardiopulmonary disease, as there is evidence showing a risk-reduction for these patients using this technique. However, for patients without this morbidity, epidural infusions do not have a favourable risk/benefit ratio for analgesia post-operatively compared to spinal or peripheral blocks. In addition, patients with epidural infusions require a higher level of post-operative monitoring to prevent respiratory depression and hypotension.
- 10.13 The major (but rare) complication of central neural block is neural axis damage, involving either the spinal cord/cauda equina or a spinal nerve root. The lumbo-sacral plexus block carries no risk of central axis injury. However, injury to the plexus has been reported⁵⁸. This block does not provide the same degree of intra-operative hypotension as a central axis block, and there is little data to suggest it confers the same benefit on the incidence of thromboembolism.
- 10.14 The femoral/sciatic/lateral cutaneous nerve or thigh block has similar advantages and disadvantages to the lumbosacral plexus block. It generally takes longer to perform than a central axis block, and will usually require the addition of general anaesthesia. Also, the sensory innervation of the hip is predominantly from the lateral cutaneous nerve of the thigh, and the other two blocks only confer small benefit for hip arthroplasty.
- 10.15 The anaesthetist should be available to assess the patient and give post-operative advice for all patients, particularly with regard the efficacy of the prescribed multi-modal pain relief. A member of the anaesthetic team should make a postoperative visit within 24 hours to assess the patient's progress on the agreed pathway [See 6.4].
- 10.16 Collaboration between the anaesthetic and surgical team at all points in the patient pathway is essential for implementation of exemplary practice.
- 10.17 The Anaesthetic Record should be part of the Clinical Record and meet nationally agreed standards. [See 11.1]
- 10.18 Multi-disciplinary clinical audit projects should be planned with a view to improving patient care.

11. <u>CLINICAL RECORD</u>

- 11.1 When this document was first produced, most clinical records were paper-based. Public and independent health providers are gradually introducing paperless clinical records. Regardless of the medium in which clinical data is recorded or stored, good clinical practice necessitates communication of clinical information and immediate access for postoperative instructions. It is essential that clinical records be reproducible and transmittable without delay, information loss or inaccuracy. Good records are a basic tool of clinical practice and should ideally be typewritten or produced on computer⁵⁹.
- 11.2 The record must include the name, date of birth and the address of the patient, and the referring practitioner should be identifiable. The hospital number should be clear, and the hospital and surgeon with responsibility for care of the patient should be named. In some units the patient will be admitted under the care of a team and, if so, this should be specified.
- 11.3 Within the record the general medical condition of the patient as well as fitness for operation should be recorded. It should contain the clinical history, the full clinical examination findings, pre-existing medical history and all current disabilities and complaints. The diagnosis of the condition and the purpose of the operation should be stated and all medication should be listed. There should be a multi-disciplinary clinical record, which may be part of a local Integrated Care Pathway (ICP).
- 11.4 The process of fully-informed consent should be recorded correctly [See 5.2, 5.3, 6.3 and 7.5] and the patient's signature witnessed as appropriate^{29,30}. The process should ensure that the patient is aware of the risks and benefits of the procedure being offered, as well as the option of not performing any procedure. The operating surgeon or another appropriately trained member of the surgical team should complete the consent form with the patient and all of the above should be in compliance with guidelines.
- 11.5 Some patients may express a wish not to learn of the significant risks of the proposed procedure. The surgeon obtaining consent should ensure that the patient is aware of their right to know, and that the operation is a major procedure with such associated risks. [See 3.5, 5.3 and 9.6]
- 11.6 The Anaesthetic Record is part of this record. [See 10.8 and 12.8]
- 11.7 Records and images should be retained indefinitely to permit long-term follow-up up and facilitate revision should it be required. [See 12.7 and 17.5]

12 <u>THE OPERATIVE AND POST-OPERATIVE RECORDS</u>

12.1 The operative note should be completed by the operating surgeon or other member of the surgical team in writing, by dictation or using a computer-generated proforma⁵⁹. Whatever means is employed, an operation note, with post-operative instructions must be available to all clinical staff involved in the patient's on-going care, prior to the patient leaving the theatre complex.

12.2 Documentation pertaining to the operation may be recorded by several members of the theatre team. The patient record should include:

- Patient identification
- Date of the operation
- The name of the operating surgeon, assistants and of the consultant or team responsible
- The name of the anaesthetist
- The type of anaesthesia employed
- The diagnosis or indication for surgery
- The procedure performed
- The position of the patient on the operating table
- Description of any other preparations or precautions undertaken. For example, catheterisation, use of calf stimulators or foot pumps
- The surgical approach used

• Description of the pathological findings and surgical steps undertaken. Also any precautionary measures, such as identification or protection of the sciatic nerve when the posterior approach is employed

• Details of tissues removed, altered or added

• Details of serial numbers of prostheses inserted. The use of bar-code reading devices can help this and other recording

• Details of bone cement, cement insertion technique or any other implanted materials

• Details of bone grafting if used. It will be unusual for non-autologous or allograft bone to be inserted in primary procedures. If so, details of its origin should be recorded

• Details of sutures or wound repair materials used

• A record of any drains or wound infiltration catheters with instructions for their use and removal

• An accurate description of any difficulties or complications encountered and how these were overcome

- Details of antibiotic prophylaxis [See Section 15]
- Details of venous thromboembolism prophylaxis [See Section 14]
- Details of the stability of the joint at completion of the procedure.

• Immediate post-operative instructions and, in particular, any variance from any agreed care pathway or rehabilitation programme

- Details of hospital sterile services department (HSSD) tracking procedures⁶⁰
- The surgeon's signature or computer equivalent
- 12.3 Post-operative progress should be documented, particularly noting any complications. The date of discharge and arrangements for further care should be recorded. The existence of an ICP should be specified, if present in an institution, and any variance from that pathway should be recorded.
- 12.4 All notes should be contemporaneous and should not be altered; errors should be identified. Orthopaedic records within the hospital records should be readily identifiable within the case note. All computer-assisted recording should conform to the Data Protection Act⁶¹.
- 12.5 Follow-up notes should allow another clinician to assume the care of the patient at any time. The following standards should apply:

• All clinicians mentioned in the record must be identified by name and designation.

• Details of written and verbal information given to the GP, patients, relatives and carers must be recorded.

• Details of all investigations considered and requested should be noted.

• There should be a daily entry of the patient's progress in the record. Any change in the patient's management or any further procedures should be recorded.

- An entry should be made whenever a doctor is called to see the patient.
- Deletion should be made with a single line and signed and dated.
- 12.6 All patients should have good quality antero-posterior and lateral radiographs of the hip before discharge from hospital.
- 12.7 There should be an agreed protocol for the retention of all documents and images.
- 12.8 The Anaesthetic Record should comply with standards laid down by that specialty. [See 10.8]
- 12.9 The clinical record in all settings (NHS, Private Practice or Independent Sector Treatment Centres) should follow the same high standard as laid down in this document.
- 12.10 Patient details should be entered into national registers^{6,8}. [See 1.5] Such information should also be available for local audit.

13. <u>THE IMPLANT</u>

- 13.1 Orthopaedic Surgeons have many devices from which to choose. Many of these have not been subject to studies of outcome for as long as ten years and guidance exists from the National Institute of Health and Clinical Excellence (NICE)^{62,63} and the Orthopaedic Device Evaluation Panel (ODEP)⁶⁴.
- 13.2 Many factors determine the surgeon's preference for an individual implant. These include their training, consultant colleagues' preference, and a desire to improve their own results. The manufacturers of such devices can have a significant effect on choice through the service they provide¹².
- 13.3 An individual theatre policy may be in place to limit the number of implants being used. Storage of a large range of implants may be impossible due to limitation of space.
- 13.4 The choice of prosthesis should be governed by evidence of the effective performance of that $implant^{6,62-64}$ and, if possible, of the operating team using it.
- 13.5 The choice of implant may be influenced by cost. Surgeons and their teams should ensure that the cost of the implant does not result in the use of an unproven or sub-standard implant. Experience has shown that apparently minor variation in design and manufacture may result in an unsatisfactory outcome for patients when such implants are used ^{65,66}. Managers should ensure that when changes in implant, cement or equipment are introduced, all staff are involved, informed and suitably trained. Any degree of change can lead to significant difficulties in the operating theatre. Resources should be available to provide appropriate training for all staff involved in the use of such new equipment or devices. [See 16.12]
- 13.6 Surgeons should be aware of information published by manufacturers in relation to each implant. This Information for Use (IFU) enclosed with each implant should be read by the surgeon.
- 13.7 Surgeons should ensure that the implants being inserted are compatible. This applies particularly to bearing surface dimensions, but also to Morse tapers and the variety of femoral head components available.
- 13.8 Manufacturers advise against the use of so-called 'cross-breeds' wherein the acetabular component is manufactured by a different maker from that of the femoral component. Many surgeons use such techniques and there is no clinical evidence that it is harmful, but surgeons should nevertheless be aware of the manufacturers' IFU.
- 13.9 Surgeons should be aware that there have been, and will be, mergers of manufacturing companies. The definition of a 'cross-breed' may therefore become difficult.
- 13.10 Occasionally a custom-made implant is necessary to perform primary hip replacement. Such an implant should be manufactured on a named-patient basis, and the reason for the choice and any special aspects should be recorded in the consent and orthopaedic records⁶⁷.
- 13.11 The published results of many implants offer little help to the surgeon wishing to make an informed choice. Most outcome research is short-term, non-comparative and does not take into account the case-mix and variations in the operative technique of the surgeon. There is great variation in the measurement of outcomes following the procedure. Surgeons should be aware of the high quality outcome studies that are published and of the advice from NICE^{1,62,68-71}.
- 13.12 The selection of a prosthesis for general use should normally be based on evidence published in peer-review journals or other acceptable resources. These include national arthroplasty registers such as the NJR in England and Wales⁸, the Scandinavian^{6,72} and Australian registries⁷³. Published evidence of satisfactory clinical follow-up of more than ten years with published life-table and survivorship curve is considered to be good supporting evidence for selection of an implant. The presentation of results should follow best statistical practice and should be available to support the use of a particular prosthesis^{6,74}.

- 13.13 A confounding factor for the surgeon is that implants with apparently good published results have been modified subsequently by the manufacturers and the clinically tested design is no longer available. Company mergers may provoke such changes. There has been a failure to realise that even minor modifications to design, material, surface finish or fixation technique can dramatically alter the performance of the implant⁶⁵. [See 13.5 and 13.9]
- 13.14 In the absence of peer-reviewed evidence of outcome to ten years, a device must be subject to on-going surveillance and preferably part of a properly conducted, ODEP compliant, prospective trial. NICE guidelines should be followed where appropriate⁶².
- 13.15 Indications for the use of metal-on-metal implants have changed over the past five years. While such implants are generally used for fewer patients, metal-on-metal resurfacing implants remain an acceptable option for younger individuals, usually males, with appropriate bone geometry, who are determined to undertake vigorous sporting activity. Guidelines for the use and follow-up of metal-on-metal hips are available from the British Hip Society website⁷⁵. Surgeons considering a patient for a metal-on-metal resurfacing or ceramic on ceramic bearings should be mindful that the performance and wear rate of the implants are particularly sensitive to component positioning and it is advisable for surgeons undertaking hip resurfacing to maintain their familiarity with the technique and scrutiny of their implant positioning.
- 13.16 The patient and hospital management must be made aware if any of the surgical or anaesthetic team may gain financially from the use of any device or medicine⁴². [See Page 4, Probity]

14 PROPHYLAXIS AGAINST VENOUS THROMBOEMBOLISM (VTE)

- 14.1 Although deep vein thrombosis (DVT) can be demonstrated by venography in 50-60% of patients after primary total hip replacement (THR), it is symptomatic in approximately 2%^{76,77}. The most severe consequence of DVT is fatal pulmonary embolism (PE). In the 1960s without thromboprophylaxis, fatal PE occurred in between 2.3%⁷⁸ and 3.4%⁷⁹. In the late 20th century without heparin, it was between 0.1% and 0.2%⁸⁰ and in the 21st century, with aspirin and compression stockings, 0.1% or less^{81,82}. Thromboprophylaxis reduces fatal PE by 70%^{78,79} and DVT by 50%⁷⁷. Accordingly, the National Institute for Health and Clinical Excellence (NICE) recommends that all patients undergoing THR be risk assessed for DVT and PE and unless contraindicated, thromboprophylaxis be prescribed.
- 14.2 The risks of developing DVT or PE are increased in patients with a previous history of DVT or PE⁸³, varicose veins with phlebitis⁸³, active malignancy, chemotherapy and radiotherapy, a first degree relative with a history of DVT or PE⁸⁴, inherited thrombophilia, previous pelvic or acetabular surgery, age > 50 years⁸³, obesity⁸⁵, hip surgery lasting longer than 1 hour and oestrogen containing oral contraceptive pills, hormone replacement therapy and Tamoxifen. The most important risk factors are proven thrombophilia and a personal history of proximal DVT or PE⁸⁶. The duration of risk of PE is 4 weeks⁷⁸ and proximal DVT 6 weeks⁸⁷.
- 14.3 Prophylactic measures are pharmacological and mechanical. Pharmacological agents comprise anticoagulant or antiplatelet drugs. Mechanical measures include foot pumps and graduated compression stockings. Both strategies reduce death from PE but not overall mortality after THR⁸⁸⁻⁹⁰ because anticoagulants cause death from bleeding⁸⁸.
- 14.4 Foot pumps are as effective as low molecular weight heparin (LMWH)⁹¹, do not cause bleeding, are tolerated by over 95% of patients but can only be used in hospital. Below knee stockings are better than above knee⁹² and are effective if the pressure gradient from distal to proximal is maintained⁹³. As legs swell after THR, stockings need to be checked regularly to ensure the garter that suspends them does not indent the calf proximally reversing the pressure gradient⁹⁴.
- 14.5 Because fatal PE is so rare, surrogate endpoints such as venography are used to assess thromboprophylactic drugs. It is almost 20 years⁷⁶ since any randomised trial has been conducted with a control group not receiving pharmacological agents. Since then, the comparator for new agents has generally been LMWH and the outcome equivalence. Advice based on such evidence is conflicting and conflicted^{90,95} with a low to consensus level of scientific evidence⁸⁶.
- 14.6 After risk assessment, patients without an increased risk of bleeding should undergo THR under spinal anaesthesia if feasible. This should be combined with mechanical and pharmacological prophylaxis. Mechanical prophylaxis encompasses well-fitting stockings and foot pumps and walking as soon as feasible. Pharmacological prophylaxis includes any of LMWH, Fondaparinux, Dabigatran, Rivaroxaban or aspirin started after 12 hours and continued for 4 to 6 weeks. LMWH has a lower incidence of bleeding than Fondaparinux, Dabigatran and Rivaroxaban⁸⁶ and a lower incidence of early return to theatre than Rivaroxaban⁹⁶. In patients with proven thrombophilia, or a history of proximal DVT or PE, the agents detailed above may be inadequate and full anticoagulation with Warfarin for 8 weeks is recommended. If the risk assessment indicates that the consequences of bleeding outweigh the benefits of pharmacological prophylaxis, surgeons may choose not to prescribe them but the reasons should be documented fully. Wound haematoma and failure of primary healing are strongly associated with an increased rate of deep infection^{36,88}. The risk of bleeding may change during or after surgery.

15. PROPHYLAXIS AGAINST INFECTION

- 15.1 Patients should be clinically screened for infection prior to the operation. [See 5.4 and 8.1]
- 15.2 All patients should receive, intravenously, an antibiotic at induction of anaesthesia⁹⁷. Further use of antibiotics in the first 24 hours after the operation is debatable^{72,98}. Each unit performing the operation should have a locally-agreed policy which should include advice from microbiologists.
- 15.3 The operation should be performed in ultra clean air theatres 60,99,100 . [See 8.2]
- 15.4 When bone cement is used, antibiotic-impregnated cement further reduces the risk of infection⁶. However when infection does occur, the resistance profile of the infecting organism(s) may be affected^{101,102}.
- 15.5 A combination of systemic antibiotics active against coagulase negative staphylococci³⁹, antibiotic impregnated cement, ultraclean air theatres and either body exhaust suits³⁶ or occlusive theatre clothing⁴¹ provides the most effective prophylaxis against infection^{6,60,99,100}.
- 15.6 There does not appear to be an increased risk of urinary tract infection if an indwelling catheter is used for only a short time in the immediate post-operative period¹⁰³.

16. <u>SURGICAL TECHNIQUE</u>

- 16.1 The benefits and risks of the operation must be discussed with the patient prior to the operation and written consent from the patients should be sought.
- 16.2 Preoperative templating, using templates provided by the implant manufacturer, is advised to predict the likely implants to be used and to plan for the restoration of offset and leg length¹⁰⁴. The use of digital templating software allows accurate planning to be carried out using digital X-rays¹⁰⁵.
- 16.3 Prior to starting the operation, the surgeon should ensure that the required surgical instruments and selected prostheses are available and sterile.
- 16.4 Before starting the operation, the surgical team should complete the World Health Organisation surgical checklist¹⁰⁶.
- 16.5 The surgical approach selected for a total hip replacement should provide a clear 360° view of the rim and face of the acetabulum. The approach should facilitate delivery of the femur into the wound to allow unimpeded instrumentation of the femoral canal.
- 16.6 The surgical approach selected should achieve these aims without the need to apply excessive forces to skin, soft tissue or bone.
- 16.7 For cemented components, the bone surface should be prepared for optimum cement penetration. Articular cartilage should be removed where present and strong cancellous bone should be exposed and preserved. The bone surfaces should be irrigated and dried before the introduction of bone cement.
- 16.8 Multiple drilled fixation pits in the acetabulum may improve fixation. Acetabular cement should be pressurised into the clean dry bone surface before introduction of the cup.
- 16.9 The distal femoral canal should be occluded with a plug and retrograde injection of cement carried out, followed by pressurisation with a proximal seal⁶.
- 16.10 For cementless implants, the bone surfaces should be prepared with dedicated instruments for the prostheses to be inserted. The surgeon should ensure optimum fit and stability of the component in the recipient bone bed.
- 16.11 Efforts should be made to restore the correct leg length and offset, to optimise the biomechanics of the hip replacement. To assist with this process, intra-operative trial reduction prior to the insertion of definitive prostheses is recommended.
- 16.12 Every effort should be made to ensure stability of the hip joint by correct implant selection, appropriate bone resection, accurate placement of the implants and assessment and correction of soft tissue tension. Repair of soft tissues at the conclusion of the operation reduces the risk of post-operative dislocation¹⁰⁷⁻¹⁰⁹.
 16.13 Intra-operative navigation using imageless^{110,111} and CT guided¹¹² techniques have been
- 16.13 Intra-operative navigation using imageless^{110,111} and CT guided¹¹² techniques have been developed with the intention of improving the accuracy with which components are positioned. Navigation accuracy may be adversely affected in larger patients^{113,114}. There is little evidence that patient outcomes are improved through the use of navigation techniques.
- 16.14 Minimally invasive techniques have been applied to the posterolateral, anterolateral and anterior surgical approaches¹¹⁵⁻¹²¹. The use of multiple incision minimally invasive technique has also been described for hip replacement^{122,123}. The claimed benefits of minimally invasive hip replacement have not been reproduced in randomized clinical trials¹²⁴ and concerns have been raised about increased complication rates using these techniques¹²⁵⁻¹²⁷.
- 16.15 Surgeons should ensure that, when using new techniques or techniques new to them, they are capable and competent to perform these. Any specific risk associated with these new techniques, together with the surgeon's own experience in them, should be shared with the patient as part of the informed consent process. Surgeons are reminded to be aware of and to follow any national or local guidelines on the introduction of new or novel techniques.

16.16 There is variation in the use of wound drains and suture materials. There is no strong evidence to support or condemn the use of wound drains¹²⁸. It is advisable to discuss the method of wound closure and the use of suction drains with the patient before the operation.

17. POST-OPERATIVE MANAGEMENT AND DISCHARGE FROM HOSPITAL

- 17.1 All patients should be made aware of the expected interventions following surgery^{31,32}. This should be part of any locally developed ICP.
- 17.2 Mobilisation following the operation should include significant input from the physiotherapy team, and patients should only be discharged from hospital when considered capable of coping in the environment at their destination.
- 17.3 Discharge planning should start before the patient's admission and is one of the important functions of a pre-admission assessment clinic. [See 5.6]
- 17.4 Patients should be given information about telephone numbers or other methods of contacting the hospital or the orthopaedic service, should problems occur.
- 17.5 Patients should be informed of the likely early review date following surgery; this will usually be within 8 weeks of the operation^{27,28}.

18. LONG-TERM FOLLOW-UP OF PATIENTS

- 18.1 Total Hip Replacements (THR) require revision for aseptic loosening most frequently in patients who were under 60 years of age at the time of their primary THR, in males and when uncemented polyethylene lined sockets have been implanted^{6,129}. Patients in their mid-seventies at primary hip replacement have a 90% chance of dying before revision is required whereas the converse applies in those under fifty¹³⁰. Most revisions occur in patients under 65 years at the time of primary THR. Follow up should be targeted at this population.
- 18.2 Most of the revision burden occurs seven years after primary hip replacement^{6,131}. Silent lysis is responsible for 30%. Progressive silent lysis results in peri-prosthetic fracture which carries increased mortality¹³² and cost compared with revision for aseptic loosening¹³³. The aim of long term follow up is to avoid this complication and unsalvageable bone loss¹³⁴.
- 18.3 Orthopaedic Data Evaluation Panel (ODEP) 10A rated implants should be followed up in the first year, once at seven years and three yearly thereafter if patients are asymptomatic and have no adverse radiographic signs. Novel or modified implants should be followed annually for the first five years, two yearly to ten and three yearly thereafter.
- 18.4 Symptoms predict revision less accurately than radiographs (Smith) and radiographic assessment is essential with AP and lateral views.
- 18.5 Follow up need not necessarily take place in Orthopaedic outpatient clinics where patients face prolonged waits for a brief appointment. Rather, the clinical state can be assessed by a postal or telephone Oxford Hip Score and radiographs performed at a local hospital and reviewed by the Hip Arthroplasty team. This is best coordinated by a permanent member of staff such as an Arthroplasty Practitioner or senior secretary.
- 18.6 Radiographs should be read by an experienced consultant, a musculoskeletal radiologist or an Arthroplasty Practitioner with appropriate training. A general radiologist or Orthopaedic trainee may not have the skills to identify early failure.
- 18.7 Routine follow up in General Practice is not advised¹³⁵ as the GP is reliant on reports which may be produced by radiologists who lack expertise in the failing hip arthroplasty.

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