Joint replacement (primary): hip, knee and shoulder

Consultation on draft guideline - Stakeholder comments table
15/10/19 – 26/11/19

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Arthroplasty Care Practitioners Association	Guideline	011	007 - 010, 035 - 041	We are concerned that this recommendation is unclear. It seems to suggest that the current system provides an acceptable route back to orthopaedic care. It seems to describe a patient visit to the GP and/or a route that may involve a physiotherapist or occupational therapist, and that this leads to further orthopaedic care in a relatively smooth pathway. Our collective experience suggests that this can be problematic as the signs and symptoms of a failing arthroplasty are not readily recognised by our colleagues in primary care and this may lead to unacceptable delays in their presentation to an orthopaedic team. We would suggest that a clear recommendation from NICE for a rapid access service to allow orthopaedic assessment, albeit patient directed, would minimise the risk for the patient. This recommendation would provide a useful statement to inform local discussions with commissioners about the long-term care of this patient group until further evidence is available.	Thank you for your comment. No evidence was identified for the evidence review on the frequency of long-term follow up. The committee were also aware that the UKSAFE study was being published and decided to make a research recommendations to avoid any future contradictory advice on the frequency of long term follow up. The committee also agreed that once a person has been discharged from orthopaedic care then should a problem arise it will be primary care that assesses and refers a person back to orthopaedic services. With this in mind they made the recommendation "Primary care practitioners should refer people who develop new or worsening pain, limp or loss of function related to their joint replacement to an orthopaedic surgical service."
Arthroplasty Care Practitioners Association	Guideline	012	004 - 006	This statement seems to suggest that the recommendations for follow up of knee arthroplasty do not exist on the BOA web site. We wondered if the committee were aware that they can be found under the BOA	Thank you for your comment. We have corrected this statement to acknowledge the BOA guide for knee replacement.

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				Standards and Guidance, Commissioning Guides, Painful Osteoarthritis of the Knee, page 8: Postoperative Care Available at: https://www.boa.ac.uk/standards-guidance/commissioning-guides.html	
Association of Trauma and Orthopaedic Chartered Physiotherapists (ATOCP)	Guideline	003	005 - 019	The rational does not state a time for the provsion of the pre-operative information and the professional netowork would request that this was specified. This is to ensure that the education was provided to those patients whom had been listed for athroplasty surgery. In additon if was felt that cosideration should be made to the below evidence that was not identified in the gudieline. 1. Berg U, Berg M, Rolfson O, Erichsen-Andersson A. Fast-track program of elective joint replacement in hip and knee-patients' experiences of the clinical pathway and care process. Journal of Orthopaedic Surgery. 2019;14(1):186. PubMed PMID: 31227003. 2. Goldsmith LJ, Suryaprakash N, Randall E, Shum J, MacDonald V, Sawatzky R, et al. The importance of informational, clinical and personal support in patient experience with total knee replacement: a qualitative investigation. BMC Musculoskeletal Disorders. 2017;18(1):127. PubMed PMID: 28340610.	Thank you for your comment. The timing of giving information was not included in the recommendations as no evidence was found to identify when the most effective time point is. The committee agreed that it could be overwhelming to provide all information in one go. We have amended the recommendation to emphasise that information should be "provided from the first appointment and whenever needed throughout the person's care". This should allow the orthopaedic team to utilise their knowledge of the pathways and people's personal needs to provide the information in a timely manner. Thank you for highlighting these studies. Berg 2019 was published after our final searches were undertaken for this guideline and therefore not included in the guideline. The focus of the patient information review was on a person's specific information needs prior to having the joint replacement. None of the following four studies fitted the protocol and were excluded for the following reasons: Hovik

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				3. Hovik LH, Aglen B, Husby VS. Patient experience with early discharge after total knee arthroplasty: a focus group study. Scandinavian Journal of Caring Sciences. 2018;32(2):833-42. PubMed PMID: 28833302. 4. Lucas B, Cox C, Perry L, Bridges J. Pre-operative preparation of patients for total knee replacement: An action research study. International Journal of Orthopaedic & Trauma Nursing. 2013;17(2):79-90. PubMed PMID: 104266613. Language: English. Entry Date: 20130524. Revision Date: 20150711. Publication Type: Journal Article. 5. Lucas B, Cox C, Perry L, Bridges J. Changing clinical team practices in preparation of patients for Total Knee Replacement: Using Social Cognitive Theory to examine outcomes of an action research study. International Journal of Orthopaedic & Trauma Nursing. 2013;17(3):140-50. PubMed PMID: 104194527. Language: English. Entry Date: 20130816. Revision Date: 20150711. Publication Type: Journal Article. 6. Specht K, Kjaersgaard-Andersen P, Pedersen BD. Patient experience in fast-track hip and knee arthroplasty - a qualitative study. Journal of Clinical Nursing (John Wiley & Sons, Inc). 2016;25(5-6):836-45. PubMed PMID: 112965608. Language: English. Entry Date: 20160224. Revision Date: 20190429.	2018 and Sprecht 2016 explored the views of people involved in a fast tracked pathway for discharge; the 2 studies by Lucas published in 2013 investigated the development of programmes preparing people for joint replacement rather than a comparison preoperative rehabilitation versus usual care. Goldsmith 2017 was relevant and the information needs were highlighted. This study has been extracted and added to the review. The resulting additions to the evidence review followed the same themes as other included studies and the committee agreed it supports the current recommendation.

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Association of Trauma and Orthopaedic Chartered Physiotherapists (ATOCP)	Guideline	004	018 - 024	The network is concerned using the word "can" when advising to complete exercises to aid recovery following arthroplasty surgery. We are aware that there is limited strong evidence to support the use of exercises and that more is required, but clinically exercises are essential to the rehabilitation of this group of patients. The use of the word "can" imply that exercises are optional, and the network would like the work "should" to be considered in preference.	Thank you for your comment. We have updated this bullet point to read "exercises to do before and after surgery that will aid recovery".
Association of Trauma and Orthopaedic Chartered Physiotherapists (ATOCP)	Guideline	009	009 and 018	We are concerned that by specifying mobilisation and exercise prescription of a patient receiving a primary total hip or total knee replacement should be by a physiotherapist and occupational therapist undermines the essential role of the therapy teams support staff. The recommendation would be a challenge to implement without the whole therapy team's involvement and thus would ask the NICE team to rephrase to highlight this. As a professional network we would request that the recommendation removes the specific professional titles of physiotherapist and occupational therapist and uses a member of the "orthopaedic" therapy team.	Thank you for your comment. For **postoperative inpatient rehabilitation** the committee are concerned about safety issues if qualified members of staff are not directly available especially for more complex cases. They agreed that the first contact with the person should be made or led by a physiotherapist or occupational therapist who can assess whether the person is medically unwell or has specific needs. They may delay rehabilitation if clinically necessary. The committee were also concerned that there is a risk that professional staff will be decommissioned and stretched very thin if

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					inpatient rehabilitation is undertaken by rehabilitation team in the first instance. With this in mind the committee agreed to keep the recommendations as written in the first draft. They also agreed to update the rationale to make it clear inpatient rehabilitation should be led by a physiotherapist or occupational therapist and that some aspects of rehabilitation can be provided by a member of the physiotherapy or occupational therapy team with suitable training and support. For **outpatient postoperative rehabilitation** the committee agrees and we have updated our recommendations and rationale to state that the advice is given by a member of the physiotherapy or occupational therapy team.
Association of Trauma and Orthopaedic Chartered Physiotherapists (ATOCP)	Guideline	010	001 - 004	The network agrees that tailored exercises are sometimes essential for the rehabilitation of these patients but would request further guidance on the identification of these patients. Are there specific traits or outcome measures that can be used to highlight the patients that will require a tailored program over self-directed exercises.	Thank you for your comment. The guideline did not include a review question on who would benefit from a tailored approach. The committee made the recommendations based on the available evidence from the review and their experience. They agreed that it is not possible to be prescriptive as it will vary by person.
Association of Trauma and Orthopaedic	Guideline	010	004 and 014	The network has raised a concern about the vague nature of the phrase "is not effective" and seek further clarification of what the	Thank you for your comment. We have revised these recommendations in light of comments by you and other stakeholders. Within these

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Chartered Physiotherapists (ATOCP)				evidence highlights as key features to suggest that the methods used are ineffective. In clinical practice this involves the use of outcome measures and are there any specific measures highlighted in the evidence that should be used to confirm when the exercise program in use is not effective.	edits we have changed the wording of the bullet point from "finds that self-directed rehabilitation is not effective" to "find that self-directed rehabilitation is not meeting their rehabilitation goals." The updated recommendation, which applies to hip, knee and shoulder replacement now reads: Offer supervised group or individual outpatient rehabilitation to people who: - have difficulties managing activities of daily living or - have ongoing functional impairment leading to specific rehabilitation needs or - find that self-directed rehabilitation is not meeting their rehabilitation goals.
Association of Trauma and Orthopaedic Chartered Physiotherapists (ATOCP)	Guideline	013	003 - 007 018, 019	There is clinical evidence that mobilisation on the day of surgery has been implemented widely across the UK in response to Enhanced Recovery recommendation adoption of Local Infiltration of Local Anaesthetic. This offers 2 significant benefits primarily to patient experience; 1. Mobilisation on the day of surgery reduces anxiety for patients suffering a disturbed night sleep with pain and worry regarding first mobilisation the following morning. 2. Full utilisation of the most effective and	Thank you for your comment. The evidence statements are based on the evidence identified for the review. The committee agree that there may be other evidence that did not fit the review protocol that may suggest a benefit of mobilisation on the day of surgery. The interventions in the 3 RCTs included in the review investigated either rehabilitation beginning on the day of surgery (1 study) or within 24 hours of surgery (2 studies). All the studies singly indicated a benefit of the intervention over delaying the start of

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				optimal multi modal pain management regime during the most painful and anxiety inducing first mobilisation. If patients are mobilised the day following surgery the opportunity to capitalise on the benefits of Local Infiltration are lost.	rehabilitation. The committee consensus was that rehabilitation should ideally begin on the day of surgery but noted that there is a greater resource impact associated with this due to the requirement to have physiotherapist or occupational therapist staff available. Therefore, with the resource impact in mind and given the evidence the committee made a recommendation for rehabilitation to start within 24 hours of surgery. However in light of your comment, the committee have changed the recommendation to state that rehabilitation should be offered, on the day of surgery if possible and no more than 24 hours after surgery.
Bayer plc	Guideline	007 - 008		We suggest that it would be appropriate to cross refer to: • Venous thromboembolism in over 16s: reducing the risk of hospital-acquired deep vein thrombosis or pulmonary embolism (2018) NICE guideline NG89 and • Rivaroxaban for the prevention of venous thromboembolism after total hip or total knee replacement in adults (2009) NICE technology appraisal guidance TA170.	Thank you for your comment. Other guidelines will be referred to in the pathway that appears on NICE's website when the guideline is published. The guidance related to venous thromboembolism prophylaxis you mention will be included in this.

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				in sections 1.7 and 1.8.	
Bristol Medical School – University of Bristol	Guideline	004	006	Needs to be expanded to clarify that the evidence base for the implant should be discussed e.g. "the choice of implant(s) and relevant evidence of both implant survival and patient reported outcomes"	Thank you for your comment. This bullet point has been changed to: "the types of implant available". The committee anticipate the risks and benefits of the different types of implant will be included as part of the discussion on the benefits and risks of available procedures.
Bristol Medical School – University of Bristol	Guideline	015	003	Outcomes can either be implant survival outcomes or clinical (patient reported outcomes) and the two may not be the same and have very different evidence bases. It may be useful to make the difference clear to the patient. The National Joint Registry for England, Wales Northern Ireland and the Isle of Man produces patient publications and it may be beneficial to signpost these to patients before the implant decision making stage.	Thank you for your comment. The committee recognises that the recommendation encapsulates both implant survival outcomes and patient reported outcomes and anticipate clinicians will discuss both with the person. Appropriate patient information sites have been signposted on the guideline's web page.
Bristol Medical School – University of Bristol	Guideline	024	023	The statement regarding the benefits of direct anterior approach is overstated and are based on theoretical benefits (that it is more minimally invasive) and differences for which there is poor evidence (may shorten recovery time). The fact that some surgeons use it routinely is not relevant to the evidence base considered for NICE guidelines as they are, effectively, single surgeon case series. Similar levels of evidence can easily be found showing that the direct anterior approach is	Thank you for your comment. The committee agree and we have removed the direct anterior approach from the recommendation and included it in the research recommendation. We have also updated our rationale and committee discussion in the evidence report.

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				associated with a higher risk of complications. It would be better to put this approach under the same recommendation as the other alternatives that adequately powered randomised trials or sufficiently robust large data observational analyses are required to at least demonstrate its non-inferiority or preferably its superiority to the widely used alternatives before it could be recommended. We are concerned that the wording as currently stands may encourage more widespread adoption when adequate evidence is not in place to support this.	
Bristol Medical School – University of Bristol	Guideline	024	024	There is no mention of the widely accepted prolonged learning curve for the direct anterior approach or the additional facilities that may be required such as intra-operative XRay that may impact cost-effectiveness.	Thank you for your comment. We have removed the direct anterior approach from the recommendation and included it in the research recommendation.
Bristol Medical School – University of Bristol	Evidence review R	007 021 024 103	(Top line of table) 011 - 014 024 - 026	We believe that an error has been made in that this report includes a feasibility study for a physiotherapy intervention (Artz et al 2017) which is deemed eligible - whilst the full randomised trial (Lenguerrand et al 2019) that followed the feasibility study is found ineligible and excluded. Please review this. See the linked studies - Artz et al 2017 [reference 3] and Lenguerrand et al 2019	Thank you, we agree that Lenguerrand 2019 is relevant and should be included in this review. This addition has now been made. The results support the committee's conclusion that individualised and self-directed rehabilitation are similarly effective for people who have undergone hip or knee joint replacement surgery.

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			(Second line of table)	[reference 47] (pages 21 and 24 respectively) Artz et al 2017 (the feasibility study) is included, and described in Table 2, page 7 Lenguerrand et al 2019 (the full report of the RCT [ARENA] which followed) is mentioned in Appendix J, Excluded Studies table, page 103 The reason for exclusion given is "Not review population".	
Bristol Medical School – University of Bristol	Evidence review D	074		**Table,** Second row, third heading, **'Line of therapy'** the APEX study described within Appendix D as "APEX trial: Wylde 2015", the following text appears in the row "**Line of therapy" - "Not applicable".** This is incorrect. The line of therapy is both applicable and well described within Wylde et al 2015 (NICE evidence review 4 reference no 236, page 55). On page 1162 of Wylde et al 2015 it is stated "**2.5**. **Standard care and intervention treatment: total knee replacement.** In line with evidence-based guidance from PROSPECT (procedure specific postoperative pain management), standard anaesthetic care consisted of a femoral nerve block and a spinal or general anaesthetic, depending on patient	Thank you for your comment. As you correctly point out the anaesthesia is very well described in the study. The 'line of therapy' box was not used in coding studies for this evidence review, but as it was part of our template we noted it as not applicable i.e. it was not applicable to the protocol for this question. The committee agreed that in practice if anaesthesia does not provide adequate pain relief then it is supplemented with analgesia. The "postoperative use of analgesia" outcome was designed to capture the use of additional analgesia.

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				factors. The intervention group received the same anaesthetic regime, plus an intraoperative local anaesthetic infiltration that consisted of 60 mL of 0.25% bupivacaine with 1 in 200,000 adrenaline. The local anaesthetic mixture was injected directly into the posterior capsule (25 mL), medial and lateral capsule (10 mL), fascia and muscle (10 mL), and subcutaneous tissues (15 mL), before wound closure. Full details of treatment in both arms are described in the protocol.	
Bristol Medical School – University of Bristol	Evidence review D	075		**Table,** Last row, heading; **'Funding'** Re the APEX study described within Appendix D as "APEX trial: Wylde 2015", the following text appears in the row "**Funding**" - "**Funding not stated**". This is incorrect. Within both the published articles on the APEX trial cited within this document, a clear statement of funding is made. See Marques et al 2015, (NICE evidence review 4 reference no 147, pages 48-49). On p 151 of the cited document it is stated: "Financial support This article presents independent research funded by the National	Thank you for your comment. This has been corrected in the evidence review.

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				Institute for Health Research (NIHR) under its Programme Grants for Applied Research programme (RP-PG-0407-10070). The views expressed in this article are those of the authors and not necessarily those of the NHS, the NIHR, or the Department of Health. The research team acknowledge the support of the NIHR, through the Comprehensive Clinical Research Network." See Wylde et al 2015, (NICE evidence review 4 reference no 236, page 55). On p 1169 of the cited document it is stated: "his article presents independent research funded by the National Institute for Health Research (NIHR) in England under its Programme Grants for Applied Research programme (RP-PG-0407-10070). The views expressed in this article are those of the authors and not necessarily those of the NHS, the NIHR, or the Department of Health. The research team acknowledges the support of the NIHR, through the Comprehensive Clinical Research Network". Please amend	
Bristol Medical School – University of Bristol	Evidence review B Evidence review for decision aids	004	013 - 016	This report was probably not considered as it was published in 2019 – but it is an NIHR project and thus the recommendation for	Thank you for your comment. The study did not meet the protocol for our review which looked at the effectiveness of decision tools

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				research (page 12, lines 20-23) may be inappropriate See: Price A, Smith J, Dakin H, Kang S, Eibich P, Cook J, et al. The Arthroplasty Candidacy Help Engine tool to select candidates for hip and knee replacement surgery: development and economic modelling. Health Technol Assess 2019;23(32) https://www.journalslibrary.nihr.ac.uk/hta/hta23320#/ref1	compared to usual care. The study you reference did not compare a decision tool to usual care. In terms of the appropriateness of the research recommendation, the committee still agree there is no standard for what a decision aid for joint replacement surgery would consist of and this seeks to address that.
British Elbow and Shoulder Society	Guideline	General	General	We welcome these guidelines and thank the committee for their work. Due to limitations in available evidence, we recognise that some aspects of the guideline essentially stray into the realms of opinion, which has so far been driven by the members of the committee. Our comments here are meant to be constructive and summarise the views of key opinion leaders in our specialty, which may be taken on board to finalise the guidelines.	Thank you for your comment. We will respond to each of your subsequent comments in turn.
British Elbow and Shoulder Society	Guideline	006	007 - 014	We are not convinced that there is sufficient evidence to recommend tranexamic acid for shoulder replacement. All but 4 studies quoted out of 107 are on hip and knee replacements so there just isn't good evidence to support its use. The fact that it is cheap and has few side effects is hardly evidence in which to make the recommendation especially as the committee	Thank you for your comment. The committee agree that there is less evidence for the use of tranexamic acid in shoulder replacement. Although there may not be the same benefits in terms of reduced transfusions in shoulder replacement, because it is not associated with high blood loss, they noted that there is still reduced bleeding and this is beneficial to the

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				acknowledges the fact that shoulder replacements virtually never need transfusions.	patient. They also noted that tranexamic acid is an inexpensive treatment. With this in mind the recommendation has been changed to 'consider' tranexamic acid for people having joint replacement.
British Elbow and Shoulder Society	Guideline	006	017 & 018	We are concerned this recommendation prevents use of antiseptic agents in wound washes without good evidence to support this recommendation. We agree antibiotic solutions should be avoided. The rationale for this recommendation states that saline wash is used to improve visibility of the operative site for the surgeon. There is another important reason for the saline wash after implantation, which is to remove debris and thus prevent third body wear of the prosthesis. To supplement the saline wash following prosthesis implantation, some surgeons use iodine or chlorhexidine mixed in saline to wash the prosthesis before wound closure. These agents are already used for skin preparation in these patients and therefore their use cannot be fully avoided. Emergence of resistance is therefore a moot point without substantiating evidence. Deploying the same agent used for skin prep to wash the implanted prosthesis provides a good opportunity to eliminate pathogens on the prosthetic surface from intra-operative seeding. Whilst intravenous	Thank you for your comment. We found no evidence to support the use of antiseptic agents in wound lavage. Furthermore the committee were aware that the surgical site infection guideline (NG125) (https://www.nice.org.uk/guidance/ng125) recommends against their use. The committee were also aware that the surgical site infection guideline makes recommendations about the use of antiseptic agents before wound closure. With this in mind the committee agreed that infection prevention is adequately covered by the recommendations to use ultra-clean air and by the use of prophylactic antibiotics as recommended in the surgical site infections guideline (NG125). We have made a cross reference to this guideline in our recommendations.

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				antibiotics remain the mainstay to prevent infection, we would suggest antiseptic washes should not be disallowed.	
British Elbow and Shoulder Society	Guideline	007	002 & 003	This recommendation may have a larger impact on resources and current practice than stated under implications and impact. Some units do not routinely use ultra-clean air theatres particularly when performing arthroplasty for trauma. This recommendation is made despite lack of clear evidence for ultra-clean air theatre on the rationale that it 'may be more effective' than conventional ventilation. The rationale for using antiseptic wash pointed out above would also be on a similar basis.	Thank you for your comment. The committee are not aware of primary elective joint replacements being undertaken in operating theatres without ultra-clean air. They agreed that the risk profile for trauma patients will be different. However, they have not discussed the use of ultra-clean air in trauma settings beyond this because it is outside the scope of this guideline.
British Elbow and Shoulder Society	Guideline	008	015 & 016	Whilst we accept the recommendation for stemmed prostheses, the evidence is less certain for stemless implants and there is not a consensus from BESS on the strength of this recommendation, which is based on small underpowered RCTs where quality of evidence in most areas is either LOW or VERY LOW. The recommendation from the RCTs is based on stemmed implants and this needs to be qualified, as there are several prostheses without stems in current use where there is the need to generate good quality evidence. Considering the limitations in current evidence, would it be more appropriate to say 'consider' rather than 'offer' conventional total shoulder	Thank you for your comment. The committee agree that the evidence is clearer for stemmed implants and not as clear for stemless. We did not review the evidence comparing stemmed versus stemless nor any other specific related to the type of implant to use (e.g. cemented versus non-cemented shoulder replacement) and therefore the committee agreed not to make recommendations on the type of implant to use. The committee discussed softening the recommendation to a 'consider'

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				arthroplasty, as the current recommendation is broad to include implants without stems? The research recommendations should include investigation of arthroplasties with and without stems across indications and populations, particularly in the younger population.	recommendation. Based on the evidence and their experience they agreed that total conventional shoulder replacement is still the best option if the glenoid bone is adequate and that the recommendation should remain as an 'offer recommendation. We have updated the rationale to state "The committee agreed that the type of implant should not be specified in the recommendation but should be part of shared decision making between the person having surgery and the surgeon."
British Elbow and Shoulder Society	Guideline	012	001 - 004	We are concerned about encouraging the use of reverse shoulder arthroplasty in younger patients with osteoarthritis and intact rotator cuff, even in the context of research. As with the other research recommendation where age (<60) has been specified, it would be more appropriate to specify an older age group (e.g.: >70) for this research recommendation.	Thank you for your comment. The committee agreed that the research question should be for all ages due to a lack of RCT evidence in any age group. They agreed that any decision to restrict the research question by age would be better left to organisation funding the research. The reason the committee included an age cut off in the humeral hemiarthroplasty research recommendation is because there was almost no evidence for people under the age of 60. The evidence predominantly related to those over the age of 60.
British Geriatrics Society	Guideline	General	General	The British Geriatrics Society will NOT be responding to this consultation	Thank you for your informing us.
British Orthopaedic Association (BOA), supported by BHS,	Guideline	General	General	We welcome the opportunity to comment on this draft guideline. We have divided the response into four sections – firstly presenting	Thank you for your comments. We have responded to each of these in turn.

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BASK, BESS				comments that apply across all of hip/knee/shoulder replacement, followed by sections specific to each joint.	
British Orthopaedic Association (BOA), supported by BHS, BASK, BESS	Guideline	005	014	**KNEE COMMENTS** Anaesthesia for knee replacement 1.3 We would agree that considering the use of nerve blocks can be beneficial but not combined femoral and sciatic.	Thank you for your comment. The committee agree that this should not be done as it reduces motor function and can delay with mobilisation of the patient can be started following surgery. We have added text to the recommendation to reflect that a nerve block can be considered but not if it impairs motor function.
British Orthopaedic Association (BOA), supported by BHS, BASK, BESS	Guideline	006	006	Tranexamic acid to minimise blood loss For hip and knee arthroplasty: Clearly there is good evidence for the use of tranexamic acid via the IV route and we strongly support this recommendation. Regarding the topical use of tranexamic acid, it should be acknowledged that reports have highlighted the potentially toxic effects to peri-articular tissues (1). In addition, we would seek to emphasize the frustration that clinicians experience when recommendations are made for what are "off-label" uses of a drug. The note 1 at the end of page 6 states that such topical use is not licensed and that the prescriber should take full responsibility for the decision. The fact that NICE recommend an unlicensed use of a drug and then expect	Thank you for your comment. The committee note that the McLean study cited related to the potentially toxic effects to periarticular tissue is an in-vitro study in which tissues are exposed to tranexamic acid for longer than would be the case in joint replacement operations. This study did not meet the review protocol and therefore was not included in the guideline. The committee agreed to recommend topical tranexamic acid as well as intravenous because it was shown to be cost-effective. They also agreed that in their experience topical (intra-articular) tranexamic acid is commonly used in combination with intravenous tranexamic acid in hip and knee

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				clinicians to take full responsibility for that decision certainly causes both conflict and confusion at a local level. For shoulder arthroplasty: We are not convinced that there is sufficient evidence to recommend tranexamic acid for shoulder replacement. All but 4 studies quoted out of 107 are on hip and knee replacements so there just isn't good evidence to support its use, especially as the committee acknowledges the fact that shoulder replacements virtually never need transfusions. Tranexamic acid toxicity in human periarticular tissues. M. McLean *Bone Joint Res* 2018;8:11–18. (This reference does not appear in the evidence review at 'Evidence review 7'.)	replacements. Overall, they believe the recommendation is in the best interests of people having hip and knee replacements. The committee agree that there is less evidence for the use of tranexamic acid in shoulder replacement. Although there may not be the same benefits in terms of reduced transfusions in shoulder replacement, because it is not associated with high blood loss, they noted that there is still reduced bleeding and this is beneficial to the patient. They also noted that tranexamic acid is an inexpensive treatment. With this in mind the recommendation has been changed to 'consider' tranexamic acid for people having joint replacement.
British Orthopaedic Association (BOA), supported by BHS, BASK, BESS	Guideline	006	016	Antibiotic or antiseptic agents in wound wash-out solutions: We agree with the conclusions of the panel that the use of antibiotics should be avoided. However, we are concerned at the recommendation not to use antiseptic agents in wound wash-out and we take the view that there is not good evidence to support this recommendation. The rationale for this	Thank you for your comment. We found no evidence to support the use of antiseptic agents in wound lavage. Furthermore the committee were aware that the surgical site infection guideline recommends against their use. With this in mind the committee agreed that infection prevention is adequately covered by the recommendations to use ultra-clean air and by the use of prophylactic antibiotics as recommended in the surgical site infections guideline (NG125)

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				recommendation states that saline wash is used to improve visibility of the operative site for the surgeon. There is another important reason for the saline wash after implantation, which is to remove debris and thus prevent third body wear of the prosthesis. To supplement the saline wash following prosthesis implantation, some surgeons use iodine or chlorhexidine mixed in saline to wash the prosthesis before wound closure. These agents are already used for skin preparation in these patients and therefore their use cannot be fully avoided. Emergence of resistance is therefore a moot point without substantiating evidence. Deploying the same agent used for skin prep to wash the implanted prosthesis provides a good opportunity to eliminate pathogens on the prosthetic surface from intra-operative seeding, and at a very low cost. Whilst intravenous antibiotics remain the mainstay to prevent infection, we would suggest antiseptic washes should not be disallowed.	(https://www.nice.org.uk/guidance/ng125). We have made a cross reference to this guideline in our recommendations.
British Orthopaedic Association (BOA), supported by BHS, BASK, BESS	Guideline	007	001	Ultra-clean air ventilation in operating theatres We strongly support the current recommendation to use ultra-clean air ventilation for the procedures in scope for this guideline.	Thank you for your comment. The committee discussed your comment and noted that the risk profile for trauma patients will be different. However, they have not discussed the use of ultra-clean air in trauma settings beyond this because as you state it is outside the scope of

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				We highlight that for joint replacement following fracture, we advocate that the same requirement for ultra-clean air theatres should apply as for elective surgery. We understand that this is slightly outside of the explicit scope of this guideline but we would strongly encourage NICE to comment on this issue, where there is variability in current practice. Our view is that arthroplasty patients receiving an operation following trauma, should be afforded the same standards of care as those for elective procedures. This can be particularly important given that those having surgery after trauma are likely to be a frail/elderly subpopulation and for whom infection can have particularly severe consequences.	this guideline.
British Orthopaedic Association (BOA), supported by BHS, BASK, BESS	Guideline	007	004	Avoiding implant selection errors The recommendation of the panel to have a formal "stop" at the time of implant checking is strongly supported. The use of a stop moment should already be standard practice. Additional suggestions: -A check when possible (i.e. depending on specific implant) the surgeon can read the actual size information on the implant itself (as	Thank you for your comment. The aim of the recommendation is that all factors are checked, not just size information on the implant. The committee agree with your suggestion for an additional check before the patient leaves the operation theatre. They decided the best time to have the second stop moment is before wound closure when there may be the opportunity to correct any error that might have occurred. We have amended the recommendation to read "Use 2 intraoperative

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				well as the label). -As an alternative to the recommendation in 1.6.2, suggest that implant stickers be checked in a "sign out" before the patient leaves the operating theatre. -Real time data entry to create an alert should be encouraged. Such systems are not widely available.	'stop moments', 1 before implantation and 1 before wound closure, to check all implant details and ensure compatibility of each component. The committee agree that real time data entry should be encouraged and have kept the recommendation to consider its use.
British Orthopaedic Association (BOA), supported by BHS, BASK, BESS	Guideline	007	013	**KNEE COMMENTS** Partial and total knee replacement We are supportive of statement 1.7.1. We suggest adding that surgeons must be adequately trained in partial knee replacement and be undertaking the procedure regularly (>12 per year) if they are to perform this. If a surgeon does not meet these criteria the surgeon should refer the patient to another surgeon who does meet the criteria. (The NJR Medical Advisory Committee and the BASK Executive have established the number as 12 per year to be proficient and skilled at the procedure.)	Thank you for your comment. The committee are aware there is a link between the exposure to the number of times an operation has been done and outcomes for the operation. This has been highlighted in the rationale where it states "The committee noted that total and partial knee replacement are very different types of procedure, and surgeons need to ensure they perform a sufficient number of each procedure every year to ensure good surgical outcomes". The committee did not look at the evidence for surgeon experience and the number of partial or total knee replacements so they have not made a recommendation in this area. They also agreed that any number could be seen as quite arbitrary in the absence of evidence.
British Orthopaedic Association (BOA), supported by BHS, BASK, BESS	Guideline	007	017	**KNEE COMMENTS** Patella resurfacing Offer patellar resurfacing to patients but risks and benefits must be explained.	Thank you for your comment. All NICE guidelines assume that the risks and benefits of any recommendation are discussed with the patient. Shared decision making is also

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					recommended as part of NICE guideline "Patient experience in adult NHS services: improving the experience of care for people using adult NHS services" (https://www.nice.org.uk/guidance/cg138) and has been cross referred to in this guideline. There is also a NICE guideline on shared decision making currently in development (https://www.nice.org.uk/guidance/indevelopment/gid-ng10120). Discussing the risk and benefits of each option was specifically highlighted in the preceding recommendation on total vs partial knee replacement because this recommends offering people a choice between 2 procedures.
British Orthopaedic Association (BOA), supported by BHS, BASK, BESS	Guideline	008	001	**HIP COMMENTS** Surgical approaches for primary elective hip replacement We support the conclusions of the panel and agree that there is no data to conclusively support one approach over another. We are pleased that the panel made no specific recommendation endorsing a particular approach. The most important comment is the recommendations that *"the surgeon should be experienced and competent in the approach they select".* We also strongly supports the	Thank you for your comment and support for the recommendation. It is noted in the rationale for the recommendation that the choice of approach should be based on the knowledge and experience of the surgeon and individual patient characteristics.

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				comment that further research is recommended.	
British Orthopaedic Association (BOA), supported by BHS, BASK, BESS	Guideline	008	015 - 016	**SHOULDER COMMENTS** Whilst we accept the recommendation for stemmed prostheses, the evidence is less certain for stemless implants and there is not a consensus from BESS on the strength of this recommendation, which is based on small underpowered RCTs where quality of evidence in most areas is either LOW or VERY LOW. The recommendation from the RCTs is based on stemmed implants and this needs to be qualified, as there are several prostheses without stems in current use where there is the need to generate good quality evidence. Considering the limitations in current evidence, would it be more appropriate to say 'consider' rather than 'offer' conventional total shoulder arthroplasty, as the current recommendation is broad to include implants without stems? The research recommendations should include investigation of arthroplasties with and without stems across indications and populations, particularly in the younger population.	Thank you for your comment. The committee agree that the evidence is clearer for stemmed implants and not as clear for stemless. We did not review the evidence comparing stemmed versus stemless nor any other specific related to the type of implant to use (e.g. cemented versus non-cemented shoulder replacement) and therefore the committee agreed not to make recommendations on the type of implant to use. The committee discussed softening the recommendation to a 'consider' recommendation. Based on the evidence and their experience they agreed that total conventional shoulder replacement is still the best option if the glenoid bone is adequate and that the recommendation should remain as an 'offer recommendation. We have updated the rationale to state "The committee agreed that the type of implant should not be specified in the recommendation but should be part of shared decision making between the person having surgery and the surgeon.**"**

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British Orthopaedic Association (BOA), supported by BHS, BASK, BESS	Guideline	009	007	Postoperative care and rehabilitation We are aware of UK concerns about opioid use and we suggest this should be covered within this guideline in relation to post-operative rehabilitation. Post-operative pain management is not currently covered by this guideline and nor we believe by any other more general NICE guidance regarding surgery. We have two comments: Firstly, where opioids are considered as an approach to management of post-operative pain, this should be short-term and with a tapering dose protocol. Secondly, we are aware that some patients are on opioids prior to surgery as part of their pain management programme; although this is not what we would consider to be best practice or routine, it is important that a patient's care programme will also support them to come off such medications post-surgery, and we recommend that this is covered by the guideline. We are also aware of and involved in another NICE workstream looking at prescribing and withdrawal from these medications.	Thank you for your comment. Postoperative pain relief was not included as an area to cover in the scope. It is being covered in the NICE guideline on perioperative care in adults (https://www.nice.org.uk/guidance/indevelopment/gid-ng10072) currently in development.
British Orthopaedic	Guideline	009	021	For patients undertaking self-directed	Thank you for your comment. We have

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Association (BOA), supported by BHS, BASK, BESS				rehabilitation, we would like to see greater emphasis on the need for clear lines of communication and ensuring patients know how to access support if required.	updated our recommendation to state: Ensure that people who are undertaking self-directed rehabilitation have • a clear understanding of their rehabilitation goals and target and the importance of doing the exercises prescribed to achieve these goals • a point of contact for advice and support.
British Orthopaedic Association (BOA), supported by BHS, BASK, BESS	Guideline	010	018	Long-term after-care Regarding routine follow up for asymptomatic patients, we note that 'The committee were unable to make recommendations for practice in this area' and recommends research. Existing BOA/BHS/BASK Commissioning guides (2, 3) outline our recommendations for routine follow-up at 6 weeks, at one year, at seven years and three yearly thereafter. We advise continuing with this existing practice. (We are also aware of the 'UKSAFE' study which is looking at the value of follow-up but is yet to publish its findings.) 2: BOA, BHS, RCSEng Hip Commissioning guide (2017): https://www.boa.ac.uk/uploads/assets/2a2182ef-979a-447b-95f671b7e73e15a9/pain%20arising%20from%	Thank you for your comment. The committee were aware that an initial follow-up appointment at around 6 weeks after the operation is standard practice throughout the NHS. Because they did not think there was variation in this practice it was decided to focus the guideline review on long term follow up for which they agreed there is variation in practice. The committee were aware that the results of the UKSAFE study were being analysed and are due to be published soon. This investigates long-term follow up and directly addresses the question asked in this guideline. The committee agreed to make a research recommendation to avoid any future contradictory advice on the frequency of long term follow up. We will send the details of the UKSAFE study to the NICE surveillance team which monitors guidelines to ensure that they

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				20the%20hip%20guide.pdf 3: BOA, BASK, RCSEng Knee Commissioning guide (2017): https://www.boa.ac.uk/uploads/assets/f1bb6329-2d48-4221-9abd2c32c5731061/painful%20oa%20knee%20guide.pdf	are up to date.
British Orthopaedic Association (BOA), supported by BHS, BASK, BESS	Guideline	011	001	Regarding follow-up for patients with symptoms, we are concerned about the general wording: "Primary care practitioners should refer people who develop new or worsening pain, limp or loss of function related to their joint replacement to the orthopaedic team." Our view is that: • All patients should have a direct route to access orthopaedic specialist care in the period after discharge while they are recovering from surgery, particularly for cases of infection. • A clear, robust, efficient pathway should be in place for all patients who develop new or worsening pain, limp or loss of function related to their joint replacement that allows prompt clinical & radiographic assessment by an appropriately trained practitioner.	Thank you for your comment. The guideline only covers long term follow up and therefore provides no guidance on any postoperative follow up appointment by the surgical team. The committee are aware that there is there is universally orthopaedic team follow-up after the operation and they anticipate that this practice will continue. Therefore any potential infection is likely to be picked up at this meeting. The committee were aware that the results of the UKSAFE study were being analysed and are due to be published soon. This investigates long-term follow up and directly addresses the question asked in this guideline. The committee agreed to make a research recommendations to avoid any future contradictory advice on the frequency of long term follow up. The committee also agreed that once a person

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					has been discharged from orthopaedic care then should a problem arise it will be primary care that assesses and refers a person back to orthopaedic services. With this in mind and in the absence of evidence for regular follow up appointments they made the recommendation "Primary care practitioners should refer people who develop new or worsening pain, limp or loss of function related to their joint replacement to an orthopaedic surgical service."
British Orthopaedic Association (BOA), supported by BHS, BASK, BESS	Guideline	012	001 - 004	**SHOULDER COMMENTS** We are concerned about encouraging the use of reverse shoulder arthroplasty in younger patients with osteoarthritis and intact rotator cuff, even in the context of research. As with the other research recommendation where age (<60) has been specified, it would be more appropriate to specify an older age group (e.g.: >70) for this research recommendation.	Thank you for your comment. The committee agreed that the research question should be for all ages due to a lack of RCT evidence in any age group. They agreed that any decision to restrict the research question by age would be better left to organisation funding the research. The reason the committee included an age cut off in the humeral hemiarthroplasty research recommendation is because there was almost no evidence for people under the age of 60. The evidence predominantly related to those over the age of 60.
British Orthopaedic Association (BOA), supported by BHS, BASK, BESS	Guideline	022	022	**KNEE COMMENTS** "Bristol Knee Score" should be "Oxford Knee Score"	Thank you for your comment. We have updated the rationale to refer to patient reported outcomes rather than specific scores. We have checked the study. The paper in

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					question repeatedly indicated they utilised the Bristol Knee Score (rather than the Oxford Knee Score) and this appears to be a valid knee score.
British Orthopaedic Association (BOA), supported by BHS, BASK, BESS	Evidence review K	015	034	**KNEE COMMENTS** The consultation document states that "the TOPKAT trial is currently in the process of publishing its results and would be a relevant trial." 5-year results of the TOPKAT study have now published and should be included in the analysis. *Beard et al. The clinical and cost-effectiveness of total versus partial knee replacement in patients with medial compartment osteoarthritis (TOPKAT): 5-year outcomes of a randomised controlled trial. Lancet. 2019 Aug 31;394(10200):746-756. Epub 2019 Jul 17.*	Thank you for your comment. The study organisers provided a draft copy of the TOPKAT results paper for the committee to review before we submitted the guideline for consultation. The committee agreed that these results fitted with the recommendations they had drafted for the guideline. The results were published during the guideline consultation and we have added them to our review. They are similar to the other 2 included studies, 4 PROMs outcomes from TOPKAT did not indicate any clinical difference between treatment groups and the length of stay outcome again indicated a benefit of UKR. 1 new outcome was reoperation within 5 years of surgery, which indicated a benefit of UKA. In terms of major revision within 5 years of surgery, the committee agreed it was too early to draw strong conclusions on major revision within that time span and the resulting evidence was not clinically significant. Now that the results have been added the

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					committee agree that the recommendation that was written for the consultation version of the guideline is still valid.
GP Survival	Guideline	003	017	We welcome the inclusion of advice to discuss returning to work whenever patients are recommended surgical procedures that will impact on their employment. GP Survival recommends that the draft guideline clarifies this recommendation to ensure that hospital teams recognise the onus is on them to provide advice and certification, if needed, to their patients. This would align the draft guidance with (1) relevant DWP guidance and (2) the NHS Standard Hospital contract. (1) the Department of Work & Pensions document 'Statement of Fitness for Work, A guide for hospital doctors' (https://www.gov.uk/government/publications/fit-note-guidance-for-hospital-doctors) specifies on p2-3 that "not issuing Med 3s denies patients the best care and leads to unnecessary duplication and extra work for GPs. In many cases it is the hospital doctor who is best placed to give advice on a patient's fitness for work." This is reiterated in the DWP document 'Questions and answers about certification and medical reports – for healthcare practitioners'	Thank you for your comment. The recommendation provides advice on what information to give to people undergoing joint replacement. They are not intended to provide details on how to give this information. We have added text to the other considerations section committee discussion of the evidence report noting that some people will be working and will therefore require return to work notes. We have also made reference to the DWP guidance in this section.

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				(https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/251504/hcp-reports-q-and-a.pdf): "The duty to provide a medical statement rests with the doctor who has clinical responsibility for the patient at the time. Hospitals are required to provide all statements for Social Security and Statutory Sick Pay purposes and statements for both inpatients and outpatients who are incapable of work. DWP have reminded hospital doctors of their responsibility to issue Med 3s in guidance which has been published on the DWP website and sent to Chief Executives of all NHS Trusts in England and Health Boards in Scotland and Wales." (p3) (2) The NHS Standard Contract for NHS acute trusts for 2017-2019 made the same points as summarised here (https://www.england.nhs.uk/south/wp-content/uploads/sites/6/2019/03/fit-notes-briefing-a-guide-for-Hospital-Doctors.-V1.-FEB2019..pdf): "it is important that fit notes are issued to patients in a way which is convenient for them and which is efficient in the use of clinical staff time. Where there is an appropriate opportunity (whether on discharge from hospital, within the emergency department or in clinic) provider clinicians must	

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				issue fit notes to appropriate patients, and their organisations must enable this, rather than expecting patients to make a separate appointment to see their GP simply for this purpose. The contract also requires that fit notes cover an appropriate period, that is, until the patient is expected to be fit for work (following surgery, for example) or until a further clinical review, if required." GP Survival would therefore recommend that the final guidance should be clear that the responsibility to counsel the patient on fitness for work, and to provide any necessary paperwork in relation to that advice, rests with the surgical team in charge of the patient's hospital care. Further, it would be helpful if details of the recommended period off work were included in documentation to both the patient and their GP.	
Johnson & Johnson Medical Ltd.	Guideline	General	General	Johnson & Johnson Medical welcome the recommendations within this draft guideline and support the conclusions of the GDG. We note that on a number of occasions the GDG utilised registry data to inform its interpretation of the evidence and decision making, and we welcome this approach by NICE for registry data to be considered alongside published trial	Thank you for your comment.

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				evidence.	
National Joint Registry	Guideline	004	013	As NICE were unable to make recommendations for practice, could they reference the NJR support tool at https://jointcalc.shef.ac.uk/	Thank you for your comment. We looked for trials evaluating the effectiveness of decision aids but found no evidence supporting their use. The suggested decision aid has only just become available and its effectiveness has yet to be assessed. With this in mind the committee made a research recommendation for decision aids.
Neurocare Europe Limited	Guideline	General	General	We are commenting on the draft guideline and on two of the evidence reviews namely (C) pre-operative rehabilitation and (R) post operative rehabilitation. We have not commented on either pre or post op rehabilitation related to shoulder joint replacement because as the committee has noted there is very little evidence in this application. We have also concentrated on TKA (rather than THA) since most of the clinical evidence of the application of our therapy is in TKA We recognise that it is not the prime purpose of this guideline to present a detailed review of the broad range of modalities which may aid rehabilitation pre and post TKA and THA. Nevertheless it is disappointing to see that only physiotherapy (self directed or group based) is	Thank you for your comment. When discussing the reviews for rehabilitation the committee discussed what would add the most value to the guideline for people having joint replacement surgery. They agreed that focusing on rehabilitation as whole was a higher priority than the individual components of rehabilitation. The specific interventions required by an individual would vary depending on that person's circumstances. For preoperative rehabilitation the committee discussed that preoperative rehabilitation programmes have been proposed as a potential way to expedite recovery times and improve overall extent of recovery in patients planning to undergo joint replacement. With

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				given prominence particularly in a situation where just about all the available evidence, including that presented by yourselves and several readily available meta-analyses published in recent years suggests that this form of exercise is only minimally effective in the short term and barely detectable in the longer term (eg 24 months). In the previous consultation on scope in response to our own and other respondents' comments the following statement was made "Specific interventions will be considered when drafting protocols for post-operative rehabilitation." This does not seem to have happened either in relation to the therapy with which our company is most familiar Neuromuscular Electronic Stimulation (NMES) and indeed others mentioned which are described as follows "These can include physical therapy, occupational therapy, nutritional counselling, acupuncture, transcutaneous electrical nerve stimulation, hydrotherapy or education interventions (preoperative teaching programs) that might aid in recovery" In other NICE publications and in this one reference is made to the characteristics of this and similar patient populations. In particular this document notes "However, these individuals often still have physical problems	this in mind the decision was to focus the review on whether preoperative programmes should be provided and whether it should involve multiple sessions, prescribed and supervised exercises and/or advice by a member of the rehabilitation team. The committee noted that these programmes can include a number of interventions such as physiotherapy, occupational therapy, nutritional counselling, acupuncture, transcutaneous electrical nerve stimulation, hydrotherapy or education interventions (preoperative teaching programs) that might aid in recovery. They also agreed that the key to preoperative rehabilitation program is the combination of educational therapy in combination with some form of physiotherapy, and this is predominantly delivered through exercises. For postoperative rehabilitation the committee agreed the focus should be on whether it is more effective for rehabilitation to start immediately, on the day of surgery or after the day of surgery; and whether it is more effective to have self-directed outpatient rehabilitation or supervised outpatient rehabilitation. Overall, the committee have left it to clinicians to decide what interventions to include in their

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				and are not fully recovered. These problems may include: muscle weakness, low endurance, reduced joint range of motion, and difficulties in performing more strenuous activities of daily living such as domestic activities, work, sports and exercise, and other leisure pursuits." And elsewhere in supporting notes "recovery for a significant proportion of people remains difficult and prolonged and many never gain optimal functionality postoperatively". Joint replacement has in recent years become a relatively routine and successful procedure in terms of the mechanical outcomes of the process yet many patients as noted above never recover their pre-operation strength, endurance and mobility. This outcome is not surprising given the evidence presented throughout these consultation documents. Irrespective of whether physical therapy supervised or self-directed, pre operation or post operation is considered, the conclusion must be that land based mild bending and stretching exercise delivered in what,across the NHS, appears to be a somewhat haphazard and inconsistent manner will not for many, perhaps most, patients deliver the transformation of mobility and attainment of a pain free life which joint replacement offers the promise of. Indeed this evidence suggests	rehabilitation. We have commented on the studies you mention in response to your comment listing the citations.

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				that there is high risk of a very successful surgical procedure of potential benefit to millions being seriously compromised by poor follow-up after care. We contend that our therapy, NMES has the clinical evidence to suggest it could transform rehabilitation at low cost. Many of the clinical trials referenced describe these effects across the range of outcomes which the committee judges to be essential. In particular please note reference 23. Implicit in the quotations in paragraph 4 above is the inescapable conclusion that if more effective and comprehensive rehabilitation is not routinely made available many patients will not recover their pre-disablement strength and mobility. Immobility undermines self-sufficiency, creates dependency and may substantially increase the cost of social care .Effective rehabilitation is good for individuals and good for society. It is clear in the material included throughout this consultation that a satisfactory level of rehabilitation is frequently not achieved.	
Neurocare Europe Limited	Guideline	General	General	NMES in TKA and THA WE have, in response to previous invitations, submitted evidence to NICE on the benefits of and clinical evidence supporting the use of neuromuscular electronic stimulation.	Thank you for your comment. As noted in our previous response the committee agreed that focusing on rehabilitation as whole was a higher priority than the individual components of rehabilitation. The specific interventions

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				Evidence of efficacy is strong in treating many conditions where progressive muscle impairment (atrophy) is one of the symptoms of the condition under treatment. NMES is considered by FDA to be indicated in six situations, these being: Increase of Local circulation; 2) Muscle re-education; 3) Relaxation of muscle spasms; 4) Maintaining or increasing range of motion; 5) Prevention or retardation of disuse atrophy; 6) Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis. NMES devices vary greatly in their electronic design, controls and output characteristics. The simplest units are small battery powered plastic bodied devices. Those used in a clinic or hospital environment are usually of the mains powered "console" type. In the past many NMES devices have been uncomfortable when used at higher intensity (voltage) settings. However many devices in use now have overcome this drawback through advances in electronic design. Our own product, the Neurocare 2000 largely avoids any problem of discomfort by utilising AC (alternating current rather than DC ,direct current) output which allows very high voltage (c350 volts) for full muscle recruitment at less than 10 milliamps of current .Current is the painful part of stimulation, most patients find	required by an individual would vary depending on that person's circumstances. Therefore the committee have not reviewed any evidence specific to NMES.

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				any output above 60 milliamps increasingly uncomfortable which inevitably undermines compliance .Electrode design and construction is also important for comfort and signal penetration; we specify the best quality available to provide optimum penetration and dispersion of the electrical signal through tissue Clinical trials can use any type of device design and this feature complicates inter trial comparisons of efficacy since the output configuration and peak power output directly determines the form and quality of therapy administered and the clinical results obtained. Broadly speaking high voltage causes stronger muscle activation but this is only tolerable and comfortable to the patient if current (amperage) is minimised The FDA indications mentioned all play a part in rehab after TKA (and THA) and it is important to note the clinical application of NMES in avoiding venous thrombosis. Patients undergoing knee or hip replacement are at high risk of thrombosis at all stages through post-op rehab and NMES which clinical trials have often shown to be superior to sequential compression devices (SCDs) in terms of promoting local circulation bring the added clinical advantage of exercising local musculature. SCDs are invariably used and	

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				trialled working in combination with low molecular weight heparin; whereas NMES is used in this application as a stand-alone intervention normally without the need for the potentially dangerous addition of Heparin. Note SCDs are also referred to as intermittent pr NMES brings many advantages to the treatment of musculoskeletal conditions being safe, comfortably within the ability of most patients to self-treat unsupervised in the home if appropriate and with initial familiarisation delivered by experienced personnel. . Side effects are minimal and limited to very occasional allergic reactions to the surface gel on electrodes We have included a list of representative clinical trial evidence which assesses the application of NMES at all stages along the (TKA) clinical pathway where in addition to improving strength ,range of motion and restoring pre disability mobility most trials report substantial reductions in pain and improved HRQoL COSTS We have not attempted a comprehensive analysis of the costs of NMES since there are many factors which must be considered which would include the stage(s) along the TKA clinical pathway when it could be used; the	

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				setting ,be it clinic, hospital or other location eg the home,the degree of supervision (if any),the expected service life of the device,the level of utilisation envisaged, the cost and expected life of consumables(electrodes) etc In a clinical setting assuming a device life of 10 years, 4 treatments per weekday with a capital cost of £2000 each treatment (45 minutes) would cost c 20 pence in terms of device cost and £1 in consumable (electrode) cost ie £1.20 per treatment. THA We have concentrated our response to this consultation on TKA which has been the subject of most clinical trial activity and where the majority of evidence has been obtained. We do not diminish the importance of effective rehabilitation post THA but acknowledge that published clinical trial information on the use of NMES in THA is sparse. The trials which we are aware of report that similar gains in strength, improvements in range of motion and reductions in pain are achieved. CONCLUSION We appreciate the opportunity to contribute to this consultation in this increasingly important subject area and would be happy to cooperate in any way to the development of knowledge	

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				and the progressive improvement in clinical practice. Clinical Trials follow	
Neurocare Europe Limited	Guideline	General	General	CLINICAL STUDIES IN TKA WITH AND WITHOUT NMES PRE-OP PHYSIOTHERAPY 1] J Arthroplasty. 2015 Sep;30(9):1657-63. doi: 10.1016/j.arth.2015.04.013. Epub 2015 Apr 11.Does Pre-Operative Physiotherapy Improve Outcomes in Primary Total Knee Arthroplasty? - A Systematic Review.Kwok IH1, Paton B1, Haddad FS1.University College London Hospital, London, UK. 2] hysiother Theory Pract. 2017 Jan;33(1):9-30. doi: 10.1080/09593985.2016.1230660. Epub 2016 Oct 13.Does preoperative physiotherapy improve postoperative, patient-based outcomes in older adults who have undergone total knee arthroplasty? A systematic review.Chesham RA1, Shanmugam S1. Department of Psychology, Social Work and Allied Health Sciences , School of Health and Life Sciences, Glasgow Caledonian University , Glasgow , UK. 3] Preoperative physiotherapy and short-term functional outcomes of primary total knee arthroplasty.Mat Eil Ismail MS[1,2], Sharifudin	Thank you for your comment. We have reviewed these studies and none of them meet the inclusion criteria for our protocols. With regard to the studies cited for preoperative physiotherapy the 4 studies you have suggested were not included in the review for the following reasons. Studies 1 and 2 are systematic reviews that were not included in this guideline review as they did not match our review protocol. We checked the studies cited in these to see in any should be included in our guideline systematic review. Studies 3 and 4 did not meet the protocol because study 3 did not include an advice aspect in the treatment group and study 4 was a prognostic study on quadriceps strength. Studies 8 to 12 on postoperative physiotherapy were not included for the following reasons. Studies 8, 9 and 11 are systematic reviews that were not included in this guideline review as they did not match our review protocol. We checked the studies cited in these to see in any should be included in our guideline systematic review. Studies 10 and 12 were not

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				MA[2,3], Shokri AA[2], Ab Rahman S[2] 4] J Rheumatol. 2005 Aug;32(8):1533-9. Preoperative quadriceps strength predicts functional ability one year after total knee arthroplasty. Mizner RL[1], Petterson SC, Stevens JE, Axe MJ, Snyder-Mackler L. PRE-OP WITH NMES 5] BMC Musculoskelet Disord. 2010 Jun 14;11:119. doi: 10.1186/1471-2474-11-119.Effects of preoperative neuromuscular electrical stimulation on quadriceps strength and functional recovery in total knee arthroplasty. A pilot study.Walls RJ[1], McHugh G, O'Gorman DJ, Moyna NM, O'Byrne JM. 6] BMC Musculoskelet Disord. 2012 Jul 3;13:118. doi: 10.1186/1471-2474-13-118.Effects of home-based resistance training and neuromuscular electrical stimulation in knee osteoarthritis: a randomized controlled trial.Bruce-Brand RA[1], Walls RJ, Ong JC, Emerson BS, O'Byrne JM, Moyna NM. 7] Clin Interv Aging. 2014 Jul 17;9:1153-61. doi: 10.2147/CIA.S64104. eCollection 2014. The effects of exercise and neuromuscular electrical stimulation in subjects with knee	included because they did not match the review protocol by comparing supervised rehabilitation to self-directed rehabilitation after joint replacement surgery. Studies 5 to 7 and 13 to 23 relate to specific rehabilitation interventions, in this case NMES. As this was not a focus of the reviews in this guideline there were not included. Prevention of DVT is covered by another NICE guideline (https://www.nice.org.uk/guidance/ng89/) and therefore references 24 to 29 were not included. Studies 30, 31 and 33 were excluded because they are prognostic studies specific to muscle strengthening. Study 31 investigates people with knee osteoarthritis who may not have had, or may not have been scheduled to have, joint replacement surgery. Study 34 was excluded as it looks only at patient tolerance of neuromuscular electrical stimulation not at the overarching effects of postoperative outpatient rehabilitation.

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				15] J Orthop Sports Phys Ther. 2007 Jul;37(7):364-71. Early neuromuscular electrical stimulation to optimize quadriceps muscle function following total knee arthroplasty: a case report.Mintken PE[1], Carpenter KJ, Eckhoff D, Kohrt WM, Stevens JE. 16] Early Neuromuscular Electrical Stimulation to Improve Quadriceps Muscle Strength After Total Knee Artroplasty: A randomized Controlled Trial.Jennifer E. Stevens-Lapsley, Jaclyn E. Balter, Pamela Wolfe, Donald G. Eckhoff, Wendy M.Kohrt Phys Ther. 2012 February; 92(2): 210–226. Published online 2011 November 17. doi: 10.2522/ptj.20110124 PMCID: PMC3269772 17] Neuromuscular Electrical Stimulation for Quadriceps Muscle Strenghening After Bilateral Total Knee Arthroplasty: A Case Series. Jennifer E Stevens, Ryan L. Mizner, Lyn Snyder-Mackler J. Orthop Sports Phys Ther. 2004;34(1):21-29. doi: 10.2519/jospt.2004.0947 13). Early Neuromuscular Electric Stimulation Improves Strength and Functional Performance After Total Knee Arthrosplasty. 18]). Response of male and female subjects	

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				after total knee arthroplasty to repeated neuromuscular electrical stimulation of the quadriceps femoris muscle. Laufer Y, Snyder-Mackler L. Am J Phys Med Rehabil. 2010 Jun;89(6):464-72. 19] Relationship between intensity of quadriceps muscle neuromuscular electrical stimulation and strength recover after total knee arthroplasty. Stevens-Lapsley JE, Balter JE, Wolfe P, Eckhoff DG, Schwartz RS, Schenkman M, Kohrt WM. Phys Ther. 2012 Sep;92(9):1187-96. Epub 2012 May 31. PHYSIOTHERAPY VERSUS NMES 20] BMJ Open. 2018 Feb 28;8(2):e020368. doi: 10.1136/bmjopen-2017-020368. Effectiveness of postdischarge interventions for reducing the severity of chronic pain after total knee replacement: systematic review of randomised controlled trials. Wylde V[1,2], Dennis J[1], Gooberman-Hill R[1,2], Beswick AD[1]. 21] Electrical Stimulation Versus Voluntary Exercise in Strengthening Thigh Musculature After Anterior Cruciate Ligament Surgery. Anthony Delitto, Steven J. Rose, Joseph M. McKowen, Richard C. Lehman, James A. Thomas and Robert A. Shively Phys. Ther. 1988; 68:660-663	

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				LR, OLaighin G. ..... "more effectively emptying the veins and soleal sinuses. This is an important finding as DVT occurs predominantly in the soleal sinuses. NMES is silent and portable and thus does not suffer many of the issues associated with IPC." GENERAL 30] Knee. 2019 Jan;26(1):79-87. doi: 10.1016/j.knee.2018.12.005. Epub 2018 Dec 29.Preoperative quadriceps weakness preferentially predicts postoperative aberrant movement patterns during high-demand mobility following total knee arthroplasty.Christensen JC[1], Mizner RL[2], Bo Foreman K[3], LaStayo PC[4], Peters CL[5], Pelt CE[6]. 31]BMC Musculoskelet Disord. 2012 Jul 3;13:118. doi: 10.1186/1471-2474-13-118.Effects of home-based resistance training and neuromuscular electrical stimulation in knee osteoarthritis: a randomized controlled trial.Bruce-Brand RA[1], Walls RJ, Ong JC, Emerson BS, O'Byrne JM, Moyna NM. 32] Early quadriceps strength loss after total	

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Neurocare Europe Limited	Evidence review R	General	General	Document Evidence review R – Outpatient hip and knee postoperative rehabilitation The Authors of this draft guideline have completed a similar evidence review of post-operation physical therapy and have reached broadly the same conclusion as for pre-op, that there is very little evidence of positive effects.	Thank you for your comment. The committee agrees that there is little evidence in this area and have made a recommendation for research related to this question. When discussing the review questions to cover the committee agreed that focusing on rehabilitation as whole was a higher priority than the individual components of

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				Whilst short term improvement is sometimes reported these are not sustained in the longer term. In commenting on the draft guideline the respondents from the University of Bristol musculoskeletal research unit who one presumes have extensive research expertise in post joint replacement therapy emphasise this conclusion in noting that "evidence for benefit not strong particularly for benefit beyond classes" (REFS,8,9,10,11,12} In the general literature specifically on rehab post TKA the point is frequently made that weakness in the quadriceps is only partially caused by atrophy (c20%) with activation defects accounting for up to c 80% and those who have researched the application of NMES post TKA have postulated that the mechanism of action of NMES may contribute to resolving activation defects which conventional physical therapy does not. A further finding of some consequence for post –op rehabilitation is an important clinical trial outcome reported by Christensen (REF 30) where it was found that pre-operative quadriceps strength reliably predicted the performance of the joint post op. "Conclusion: Our findings highlight patients' preoperative quadriceps strength as a meaningful predictor of postoperative performance. Preoperative	rehabilitation. The specific interventions required by an individual would vary depending on that person's circumstances. Therefore the committee have not reviewed any evidence specific to NMES or muscle strengthening. We have checked the references you cite none of which meet our review protocols and are therefore not included in this guideline.

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				quadriceps strength should be addressed when considering the knee's ability to contribute to higher demanding mobility tasks following surgery. Clinical trial 5 makes a similar point.	
Neurocare Europe Limited	Evidence review C	General	General	Document Evidence review C – Preoperative rehabilitation We again draw attention to the probable physical status of this patient cohort in the weeks immediately preceding surgery. Firstly their inclusion on the list for operation will have been long delayed in most parts of the country so that they will probably be experiencing intense pain and the knee or hip to be replaced may be sufficiently unstable for confident ambulation so that any form of physical exercise may be an unrealistic (and probably to the patient, an unwelcome) expectation on the part of therapists. Patients who are candidates for joint replacement are becoming increasingly older, relatively immobile and increasingly less able to undertake volitional exercise at the level of intensity necessary to bring about measurable improvements in physical function and this underlying incapacity must be recognised in both the design of and the expected outcomes	Thank you for your comment. The committee agrees that there is little evidence in this area and have made a recommendation for research related to this question. When discussing the review questions to cover the scope, the committee agreed that focusing on rehabilitation as whole was a higher priority than the individual components of rehabilitation. The specific interventions required by an individual would vary depending on that person's circumstances. Therefore the committee have not reviewed any evidence specific to NMES or muscle strengthening. We have checked the references you cite none of which meet our review protocols and are therefore not included in this guideline.

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				from both pre-op and post-op rehabilitation. This draft guideline has presented the results of an extensive literature search which has sought to establish whether there is sufficiently robust clinical evidence to establish a clear superiority of self directed physiotherapy over supervised physiotherapy or vice versa in the pre-operation period. The critical outcomes were agreed to be quality of life (QOL), Patient Reported Outcome Measures (PROMs), time until joint replacements were revised, depression, and disability The analysis has concluded that there is insufficient evidence to establish whether either self-directed or supervised physiotherapy is the more effective. Frankly it has concluded that neither option is effective (in terms of the critical outcome measures) other than perhaps in reducing length of hospital stay which as the committee acknowledges is a somewhat imprecise measure likely to be affected by other operational considerations and perhaps subject to assessment bias. If the clinical trials selected by the committee are considered in conjunction with the recent meta-analyses (REFS 1,2,3,) which we have highlighted and amplified by the comments submitted by Bristol University in the scope	

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				consultation it is difficult not to conclude that for this patient population after complex surgery, basic physiotherapy is fundamentally ineffective. It will not by itself, remedy the strength, range of motion and mobility issues as well as promote a sufficient level of well being for near normal scores to be registered on HRQoL indices by fully rehabilitated patients.	
Primary Care Rheumatology and MSK Medicine Society	Guideline	003	General	Information and shared decision making …. The PCRMM were pleased to see that shared decision making was recommended. There was no recommendation around decision aids. We were not sure if scores such as the Oxford knee and hip score had been included in this evidence search and the society would value some more definitive advice on using these types of scoring system. Regarding possible rationing of joint replacement sue to BMI we did not find reference to this in the guideline although it is mentioned in NICE OA guideline. Given that this draft is for consideration by both primary & secondary care,we are concerned that not enough emphasis is placed on measures which should be taken to possibly delay referral to secondary care initially where appropriate, with attention to	Thank you for your comment. The guideline did not include a review on which scoring system to use so we are unable to provide guidance on this. Scoring systems such as the Oxford Knee Score (OKS) and Oxford Hip Score (OHS) were used as an outcome measure in the following reviews included in this guideline: preoperative rehabilitation, tranexamic acid, partial vs total knee replacement, patella resurfacing, surgical approach for hip replacement and outpatient hip and knee rehabilitation. The effect of BMI on outcomes following joint replacement was excluded from this guideline as it is covered by the osteoarthritis guideline CG177 which is currently being updated. This includes a review on preoperative patient factors (e.g. BMI or age) associated with benefits or harms after joint replacement surgery.

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				weight management & use of physiotherapy to try & improve both activities of daily living pre-referral & post-operative outcomes. Furthermore, there does not appear to be any reference to standardizing post-operative anticoagulation in an effort to address the high risk of venous thromboembolism & it's consequences following orthopaedic procedures. Additionally, the question of peri-operative anticoagulation for those patients already on coumarins or NOACs, & where responsibility for formulating a 'bridging plan' for managing such patients lies, appears to have been overlooked.Given that our experience shows confusion,lack of clarity & inconsistency in the designation of responsibility in this area,this would represent the perfect opportunity to make clear where and with whom this responsibility lies.	Venous thromboembolism prophylaxis is covered bya separate NICE guideline and bridging therapy has been reviewed by the perioperative care guideline. A link to this will be in the pathway for this guideline.
Primary Care Rheumatology and MSK Medicine Society	Guideline	009	007	**Section 1.10 page 9** We are concerned that the evidence that NICE have looked at looks very poor with small numbers involved and very few of the studies being in the UK. Their recommendations do reflect this but to they seem quite vague and open to interpretation/misinterpretation... We would worry that commissioners would use this to decommission a lot of post op rehab apart	Thank you for your comment. The committee discussed your comment with reference to all the postoperative rehabilitation recommendations. For postoperative rehabilitation in hip and knee replacement the evidence and consensus suggested that self-directed rehabilitation was, for many people, as effective as supervised

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				from for the very limited group mentioned and we're not convinced that the evidence would support this.	rehabilitation. The committee also noted that there is potential cost savings associated with self-directed rehabilitation. While self-directed rehabilitation is recommendation for most people having hip or knee replacement the committee also recommend that should this not be working then supervised group or individual rehabilitation should be offered. For postoperative rehabilitation in shoulder replacement the evidence was less clear and the consensus was that any of the 3 options should be offered (i.e. self-directed or supervised group or individual rehabilitation). Overall, the committee intended for all people to have effective rehabilitation. We have updated the outpatient postoperative rehabilitation recommendations and the rationales for both the inpatient and outpatient postoperative rationales to make these clearer.
Royal College of Anaesthetists	Guideline	General	General	We are disappointed that laminar flow is still recommended despite a lack of evidence.	Thank you for your comment. The committee discussed the ultra-clean air recommendations again and are happy that their original conclusion is the right recommendation. We have added more explanation to the rationale noting that the committee agreed that patient safety is the primary consideration and that infection after a joint replacement is a serious complication. Because of this, and given the

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					uncertainty of the evidence, the committee agreed to recommend that current practice be maintained. Other stakeholders also supported the recommendation.
Royal College of Nursing	Guideline	General	General	This seems a well-written document with appropriate review of evidence and a considered review presented along with key areas for further research.	Thank you for your comment.
Royal College of Nursing	Guideline	General	General	**Questions** In response to the questions below: Which areas will have the biggest impact? - Our reviewer considered that the recommendation for preoperative rehabilitation (including pre/post-operative exercises) has potential to positively impact on patient outcomes and welcomed the recommendation. This recommendation will help standardise practice although may have resource implications for some healthcare providers where this is not currently delivered. Examples of best practice would help guide providers who do not currently deliver this service.	Thank you for your comment. The committee agree it will have resource implications for some providers although they do not anticipate this will lead to a substantial change in practice for all the NHS. Preoperative rehabilitation advice is recommended rather than a preoperative rehabilitation package. The committee agreed that most services currently offer advice.
Royal College of Nursing	Guideline	General	General	The Royal College of Nursing (RCN) welcomes the opportunity to comment on the NICE guidelines: Joint replacement (primary):	Thank you for your comments. We have responded to each in turn.

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				hip, knee and shoulder. The RCN invited members with expertise and experience of caring for people in this clinical area to review the document on the RCN's behalf. The comments below reflect the views of our reviewers.	
Royal College of Occupational Therapists	Evidence review P (inpatient)	016	002	Pre-operative education is a significant feature of inpatient outcomes for arthroplasty patients as part of their psychological approach and expectations for their admission. Addressing clear details of inpatient rehab and expected time frames, including ideal length of stay, during the preoperative assessment is important. Could add expected length of stay to Evidence C.	Thank you for your comment. The recommendations on shared decision making and patient information include advising people on what to expect before, during and after surgery, including length of hospital stay, recovery and rehabilitation. The committee discussion related to this, which includes preoperative education, is in Evidence report A and length of stay is discussed here in relation to the evidence identified. Evidence report C is related to preoperative rehabilitation programmes rather than general preoperative education.
Royal College of Occupational Therapists	Evidence review P (inpatient)	019	016 - 019	Positive inclusion of cognitive presentations	Thank you for your comment
Royal College of Occupational Therapists	Evidence review P (inpatient)	019	029 - 035	Excellent inclusion	Thank you for your comment
Royal College of Occupational Therapists	Evidence review P (inpatient)	020	010	Agree with aim of 2 week time frame. This would be very challenging with current outpatient therapy resources	Thank you for your comment. We could not find reference to a 2 week time frame in the inpatient evidence report and assume you are referring to the outpatient evidence report for

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					hip and knee replacement. Here the discussion includes other factors the committee took into account when making recommendations. The 2 week time frame mentioned in this context is related to one committee members' orthopaedic centre pick up people who are not doing well with their postoperative rehabilitation. It is mentioned in this report as an example of how rehabilitation works in practice. Other orthopaedic centres do this differently. This guideline does not make any recommendation for a 2 week review.
Royal College of Occupational Therapists	Evidence review C (preoperative rehab)	General		Excellent consideration of broad health challenges faced by the arthroplasty patients.	Thank you for your comment
Royal College of Occupational Therapists	Evidence review C (preoperative rehab)	006	014	Although alternative elements of physical and psychological elements are considered in this sect ion, 'physical therapy' is not a term used in the UK and is not referenced in the other documents. Recommend changing to physiotherapy.	Thank you for your comment. This has been updated.
Royal College of Physicians and Surgeons of Glasgow	Guideline	General		The Royal College of Physicians and Surgeons of Glasgow although based in Glasgow represents Fellows and Members throughout the United Kingdom. While NICE has a remit for England, many of the recommendations are applicable to all devolved nations including Scotland. They should be considered by the relevant Ministers	Thank you for your comment.

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				of the devolved governments. The College welcomes this Guideline in an important area. It is generally supportive of this guideline.	
Royal College of Physicians and Surgeons of Glasgow	Guideline	General		Many funders of health care (eg CCGs) restrict patient for hip and knee arthroplasty on the basis of BMI. BMI is assessed usually on the basis of weight and height. Patients with symptomatic hip and knee arthritis cannot extend to their full height because of flexion deformity of the lower limb (either fixed or functional because of pain) giving a falsely high BMI. The evidence that raised BMI gives worse outcome is very limited. There is no discussion on this guideline.	Thank you for your comment. The effect of BMI on outcomes following joint replacement was excluded from this guideline as it is covered by the osteoarthritis guideline CG177 (https://www.nice.org.uk/guidance/cg177) which is currently being updated. This includes a review on preoperative patient factors (e.g. BMI or age) associated with benefits or harms after joint replacement surgery. **The committee agreed that the same principles that relate to BMI and osteoarthritis would apply to other people having elective joint replacement.**
Royal College of Physicians and Surgeons of Glasgow	Guideline	General		There is no discussion of management of patients on Immunosuppression or biologic therapy for inflammatory arthritis. It is usual to stop biologics (British Society for Rheumatology Guidance) pre and post operatively but not methotrexate (Grennan et al ANN RH DIS 2001, 60 (3), 214-7)	Thank you for your comment. Stopping and restarting medications was not prioritised for review in this guideline so no recommendations have been made relating to this. However, the guideline is expected to be used by clinicians who should also use their clinical judgement to decide which medicines should be stopped before surgery. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.

Joint replacement (primary): hip, knee and shoulder

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Royal College of Physicians and Surgeons of Glasgow	Guideline	005	001, 009, 016	Many surgeons feel that senior anaesthetic colleagues should be closely involved in any discussion recommending particular forms of anaesthesia, to ensure that patients are fully informed of ALL risks, and also so that the methods recommended will actually be available on the day of surgery - this can depend on availability, skill level and experience of the individual anaesthetist.	Thank you for your comment. The committee agree that senior anaesthetic colleagues need to be available to discuss anaesthetic options with individuals. They agreed the important thing is that the individual gets access to information about the options for anaesthesia in advance of surgery, along with their risks and benefits. They should also have access to an anaesthetist experienced in providing anaesthesia for joint arthroplasty in advance of surgery - this could be a 'phone conversation if appropriate. The gateway to this can be the orthopaedic clinic or pre-assessment, depending on the hospital's pathway, but the key is information and access before the day of surgery. They agreed there doesn't need to be a face-to-face meeting with a "senior" anaesthetist for all patients." We have amended our rationale related to shared decision making and patient information to make it clear that discussions could be with any suitably qualified member of the multidisciplinary team. Should a person have specific needs then the multidisciplinary team member with the appropriate experience will be consulted and involved in discussions.

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Royal College of Physicians and Surgeons of Glasgow	Guideline	006	006	**point 1.4** Although the use of tranexamic acid to prevent bleeding is discussed there is no discussion of drugs to prevent venous thrombo-embolism. In many hospitals there are blanket policies to prevent this. The College's understanding is that this area is not clear cut amongst orthopaedic surgeons. Some discussion particularly in relation to co- prescription with tranexamic acid would be helpful.	Thank you for your comment. Venous thromboembolism (VTE) prophylaxis is covered by another NICE guideline (https://www.nice.org.uk/guidance/ng89/). We have added some detail to the committee discussion about the co-prescription of tranexamic acid and VTE prophylaxis as suggested. The committee agreed tranexamic acid is only offered during the surgical period and that the effects of this will have worn off by the time pharmacological VTE prophylaxis is started postoperatively. The committee are also aware that if VTE prophylaxis is given preoperatively it is stopped ahead of surgery.
Royal College of Physicians and Surgeons of Glasgow	Guideline	006	015	**point 1.5** There is no discussion of the use of prophylactic parenteral antibiotics.	Thank you for your comment. The use of prophylactic antibiotics was considered standard practice and therefore this area was not included in the guideline. We have cross referred to NICE guideline on surgical site infections NG125 (https://www.nice.org.uk/guidance/ng125) where they are recommended.
The Association for Perioperative Practice	Guideline	General	General	On behalf of our associations 7,000 plus members, who practice within the operating theatres of the UK, can I express our gratitude for this excellent guideline review. It is a substantial piece of excellent evidence based information that will support safe patient surgical outcomes, challenge orthopaedic	Thank you for your comment.

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				departments to review current practice and enable practice change where indicated. Well done to all those involved in the development of this guideline. We will support and recommend its use to our members involved in the care of patients undergoing joint replacement surgery, when published.	
The Association for Perioperative Practice	Guideline	General	General	In reviewing the text of this guideline I recognise the perioperative phases of surgery: Preoperative : Pre-habilitation, assessment, education and increasing demands for shorter hospital stays involved in Enhanced recovery programs. Operative Phase; Patient safety, Human factors, surgical intervention and surgical care team development and Immediate post-operative care, communication and onward recovery.	Thank you for your comment.
The Association for Perioperative Practice	Guideline	General	General	As an experience Surgical Care Practitioner, within the new Medical Associate Profession group, I recognise the significance of the joint replacement guideline in supporting the way in which surgical care is now being delivered across the country by Advanced Clinical Practitioners as fixed members of staff, with surgical trainees of all levels "passing through" orthopaedic department on their surgical apprenticeships! This guideline will support this group of practitioners in supporting and enforcing evidence based care under the leadership of the Consultant Surgeon.	Thank you for your comment.

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The Association for Perioperative Practice	Guideline	General	General	Links to Surgical Site Surveillance guideline needs to made in this document as they support each other in ensuring surgical site infection prevention remains the significant focus of perioperative practice: To establish and maintain a safe surgical environment in which joint replacements can be undertaken.	Thank you for your comment. This guideline now cross refers to the surgical site infection guideline.
The Association for Perioperative Practice	Guideline	General	General	As the lead perioperative staff association within the UK, we look forward to the publication of this guideline and support it in its current state, having no further observations or comments to make. Regards and appreciation	Thank you for your comment.
The Chartered Society of Physiotherapy	Guideline	027 - 028	025 - 030 001 - 012	**1.10.2 Outpatient rehabilitation after hip or knee replacement** We are concerned this rational is contradictory where it states '*The committee agreed that outpatient rehabilitation after hip or knee replacement is essential*" whilst going to justify the recommendations that not everyone should get outpatient rehabilitation. The proposition is that for many, a self-directed and self-delivered programme is acceptable. If this recommendation is adopted it will have a significant effect on whether, and how, services are commissioned and delivered, and in addition may have an impact on patient outcomes. Where patients are discharged with a home exercise plan and with no planned follow-up, it	Thank you for your comment. The committee has reviewed and updated the rationale in light of your comments. The evidence suggested that self-directed rehabilitation and supervised rehabilitation are similarly effective. Therefore a recommendation was made for self-directed as this would be substantially cost saving. There are further recommendations for people who are thought to require supervised rehabilitation to access this care. This includes people who find self-directed rehabilitation is not meeting their rehabilitation goals. Including supervised rehabilitation for certain groups ensures these services are commissioned and delivered to the current high standard across

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				must be accepted that some patients will not seek further advice even where their condition dictates that supervised input would be necessary. An exercise leaflet or booklet provided at discharge cannot reasonably cover every individual eventuality that may materialise. Patients will be followed up by their surgeon at 6 weeks post-op and this then would be the logical point at which patients not making the anticipated progress would be referred back into out-patient services. There may then be a waiting list for treatment, resulting in unacceptable delay and/or variation in quality of rehab provided and possibly poorer patient outcome where supervised rehab is no longer provided. We are not satisfied that this recommendation reflects current practice at all. Ordinarily patients are all followed up at least once routinely post-op , at which point a further clinical decision is made as to whether self-directed, individual or group therapy is in the best interests of the patient's individual needs.	the NHS. The guideline only covers long term follow up. The committee are aware that there is there is universally orthopaedic team follow-up after the operation and they anticipate that this practice will continue. Should a problem with the person's rehabilitation be identified at this appointment then the committee expect the physiotherapy and occupational therapy team would be notified. We have updated the recommendations to ensure that people who are undertaking self-directed rehabilitation have a clear understanding of their rehabilitation goals and target and the importance of doing the exercises prescribed to achieve these goals.
The Chartered Society of Physiotherapy	Guideline	004	017 - 024	**1.2 Preoperative rehabilitation** We recommend that this guideline is clarified to ensure that such advice is given by the professional group which is recognised as	Thank you for your comment. The committee agreed that an appropriate professional should deliver the care and that this is implied within the recommendation. They did not specify a

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				holding expertise in exercise and rehabilitation for a population group that may have multi-morbidities, such as the physiotherapy workforce of registered physiotherapists and physiotherapy support workers.	particular professional group as they agreed a number of people within the multidisciplinary orthopaedic team could be trained to give preoperative rehabilitation advice. Different trusts use different specialists all appropriately trained to deliver this care, for example some trusts use physiotherapists while others use nurses. It is anticipated that people with specific needs such as those with multi-morbidities will be identified and managed appropriately. The committee also agreed that the recommendation is only for preoperative advice and it is anticipated that a senior member of the rehabilitation team would have oversight on what advice is provided.
The Chartered Society of Physiotherapy	Guideline	009	007 - 015	**1.10.1 Inpatient rehabilitation** We are concerned that this recommendation may imply that only a registered physiotherapist can offer the initial rehabilitation post –surgery. We are concerned that although subtle, this wording could significantly impact effective deployment of the in-patient physiotherapy workforce in this context.	Thank you for your comment. The committee are concerned about safety issues if qualified members of staff are not directly available especially for more complex cases. They agreed that the first contact with the person should be made or led by a physiotherapist or occupational therapist who can assess whether the person is medically unwell or has specific needs. They may delay rehabilitation if

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				There is clear evidence that within agreed local protocols and parameters certain patients post elective hip and knee replacement, are triaged straight to a higher level support worker. Delivering a pathway of care in this situation is certainly within the scope of a Band 4 role and is an established, safe and successful approach to workforce deployment in this context. It is the use of the word 'physiothera**pist** or occupation thera**pist**' that could de-rail practice, and does not dovetail with the evidence review which talks about assessment and management by physiotherapy and OT **teams.** This seems more an issue of misunderstanding how teams operate in practice and the role of their support workers, rather than a necessary directive from the evidence. We suggest the wording is amended to 'A member of the physiotherapy or occupational therapy team should…..'	clinically necessary. The committee were also concerned that there is a risk that professional staff will be decommissioned and stretched very thin if inpatient rehabilitation is undertaken by rehabilitation team in the first instance. With this in mind the committee agreed to keep the recommendations as written in the first draft. They also agreed to update the rationale to make it clear inpatient rehabilitation should be led by a physiotherapist or occupational therapist and that some aspects of rehabilitation can be provided by a member of the physiotherapy or occupational therapy team with suitable training and support.
The Chartered Society of Physiotherapy	Guideline	009	018 - 020	**1.10.2 Outpatient rehabilitation after hip or knee replacement** We are concerned that this recommendation may imply that only a registered	Thank you for your comment. The committee agree and have updated our recommendations and rationale to state that the advice is given by a member of the physiotherapy or

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				physiotherapist can offer the initial rehabilitation post –surgery. We are concerned that although subtle, this wording could significantly impact effective deployment of the in-patient physiotherapy workforce in this context. There is clear evidence that within agreed local protocols and parameters certain patients post elective hip and knee replacement are triaged straight to a higher-level support worker. Delivering a pathway of care in this situation is certainly within the scope of a Band 4 role and is an established, safe and successful approach to workforce deployment in this context. It is the use of the word 'physiothera**pist** or occupation thera**pist**' that could de-rail practice, and does not dovetail with the evidence review, which talks about assessment and management by physiotherapy and OT **teams.** This seems more an issue of misunderstanding how teams operate in practice and the role of their support workers, rather than a necessary directive from the evidence. We suggest the wording is amended to 'A member of the physiotherapy or occupational therapy team should…..'	occupational therapy team.

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The Chartered Society of Physiotherapy	Evidence review R	010	013 - 014	There are no registered physiotherapists at Band 4. The registered workforce banding start at Band 5. We are concerned that the title is misleading as it uses the word 'physiotherapist'. This seems more an issue of misunderstanding how teams are structured in practice and the role of support workers, rather than a necessary directive from the evidence. The wording ought to be replaced with "Cost per hour of a hospital based physiotherapy or occupational therapy teams by band". If the document does wish to refer to registered physiotherapists only it must remove Band 4. However, there must be an additional table to reflect the costs of support workers at bands 3 and 4 to reflect the enormous contribution this element of the physiotherapy workforce provides to rehabilitation.	Thank you for your comment. A foot note has been added to the costs table to make this clear. It reads "Note that the registered workforce starts at Band 5. Staff may also be on Band 3, however the PSSRU does not include unit costs for this Band".
The Chartered Society of Physiotherapy	Evidence review P	010	013 - 015	There are no registered physiotherapists at Band 4. The registered workforce banding start at Band 5. We are concerned that the title is misleading as it uses the word 'physiotherapist'.	Thank you for your comment. A foot note has been added to the costs table to make this clear. It reads "Note that the registered workforce starts at Band 5. Staff may also be on Band 3, however the PSSRU does not include unit costs for this Band".

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				This seems more an issue of misunderstanding how teams are structured in practice and the role of support workers, rather than a necessary directive from the evidence. The wording ought to be replaced with "Cost per hour of a hospital based physiotherapy or occupational therapy teams by band". If the document does wish to refer to registered physiotherapists only it must remove Band 4. However, there must be an additional table to reflect the costs of support workers at bands 3 and 4 to reflect the enormous contribution this element of the physiotherapy workforce provides to rehabilitation.	
The University of Birmingham, Department of Chemical Engineering	Guideline	021	004	A recommendation for research: We very much support the recommendation that this type of joint replacement surgery should be carried out in ultra clean air operating theatres. We recognise the lack of good recent trial evidence and the fact that some aspects of surgery have changed since the MRC trial of ultra clean air was carried out. There would unfortunately be an enormous cost and difficulty involved in repeating the randomised trial, because infection rates are already quite low in contemporary clinical	Thank you for your comment and support of the recommendation. The committee agree that some aspects of surgery have changed since the MRC trial was carried out and that repeating the research would be costly and difficult. Thank you for the citation. The GISIO-ISChIA study highlights the variability of nominally similar ventilation systems in preventing microbial air contamination. The committee agree that it would be beneficial if future ventilation systems were extensively tested in

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				practice, so very large numbers of patients would need to be recruited. We would point out however that the MRC trial was also designed to show that infection correlates with the amount of microbiological contamination in the operating theatre, and this conclusion definitely remains valid. We would wish to emphasise the very large economic cost of deep infection in joint replacement and other types of prosthetic implants surgery, but more importantly, the enormous cost in human suffering for the patients involved. This means that research work that only reduces the average deep infection rate by a very small percentage will have an immediate payback. If you review the literature in this area you will see that a lot of work was carried out in this area in the 1970s and 80s, as joint replacement surgery was introduced, but there is very little recent work using contemporary microbiological and engineering techniques. This area of research is also relevant to other types of implant surgery such as spinal surgery, heart valves, neurosurgical shunts and vascular grafts.	this regard. However, the committee has not made a research recommendation on the effects of engineering factors, infection prevention measures and human factors on microbiological contamination in prosthetic implant surgery because it was not part of the review question asked in this guideline. The review question for this guideline looked at the effectiveness of ultra-clean air on quality of life and infection rather than the levels of microbial contamination. Therefore the GISIO-ISChIA study and other studies investigating levels of microbial contamination were not included in the guideline.

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				It is remarkable that pharmaceutical production lines have mandatory microbiological monitoring every shift but not a single orthopaedic operating theatre in ever monitored or tested during surgery. A paper funded by the Italian Health Ministry (Agodi, A et al Operating theatre ventilation systems and microbial air contamination in total joint replacement surgery: results of the GISIO-ISChIA study. Journal of Hospital Infection 90 (2015) 213e219) shows the very wide variability in the microbiological performance of this type of operating theatre, so there is likely to be significant room for improvement in engineering and clinical practice. We think that NICE should make a recommendation for further research into: "The effects of engineering factors, infection prevention measures and human factors on microbiological contamination in prosthetic implant surgery"	
University Hospitals Birmingham NHS Foundation Trust	Guideline	003	007	Our trust implements this approach and provides appropriate information for the shoulder replacement they are being offered.	Thank you for your comment.

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University Hospitals Birmingham NHS Foundation Trust	Guideline	009	009	Our trust is a district general hospital with respect to shoulder replacements and operates on and rehabilitates patients with shoulder replacements. Patients following shoulder replacement are currently offered inpatient rehabilitation within 24 hours of a primary replacement. We agree it is important to include advice on managing activities of daily living and a home exercise program.	Thank you for your comment.
University Hospitals Birmingham NHS Foundation Trust	Guideline	010	007	We were initially concerned that this recommendation is not in line with our current practice at a district general hospital. Currently, we offer all patients outpatient rehabilitation following their shoulder replacement. Our patients who have an elective shoulder replacement are generally quite elderly. They are seen within 24 hours for ambulation and wrist and elbow exercises with advice on activities of daily living and what they need to progress to. They are always discharged with their shoulder in a sling. The guidance states to offer supervised group or individual outpatient rehabilitation if the person has difficulty managing activities of daily living. In our experience all our patients have difficulty managing activities of daily living as they are effectively one-handed. Post operatively, our patients will not mobilise their shoulder for 10 days or more. Although we may advise them on how to start these exercises in the future	Thank you for your comment. We have updated our recommendations and rationale in light of your comment. The intended meaning has stayed the same but the wording has changed. We have also introduced more bullet points to the recommendations to make it easier to read. This includes making it clearer that people undertaking self-directed rehabilitation have: "• a clear understanding of their rehabilitation goals and the importance of doing the exercises prescribed to achieve these goals • a point of contact for advice and support."

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				we find that when we see them for a review at 2 weeks they have difficulty remembering the exercises and are often struggling because of pain. At this stage we may need to adapt the exercises depending on the individual presentation. On reading the rational and impact for this recommendation it seems that our experience was in line with usual care and there was no consensus to change usual care. However we feel that the wording of the recommendations is unclear and would benefit from reviewing as indeed the majority of people with following a shoulder replacement will need rehabilitation post operatively. We understand the committee does not want to make this a certainty but rewording the recommendation to make it clearer will minimise risk that patients who need rehabilitation following shoulder replacements are not missed because of this guidance.	
Versus Arthritis	Guideline	General	General	Versus Arthritis is the charity formed by Arthritis Research UK and Arthritis Care joining together. We work alongside volunteers, healthcare professionals, researchers and friends to do everything we can to push back against arthritis. Together, we develop breakthrough treatments, campaign for arthritis to be a priority and provide support. Our remit	Thank you for comments. We have responded to each in turn.

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				convers all musculoskeletal conditions which affect the joints, bones and muscles including osteoarthritis, rheumatoid arthritis, back pain and osteoporosis.[i]	
Versus Arthritis	Guideline	General	General	Arthritis and musculoskeletal conditions affect 18.8 million people in the UK and are the single biggest cause of pain and disability. Cumulatively, the healthcare costs of osteoarthritis and rheumatoid arthritis will reach £118.6 billion over the next decade.[ii] Musculoskeletal conditions account for around a fifth of all sickness absence and result in the loss of around 28 million working days to the UK economy each year.[iii]	Thank you for this information.
Versus Arthritis	Guideline	General	General	We are pleased to have this opportunity to make comments on the draft of the proposed NICE Guideline on joint replacement (primary): hip, knee and shoulder.[iv] Osteoarthritis was the primary cause of 90% and 98% of primary hip and knee replacements in the England, Wales and Northern Ireland in 2017.[v] The National Joint Registry's 15th Annual Report in 2018 showed that there were 105,306 hip replacement procedures and 112,836 knee replacement procedures in 2017.[vi]	Thank you for this information.
Versus Arthritis	Guideline	General	General	Given that the main modifiable risk factors for lower-limb osteoarthritis are obesity and physical inactivity, a public health approach is crucial to reducing the risk of developing osteoarthritis and preventing symptoms from	Thank you for your comment. Programmes for managing pain in osteoarthritis are out of scope for this guideline although the committee are aware of their existence. We have not made recommendations on timing of

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				worsening for those who are diagnosed. Regular physical activity and the provision of programmes such as ESCAPE-pain may help to reduce the risk of hip and knee osteoarthritis pain and improve physical function.[vii] In addition, increasing the use of shared decision making for people with osteoarthritis will help ensure that other treatment approaches can be explored before considering hip or knee replacement surgery. Nonetheless, there are people with osteoarthritis whose condition is so severe that joint replacement surgery will be their only option to alleviate pain, improve mobility and the ability to self-manage. Evidence shows that hip and knee joint replacement surgery is clinically and cost effective[viii, ix ,x, xi] and can help to restore mobility and reduce pain. Versus Arthritis believes that people should have access to joint replacement surgery within timeframes that are likely to be most effective.	referral for joint replacement surgery because the guideline covers joint replacement once a person has already been referred to the surgical team. The osteoarthritis guideline CG177 which is currently being updated covers referral for joint replacement. The committee agree that it is important to for the person to explore all options for the management of their condition. Consequently they have updated the recommendations on shared decision making. This now includes a bullet point to ensure that the alternatives to joint replacement are included in discussions with orthopaedic services. Although this would have already been discussed before referral the committee agreed that it is important for people to be able to discuss whether to go ahead with joint replacement..
Versus Arthritis	Guideline	General	General	Versus Arthritis currently delivers personalised support and information services that support shared decision making through the *Living Well with Arthritis* programme that operates across England. This is delivered either over the phone or face to face by people with	Thank you for your comment and this information. We have not made recommendations related to referral for joint replacement surgery because the guideline covers joint replacement

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				arthritis.[xii] Versus Arthritis also delivers peer-led shared decision-making services, commissioned by Clinical Commissioning Groups (CCGs) on five sites: Northumberland, West Berks, Frimley, Surrey Heartlands and East Riding of Yorkshire. These shared decision-making services provide participants with information about alternatives to surgery, such as weight management, exercise and pain management. In addition, these commissioned shared decision-making services share best practice from NICE guidelines with patients, signposting relevant sections, such as rights to access treatment and best practice guidance on the importance of maintaining healthy body weight.	once a person has already been referred to the surgical team. The osteoarthritis guideline CG177 which is currently being updated covers referral for joint replacement. The committee agree that it is important to for the person to explore all options for the management of their condition. Consequently they have updated the recommendations on shared decision making. This now includes a bullet point to ensure that the alternatives to joint replacement are included in discussions with orthopaedic services. Although this would have already been discussed before referral the committee agreed that it is important for people to be able to discuss whether to go ahead with joint replacement.
Versus Arthritis	Guideline	General	General	This response sets out our comments on four specific aspects: 1) Draft guideline wording on the information, shared decision making, and decision aids offered for people offered hip, knee or shoulder replacement; 2) Draft recommendations for clinical practice; 3) Draft recommendations for research;	Thank you for your comments. We have responded to each of these in turn.

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				4) Evidence presented in the evidence review document 'Evidence review B – decision aids'"	
Versus Arthritis	Guideline	003	005 - 019	Draft guideline wording: Information for people offered hip, knee or shoulder replacement There are many benefits of better communication around treatment decisions, which the guideline should recognise, including: • Good communication facilitates comprehension of medical information, and allows for better identification of patients' needs, perceptions, and expectations. • Patients are more likely to be satisfied with their care and are more likely to share pertinent information for accurate diagnosis of their problems, follow advice, and adhere to the prescribed treatment. • Patients' agreement with the doctor about the nature of the treatment and need for follow-up is strongly associated with their recovery. • Studies have shown correlations between a sense of control and the ability to tolerate pain, recovery from illness and daily functioning. Enhanced psychological adjustments and better mental health have also been reported.	Thank you for your comment. The committee agree with your thoughts. Our recommendations cover the information people would benefit from having specific to joint replacement prior to their surgery. Your comment looks more broadly at the benefits of good communication of medical information and the advantages of engaging people in discussing their management. This is covered by the NICE guideline on patient experience in adult NHS services. We have linked to this guideline and avoided repeating the same recommendations here. The recommendations in this guideline relate to shared decision making and information needs specific to joint replacement.

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				• Some studies have observed a decrease in length of hospital stay and therefore the cost of individual medical visits and fewer referrals. • A more patient-centered encounter results in better patient and doctor satisfaction. • Satisfied patients are less likely to lodge formal complaints or initiate malpractice complaints. Satisfied patients are advantageous for doctors in terms of greater job satisfaction, less work-related stress, and reduced burnout.[xiii]	
Versus Arthritis	Guideline	004	001 - 016	<u>Draft guideline wording: Shared decision making</u> This section lists items which should be included in a discussion to support shared decision for joint replacement surgery with a person and their family and carer (as appropriate). This list seems incomplete. It should include the following items which must always be an option at every stage along the clinical pathway: • the option of taking no further action and its consequences and • alternatives to surgery including pharmacological and non-pharmacological pain management, weight loss, physical activity.	Thank you for your comment. The committee agrees with your suggestion and has revised the recommendations on shared decision making. This now includes a bullet point to ensure the discussions include 'the alternatives to joint replacement surgery'. We did not include a question on how to capture shared decision making conversations so have not made a recommendation in this area. There is a NICE guideline on shared decision making in development expected to be published in April 2021.

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				Whilst the scope of the draft guideline is predominantly about the part of pathway once people have decided to have surgery, we would argue that even once a decision has been made to go ahead with surgery, these options should be reviewed. To establish good practice in shared decision making conversations, it is important that data in shared decision making conversations is captured in a format that can enable outcomes to be assessed and used to improve practice.	
Versus Arthritis	Guideline	004	013 - 016	<u>Draft recommendations for clinical practice</u> It is noted that the Committee were not able make a recommendation around the use of decision aids, stating the lack of conclusive evidence collated in evidence review B that decision aids improve clinical outcomes (see also comments in section 11 below). However, the failure to make a recommendation, including one based on consensus of expert opinion, seems inconsistent with other NICE guidance, including Clinical Guideline 138 on patient experience in adult NHS services, which states that 'If suitable high-quality decision aids are	Thank you for your comment. The committee agree that decision aids can be a useful and may help people offered a joint replacement understand their options about their care. Evidence from studies of decision aids for joint replacement showed that their content varied widely. This led the committee to question the definition of a decision aid and what its components should be. Their view is that a decision aid should not simply be a means of providing information, but should actively help people to participate in making decisions about their care. The committee were therefore unable to recommend any particular decision aid for joint replacement and made a recommendation for research.

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				available, offer them to the patient.'[xiv] A recommendation should be added that **clinicians and services should adopt the use of suitable high-quality decision aids.** Furthermore, while the recommendation may be in direct response to the scope, wording which focuses on the use of decision-support tools ignores the evidence about what is needed, more broadly, to support people to take part in decisions about their health. The guideline's clinical recommendations should therefore be extended to confirm that systems of support for shared decision making should be in place. This should include not only a narrow focus on decision support tools and the clinical training needed to use them, but also the need for group-based approaches such as OAK (for osteoarthritis of the knee)[xv], and peer supported programmes such as the one offered by Versus Arthritis (as above).	A recommendation has been made to support shared decision-making and to support its place in the joint replacement process. We have also added a bullet point to this recommendation to ensure that alternatives to joint replacement are discussed with orthopaedic services. after they have been referred for surgery. Although this would have already been discussed before referral the committee agreed that it is important for people to be able to discuss whether to go ahead with joint replacement.. We did not ask a review question on the use of group based approaches and peer support programmes in general. The two you have highlighted were not included in the guideline as they are for all people with osteoarthritis, not just those referred to orthopaedic services.
Versus Arthritis	Guideline	011	020 - 023	<u>Draft research recommendations</u> We believe that the draft recommendation relating to decision aids should be moved the list of 'key recommendations', so that this type of research is prioritised. The guideline should also encourage innovation in the development of decision aids and in consultation skills	Thank you for your comment. The committee discussed your comment and do not agree that this should be a key research recommendation. While they agree it is important other recommendations for research were considered to be a higher priority than decision aids.

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				supporting their use. This would align with the scope of the NICE guideline on Shared Decision Making[xvi] and reflect NHS England's priorities in the Long Term Plan around ensuring that shared decision making is embedded in clinical pathways. [xvii,xviii,xix] The draft research recommendation on decision aids ('*Decision aids: What are the components of a decision aid to support people referred for elective joint replacement in making decisions about their treatment, for example the type of procedure, timing and implant choice')* should also be amended and made broader to include research to understand how to optimise systems of support for shared decision making, including the role for group-based and peer-supported approaches. Research in this area would help to develop decision aids that can be used in shared decision making services commissioned by the NHS, helping patients and clinicians to make more informed choices about whether to choose joint replacement surgery.	The research question is restricted to decision aids rather than broader issues of shared decision making and how to optimise systems of support because this was the focus of the review question in the guideline. Recommendations related to this may be covered by the NICE guideline on shared decision making in development you mention (https://www.nice.org.uk/guidance/indevelopment/gid-ng10120).
Versus Arthritis	Evidence review B – decision aids	034	004 -	We are concerned about aspects of the evidence review B document, which outlines the evidence base around decision aids, and about some of the terminology included in the	Thank you for your comment. The committee agreed that decision aids can be a useful way of helping people offered joint replacement surgery understand their options and make

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			011	evidence review. In particular, in our view, the language used to characterise the role of decision aids is	decisions about their care. The text as written did not accurately reflect the committee's view of decision aids and we have revised this and the rationale to more accurately reflect their view. In particular, we have: - removed any reference to the evidence being inconsistent - removed reference to potential medico-legal problems (which is a finding from the evidence review rather than the committee's view) - reworded the text which made reference to 'surgical decision making', 'the surgeon decided' and the text related to 'fear of joint replacement'.
		034	022 - 033	inappropriate given the requirement for there to be a shared decision about treatment like joint replacement surgery.[xx] Despite the evidence review implying that decision support tools could raise 'potential medical legal problems', in our view there is evidence that	
		034	022 - 033	decision support tools can actually reduce the risk of litigation.[xxi] Whilst patients and clinicians can choose not to use decision support tools, they can be valuable in supporting clinicians to provide information to patients, and in assisting	
		034	012 - 021	patients to make a more informed choices treatment, and the choice not to use them should be driven by the patient's preferences. The evidence review B states that '*The evidence found was inconsistent... more outcomes indicated no clinical difference rather than a benefit of decision aids.'* It is important to recognise that decision support tools are not intended to improve clinical outcomes, as their purpose is to support decision making to improve quality and experience of clinical care in line with best practice guidance, including	

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				from NICE in line with the NHS long-term plan, and to ensure adequate consent in line with current legal principles.[xxii] The evidence review B states that '*The evidence found was inconsistent in terms of the details of what constitutes a decision aid ….'* In fact, there are a wide range of decision support tools, in the two broad categories of 'in consultation' tools and 'out of consultation' tools. We believe that it is entirely possible for NICE to develop a broad definition of a decision aid that would be widely accepted and would be helpful and appropriate to include in this guideline, and this would be consistent with NICE Guidelines elsewhere.[xxiii] In additional there are problems with the terminology in the evidence review document, specifically the reference to the 'fear of joint replacement'. It is entirely legitimate for patients to be wary, or even fearful of major surgery - the evidence review should not be dismissive of these concerns. The text also refers to 'surgical decision making' and 'the surgeon decided' which is out of step with the ethos of a shared decision making approach. This language must be improved.	
Zimmer Biomet	Guideline	General		Zimmer Biomet welcomes the recommendations made in the guideline	Thank you for your comment.

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Zimmer Biomet	Guideline	022	021 - 025	The evidence (Studies that compared partial with total knee replacement) is stated as having little relevance, due to the studies being conducted on implants no longer in use. The TOPKAT study, published in July 2019 (see comment 4) substantiates these benefits in an RCT with implants that are currently in use and should be included for the reasons stated in evidence review K, page 15, line 34.	Thank you for your comment. The study organisers provided a draft copy of the TOPKAT results paper for the committee to review before we submitted the guideline for consultation. The committee agreed that these results fitted with the recommendations they had drafted for the guideline. The results were published during the guideline consultation and we have added them to our review. They are similar to the other 2 included studies, 4 PROMs outcomes from TOPKAT did not indicate any clinical difference between treatment groups and the length of stay outcome again indicated a benefit of UKR. 1 new outcome was reoperation within 5 years of surgery, which indicated a benefit of UKA. In terms of major revision within 5 years of surgery, the committee agreed it was too early to draw strong conclusions on major revision within that time span and the resulting evidence was not clinically significant. Now that the results have been added the committee agree that the recommendation that was written for the consultation version of the guideline is still valid.
Zimmer Biomet	Guideline	022 023	027 - 029	It is known that better results are obtained by increasing the numbers of partial knees	Thank you for your comment. The committee agree and have removed reference to partial

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			001 - 007	performed, so the focus on the potential benefits and risks of partial knee replacement in the "active lifestyle" population is of concern as this could be perceived as a limitation of indication. Partial knee replacement surgery has been shown to demonstrate reduction of rates deep infection, DVT, stroke and MI. As these benefits are important to the whole population with OA of the medial compartment of the knee, particularly those at risk of such complications, consideration should be given to avoidance focus on the "active lifestyle population" alone.	knee replacement being beneficial to people with an active lifestyle. Both the rationale of the guideline and committee discussion have been updated.
Zimmer Biomet	Guideline	025	017 - 020	Please see detailed comments in comment 7	Thank you for your comment. Please see our response to your comment.
Zimmer Biomet	Evidence review N	013	020 - 028	It is understandable how the committee has reached the research recommendation based on the three papers supporting this decision, with only one from within the past ten years. Consideration should be given to including research into other comorbidities as in addition to an intact cuff, there could also be further factors affecting the decision to use a Hemi, Total or Reverse shoulder which haven't been assessed and may contradict any recommendations that are made.	Thank you for your comment. The committee noted that there are a number of potential confounders in shoulder replacement, including type B2 glenoids. The agreed that they would not include this level of detail in the research question and would leave it to research funders to determine the exact level of detail to cover. We assume the study you cite is Mehta and Aleem, Management of the B2 Glenoid in Glenohumeral Osteoarthritis. Orthop Clin North

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				For example, bony defects are also important to assess when deciding between a total shoulder or reverse shoulder. Type B2 glenoids need to be managed differently (management of the B2 glenoid in gleno-humeral osteoarthritis, Mehta et al, 2019), even though the cuff may be intact.	Am. 2019 Oct;50(4):509-520. doi: 10.1016/j.ocl.2019.05.006. Epub 2019 Jul 31. This was not published by the time of the final searches and does not appear to meet the inclusion criteria of the review protocol. It has not been considered for inclusion in the guideline.
Zimmer Biomet	Evidence review K	015	034	The TOPKAT study has been published in the Lancet and does add valuable supporting information to the evidence review. It also may help to inform the recommendations with regards to the points made in comments 2 and 3 above. http://dx.doi.org/10.1016/S0140-6736(19)31281-4	Thank you for your comment. The study organisers provided a draft copy of the TOPKAT results paper for the committee to review before we submitted the guideline for consultation. The committee agreed that these results fitted with the recommendations they had drafted for the guideline. The results were published during the guideline consultation and we have added them to our review. They are similar to the other 2 included studies, 4 PROMs outcomes from TOPKAT did not indicate any clinical difference between treatment groups and the length of stay outcome again indicated a benefit of UKR. 1 new outcome was reoperation within 5 years of surgery, which indicated a benefit of UKA. In terms of major revision within 5 years of surgery, the committee agreed it was too early to draw strong conclusions on major revision within

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					that time span and the resulting evidence was not clinically significant. Now that the results have been added the committee agree that the recommendation that was written for the consultation version of the guideline is still valid.
Zimmer Biomet	Evidence review K	058	Table 11	The Liddle 2014 study has been excluded due to "not enough data on type of UKA." It seems a strange decision as this provides valuable supportive data on the adverse outcomes after total and unicompartmental knee replacement in 101 330 matched patients. The study states that it excludes patello-femoral OA and if it is the brand of devices used that is the area of uncertainty, this is at odds with one of the reported strengths of the study, which is the use of an unselected registry sample and the consequent reduction the likelihood of sampling bias.	Thank you for your comment. This was an incorrect reason for exclusion. The study was excluded because it was a non-randomised study and we had enough randomised evidence to make a recommendation. We have corrected the reason for its exclusion in the evidence report.

**None of the stakeholders who comments on this clinical guideline have declared any links to the tobacco industry.*

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