# Joint replacement (primary): hip, knee and shoulder

## Consultation on draft scope
## Stakeholder comments table

## 08/01/2018 to 05/02/2018

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| Aquatic Therapy association of Chartered Physiotherapists (ATACP) | 9 | 239-246 | Rehabilitation should specifically mention aquatic therapy as a preferred method of early post-op rehabilitation for TKA and THA. See evidence listed below:<br><br>Wilkins,B. The Effectiveness of Aquatic Therapy Following Total Hip or Total Knee Arthroplasty: A Systematic Literature Review. Aqualines, Volume 29, Number 2, 2017<br>This review demonstrates that aquatic therapy offers a valuable rehabilitation pathway for THA and TKA patients that translates into clinically meaningful outcomes and should be recommended with or without land-based rehabilitation. Furthermore, for individuals who have pain or functional limitations to participate in land exercise, AT presents the best opportunity for post-surgical rehabilitation.<br><br>Giaquinto S, Ciotola E, Dall'Armi V, Margutti F (2010) Hydrotherapy after total knee arthroplasty. A follow-up study. Arch GerontolGeriatr 51: 59-63.<br>Patients treated with hydrotherapy (HT) for six months after discharge from a rehabilitation unit after TKA showed better subjective functional outcome, compared to the non-HT land-kinesis group: the study showed reduced pain, stiffness and function impairment with HT.<br><br>Liebs TR, Herzberg W, Rüther W, Haasters J, Russlies M, et al. (2012) Multicenter randomized controlled trial comparing early versus late aquatic therapy after total | Thank you for the suggestions. The committee will consider post-operative rehabilitation interventions when drafting the review protocols for question 10. Hydrotherapy and interventions with aquatic therapy will therefore be considered as potentially eligible interventions. |

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| | | | hip or knee arthroplasty. Arch Phys Med Rehabil93:192-199. A multi center RCT, to evaluate whether the timing of aquatic therapy affected clinical outcomes after TKA, showed that all the primary outcomes (as assessed by the WOMAC scale) were better in the early aquatic therapy group. Hydrotherapy positively influenced mood and socialisation, and promoted social relationships such as friendship and feelings of well-being.<br><br>Rahmann AE, Brauer SG, NitzJC (2009) A specific inpatient aquatic physiotherapy program improves strength after total hip or knee replacement surgery: a randomized controlled trial. Arch Phys Med Rehabil90:745-755. A study evaluated the effect of inpatient aquatic physiotherapy (comprising an aquatic physiotherapy session or nonspecific water exercise) in addition to the usual land physiotherapy from day four after TKA. The recovery of strength, function and gait speed, measured on day 14, was all better in the specific aquatic exercise group. | | |
| Association of British Healthcare Industries (ABHI) | General | | ABHI are absent from the list of registered stakeholders, despite being registered. ABHI should be added to correctly reflect status<br>It would be useful to analyse outcomes as it relates to indications as outcomes may differ for different patient | Thank you for your comment. We have contacted NICE to add the suggested stakeholders to the published list of stakeholders.<br><br>Outcomes will be will be decided on by the committee | |

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| | | | populations.<br>In the main outcomes and when it comes to revision of joint replacement, it would be helpful to run analysis for different causes of revision (infection, aseptic loosening, instability, etc.) and separate between device-related and non-device related.<br>It would be useful to include re-operation w/o revising the implants in the main outcome. | for each question when the review protocols are written. We will consider these outcomes for the appropriate questions. |
| Association of British Healthcare Industries (ABHI) | | 218 | We advise that NICE reconsiders its proposal for a new review of the clinical and cost effectiveness of "cemented vs cementless vs hybrid" hip replacement. Firstly, we are surprised to see duplication of this work, because a comprehensive analysis to address this same question was completed as part of Technology Appraisal 304 on total hip replacement, reviewed by the NICE Technology Appraisal Committee and published in the final Technology Appraisal Guidance on the NICE website. This TA guidance was only reviewed again by NICE in 2017. From the work done by NICE as part of this TA Guidance, we know that implant revision rate is the single most important driver of costs and QALYs and we request that the collaborative work between industry, BOA and NICE to develop this TA recommendation be fully absorbed into this CG. Secondly, blanket recommendations such as those driven by GIRFT are unhelpful at this broad level because of the significant | Thank you for your comment. We have removed these draft questions from the scope, and the committee will ensure the final questions do not conflict with TA304 |

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| | | | differences in implant performance within class by factors including implant bearing surface, head size and collar type, and also patient age, as demonstrated in UK and Australian Joint Registries. Very clear recommendations were made in TA304 on minimum revision rate benchmarks for implant selection to drive cost effective decision making. We request that TA304 be incorporated into this CG on JR for total hip replacement. | |
| Association of British Healthcare Industries (ABHI) | 1 | 21 | There is indeed variability in the joint replacement operations offered to patients within the NHS, particularly with regards to the wide range of joint implants as highlighted by GIRFT. But whilst the implant needs to offer the NHS excellent value for money, the choice needs to be set within the context of a clinical decision. A prosthesis is selected by the surgeon to match a proven technology to the patient's individual requirements to increase the likelihood of the best possible outcome for that patient. Surgeons make choices on which prosthesis to use based on several factors including their previous training, the class of prosthesis to be used, and the quality of clinical evidence for a prosthesis and the characteristics of the patient such as age, activity levels and body mass index. They also make choices on prosthesis based on personal experience of patient outcomes observed with | Thank you for your comment. We have included an extra question on decision aids for assessing people's needs for joint replacement to try to address this issue. We have not included specific types of implants as we think this is better covered outside of this guideline. |

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| | | | specific implants in their own practices. It is important for NICE to be mindful of this when developing recommendations around implant types because there are fundamental reasons for the variability in operations offered to patients. | |
| Association of British Healthcare Industries (ABHI) | 2 | 40 | The role of ODEP in the assessment of projected revision rates for hip and knee implants is established and should be incorporated into this CG by NICE. ODEP ratings play a significant role in signposting the NHS to purchase the most clinically effective hip and knee implants, as acknowledged in previous NICE Technology Appraisal recommendation where a benchmark revision rate for implants was set for the NHS. Please could ABHI make very clear the industry position on ODEP for shoulders so NICE is fully aware that ODEP for shoulders does not carry the same status as for hip/knee. | Thank you for your comment. We agree that ODEP ratings provide expert, independent assessment of clinical safety and are utilised by the NHS. They will be considered when setting inclusion criteria for the review protocols. However, we do not see the need to include a review on them as we think this is better covered outside of this guideline.<br><br>We are aware that ODEP for shoulders has only just started and the methodology is still evolving and so is not as established as it is in hips and knees They will be considered when setting inclusion criteria for the review protocols. However, we have not included a specific review on them as we think this is better covered outside of this guideline. |
| Association of British Healthcare Industries (ABHI) | 4 | 102 | Is 'assessment and diagnosis' to be excluded from the CG on the basis that is it captured in the Osteoarthritis CG (2014)? This CG makes clear recommendations that adults diagnosed with OA are to be supported with non-surgical treatments for at least 3 months before referral for consideration of joint surgery. It also makes clear that | Thank you for your comment. We anticipate cross-referring to the osteoarthritis guideline (CG177) to avoid duplication. This guideline starts at the point people are referred for consideration to surgery. We have now also included a question on decision aids for assessing adults' needs for joint replacement. |

# Joint replacement (primary): hip, knee and shoulder

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| | | | HCPs should not use scoring tools to assess eligibility for consideration of joint surgery, and that patient characteristics such as age and obesity should not be used to restrict access to surgery. We are supportive of not duplicating this work. However, the recommendations from the OA CG on assessment and referral to consideration of joint surgery are pertinent and should be fully incorporated in the new CG. Awareness of the cost savings orthopaedic surgery can deliver to the NHS needs to be raised, particularly in light of decisions by commissioners to restrict access to JR surgery as evidenced in the ABHI 'Hip & Knee Replacement: Hidden Barriers' report, contradicting existing NICE recommendations in the OA CG and TA304…… | |
| Association of British Healthcare Industries (ABHI) | 8 | 217 | With regards to hip replacement surgery, we note that reverse hybrid hip replacement is not explicitly mentioned in the draft scope. In the 2017 NJR report, 22,500 reverse hybrid hip procedures were recorded, representing 2.5% of all total hip replacements in the 2017 NJR. We therefore request that reverse hybrid implants be included in any review of total hip replacement. | Thank you for your comment. Reverse hybrid hip replacement will be considered and may be included as a specific intervention when defining the question covering cement versus uncemented versus hybrid hip implants. |
| Belfast Health and Social care trust | general | general | In response to the question: Which interventions or forms of practice might result in cost saving recommendations if included in the guideline? The role | Thank you for your comment. We have not prioritised this as an area to cover in this guideline. We have focused on non-pharmacological interventions and |

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| | | | of the clinical pharmacist including independent prescriber is important in ensuring clinical and cost effectiveness from pre-op assessment stage, 'ADOS-admission on day on surgery' right through to discharge eg by medicines optimisation, and facilitating discharge planning thus minimising length of stay | rehabilitation rather than staffing and human resources around delivery. The role of a clinical pharmacist would be more in keeping with a service delivery guideline and we believe there is unlikely to be sufficient evidence in this area to make firm recommendations. NICE has also published a guideline on Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes (https://www.nice.org.uk/guidance/ng5) which mentions the role of pharmacists in a patient's care pathway. |
| Belfast Health and Social care trust | general | general | Would be useful to have a clinical pharmacist rep on guideline development committee or clinical pharmacy group registered as stakeholders | Thank you for your comment. The UKCPA is a registered stakeholder. A pharmacist may be recruited as a co-opted member to advise on relevant topics. Currently, there are no plans to include questions relating to medications and therefore there is no need for a pharmacist. |
| British Elbow & Shoulder society (BESS) | General | | I think it is unlikely to be productive to consider assessment for surgery in SHOULDER after referral (cannot comment on hip and knee). As unlike hip and knee replacement the types and reasons for shoulder replacement are wider – eg primary OA cuff intact, cuff arthropathy – needing reverse shoulder replacement. Shoulder replacement lacks some of the markers used for lower limb replacement eg walking distance and sleeping at night. - Might be a topic for research though. | Thank you for your comment. We have included a question related to decisions aids to address the issue of indications for surgery. If no evidence is identified it may be that the committee decide to make a research recommendation to help address this issue. |
| British Elbow & | General | | Draft scope of the document seemed to cover most | Thank you for your comment. |

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| Shoulder society (BESS) | | | areas | |
| British Elbow & Shoulder society (BESS) | General | General | Clinical decisions on choosing the type of shoulder arthroplasty are usually based on a combination of patient factors, underlying pathology, rotator cuff status and joint biomechanics. Simple head to head comparison of different types of replacement are therefore misleading, as the indications for the types of replacement and associated prognostic factors are likely to be different. | Thank you for your comment. This was discussed and it was agreed there are cases for direct comparison. This question seeks to address this. It was also noted that the overlap you mention is believed to be increasing in frequency making this an important area to cover. |
| British Elbow & Shoulder society (BESS) | General | General | Extended indications for Reverse Shoulder Arthroplasty (RSA) have made this the largest single category of shoulder replacement within the National Joint Registry. It is however not clear whether RSA is superior to conventional shoulder replacement in older patients with intact (or attenuated but not torn) rotator cuff and guidance on this aspect would be helpful. | Thank you for your comment that this is an important question. A comparison of reverse shoulder replacement to conventional total shoulder replacement is included in the guidelines scope and any evidence identified will likely involve specific age groups. If the evidence permits we will also consider analysing the older patient separately |
| British Elbow & Shoulder society (BESS) | General | General | Guidance on peri-operative care; pre-habilitation and post-operative rehabilitative physiotherapy to optimise outcomes and reduce the need for secondary interventions may help reduce overall costs. | Thank you for your comment. These areas are included in the scope. The clinical and cost effectiveness evidence will be reviewed for all the scope topics. |
| British Elbow & Shoulder society (BESS) | General | General | It would be useful to extend the scope of the guidance for shoulder arthroplasty to look at pathways of care, where there are more likely to be cost saving alternatives, for example, use of nerve blocks / ablation | Thank you for your comment. The focus of the guideline is related to joint replacement once a person has decided to have the procedure. Therefore, we have not included review questions related to interventions to be |

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| | | | for selected patients as an alternative to RSA. Improving pathways of care, including peri-operative care and pain management are more likely to lead to improved outcomes and patient experience rather than implant selection alone. | used before a person gets to the joint replacement stage. We have included reviews related to anaesthesia choice, which covers 1 aspect of pain management.<br><br>There is also a NICE guideline in development on perioperative care, which will look at more generic perioperative management (https://www.nice.org.uk/guidance/indevelopment/gid-ng10072/documents). |
| British Infection Association (BIA) | general | general | Infection prevention is included but infection management is not mentioned. Revisions will of course often take place in the context of active infection and this needs to be included in the scope. | Thank you for your comment. We could not cover all areas of infection and have prioritised infection prevention rather than its management. The guideline aims to explore primary joint replacement and has therefore excluded revision joint replacement (irrespective of the indication for revision). This because the issues to cover for revision surgery are likely to be quite extensive, different to those covered for primary joint replacement and therefore could cover a guideline in itself. Consequently, we have not included the management of infection in the context of revisions. |
| British Orthopaedic Research Committee (BORC) | 3 | 74 | It is unclear if joint resurfacing is included or excluded. | Thank you for your comment. The committee will discuss this when protocols for the specific questions related to joint replacement are discussed. |
| British | 3 | 74 | Consideration should be given to whether age should be | Thank you for your comment. Different age groups will |

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| Orthopaedic Research Committee (BORC) | | | independently considered. The pathology in younger people having in particular hip replacements is very different to older people, with congenital abnormalities far more common in the young. In response to this some surgeons specialise in young adult hips, and the NJR demonstrates different materials are frequently used in younger people compared to older people. Given there are therefore differences in the pathology, implants used and specialisation of surgeons, consideration should therefore be given to whether young adults (<50years as a ball-park cut-off) warrant separate consideration to older adults. The economic effects will also substantially differ between the young and old. | be considered as part of the review questions. When the protocols are discussed, the committee will consider if different age groups need to be addressed by separate reviews.<br><br>The cost effectiveness evidence will be reviewed for all the population subgroups included in this review question and any relevant differences will be discussed with the committee. |
| British Orthopaedic Research Committee (BORC) | 3 | 74 | Certain pathologies may warrant separate consideration for reasons similar to above – i.e. Rheumatoid arthritis. There is evidence from Canada to suggest that outcomes following arthroplasty in people with Rheumatoid Arthritis are better amongst those surgeons who have experience of operating on this specific patient group (i.e. higher volumes for specific indications). Arth Rheum. 2014. 66(3): 488-496. | Thank you for your comment. When protocols are discussed, the committee will consider if underlying cause for joint replacement need to be addressed by separate reviews. |
| British Orthopaedic Research Committee (BORC) | 7 | 185 | No consideration is given to surgeon/ centre experience amongst the specific questions. A big issue for the surgical community has been how many joint replacements are enough to maintain competence, with much written about this – and funnel plots produced | Thank you for your comment. In the UK, the National Joint Registry (NJR) scrutiny committees closely monitor centre and surgeon outcome data, provide feedback, and drive quality improvement. As such we have not prioritised this as an area to include in the guideline. |

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| | | | nationally to clearly demonstrate surgeon and centre volumes. This is not considered within the guideline. | |
| British Society for Rheumatology (BSR) | General | General | We welcome this guideline because of the variation in practices, especially post-operative rehabilitation, that are well described in Section 1 | Thank you for your comment. |
| British Society for Rheumatology (BSR) | General | General | If revision surgery is not included, the title and document should refer to "primary joint replacement" | Thank you for your comment. We have changed the title to 'Joint replacement (primary): hip, knee and shoulder' to specify that the guideline exclusively covers primary joint replacement. In addition, the scope highlights that the guideline only covers primary joint replacement. |
| British Society for Rheumatology (BSR) | 4 | 103 | We would suggest that revision surgery, a highly costly procedure in terms of patient burden and hospital costs, should be considered for inclusion. | Thank you for your comment. We agree that revision is a very costly procedure. However, the scope of this review is already extensive and so it will focus on primary joint replacement. The issues to cover for revision surgery are likely to be quite extensive, different to those covered for primary joint replacement and therefore could cover a guideline in itself. Consequently, it was decided to limit the guideline to primary joint replacement only.<br><br>Revision surgery will be included as an outcome in individual review questions. |
| British Society for | 8 | 225 | Q8.1 is not quite correct. Total knee and partial knee replacements are not competitive options; the questions | Thank you for your comment. It was suggested at the stakeholder workshop that there is benefit in a direct |

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| Rheumatology (BSR) | | | seem to be whether partial knee replacement should be performed, and what are the indications? | comparison for some patients. This question will be defined further when protocols are developed. |
| Heraeus Medical | General | General | Heraeus Medical supports the draft scope and we are happy to provide any supporting clinical evidence related to Heraeus Medical products when appropriate. | Thank you for your comment. |
| Homerton University Hospital NHS Foundation Trust | 7 | 190 | What variation exists in terms of patient information and decision aid recommended? A similar GIRFT approach to standardise this nationally would be beneficial to allow recommendations which could be interpreted within the context of local provision. | Thank you for your comment. We have included shared decision-making and we hope to be able to make recommendations to standardise practice in this area. |
| Homerton University Hospital NHS Foundation Trust | 9 | 253 | The inclusion of patient reported experience measures (PREMS) would be a useful addition to the outcome measures highlighted. | Thank you for your comment. This is not meant to be a comprehensive list of outcomes. The committee will consider specific outcomes when setting the review protocols. |
| Homerton University Hospital NHS Foundation Trust | 9 | 259 | Consider effect of response rate on joint arthroplasty patient response e.g where return rates are low the effects of a self-selecting population on survey results should be considered. | Thank you for your comment. We will consider this when doing the reviews. |
| Homerton University Hospital NHS Foundation Trust | 9 | 259 | Consider inclusivity of clinical outcome measures and decision aids for patients with low levels of literacy | Thank you for your comment. We will consider this when defining protocols and making recommendations. |
| Homerton University Hospital NHS | 9 | General | Consider measures of socioeconomic deprivation when evaluating outcome of arthroplasty | Thank you for your comment. We will consider including this factor when the review protocols are written. |

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| Foundation Trust | | | | |
| Homerton University Hospital NHS Foundation Trust | 9 | general | Where joint replacement surgery provided out of area Hospitals or by private providers is not followed by joined up rehabilitation with local NHS providers. Local teams rely on ad hoc referrals, which may or may not include details of a post-operative protocol or recommendations.<br>Private or out of area surgical providers should plan for a smooth transition pathway to ensure timely, funded and post-operative rehabilitation. | Thank you for your comment. The focus of the scope of the guideline is about what should be done rather than how to deliver a service for joint replacement. We believe there is unlikely to be sufficient evidence for service delivery reviews in this area to make firm recommendations.<br><br>The recommendations from this guideline will however aim to help inform commissioners and providers on the clinical requirements for best outcomes and will therefore indirectly inform service delivery needs. The guideline will apply to all service providers, including subcontractors, involved in treating NHS patients. |
| Homerton University Hospital NHS Foundation Trust | 9 | general | As part of the informed consent process, patients opting for joint replacement surgery out of area or with private providers should be advised on the provision made for them to have post-operative rehabilitation closer to home. | Thank you for your comment. We have concentrated the scope of the guideline on what should be done and not how to deliver a service for joint replacement. This is addressed in part by the patient experience guideline CG138 (https://www.nice.org.uk/guidance/cg138/) that recommends patients are given information about relevant treatment options and services they are entitled to. |
| Johnson & Johnson Medical Ltd | General | General | Johnson & Johnson Medical Ltd are registered as stakeholders to this CG but are absent from the published list of stakeholders – please could this list be updated. Of note, Key stakeholders including The British | Thank you for your comment. We have contacted NICE to add the suggested stakeholders to the published list of stakeholders. |

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| | | | Orthopaedic Association (BOA) and Association of British Healthcare Industries (ABHI) are also absent from this list. | |
| Johnson & Johnson Medical Ltd | General | General | To revisit the conversation at the NICE scoping workshop for this CG, the draft scope proposed is extremely broad and ambitious. To deliver a credible CG within the timeframe set we would advocate for a revised, streamlined version of this scope to be developed by NICE to better focus the CG on areas of real benefit to the NHS. We have therefore suggested within this response some areas we consider to be of particular value, plus requests to better incorporate relevant existing NICE guidance and recommendations into this new CG. | Thank you for your comment. We have thought about the breadth of the guideline scope and believe it is manageable. |
| Johnson & Johnson Medical Ltd | General | NICE consultation question 1 | "Which interventions or forms of practice might result in cost saving recommendations if included in the guideline?" | Thank you for your comment. We have responded to your comment in the following box. |
| Johnson & Johnson Medical Ltd | General | NICE consultation question 1 | Despite the published evidence supporting the clinical and cost effectiveness of total hip and knee replacement surgeries (Jenkins et al. 2013, TA304), these procedures are still frequently regarded as 'not cost effective' or of 'limited value' by commissioners. The recently published report 'Hip & Knee Replacement: Hidden Barriers' by the Association of British HealthCare Industries (ABHI) has further demonstrated this. As discussed at the NICE scoping workshop for this | Thank you for your comment.<br><br>We have included an extra question on decision aids for assessing whether joint replacement is appropriate for individuals to try to address this issue. The guideline population includes those referred for consideration of a primary elective joint replacement. It is anticipated that some conservative management may have been appropriate to try first. |

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| | | | Guideline, we request that NICE addresses this in the first instance by reviewing the clinical and cost effectiveness of joint replacement vs non-surgical treatment. | |
| Johnson & Johnson Medical Ltd | 1 | 21 | There is indeed variability in the joint replacement operations offered to patients within the NHS, particularly with regards to the wide range of joint implants as highlighted by GIRFT. But whilst the implant needs to offer the NHS excellent value for money, the choice needs to be set within the context of a clinical decision. A prosthesis is selected by the surgeon to match a proven technology to the patient's individual requirements to increase the likelihood of the best possible outcome for that patient. Surgeons make choices on which prosthesis to use based on several factors including their previous training, the class of prosthesis to be used, and the quality of clinical evidence for a prosthesis and the characteristics of the patient such as age, activity levels and body mass index. They also make choices on prosthesis based on personal experience of patient outcomes observed with specific implants in their own practices.<br>It is important for NICE to be mindful of this when developing recommendations around implant types because there are fundamental reasons for the variability in operations offered to patients. | Thank you for your comment. We have included an extra question on decision aids for assessing whether joint replacement is appropriate for individuals to try to address this issue. We have not included specific types of implants as we think this is better covered outside of this guideline. |

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| Johnson & Johnson Medical Ltd | 2 | 40 | The role of ODEP in the assessment of revision rates for hip and knee implants is established and should be incorporated into this CG by NICE. ODEP ratings provide expert, independent assessment of clinical safety and are utilised by the NHS to signpost the most clinically effective hip and knee implants to meet the benchmark revision rates defined for the NHS by previous NICE Technology Appraisal recommendations. | Thank you for your comment. We agree that ODEP ratings provide expert, independent assessment of clinical safety and are utilised by the NHS. They will be considered when setting inclusion criteria for the review protocols. However, we do not see the need to include a review on them as we think this is better covered outside of this guideline. |
| Johnson & Johnson Medical Ltd | 4 | 102 | Is 'assessment and diagnosis' to be excluded from the CG on the basis that is it captured in the Osteoarthritis CG (2014)? This CG makes clear recommendations that adults diagnosed with OA are to be supported with non-surgical treatments for at least 3 months before referral for consideration of joint surgery. It also makes clear that HCPs should not use scoring tools to assess eligibility for consideration of joint surgery, and that patient characteristics such as age and obesity should not be used to restrict access to surgery. We are supportive of not duplicating this work. However, the recommendations from the OA CG on assessment and referral to consideration of joint surgery are pertinent and should be fully incorporated in the new CG. Awareness of the cost savings orthopaedic surgery can deliver to the NHS needs to be raised, particularly in light of decisions by commissioners to restrict access to JR surgery as evidenced in the ABHI 'Hip & Knee | Thank you for your comment. We anticipate cross-referring to the osteoarthritis guideline (CG177) to avoid duplication. This guideline starts at the point people are referred for consideration to surgery. We have now also included a question on decision aids for assessing adults' needs for joint replacement. |

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| | | | Replacement: Hidden Barriers' report, contradicting existing NICE recommendations in the OA CG and TA304. | |
| Johnson & Johnson Medical Ltd | 4 | 104 | For clarity and to correctly reflect the scope for this CG, we suggest that non-relevant guidance be removed from the related NICE guidance section. This includes NICE guidance on wrist and hand surgery (IPG271, IPG110, IPG111), ankle surgery (IPG538), temporomandibular joint surgery (IPG500) and revision surgery (MIB13). | Thank you for your comment. We have removed these from the list. |
| Johnson & Johnson Medical Ltd | 4 | 104 | Although its Quality Standard is included, the Osteoarthritis Clinical Guideline (2014) is missing from the list of related NICE guidance. As stated in the draft scope, 90% of joint replacements are indicated for OA and this CG makes some fundamental recommendations on referral for joint replacement surgery. We request that this be added for completeness. | Thank you for your comment. This guideline is included in the list of related NICE guidance. |
| Johnson & Johnson Medical Ltd | 8 | 217 | With regards to hip replacement surgery, we note that reverse hybrid hip replacement is not explicitly mentioned in the draft scope. In the 2017 NJR report, 22,500 reverse hybrid hip procedures were recorded, representing 2.5% of all total hip replacements recorded since the NJR started collecting data in 2003. We therefore request that reverse hybrid combinations be included in any review of total hip replacement. | Thank you for your comment. Reverse hybrid hip replacement may be considered when review protocols on joint replacement surgery are developed. The committee will ensure that the final questions do not conflict with TA304. |

# Joint replacement (primary): hip, knee and shoulder

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| Johnson & Johnson Medical Ltd | 8 | 218 | We advise that NICE reconsiders its proposal for a new review of the clinical and cost effectiveness of "cemented vs cementless vs hybrid" hip replacement. Firstly, we are surprised to see duplication of this work, because a comprehensive analysis to address this same question was completed as part of Technology Appraisal 304 on total hip replacement, reviewed by the NICE Technology Appraisal Committee and published in the final Technology Appraisal Guidance on the NICE website. This TA guidance was only reviewed again by NICE in 2017. From the work done by NICE as part of this TA Guidance, we know that implant revision rate is the single most important driver of costs and QALYs and we request that the collaborative work between industry, BOA and NICE to develop this TA recommendation be fully absorbed into this CG.<br>Secondly, blanket recommendations such as those driven by GIRFT are unhelpful at this broad level because of the significant variation in implant performance within class due to implant factors such as the bearing articulation, head size and collar type; patient factors such as age, gender, diagnosis and concomitant disease; and surgeon factors such as annual volume of operations and level of experience. This variation is reported in multiple sources, including | Thank you for your comment. We have removed these draft questions from the scope, and the committee will ensure the final questions do not conflict with TA304. |

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| | | | the UK NJR and AOA NJRR.<br>Very clear recommendations were made in TA304 on minimum revision rate benchmarks for implant selection to drive cost effective decision making. We request that TA304 be incorporated into this CG on JR for total hip replacement. | |
| Johnson & Johnson Medical Ltd | 8 | 221 | With regards to the review of the clinical and cost effectiveness of hip implant bearing surface with a "CoP vs CoC vs MoP" comparison, NICE TA304 in 2017 on total hip replacement concluded that it is difficult to make definitive recommendations on cost effectiveness because of the significant variability in revision rate between individual implants. To provide an example of this using data published in 2017 NJR, implant specific revision rates within the cemented MoP class range from 2.14% (95%CI 1.87 – 2.45%) to 4.12% (95%CI 3.71 – 4.57%) at 10 years. We request that NICE incorporates the learnings and collaborative work carried out as part of this TA Guidance development. | Thank you for your comment. We have removed these draft questions from the scope, and the committee will ensure the final questions do not conflict with TA304 |
| Johnson & Johnson Medical Ltd | 10 | 274 | The Osteoarthritis Clinical Guideline (2014) is missing from the NICE pathway. As stated in the draft scope, 90% of joint replacements are indicated for OA and this CG makes some fundamental recommendations on referral for joint replacement surgery. As stated previously in our feedback, the recommendations from | Thank you for your comment. We have reviewed the pathway following stakeholder comments. The pathway will be on joint replacement in general, rather than specifically limited to hip, knee and shoulder joint replacement hence the IPGs on other types of joint replacement. |

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| | | | the OA CG on assessment and referral to consideration of joint surgery are pertinent and should be fully incorporated in the new CG. We request that it be incorporated into the NICE pathway. | |
| Johnson & Johnson Medical Ltd | 11 | 290 | We request that NICE reviews its Guidance included in the NICE Pathway list rows 290-299. Many listed are not relevant to the scope of this CG. We request that the related NICE guidance lists be reviewed and updated accordingly in line with the CG scope. | Thank you for your comment. We have reviewed the pathway following stakeholder comments. The pathway's starting point is person having primary elective joint surgery. Therefore, it won't discuss indications for joint surgery. There will be a link from the osteoarthritis pathway to the new pathway. |
| Musculoskeletal Research Unit, University of Bristol | General | General | Where insufficient evidence is found to make a recommendation, research recommendations should be made and these should be comprehensive. | Thank you for your comment. Research recommendations will be considered if there is insufficient evidence. |
| Musculoskeletal Research Unit, University of Bristol | General | General | The relative performance of different constructs needs to be considered to establish the safest and most cost effective options according to patient gender, age and diagnosis. | Thank you for your comment. The committee will consider patient sex, age and diagnosis as factors when writing the review protocols. |
| Musculoskeletal Research Unit, University of Bristol | General | General | The cost effectiveness of referral pathways involving intermediate steps between primary and secondary care should be considered. | Thank you for your comment. The guideline starts at the point that a patient has been referred to secondary care for consideration for a joint replacement. Recommendations related to referral to secondary care are covered in the osteoarthritis guideline (https://www.nice.org.uk/guidance/cg177) and therefore we have not included it in this guideline to avoid |

# Joint replacement (primary): hip, knee and shoulder

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| | | | | duplication. |
| Musculoskeletal Research Unit, University of Bristol | General | General | The clinical and economic evidence for referral thresholds and criteria (such as the use of Oxford Scores, arbitrary periods of failed conservative therapy, BMI and smoking status) should be investigated. | Thank you for your comment. The guideline starting point is once a person has already been referred for consideration of joint surgery. Therefore, it won't discuss thresholds and criteria for referral for joint surgery. Recommendations related to referral to secondary care for consideration of joint surgery are covered in the NICE guideline on osteoarthritis (https://www.nice.org.uk/guidance/cg177) and therefore will not be covered here. |
| Musculoskeletal Research Unit, University of Bristol | General | General | Recommendations should consider constructs and not implants in isolation as implants fail as part of a construct. Changing one element of a construct (e.g. bearing) hugely changes the failure rate. Looking at implants in isolation thus makes no sense. | Thank you for your comment. We will discuss this with the committee when we write the review protocols for the specific joint surgery questions. |
| Musculoskeletal Research Unit, University of Bristol | General | General | We are concerned to raise the issue of the management of chronic pain within the guideline– highlighting the current lack of evidence for effective interventions in TKR : https://goo.gl/maVhiQ<br>…and as regards post-surgical pain more generally: https://www.ncbi.nlm.nih.gov/pubmed/28681962. These as well as other outputs of the STAR programme may be of interest; particularly the outcomes of an ongoing RCT (NIHR funded STAR trial) which will report on the evaluation of an intervention for those with longterm pain following TKR | Thank you for your comment. This area was not prioritised for inclusion in this guideline as it was not clear that the committee would be able to make a recommendation. However, NICE is currently developing a guideline on chronic pain which seeks to address pain management programmes. The results from the STAR trial, which is not due to end until August 2020, may be considered in a future update of this guideline. |

# Joint replacement (primary): hip, knee and shoulder

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| Musculoskeletal Research Unit, University of Bristol | General | General | The drug and duration of prophylaxis for VTE should be considered as well as the effect of multimodal therapy. Stratification by age and gender is important | Thank you for your comment. Venous thromboembolism (VTE) prophylaxis is covered in a recently published update to the NICE guideline (https://www.nice.org.uk/guidance/ng89). |
| Musculoskeletal Research Unit, University of Bristol | General | General | Occupational therapy. When should aids and appliances be provided – before surgery may prevent delays to discharge? Should they be provided? Hip precautions? | Thank you for your comment. There are review questions on the clinical and cost effectiveness of pre- and postoperative rehabilitation that we hope will address these issues. |
| Musculoskeletal Research Unit, University of Bristol | General | Question 1 | We cannot answer the question as set, at present. Cost savings will be made if interventions /forms of practice are effective. Establishing the evidence for effectiveness is surely part of the guideline development process to come | Thank you for your comment. We will be looking at the clinical and cost effectiveness for all interventions. With this question, we were seeking to ascertain whether stakeholders were aware of any specific area(s) that need to be considered. |
| Musculoskeletal Research Unit, University of Bristol | 1 | 13, 16, 17 | It is not the 'UK National Joint Registry' [NJR]. NJR covers England, Wales, Northern Ireland and Isle of Man - as reflected in its report title http://www.njrreports.org.uk/Portals/0/PDFdownloads/NJR%2014th%20Annual%20Report%202017.pdf. Add in data from Scottish Arthroplasty Project for full UK figures: http://www.arthro.scot.nhs.uk/docs/2017/2017-08-08-SAP-Publication-Report.pdf?1<br>As this guideline relates to primary elective joint replacement, it would be good to present numbers of primaries here (93, 234 hip and 102,519 knees including unicompartmental ) | Thank you for your comment. We have corrected this and refer to it as the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man and only included figures from the 2017 NJR report. We have also added the numbers of primary elective replacements from this report. |

# Joint replacement (primary): hip, knee and shoulder

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| Musculoskeletal Research Unit, University of Bristol | 1 | 16 | The age at which joint replacement is performed is not becoming younger, the average age is static and has been for the duration of the NJR. There is very little change in the age groups across the period the NJR has been recording data. | Thank you for this comment. We have removed this statement from the scope. |
| Musculoskeletal Research Unit, University of Bristol | 4 | 90 | Consider findings from the NIHR funded RESTORE programme published here: https://www.ncbi.nlm.nih.gov/pubmed/27559567 | Thank you for the citation. We will consider this for inclusion in the appropriate reviews. |
| Musculoskeletal Research Unit, University of Bristol | 4 | 91 | Consider findings from the following relevant publications: https://www.ncbi.nlm.nih.gov/pubmed/25659070;https://www.ncbi.nlm.nih.gov/pubmed/26116078 (APEX studies); and https://www.ncbi.nlm.nih.gov/pubmed/24996539 (systematic review of the effectiveness of local anaesthetic infiltration for perioperative pain control in total hip/knee replacement) | Thank you for the citations. These will be considered for inclusion in the anaesthesia reviews. |
| Musculoskeletal Research Unit, University of Bristol | 4 | 94 | There are few studies that will provide evidence of methods to reduce wrong implant selection (side and size mismatches).<br>In areas such as this, consideration should be given to providing guidance NHS wide on established methods that would reduce this, even if not the subject of trials, examples include barcode scanning live in theatre | Thank you for your comment. We are aware that there may not be evidence for this. We will consider your suggested interventions when writing the protocols for this question. |

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| | | | allowing checking against the listed procedure. Recommendations should also extend to the requirement to improving implant labelling by manufacturers to focus on data essential to patient safety. | |
| Musculoskeletal Research Unit, University of Bristol | 4 | 94 | Consider findings from ":*Choice of implant combinations in total hip replacement: systematic review and network meta-analysis.* https://www.ncbi.nlm.nih.gov/pubmed/29097396 | Thank you for your comment. We are assuming your comment relates to line 95 on hip replacement surgery, as this is what the cited reference addresses. We have now removed the questions related to hip implant choice to avoid duplication with NICE technology assessment for hip replacement (https://www.nice.org.uk/guidance/ta304). Specific questions will be considered when the committee convenes. |
| Musculoskeletal Research Unit, University of Bristol | 4 | 98 | Consider findings from "*Effectiveness of physiotherapy exercise following total knee replacement: systematic review and network meta-analysis.* https://www.ncbi.nlm.nih.gov/pubmed/25886975 | Thank you for the citations. These will be considered for inclusion in the reviews related to postoperative rehabilitation for knee surgery. |
| Musculoskeletal Research Unit, University of Bristol | 7 | 190 | Developing standard lists of complications and rates to inform the consent process that could then be individualised to patients would be very useful. | Thank you for your comment. |
| Musculoskeletal Research Unit, | 7 | 198-199 | The systematic review performed within the NIHR RESTORE programme showed small short term benefits | Thank you for your comment. We will examine this evidence when we do the reviews for this area. If the |

# Joint replacement (primary): hip, knee and shoulder

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| University of Bristol | | | for pre-surgical exercise and education relating to physical function, anxiety in hospital and mobilisation, but no long-term benefits. There are numerous other systematic reviews with similar conclusions, all based on generally small RCTs | evidence is uncertain, then the committee will consider making a research recommendation. |
| Musculoskeletal Research Unit, University of Bristol | 8 | 200-203 | NIHR funded APEX RCT shows that LIA is effective and cost effective in reducing long-term pain in hip replacement (https://www.ncbi.nlm.nih.gov/pubmed/25659070 https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-015-0389-1). In knee replacement, evidence is weaker and LIA may not add to the pain control afforded by FNB. An RCT exploring this is ongoing but will only follow patients to 12 weeks (http://bmjopen.bmj.com/content/5/12/e009898). Systematic reviews highlight the difficulties of meta-analysis in THR and TKR anaesthesia studies – patient care varies widely between studies (pre-op, peri-op and post-op care) and it is difficult to synthesise evidence comparing evidence (https://www.ncbi.nlm.nih.gov/pubmed/24939863 https://www.ncbi.nlm.nih.gov/pubmed/24996539). Important to remember the limited value of short-term pain outcomes in RCTS of peri-operative pain management. Key outcomes are **long-term.** | Thank you for the citations. These will be considered for inclusion in the anaesthesia review(s). We will also consider your comment on long-term outcomes when we define the time point for outcomes in the protocols. |
| Musculoskeletal | 8 | 204-207 | There are numerous systematic reviews of tranexamic | Thank you for the citations. These will be considered for |

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| Research Unit, University of Bristol | | | acid use in relation to blood loss and need for transfusions. In our ongoing review looking at long-term pain outcomes after pre-, peri- and post-op interventions, tranexamic acid was compared with control in 3 RCTs at low risk of bias [1-4]. In all studies, control patients required more transfusions. In 1 study including 180 patients, there was no significant difference between groups in WOMAC pain at 1 year [42]. In another study with 48 patients, there was no significant difference in WOMAC score at 6 months (p=0.282) [41]. One study evaluated 2 tranexamic acid doses and saline control [43]. There were no significant differences in WOMAC score between groups.<br>In 1 RCT at low risk of bias, continuous tranexamic acid infusion was compared with a single bolus in 106 patients [44]. There were no differences in KSS at 6 months (p=0.90) or blood loss.<br>1. Sa-Ngasoongsong P, Channoom T, Kawinwonggowit V, Woratanarat P, Chanplakorn P, Wibulpolprasert B, Wongsak S, Udomsubpayakul U, Wechmongkolgorn S, Lekpittaya N. *Postoperative blood loss reduction in computer-assisted surgery total knee replacement by low dose intra-articular tranexamic acid injection together with 2-hour clamp drain: a prospective triple-blinded randomized controlled trial.* Orthopedic reviews 2011;3(2):e12. | inclusion in the tranexamic acid review(s). |

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| | | | 2. Kim TK, Chang CB, Kang YG, Seo ES, Lee JH, Yun JH, Lee SH. *Clinical value of tranexamic acid in unilateral and simultaneous bilateral TKAs under a contemporary blood-saving protocol: a randomized controlled trial.* Knee surgery, sports traumatology, arthroscopy : official journal of the ESSKA 2014;22(8):1870-8.<br>3. Sa-Ngasoongsong P, Wongsak S, Chanplakorn P, Woratanarat P, Wechmongkolgorn S, Wibulpolprasert B, Mulpruek P, Kawinwonggowit V. *Efficacy of low-dose intra-articular tranexamic acid in total knee replacement; a prospective triple-blinded randomized controlled trial.* BMC musculoskeletal disorders 2013;14:340.<br>4. Hourlier H, Reina N, Fennema P. *Single dose intravenous tranexamic acid as effective as continuous infusion in primary total knee arthroplasty: a randomised clinical trial*. Archives of orthopaedic and trauma surgery 2015;135(4):465-71. | |
| Musculoskeletal Research Unit, University of Bristol | 8 | 208 | Infection prevention should be extended to include skin preparation, antibiotic prophylaxis and the use of exhaust hoods. | Thank you for your comment. We prioritised wound lavage and laminar flow as the issues that would add the most value to cover for infection prevention. |
| Musculoskeletal Research Unit, University of Bristol | 8 | 211-212 | See MRC trial from early 1980s. Doubts more recently from joint registry analyses | Thank you for the suggestions. These will be considered for inclusion in the laminar flow review. |

# Joint replacement (primary): hip, knee and shoulder

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| Musculoskeletal Research Unit, University of Bristol | 8 | 217 | Hip replacement surgery implants, should be extended to include head sizes and bearings such as dual mobility versus standard bearings. | Thank you for your suggestions. Many aspects related to hip replacement surgery were recently updated in the NICE technology appraisal (https://www.nice.org.uk/guidance/ta304). Consequently, we will not be covering these areas to avoid duplication. |
| Musculoskeletal Research Unit, University of Bristol | 8 | 217-223 | Elsa Marques' project (http://www.bmj.com/content/359/bmj.j4651) has much of interest. Paraphrasing the conclusions of Chris Fawsitt's 2017 ISPOR poster:<br>• The older the patient, the higher the probability that small head cemented MoP implants are optimal.<br>• CoP implants are optimal for adults aged under 65, with large head hybrid implants preferable in males.<br>The economic analysis from this work is currently with *BMC Medicine* and should be attended to when published. Findings have implications for national guidance, clinical practice, and commissioning of services. | Thank you for your suggestions. A lot of aspects related to hip replacement surgery were recently updated in the NICE technology appraisal (https://www.nice.org.uk/guidance/ta304). Consequently, we will not be covering these areas to avoid duplication. |
| Musculoskeletal Research Unit, University of Bristol | 8 | 224 | Knee replacement surgery, should be extended to include implant fixation, constraint, patient specific instruments and implants and navigation. | Thank you for your suggestions. We will consider these when we discuss the questions related to knee replacement surgery. |
| Musculoskeletal | 9 | 239-248 | Please note the conclusions of a recent systematic | Thank you for the citations. These will be considered for |

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| Research Unit, University of Bristol | | | review of physiotherapy exercise after TKR: (https://www.biomedcentral.com/track/pdf/10.1186/s12891-015-0469-6?site=bmcmusculoskeletdisord.biomedcentral.com). Also after THR (http://www.physiotherapyjournal.com/article/S0031-9406(15)00006-1/abstract). Evidence for value not strong, particularly for benefit beyond end of classes.<br><br>More recently some fully powered studies with economic analyses are of interest:<br>MARKER (Fransen 2017) (https://www.ncbi.nlm.nih.gov/pubmed/27868384). Outpatient group exercise. N=422. No difference in pain or activity limitations at 12 months<br>3 important studies will report soon:<br>ARENA – outpatient group physiotherapy (n=256)<br>CORKA – community-based targeted at patients at risk of poor outcome (n=620)<br>TRIO – rehabilitation targeting people with slow recovery (n=440) | inclusion in the postoperative rehabilitation review for total knee replacement. |
| Musculoskeletal Research Unit, University of Bristol | 9 | 249-252 | The paper *Follow-up after arthroplasty of the hip and knee : are we over-servicing or under-caring?* (https://www.ncbi.nlm.nih.gov/pubmed/29305444) suggests that 'virtual' clinicals and those run by | Thank you for your suggestions. We will consider this when we decide on the final question for long-term monitoring. |

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| | | | advanced physiotherapy practitioners are possible solutions to follow up outcomes for arthroplasty patients | |
| Musculoskeletal Research Unit, University of Bristol | 9 | 253 | We need to balance pragmatism with rigor in choice of measures (e.g. the Harris Hip Score), or much important research will be ignored. | Thank you for your comment. We will carefully consider relevant outcomes for each review question. This list of outcomes is just the main outcomes to be considered and not an exhaustive list. |
| Neurocare Europe Limited | General | 98 239 | Post-operative rehabilitation<br><br>The use of NMES in post-operative rehabilitation has been extensively researched and in general the results mirror those obtained in preoperative mode Most of the trials referenced are in post TKA rehabilitation with a further three which cover rehabilitation post THA .We are not aware of any trials which demonstrate that NMES produces similar outcomes post shoulder replacement but given the principal mechanisms of action (muscle activation improves muscle capacity and promotes local circulation) there is no reason to conclude that effects would be any less beneficial.<br><br>In another context, (Clinical Guideline 83 Rehabilitation after critical illness),NICE have noted that "The general perception among patients, families and most healthcare professionals is that these people undergo a rapid convalescence and recover to their previous life, in | Thank you for your comment. Specific interventions will be considered when drafting protocols for post-operative rehabilitation. |

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| | | | terms of both quantity and quality." Guideline 83 goes on to acknowledge that this is rarely the case; long term rehabilitation being both complex and under-resourced and we contend that the same quotation could equally be made regarding rehabilitation post joint replacement where many, perhaps the majority, of patients rarely regain pre-disablement strength, endurance and mobility and are relieved of pain.<br><br>Our other general comments made in the above section are also relevant in this section. However there are some further points which we wish to make some of which have as their source material from the Clinical Trials included in Appendix 2<br><br>1) Two trials (TKA 5&7) note that some patients reached the maximum output of the NMES device in use in the trial and could have been comfortable with more intensive stimulation .This is a crucial observation since a similar trial also detects a direct correlation between strength of electrical signal and the progress of strength gain.<br>2) One trial in making a similar point reports that "console" devices which are mains powered are more effective than the smaller and inevitably cheaper battery powered devices | |

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| Neurocare Europe Limited | 4 & General | 90 197 | Preoperative Rehabilitation<br>We are unsure whether the intention of this heading is to solicit comment on patients who have been diagnosed and scheduled for joint replacement surgery or more generally for those who are suffering osteo-arthritis and are on a pathway which may lead to this outcome. Our comments below embrace both categories<br><br>In either case we are mindful of recent (Jan 2018) CCG pronouncements which impose new and increasingly stringent criteria on eligibility for joint replacement and now appear to include as candidates only those who are functionally immobile and/or suffering the most continuous intense pain. This will obviously exclude a very large number of patients whose symptoms are less severe and for whom no effective treatments, other than painkillers and relatively ineffective ointments are available in current NHS practice.<br><br>Our business consists of the manufacture and marketing of electrotherapy devices. Electrotherapy in general and Neuromuscular Electronic Stimulation (NMES) in particular have ( largely outside the UK) become well established therapy in many fields and this adoption is supported by an ever broadening body of high quality clinical evidence which we believe is exemplified by the | Thank you for your comment. The question on preoperative rehabilitation is about optimising patients for surgery once listed for joint replacement. The guideline starts at the point that adults are referred for consideration of joint replacement.<br><br>We have added a question about decision aids for assessing adults for joint replacement to attempt to address this concern.<br><br>Specific interventions will be considered when drafting protocols for the questions. |

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| | | | clinical trials which we have referenced in this response.<br><br>It is part of our purpose in responding to this opportunity for consultation to bring further to your attention this therapy and the evidence which supports it since despite some 25 years of successful adoption in the USA and elsewhere it has not entered NHS practice in anywhere other than in a small number of specialised area such as rehabilitation post SCI.<br><br>In the trials referenced below (Appendix1) we have attempted to demonstrate that NMES should by now be considered a well proven intervention for treating patients pre operation to relieve pain and improve mobility, in some cases obviating the need for surgical intervention and in others by providing improved mobility and durable pain relief whilst awaiting surgery<br><br>There is a broad consensus which emerges from the referenced trials as follows:<br>1] NMES when used alone or alongside conventional therapy brings statistically significant improvements in muscle strength, range of motion and reduction in pain. Of note is the general conclusion from these trials that gains in functional capability and reductions in pain are sustained suggesting that the therapy is addressing | |

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| | | | underlying causal factors rather than providing temporary amelioration.<br>1 continued<br><br>2} Preoperative NMES may also improve subsequent speed and quality of recovery post-surgery ( one trial considering TKA tested this effect) and we also have anecdotal evidence that NMES when applied intensively for some days immediately preceding the operation may by improving circulation to and removing fluid from the joint thus relieving inflammation have the effect of facilitating the surgical procedure.<br><br>3) NMES when used alone in a patient population unable to undertake volitional exercise is an acceptable substitute and achieves similar improvements | |
| Neurocare Europe Limited | 178 | | Health Economic considerations<br><br>Health Economic Treatment cost will vary taking into consideration the setting in which the treatment is delivered. If the Patient is supervised throughout the treatment session the current (eg Physiotherapist ) cost of circa £40 per hour will need to be added to the hourly cost of the Device and consumables | Thank you for your comment. Clinical and cost effectiveness evidence will be reviewed for all the areas included in the scope. Relevant costs, including downstream costs and savings, will be considered. Specific interventions will be considered when developing the review protocols for the questions.<br><br>Rigorous literature search strategies will be adopted to identify all eligible evidence around each specific guideline question, including pre- and post-operative |

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| | | | This is an inexpensive therapy both in terms of initial equipment purchase and ongoing consumable costs. For our own Device the individual (45 minute) treatment cost, assuming that over a 10 year life approx 10,000 treatments are delivered in a clinical setting the (device plus consumable) cost would be less than £2 per event In a health economic evaluation undertaken on our device where the cost effectiveness of enhanced wound healing was considered the device was shown to be cost effective and cost saving in most usage scenarios .A full copy of this report is available on request<br><br>This therapy is inherently safe and easily administered. After familiarisation Patients can readily self-treat and in the case of our device can safely adjust voltage intensity for optimal treatment effect<br><br>Appendices<br>Appendix 1<br>ARTHRITIS- Treatment with NMES Pre-operation<br>1] Quadriceps Femoris Neuromuscular Electrical Stimulation Program in subjects with Severe Knee Osteoarthritis.R.J. Walls, G. McHugh, N.M. Moyna and J.M. Obyrne - J Bone Joint Surg Br 2009 vol. 91-B no. SUPP III 457<br>Results There were similar, significant improvements in | rehabilitation. A call for evidence may be issued if the committee feels this is required. As a stakeholder, you will be notified if this happens and you will be encouraged to submit your evidence. |

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| | | | functional capacity for the RT and NMES groups at week 8 compared to week 1 ($p \leq 0.001$) and compared to the control group ($p < 0.005$), and the improvements were maintained at week 14 ($p \leq 0.001$). Cross sectional area of the QFM increased in both training groups (NMES: +5.4%; RT: +4.3%; $p = 0.404$). Adherence was 91% and 83% in the NMES and RT groups respectively ($p = 0.324$). Conclusions Home-based NMES is an acceptable alternative to exercise therapy in the management of knee OA, producing similar improvements in functional capacity. Trial registration: Current Controlled Trials ISRCTN85231954<br><br>2} Phys Ther. 2007 Aug;87(8):1064-77. Epub 2007 Jun 6.<br>Neuromuscular electrical stimulation and volitional exercise for individuals with rheumatoid arthritis: a multiple-patient case report.Piva SR1, Goodnite EA, Azuma K, Woollard JD, Goodpaster BH, Wasko MC, Fitzgerald GK.<br>OUTCOMES:One patient did not tolerate the NMES treatment, and 2 patients did not complete at least half of the proposed treatment. Patients who completed the NMES and volitional exercise program increased their lean muscle mass, muscle strength, and physical function. | |

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| | | | DISCUSSION:Because of the small sample, whether NMES combined with exercises is better than exercise alone or NMES alone could not be determined. However, the outcomes from this multiple-patient case report indicate that NMES is a viable treatment option to address muscle atrophy and weakness in patients with RA. Strategies to increase tolerance and adherence to NMES are warranted.<br>Appendix 1 cont<br>3} Walls et al., Effects of preoperative neuromuscular electrical stimulation on quadriceps strength and functional recovery in total knee arthroplasty. A pilot study BMC Musculoskeletal Disorders 2010, 11:119<br>Results: Overall compliance with the programme was excellent (99%). Preoperative QFM strength increased by 28% ($p > 0.05$) with associated gains in walk, stair-climb and chair-rise times ($p < 0.05$). Early postoperative strength loss (approximately 50%) was similar in both groups. Only the NMES group demonstrated significant strength (53.3%, $p = 0.011$) and functional recovery ($p < 0.05$) from 6 to 12 weeks post-TKA. QFM CSA decreased by 4% in the NMES group compared to a reduction of 12% in the control group ($P > 0.05$) at 12 weeks postoperatively compared to baseline. There were only limited associations found between objective and subjective functional outcome instruments | |

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| | | | Conclusions: This pilot study has shown that preoperative NMES may improve recovery of quadriceps muscle strength and expedite a return to normal activities in patients undergoing TKA for OA. Recommendations for appropriate outcome instruments in future studies of prehabilitation in TKA have been provided.<br><br>4] The Treatment of Osteoarthritis of the Knee with Pulsed Electrical Stimulation. Zizic TM, Hoffman KC, Holt PA, Hungerford DS, O'Dell JR, Jacobs MA, Lewis CG, Deal CL, Caldwell JR, Cholewcynski JG, et al. J Rheumatol. 1995 Sep;22(9):1757-61.<br>RESULTS:Patients treated with the active devices showed significantly greater improvement than the placebo group for all primary efficacy variables in comparisons of mean change from baseline to the end of treatment ($p < 0.05$). Improvement of > or = 50% from baseline was demonstrated in at least one primary efficacy variable in 50% of the active device group, in 2 variables in 32%, and in all 3 variables in 24%. In the placebo group improvement of > or = 50% occurred in 36% for one, 6% for 2, and 6% for 3 variables. Mean morning stiffness decreased 20 min in the active device group and increased 2 min in the placebo group | |

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| | | | (p < 0.05). No statistically significant differences were observed for tenderness, swelling, or walking time. CONCLUSION:The improvements in clinical measures for pain and function found in this study suggest that pulsed electrical stimulation is effective for treating OA of the knee. Studies for long term effects are warranted.<br><br>5] Effects of quadriceps electrical stimulation program on clinical parameters in the patients with knee osteoarthritis.Durmuş D, Alayli G, Cantürk F.Clin Rheumatol. 2007 May;26(5):674-8. Epub 2006 Aug 1 Both groups showed significant improvements in pain, physical function, and stiffness scores after the therapy. There were statistically significant improvements in 50 m walking time and 10 steps stairs climbing up-down time and 1 RM and 10 RM values indicating the improvement in muscle strength. In addition, there were no significant differences between the groups after the therapy. We conclude that electrical stimulation treatment was as effective as exercise in knee osteoarthritis and electrical stimulation treatment can be suggested especially for the patients who have difficulty in or contraindications to perform an exercise program.<br><br>6] Sao Paulo Med J. 2013;131(2):80-7.Is neuromuscular electrical stimulation effective for improving pain, | |

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| | | | function and activities of daily living of knee osteoarthritis patients? A randomized clinical trial.Imoto AM1, Peccin MS, Teixeira LE, Silva KN, Abrahão M, Trevisani VF.<br>RESULTS:Eighty-two patients completed the study. From intention-to-treat (ITT) analysis comparing the groups, the NMES group showed a statistically significant improvement in relation to the control group, regarding pain intensity (difference between means: 1.67 [0.31 to 3.02]; P = 0.01), Lequesne index (difference between means: 1.98 [0.15 to 3.79]; P = 0.03) and ADL scale (difference between means: -11.23 [-19.88 to -2.57]; P = 0.01).<br>CONCLUSION: NMES, within a rehabilitation protocol for patients with knee osteoarthritis, is effective for improving pain, function and activities of daily living, in comparison with a group that received an orientation program.<br>7<br>CONCLUSION: Patients with knee OA have decreased strength, muscle thickness, and fascicle length in the knee extensor musculature compared to age and sex-matched controls. NMES training of short duration appears to offset the changes in quadriceps structure and function, as well as reduces joint pain, joint stiffness, and functional limitation in patients with knee OA. | |

# Joint replacement (primary): hip, knee and shoulder

## Consultation on draft scope
## Stakeholder comments table

## 08/01/2018 to 05/02/2018

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| | | | Appendix 1 cont<br>7] Neuromuscular Electrical Stimulation (NMES) Reduces Structural and Functional Losses of Quadriceps Muscle and Improves Health Status in Patients with Knee Osteoarthritis Marco Aure´lio Vaz,1 Bruno Manfredini Baroni,1 Jeam Marcel Geremia,1 Fa´bio Juner Lanferdini,1 Alexandre Mayer,1 Adamantios Arampatzis,2 Walter Herzog3 1 Received 17 January 2012; accepted 11 October 2012 Published online 8 November 2012 in Wiley Online Library (wileyonlinelibrary.com). DOI 10.1002/jor.22264<br>RESULTS: NMES training increased vastus lateralis thickness (from 12.6 to 14.2 mm) and fascicle length (from 19.6% to 24.6%). Additionally, NMES training increased the knee extensor torque by 8% and reduced joint pain, stiffness, and functional limitation. NMES training appears to offset the changes in quadriceps structure and function, as well as improve the health status in patients with knee OA.<br>CONCLUSION: Patients with knee OA have decreased strength, muscle thickness, and fascicle length in the knee extensor musculature compared to age and sex-matched controls. NMES training of short duration appears to offset the changes in quadriceps structure and function, as well as reduces joint pain, joint stiffness, and functional limitation in patients with knee OA. | |

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| | | | 8] J Rheumatol. 2003 Jul;30(7):1571-8. A home-based protocol of electrical muscle stimulation for quadriceps muscle strength in older adults with osteoarthritis of the knee. Talbot LA1, Gaines JM, Ling SM, Metter EJ. Results : The stimulated knee-extensor showed a 9.1% increase in 120 degrees PTIso compared to a 7% loss in the EDU group (time x group interaction for 120 degrees PTIso; p = 0.04). The chair rise time decreased by 11% in the NMES group, whereas the EDU group saw a 7% reduction (p = 0.01, time; p = 0.9, group). Similarly, both groups improved their walk time by approximately 7% (p = 0.02, time; p = 0.61 group). Severity of pain reported following intervention did not differ between groups. Conclusion: In older adults with knee OA, a home-based NMES protocol appears to be a promising therapy for increasing QF strength in adults with knee OA without exacerbating painful symptoms.<br><br>APPENDIX 2 TREATMENT WITH NMES POST SURGICAL REHABILITATION<br>HIP REPLACEMENT<br>1] World Journal of Sport Sciences 4 (1): 41-47, 2011 ISSN 2078-4724 © IDOSI Publications, 2011 Corresponding Author: Seham Alsayed Alghamry, Department of Sports Health Sciences, | |

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| | | | Faculty of Physical Education, Helwan University, Egypt. Effectiveness of Physical Rehabilitation and Electro-Stimulation after Hip Joint Replacement Surgery.<br><br>After patients completed the program, bilateral maximal isometric measurements of gravity-corrected hip extension and flexion torque were obtained; EMG and assess pain for the group and percentages were calculated to compared with the non-affected extremity. Results showed that patients after finished 12-week program with higher percentages for both extension and flexion torque when compared with the other extremity measurements flexion and extension. These results indicate that patients in this program can achieve high individual thigh musculature strength, hip range of motion and decreased pain.<br><br>2] Arch Phys Med Rehabil. 2008 Dec;89(12):2265-73. doi: 10.1016/j.apmr.2008.05.024Low-frequency electric muscle stimulation combined with physical therapy after total hip arthroplasty for hip osteoarthritis in elderly patients: a randomized controlled trial.Gremeaux V1, Renault J, Pardon L, Deley G, Lepers R, Casillas JM. RESULTS: Low-frequency electric muscle stimulation was well tolerated. It resulted in a greater improvement in strength of knee extensors on the operated side (77% | |

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| | | | vs 23%; P<.01), leading to a better balance of muscle strength between the operated and non-operated limb. The low-frequency electric muscle stimulation group also showed a greater improvement in FIM scores, though improvements in the walk tests were similar for the 2 groups, as was LOS.<br>CONCLUSIONS: Low-frequency electric muscle stimulation is a safe, well-tolerated therapy after THA for hip OA. It improves knee extensor strength, which is one of the factors leading to greater functional independence after THA.<br><br>3] J Orthop Surg Res. 2013 Mar 5;8:3. doi: 10.1186/1749-799X-8-3.Haemodynamic performance of neuromuscular electrical stimulation (NMES) during recovery from total hip arthroplasty. Broderick BJ1, Breathnach O, Condon F, Masterson E, Ólaighin G.<br>This study showed that applying NMES to the calf muscles of patients in the early post-operative period following THA produces popliteal blood flow velocities that far exceed resting in the operated and in the un-operated limb. NMES induced a peak velocity in the popliteal vein that reached nearly four times as high as resting. NMES induced a mean velocity that was also approximately four times as high as resting and volume flow was seven times that of resting.Conclusions:NMES | |

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| | | | produces a beneficial hemodynamic response in patients in the early post-operative period following orthopaedic surgery. This patient group found extended periods of calf-muscle NMES tolerable<br><br>TKA Post Surgical Rehabilitation<br><br>4] BMC Musculoskelet Disord. 2010; 11: 119. Published online 2010 Jun 14. doi: 10.1186/1471-2474-11-119 PMCID: PMC2896350 Effects of preoperative neuromuscular electrical stimulation on quadriceps strength and functional recovery in total knee arthroplasty. A pilot study Raymond J Walls, 1,2 Gavin McHugh,1,2 Donal J O'Gorman,2 Niall M Moyna,2 and John M O'Byrne1<br>Results Overall compliance with the programme was excellent (99%). Preoperative QFM strength increased by 28% ($p > 0.05$) with associated gains in walk, stair-climb and chair-rise times ($p < 0.05$). Early postoperative strength loss (approximately 50%) was similar in both groups. Only the NMES group demonstrated significant strength (53.3%, $p = 0.011$) and functional recovery ($p < 0.05$) from 6 to 12 weeks post-TKA. QFM CSA decreased by 4% in the NMES group compared to a reduction of 12% in the control group ($P > 0.05$) at 12 weeks postoperatively compared to baseline. There | |

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| | | | were only limited associations found between objective and subjective functional outcome instruments. Conclusions: This pilot study has shown that preoperative NMES may improve recovery of quadriceps muscle strength and expedite a return to normal activities in patients undergoing TKA for OA. Recommendations for appropriate outcome instruments in future studies of prehabilitation in TKA have been provided.<br><br>5] Phys Ther. 2012 Sep;92(9):1187-96. doi: 10.2522/ptj.20110479. Epub 2012 May 31.Relationship between intensity of quadriceps muscle neuromuscular electrical stimulation and strength recovery after total knee arthroplasty. Stevens-Lapsley JE1, Balter JE, Wolfe P, Eckhoff DG, Schwartz RS, Schenkman M, Kohrt WM.<br>RESULTS: At 3.5 weeks, there was a significant association between NMES training intensity and a change in quadriceps muscle strength (R(2)=.68) and activation (R(2)=.22). At 6.5 weeks, NMES training intensity was related to a change in strength (R(2)=.25) but not to a change in activation (R(2)=.00). Furthermore, quadriceps muscle fatigue occurred during NMES sessions at 3.5 and 6.5 weeks, whereas quadriceps muscle activation did not change. | |

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| | | | LIMITATIONS: Some participants reached the maximal stimulator output during at least 1 treatment session and might have tolerated more stimulation.<br>CONCLUSIONS: Higher NMES training intensities were associated with greater quadriceps muscle strength and activation after TKA<br><br>6] Does Electric Stimulation of Vastus Medialis Muscle Influence Rehabilitation After Total Knee Replacement? Kyriakos Avramids, MD, MSc, FRCS(Ed); Theofilos Karachalios, MD, DSc, PHD; Konstantinos Popotonasios, MD; Dimitrios Sacorafas, MD; Athanasios A. Papathanasiades, MD, PhD; Konstatinos, N. Malizos, MD,PhD Orthopeadics - March 2011 – Volume 34. Issue 3:175 DOI: 10.3928/014774477-20110124-06<br>Patients in group A demonstrated a statistically significant increase in walking speed, Oxford Knee Score, and American Knee Society function score compared to those in group B at 6 weeks (P=.003, .001, and .001, respectively) and at 12 weeks (all P=.001). A statistically significant increase in the SF-36 physical component summary score was observed at 6, 12, and 52 weeks (all P=.001). Three patients found the sensation of the electrical stimulation uncomfortable and abandoned its use. No skin reactions and surgical site infections were observed. Electrical stimulation of the | |

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| | | | vastus medialis muscle in addition to conventional physiotherapy improves functional recovery and early rehabilitation after TKR.<br><br>7] 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<br>RESULTS:At 3.5 weeks after TKA, significant improvements with NMES were found for quadriceps and hamstring muscle strength, functional performance, and knee extension active range of motion. At 52 weeks, the differences between groups were attenuated, but improvements with NMES were still significant for quadriceps and hamstring muscle strength, functional performance, and some self-report measures.<br>LIMITATIONS:Treatment volume was not matched for both study arms; NMES was added to the standard of care treatment. Furthermore, testers were not blinded during testing, but used standardized scripts to avoid bias. Finally, some patients reached the maximum stimulator output during at least one treatment session | |

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| | | | and may have tolerated more stimulation.<br>CONCLUSIONS:The early addition of NMES effectively attenuated loss of quadriceps muscle strength and improved functional performance following TKA. The effects were most pronounced and clinically meaningful within the first month after surgery, but persisted through 1 year after surgery.<br><br>8] J Orthop Sports Phys Ther. 2004 Jan;34(1):21-9. Neuromuscular electrical stimulation for quadriceps muscle strengthening after bilateral total knee arthroplasty: a case series. Stevens JE1, Mizner RL, Snyder-Mackler L.<br>RESULTS: At 6 months, the weak NMES-treated legs of 4 of 5 patients in the NMES group had surpassed the strength of the contralateral leg. In contrast, none of the weak legs in the exercise<br>Appendix 2 cont<br>8] J Orthop Sports Phys Ther. 2004 Jan;34(1):21-9. Neuromuscular electrical stimulation for quadriceps muscle strengthening after bilateral total knee arthroplasty: a case series. Stevens JE1, Mizner RL, Snyder-Mackler L.<br>RESULTS: At 6 months, the weak NMES-treated legs of 4 of 5 patients in the NMES group had surpassed the strength of the contralateral leg. In contrast, none of the | |

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| | | | weak legs in the exercise group were stronger than the contralateral leg at 6 months. Changes in quadriceps muscle activation mirrored the changes exhibited in strength.<br>CONCLUSION: When NMES was added to a voluntary exercise program, deficits in quadriceps muscle strength and activation resolved quickly after TKA.<br><br>9] PMID:14964588 DOI: 10.2519/jospt.2004.34.1.21 Response of male and female subjects 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.<br>CONCLUSIONS: After total knee arthroplasty, most elderly subjects can tolerate neuromuscular electrical stimulation at current intensities sufficient to elicit quadriceps femoris muscle contractions within the therapeutic range recommended for muscle strengthening. Although male subjects can tolerate stronger current intensities, similar %MVIC is activated in female and male subjects with impaired muscle function, indicating a similar potential for treatment effectiveness.<br><br>10] The effect of neuromuscular electrical stimulation on | |

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| | | | functional status and quality of life after knee arthroplasty: a randomized controlled study Demet Tekdos Demircioglu, MD,1,* Nurdan Paker, MD,2 Elif Erbil, MD, PhD,2 Derya Bugdayci, MD,2 and Tuluhan Yunus Emre, MD3<br>RESULTS: Both the NMES group had 30 patients each, with 2 and 1 male patients respectively. The comparisons of WOMAC results at month 1 revealed that pain, stiffness, and total scores of the NMES group was significantly better than those of control group at the first and third months. Significantly better physical function and SF-36 subscales, except mental health, were found for the NMES group at the first month of follow-up. [Conclusion] The inclusion of the neuromuscular electrical stimulation program after knee arthroplasty was more effective at providing rapid improvements in knee pain, walking distance and quality of life.<br><br>11] Early neuromuscular electrical stimulation to optimize quadriceps muscle function following total knee arthroplasty: a case report.Mintken PE1, Carpenter KJ, Eckhoff D, Kohrt WM, Stevens JE<br>DISCUSSION: Mitigating quadriceps muscle weakness immediately after TKA using early NMES may improve functional outcomes, because quadriceps weakness has | |

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| | | | been associated with numerous functional limitations and an increased risk for falls. Despite presenting preoperatively with substantial quadriceps torque and activation deficits, the patient in this case demonstrated improvements in quadriceps function at all the times measured, all of which were superior to those reported in the literature. The patient also made substantial improvements in functional outcomes, including the Knee Injury and Osteoarthritis Outcome Score (KOOS), 6-minute walk test, timed up and go (TUG) test, stair-climbing test, and the SF-36 Physical Component Score. Appropriately controlled clinical trials will be necessary to determine whether such favorable outcomes following TKA are specifically attributable to the addition of NMES to the rehabilitation program.<br><br>12] The use of neuromuscular electrical stimulation to improve activation deficits in a patient with chronic quadriceps strength impairments following total knee arthroplasty.Petterson S1, Snyder-Mackler L. OUTCOMES: The patient demonstrated a 25% improvement in left quadriceps femoris maximal volitional force output following 16 treatments of combined NMES and volitional strength training over a 6-week period. The patient's volitional muscle activation improved from a CAR of 0.83 before treatment to 0.97 | |

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| | | | after treatment. At discharge from physical therapy and at his 18-month postoperative follow-up, the patient's left quadriceps strength was only 4% lower than his right quadriceps strength. At the 24-month follow-up, the patient's left quadriceps strength was 6% stronger than his right quadriceps strength.<br>DISCUSSION: The patient was able to achieve symmetrical quadriceps strength and complete muscle activation following 6 weeks of NMES and volitional strength training. An intense strengthening program may have the potential to reverse persistent strength-related impairments following TKA. | |
| NHS England | General | General | We welcome the review of this clinical guideline and are pleased that it will include the role of pre and post rehabilitation. We support the engagement of AHPs in this review particularly around the pre and post-operative rehabilitation stages considering when this is best delivered, for how long and by who as part of the overall effectiveness (MD) | Thank you for your comment. We agree that pre- and post-operative rehabilitation is an important topic to cover in this guideline. |
| NHS England | General | General | I note that the scope as planned includes 'information and support needs (for people and their families)' and excludes 'indications' and assessment and diagnosis'. I would be keen to ensure that the scope does include shared decision making with patients, including a description of alternatives to joint replacement. In particular SDM is key to decisions about timing of joint | Thank you for your comment. We have added additional question to cover decision aids for assessing whether joint replacement is appropriate for an individual. |

# Joint replacement (primary): hip, knee and shoulder

## Consultation on draft scope
## Stakeholder comments table

## 08/01/2018 to 05/02/2018

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| | | | replacement surgery (CIC) | |
| NHS England | 3 | 75 | The draft scope currently does not consider implications for people with underlying medical conditions affecting joints for example inflammatory joint pathologies. | Thank you for your comment. When protocols are discussed, the committee will consider if separate reviews need to address the underlying cause(s) for joint replacement. |
| NHS England | 4 | 89 | The scope could be improved by including considerations for pre-operative assessment of patients particularly those patients who are overweight, smokers or suffer from co-morbid conditions that may affect post-operative recovery. | Thank you for your comment. Preoperative assessment in general has not been prioritised as an area for inclusion. There is a perioperative care NICE guideline currently in development that will cover aspects of preoperative assessment including identifying and measuring risk of adverse events in adults who will be undergoing surgery.<br><br>We have included a question on decision aids for assessing whether joint replacement is appropriate. The factors you mention may be included as part of these decision aides. These factors may also be considered as subgroup analyses within individual reviews. |
| NHS England | 9 | 239 | The scope could be improved by including considerations about immediate post-operative care particularly role of community services and their clinical and cost-effectiveness. | Thank you for your comment. We prioritised the timing and duration of physiotherapy for inclusion in the guideline. We could not include all areas, so we have not prioritised the role of community services because we believe there is unlikely to be sufficient evidence in this area to make firm recommendations.<br><br>We will not impose a restriction on where the post- |

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| | | | | operative rehabilitation will be delivered and therefore the role of community services in delivering rehabilitation and recovery interventions may be identified. | |
| NHS England | 12 | 303 | Draft currently does not consider clinical and cost effectiveness of primary healthcare practitioners in provision of pre-operative assessment of patients and immediate post-operative phase of their recovery. | Thank you for your comment. The guideline starts once the individual has been referred for consideration of having a replacement. Therefore, we have not covered areas a primary care practitioner may consider before referring patients to secondary care (for example, not referring those clearly unfit for surgery such as those with unstable medical comorbidities). Secondary care preoperative assessment is about final fitness for surgery and anaesthesia, which cannot be done in primary care. Consequently, the effectiveness of primary healthcare practitioners in preoperative assessment has not been included in the scope for this guideline. | |
| RCGP | | | This mainly relates to secondary care as indications for joint replacement have been specifically excluded. . This is a particularly important topic for primary care and commissioners as many Clinical and Commissioning groups (e.g. North Staffordshire CCG and Stoke CCG) have in place access criteria based on patients symptoms before they will fund treatment. This gives rise to variability in rates of replacement ("post code lottery") and a standard approach is needed. | Thank you for your comment. We have now included an extra question on decision aids for assessing whether joint replacement is appropriate for individuals to try and address this issue. | |
| RCGP | 4 | 101 | It's surprising that this draft scope will not cover the indications for joint replacement surgery. Reading | Thank you for your comment. We have now included an extra question on decision aids for assessing whether | |

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| | | | SHfurther down, it looks as if it is because the indications appear in other guidelines (presumably those covering the various osteoarthritides). This would make sense, though:<br>1. It would help to add this as a note to line 101<br>2. There is a minor concern that participants reported in studies that are reviewed for this guideline have similar degree of disease severity to those recommended for surgery in the other guidelines. | joint replacement is appropriate for individuals to try and address this issue. |
| Royal College of Anaesthetists (RCoA) | General | General | Composition of the Guideline Development Group<br><br>With guidance on anaesthesia and analgesia as one of the key outcomes of the guideline, the GDG membership as suggested would in our opinion lack the knowledge, clinical skills and experience to be authoritative on this subject. We would therefore strongly recommend that anaesthetists be full members of the GDG rather than co-opted members. As there is often little overlap between anaesthetists who specialise in lower limb joint replacement and upper limb joint replacement, and given that there are significant differences between patient populations and anaesthetic techniques used for these two clinical areas, we would recommend that at least two anaesthetists be full GDG members. Further, we would recommend that a peri-operative physician be included in full GDG | Thank you for your comment. Following stakeholder comments and on reflection, we agree that recruiting an anaesthetist as a full member would be beneficial. |

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| | | | membership, as they will have valuable contributions to make to the topics of information and support needs, prehabilitation, the use of tranexamic acid, and infection control. Inclusion of clinicians other than orthopaedic surgeons is supported by NICE's own guidance on GDGs, which demands that "Membership of the GDG… needs to be multidisciplinary". | |
| Royal College of Anaesthetists (RCoA) | 1 | 24 - 27 | This sentence is difficult to read and understand – could be rephrased for greater clarity. | Thank you for your comment. We have reviewed the text and rephrased for clarity following stakeholder comments. |
| Royal College of Anaesthetists (RCoA) | 7 | 191 | Information about anaesthetic risks should be included in the information. | Thank you for your comment. This will be considered when drafting recommendations. |
| Royal College of Anaesthetists (RCoA) | 8 | 201 | When considering the options for anaesthesia and analgesia, the following should be included:<br>• General anaesthesia, neuraxial (spinal and epidural) anaesthesia, and regional anaesthesia.<br>• Neuraxial (spinal and epidural) analgesia, regional analgesia (nerve blocks), and peri-articular infiltration techniques. | Thank you for your comment. The specific interventions in these draft questions will be listed when setting the protocol, which will define the population, interventions, comparators and outcomes to be considered. This is only done when the committee convene and discuss the detail of each review. We will ensure the committee considers your suggestions. |
| Royal College of Anaesthetists (RCoA) | 8 | 201 | An assessment of the cost and clinical effectiveness of anaesthetic and analgesic techniques should prioritise an assessment of their safety in patients undergoing the surgical procedures addressed. | Thank you for your comment. The outcomes to be included in the clinical evidence review protocol, including both benefits and harms, will be agreed with the committee during guideline development. Relevant costs will be presented to the committee, including those |

# Joint replacement (primary): hip, knee and shoulder

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| | | | | of any adverse events. |
| Royal College of Anaesthetists (RCoA) | 9 | 260 | Postoperative Nausea and Vomiting should be included in the outcomes. | Thank you for your comment. This will be considered when writing the review protocols. |
| Royal College of Nursing (RCN) | General | General | The Royal College of Nursing (RCN) welcomes proposals by National Institute for Health and Care Excellence to develop clinical guideline on hip, knee and shoulder joint replacements.<br><br>The RCN invited comments from those who have knowledge of this topic and/or care for people with this need.<br><br>The comments below reflect the views of our reviewers. | Thank you for your comment. |
| Royal College of Nursing (RCN) | General | General | The draft scope seems comprehensive.<br><br>The proposed guidance scope for hip, knee and shoulder replacement is appropriate. The scope addresses areas which will look at the procedures equally. | Thank you for your comment. |
| Royal College of Nursing (RCN) | 3 | 62 | Considerations for age, disability and religion have been acknowledged and proposes to address the process appropriately. We are not able to offer any further suggestions that would improve the equality and diversity at this stage of the development. | Thank you for your comment. |

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| Royal College of Nursing (RCN) | 4 | 100 | The exclusion criteria seem appropriate. | Thank you for your comment. |
| Royal College of Surgeons Edinburgh | | | The scope is too broad (THR / TKR and TSR are all very different operations in terms of patient profile, frequency and outcomes. | Thank you for your comment. We agree the scope is broad but we believe we can cover the areas listed within. |
| Royal College of Surgeons Edinburgh | | | The pre-operative management options prior to these procedures vary widely depending on the joint and cannot be generalised across all. | Thank you for your comment. We did not prioritise specific preoperative management options for inclusion in this guideline. There is a NICE guideline currently in development that will address peri-operative care. More detail of this guideline can be found here: https://www.nice.org.uk/guidance/indevelopment/gid-ng10072. There is also a published NICE guideline on preoperative testing available fromhttps://www.nice.org.uk/guidance/ng45 |
| Royal College of Surgeons Edinburgh | | | Wrong implant selection - no idea if there is evidence based research to suggest one method of doing this is any better than any other. | Thank you for your comment. NHS England has highlighted this issue as a key safety issue in joint replacement. Thus, the issue has been included in the guideline, and we will undertake a review the evidence that may reduce wrong implant selection. |
| Royal College of Surgeons Edinburgh | | | With Regard to TSR the indications for Reverse vs Standard although with occasional overlap are different so how do we compare | Thank you for your comment. This was discussed and it was agreed there are cases for direct comparison. This question seeks to address this. It was also noted that the overlap you mention is believed to be increasing in frequency making this an important area to cover. |
| Royal College of | | | The questions being asked individually may be of clinical | Thank you for your comment. We have prioritised the |

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| Surgeons Edinburgh | | | relevance i am not sure that they sit together as a whole. | main areas of concern based on the clinical issues identified at the stakeholder workshop. We have tried to include a chronological (patient-flow) theme in the most useful questions from pre-operative decision-making to post-operative long-term surveillance. |
| Royal College of Surgeons Edinburgh | | | Which interventions or forms of practice might result in cost saving recommendations if included in the guideline?<br>- physiotherapy and hyaluronic acid injections | Thank you for your comment. Physiotherapy is included in the guideline. Hyaluronic acid injections are not included as the guideline covers adults referred for consideration for surgery. |
| Royal College of Surgeons Edinburgh | | | Should the guideline also consider assessment for surgery in joint replacement after referral?<br>- In my view there are 2 factors which influences outcome- Ability of patient to be complaint with rehabilitation after surgery and access to specialist shoulder physiotherapy. Units, which do not have specialist shoulder physotherapists, should not be doing the procedure. | Thank you for your comment. We have now included indications for surgery after referral in the revised scope. Stakeholder feedback highlighted the potential benefit of exploring whether decision aids could help identify people most likely to benefit from joint replacement and this is now a review question in the guideline. |
| South Worcs CCG | 4 | 101 | Indications for Joint Replacement<br>The indications for joint replacement may affect outcomes and therefore are relevant for inclusion as part of the scope of work to be undertaken. If the indication is osteoarthritis as is likely to be the case in the majority, then the threshold for intervention becomes relevant in terms of disease severity and associated benefit/outcome. This leads onto assessment and | Thank you for your comment. We have added a question on decision aids for assessing whether joint replacement is appropriate for adults to try and address this issue. |

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| | | | diagnosis: | |
| South Worcs CCG | 4 | 102 | Assessment and Diagnosis<br>Whilst the detail of the assessment including tests and investigations are not relevant to this scope, the severity of disease established during this process may influence prognosis and outcomes. From a commissioning organisation perspective it would be useful if NICE could include within the scope the thresholds that could be used to influence a decision to proceed to surgery; this may include simple facts established during the assessment eg.osteoarthritis on X-ray using the Kellgren and Lawrence classification or may involve use of a validated tool assessing functional impairment eg. Oxford hip/knee or ACHE.<br>There has been some debate nationally regarding the impact of body mass index on outcomes following hip and knee replacement surgery and this too would be worthy of inclusion in the scope to help guide providers and commissioners.<br>Finally, the impact of smoking on outcomes following hip, knee or shoulder replacement surgery is also relevant and should be addressed.<br>Clarification of these issues will set a standard for commissioning organisations and help minimise the current inconsistency and unfairness arising from differing commissioning policies across CCGs in | Thank you for your comment. We have added a question on decision aids for assessing whether joint replacement is appropriate for adults to try to address this issue. |

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| | | | England. | |
| Stryker | 1 | 21 | An implant is selected by the surgeon to maximise the best possible potential outcome for a particular patient. | Thank you for your comment. We agree a surgeon seeks to maximise the best potential outcome for a patient. This introductory section highlights that there is variability, not just in implant design but also in operations and fixation methods. This guideline aims to address the most important issues related to this variability in order to improve outcomes for the patient. |
| Stryker | 2 | 40 | ODEP should be included here as it is plays a significant role in signposting the NHS to purchase the most clinically effective hip and knee implants, as acknowledged in previous NICE Technology Appraisal recommendation where a benchmark revision rate for implants was set for the NHS. | Thank you for your comment. We agree that ODEP ratings provide expert, independent assessment of clinical safety and are utilised by the NHS. They will be considered when setting inclusion criteria for the review protocols. However, we do not see the need to include a review on them as we think this is better covered outside of this guideline. |
| Stryker | 8 | 213 | This should already be covered by Standard Operating Procedures and checks within operating theatres. | Thank you for your comment. We felt that while efforts are made through Standard Operating Procedures within operating theatres to minimise this risk, there is some evidence that such events do occur, and, as part of commissioning, given the severity of these events, NHS England has asked us to include this question within the guidelines. |
| Stryker | 8 | 217 | Reverse hybrids should be added | Thank you for your comment. This will be considered when drafting the protocols. |
| Stryker | 8 | 224 | Total knee and partial knee arthroplasty have different | Thank you for your comment. This was discussed and it |

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| | | | indications therefore comparison would not be meaningful. | was agreed there are cases for direct comparison. This question seeks to address this. |
| The British Association of Prosthetists and Orthodontists (BAPO) | | | Question 1 - Which interventions or forms of practice might result in cost saving recommendations if included in the guideline?<br><br>Response – There is growing evidence to suggest that offloading knee braces (orthoses) are effective in treating Unicompartment knee OA and as such may delay or prevent need for knee replacement and so save the care provider financial resource that would otherwise be spent on costs of surgery and post-surgical rehab. There is also evidence to suggest that these orthoses can significantly reduce knee pain which in turn would reduce spend on pain relieving medications.<br><br>*Lee PY, Winfield TG, Harris SR, et al. BMJ Open Sport & Exercise Medicine 2017;2:e000195. doi: 10.1136/bmjsem-2016-000195*<br><br>*Feehan NL, Trexler GS, Barringer WJ. The effectiveness of off-loading knee orthoses in the reduction of pain in medial compartment knee osteoarthritis: a systematic review. Journal of Prosthetics and Orthotics 2012; 24(1):* | Thank you for your comment.<br><br>The guideline includes people who have already been referred for consideration for surgery. Offloading knee braces (orthoses) would be considered as an intervention before this stage and therefore are not included in the scope of this guideline. |

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| | | | *39-49* | |
| University of Strathclyde | General | General | Prerehabilitation and rehabilitation post knee surgery could result in cost saving recommendations if included in the guideline However much of the research has used clinical scores with which to evaluate the outcome and these are insensitive to patient functional change | Thank you for your comment. The economic evidence review will consider all relevant costs and savings for the interventions included in the guideline. The outcomes that will be included in the review protocol will be agreed with the committee during development including the choice of the outcome measures to consider. |
| University of Strathclyde | General | General | Uni compartment knee replacement if properly undertaken by a high frequency (25+ per year) and high quota (20%) surgeon has evidence of better outcome and less cost per case both of which have economic benefits than total knee arthroplasty | Thank you for your comment. The economic evidence review will consider all relevant costs and savings, including downstream cost saving associated with better outcomes, for the interventions included in the guideline. Uni-compartment knee replacement will be considered when writing the protocol for the knee surgery question. We note your comment on surgeon volume and will consider this as a subgroup within this review . |
| Warwick Medical School | 4 | 101 | The draft scope excludes indications for joint replacement. But this probably has the most important influence on outcome of any factor. Without considering appropriate indications, the panel will not be able to adequately advise on the best management of patients who have been referred to secondary care for a joint replacement.<br><br>The NICE clinical guideline CG177 made recommendations about referral for joint replacement, | Thank you for your comment. We have included an extra question on decision aids for assessing whether joint replacement is appropriate for adults to try and address this issue. |

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| | | | which was reflected in the Quality Statement, QS87, but the decision in secondary care about when a joint replacement is indicated has not been covered by NICE and is probably the most important question that these guidelines should answer. | |
| Zimmer Biomet | 4 | 102 | "Areas that will not be covered" includes assessment and diagnosis. There is considerable controversy surrounding restriction of access to total joint replacement made on arbitrary grounds such as Body Mass Index (BMI), smoking history and pain thresholds. Work should be done to ensure that when any patient is denied access to treatment there is valid medical evidence to support this. | Thank you for your comment. We will consider cross-referring to the recommendations in the osteoarthritis guideline CG177 to address this issue. |
| Zimmer Biomet | 8 | 218 | It is difficult to compare the various types of hip replacements when patient cohorts are different. For example, he National Joint Registry for England, Wales, Northern Ireland and the Isle of Man (NJR) reports the average age of a patient receiving an uncemented total hip replacement (THR) as 64 - eleven years younger than patients receiving cemented THR. Age, activity levels and life expectancy all play a significant role in implant outcomes. Whilst 13 year outcomes in the NJR may be similar between different constructs, there is a risk that a shift in implant choice in the younger patient group (as highlighted above) could be detrimental to | Thank you for your comment. We usually include RCTs, or in the absence of these cohort studies that have adjusted for predefined confounders to ensure we have matching groups. |

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| | | | implant performance. We therefore recommend that true matched cohorts are used to make valid comparisons and create guidance which will not make things detrimental for certain patient groups. | |
| Zimmer Biomet | 8 | 218 | An updated costing exercise should be conducted. Pricing of implants has changed dramatically over the past decade and some of the perceived differences in implant costs may no longer be valid. Under new commercial arrangements, the overall cost of conducting hip replacement operations when considering all costs such including consumables, operating theatre times and instrumentation requirements are often very similar. | Thank you for your comment. The economic evidence review will seek to identify the most applicable published evidence in this area. The more recent studies will be rated as more applicable than older studies. Where no published evidence exists, unit costs of these interventions will be presented to the committee. These unit costs will be based on the most recent national unit cost sources. |
| Zimmer Biomet | 8 | 225 | Comparing the clinical and cost effectiveness of total knee replacement (TKR) versus partial knee replacement (PKR)<br><br>Zimmer Biomet encourages this analysis, with the understanding that in previous such attempts, fair comparison of TKR and PKR have been hampered by differences in the baseline characteristics of patients being offered each procedure. As the guideline, page 4 line 101 does not intend to cover indication, it should be noted that only patients who are eligible for either TKR or PKR should be included in this comparison. | Thank you for your comment. This is a valid point and we will ensure when defining the population for this review question that this is included as one of the inclusion/exclusion criteria. |
| Zimmer Biomet | 8 | 225 | Comparing the clinical and cost effectiveness of total knee replacement (TKR) versus partial knee | Thank you for your comment. The exact outcomes to be considered in this review question will be discussed with |

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| | | | replacement (PKR)<br><br>As revision is noted as a main outcome, both the nature and cost of revision should also be taken into account as implant-related complications after PKR are usually treated by a primary TKR. When the same problems of loosening or implant failure result in reoperation after TKR, they are often treated with much more complex surgery and by larger revision devices involving stems and augments. | the committee during guideline development. The variation in the cost of revision procedures will be highlighted to the committee. Additionally, all relevant costs, including downstream costs, will be presented to the committee if no relevant published cost effectiveness evidence is identified. |
| Zimmer Biomet | 8 | 225 | Comparing the clinical and cost effectiveness of total knee replacement (TKR) versus partial knee replacement (PKR)<br><br>Intraoperative complications are not considered as a main outcome measure (page 9 line 253), stroke, myocardial infarction, thrombo embolism, blood transfusion, and admission to critical care have been shown to be much more common after TKR than after PKR and would have an influence on patient safety considerations and the relative cost-effectiveness of the two procedures.<br><br>As previously mentioned in comment two, we would urge that intra-operative complications are included as main outcome measures | Thank you for your comment. This list of the "main outcomes" is not meant to be exhaustive. The relevant outcomes to include for each review question will be agreed with the committee when writing the review protocols. The economic evidence review will consider all relevant costs, including the cost of managing these complications. |

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| Zimmer Biomet | 9 | 253 | "Main Outcomes" – in the reasons given for "Why the guideline is needed", page 1 line 25, and specific reference is given to different levels of complications as a result of variability in options. There are a variety of intraoperative and immediate post-op complications that would not necessarily be captured in the "main outcomes" listed, yet would have a major bearing on the cost-effectiveness of comparative treatments. It would therefore be prudent to include such complications (for example stroke, myocardial infarction, thrombo embolism, blood transfusion, and admission to critical care) collectively as a "main outcome." | Thank you for your comment. This list is not meant to be exhaustive. The relevant outcomes to include for each review question will be agreed with the committee when the review protocols are written. |
| Zimmer Biomet | 9 | 258 | Revision of joint replacement is listed as a main outcome and as such, it is of critical importance that the data to support this is robust.<br><br>The National Joint Registry for England, Wales, Northern Ireland and the Isle of Man (NJR) Medical Director and Chairman expressed concern in the most recent annual report stating "The failure of hospitals to upload revision procedures into the NJR is concerning, as linked revision procedures form the basis of the analyses of implant failure and surgical performance – which fundamentally underpin the core purpose of the NJR." | Thank you for your comment. We will consider our appropriate data sources when defining the protocols. |

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| | | | We therefore recommend that other global registries also need to be consulted as data sourced from the NJR alone could be misleading, particularly when looking at specific sub-set data. | |