Appendix B: Stakeholder consultation comments table

2019 surveillance of <u>Hip fracture: management</u> (2011)

Consultation dates: 30 August to 12 September 2019

1. Do you agree with the proposal to partially update the guideline?			
Stakeholder	Overall response	Comments	NICE response
The Society & College of Radiographers	Yes	The Society & College of Radiographers and advisory group members who responded to the consultation consider the imaging options in occult hip fracture to be both up to date and reflecting current clinical practice.	Thank you for your support for the recommendations on imaging options in occult hip fracture.
Bone, Joint and Muscle Trauma Cochrane Review Group (BJMT)	Yes	 WHiTE 3 is an important new study which is very likely to influence one of recommendations in the guidance. Beyond that, our assessment is that definitive evidence from equivalent trials is not yet available. Funded by a Cochrane Programme Grant (NIHR SRP 16/114/15), BJMT are undertaking a suite of Reviews on hip fracture which will complete after this update. These are being prepared with the intention of directly informing 	Thank you for your support for our proposal to update recommendation 1.6.4 based on evidence from the WHITE3 trial. Thank you for highlighting <u>a programme of high priority reviews for</u> the management of patients with hip fracture: a collaboration which <u>can inform future healthcare policy guidance</u> NIHR Cochrane reviews project. The ongoing <u>NIHR Cochrane reviews</u> and the <u>WHITE4</u> study looking at sliding hip screw versus X-Bolt Dynamic Plating System for trochanteric fractures which is also in preparation for publication

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

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		a more global review of the guidance at the next surveillance timepoint. https://www.journalslibrary.nihr.ac.uk/programmes/sr/161 1415/	could potentially affect several recommendations within section 1.6. To ensure efficiencies in the update process these studies will be assessed as soon as possible and their impact on section 1.6 will be considered.
NHS England/Improvement	Yes	No additional comments	Thank you for your response.
The Chartered Society of Physiotherapy	Yes	No additional comments	Thank you for your response.
Smith & Nephew UK Limited	No	We think that Recommendation 1.6.7 ("Use extramedullary implants such as a sliding hip screw in preference to an intramedullary nail in patients with trochanteric fractures above and including the lesser trochanter (AO classification types A1 and A2)") should be included within the scope of the guideline update to reflect the growing evidence over best treatment options for AO/OTA 31-A2 fractures.	Thank you for your detailed response and highlighting the 15 studies. We have considered the 15 studies supplied and highlighted whether these studies were included in our evidence summary or the rationale if they were not included (see below). Currently the RCT level evidence does not appear to show a consistent benefit of intramedullary nails over extramedullary devices.
		 We performed a systematic literature review on PubMed in March 2019 and identified 42 comparative clinical studies published in the last 5 years that reported outcomes from treatment of A2 fractures. Fifteen of these studies directly compared outcomes following the use of intramedullary (IM) implants versus extramedullary (EM) implants and included patients with A2 fracture patterns (Duymus et al 2019, Tucker et al 2018, Ronga et al 2017, Singh et al 2017, Whale et al 2016, Bretherton and Parker 2016, Sanders et al 2016, Page et al 2016, Reindl et al 2015, Zehir et al 2015, Chehade et al 2015, Suh et al 2015, Wang et al 2014, Guerra et al 2014, Haq et al 2014). Oftentimes, the A2 patient group was split to combine the A2.1 group with A1 fractures (referred to collectively as "stable" fracture patterns) and the A2.2 	At the time of guideline development, the committee who developed the original guideline noted that none of the studies reported had shown any advantage of intramedullary devices over extramedullary devices. Intramedullary devices had been shown to have a higher re-operation rate due to an increased incidence of periprosthetic fracture both in the perioperative period and the postoperative period (risk ratio 5.61). In patients with trochanteric fractures above and including the lesser trochanter (AO classification types A1 and A2) the price of intramedullary fixation devices varied but on average was three times the price of sliding hip screws for short nails and five times the price for long nails. As pointed out in the clinical evidence statement, no significant benefit had been proven of the advantages of intramedullary devices over

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 In the composite In the composite	 A2.3 groups were combined with A3 fractures rred to collectively as "unstable" fracture erns). e 3 randomised controlled trial (RCT) studies that pared IM and EM implants that included patients only A2 fractures, all demonstrated more urable outcomes in the IM fixation group:- o Bretherton and Parker (2016) demonstrated that IM implants had lower medialisation values compared to EM implants for A2 fractures. This was beneficial for patients because they reported that higher medialisation was associated with worse pain and mobility scores at 1 year. This study advocated considering A2 fracture patterns as a separate group from A1 fractures. o Zehir et al (2015) concluded that IM implants offered better recovery than EM implants with shorter length of hospital stay and more patients able to walk independently at 6 months, whereas both possessed the same risk of postoperative complications. They concluded that the IM option studied seemed to be the optimal choice in patients with unstable trochanteric fractures. o Reindl et al (2015) reported less femoral neck shortening with IM implants compared to EM implants, albeit with no statistically significant differences for primary or secondary clinical outcomes. e of the RCT-level studies identified in the SLR ssed A2.2 and A2.3 fractures in isolation, but two of three) observational studies suggested that IM ants had better outcomes than EM implants mus et al 2019; Chehade et al 2015). Suh et al 5) suggested that there were no clinical 	extramedullary devices, so the GDG agreed to consider extramedullary implants cost-effective for hip fracture patients. The ongoing NIHR Cochrane reviews and the WHITE4 study looking at sliding hip screw versus X-Bolt Dynamic Plating System for trochanteric fractures which is also in preparation for publication could potentially affect several recommendations within section 1.6. To ensure efficiencies in the update process these studies will be assessed as soon as possible and their impact on section 1.6, including recommendation 1.6.7, will be considered.
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 differences between IM and EM implants for their patient cohort of A2.2 and A2.3 patients. In all studies that assessed unstable fractures patterns (A2.2, A2.3 and A3 combined), overall better outcomes were identified with IM implants compared to EM implants (Haq et al 2014, Tucker et al 2018, Whale et al 2016). 	
Based on these findings, and accepting that differences exist between studies in terms of exact fracture patterns included and outcomes assessed ("differences in populations and interventions makes comparison difficult", page 26 of the consultation document), we would like to suggest that no recommendation on device option is made for A2 fractures. An alternative option would be to adjust this recommendation to apply to A1 and A2.1 (rather than A2 as a whole group), which is more consistent with the literature and better supported by the available evidence.	
Addressing this recommendation is of particular importance since this NICE guideline (via the Best Practice Tariff) is restricting surgeon choice for the treatment of these fracture patterns.	
 References: 1. Duymus TM, Aydogmus S, Ulusoy I, et al. 2019. Comparison of intra- and extramedullary implants in treatment of unstable intertrochanteric fractures. J 	1. Would be excluded as non-RCT
 Clin Orthop Trauma; 10(2):290-5. Tucker A, Donnelly KJ, Rowan C, et al. 2018. Is the best plate a nail? A review of 3230 unstable intertrochanteric fractures of the proximal femur. J Orthop Trauma; 32(2):53-60. Ronga M, Bonzini D, Valoroso M, et al. 2017. Blood loss in trochanteric fractures: multivariate analysis 	 Would be excluded as non-RCT Would be excluded as non-RCT
comparing dynamic hip screw and Gamma nail. Injury;48 Suppl 3:S44-7.	

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 Singh AK, Narsaria N, G R A, et al. 2017. Treatment of unstable trochanteric femur fractures: proximal femur nail versus proximal femur locking compression plate. Am J Orthop (Belle Mead NJ): 446/2:E116-E123. Whale CS, Hulet DA, Beebe MJ, et al. 2016. Cephalomedullary nail versus siding hip screw for fixation of AO 31 A1/2 intertrochanteric femoral fracture: a 12-year comparison of failure, complications, and mortality. Curr Orthop Pract; 27(6):604-13. Bretherton CP, Parker MJ. 2016. Femoral medialization, fixation failures, and functional outcome in trochanteric hip fractures treated with either a sliding hip screw or an intramedullary nail from within a randomized trial. J Orthop Trauma; 30(12):642-6. Sanders D, Bryant D, Tieszer C, et al. 2016. A multicentre randomized control trial comparing a novel intramedullary device (InterTAN) versus conventional treatment (sliding hip screw) of geriatric hip fractures. J Orthop Trauma; 31(1):1-8. Page PR, Lord R, Jawad A, et al. 2016. Changing trends in the management of intertrochanteric hip fractures - J a single centre experience. Injury; 47(7):1525-9. Reindl R, Harvey EJ, Berry GK, et al. 2015. Intramedullary versus extramedullary fusition for unstable intertrochanteric fractures: a prospective randomized controlled trial. J Bone Joint Surg Am; 97(23):1905-12. Zehir S, Zehir R, Zehir S, et al. 2015. Proximal femoral nail antirotation against dynamic hip screw for unstable trochanteric fractures: a prospective randomized comparison. Eur J Trauma Emerg Surg; 41(4):393-400. Chehade MJ, Carbone T, Awwad D, et al. 2015. Influence of fracture stability on early patient mortality and reoperation after pertrochanteric and 	 Thank you for highlighting this study. We originally excluded this study as due to the volume of RCT level studies in the area, studies with less than 50 patients were excluded. We have now included this in our evidence summary for completeness and it does not impact the decision to not update recommendation 1.6.7. Would be excluded as non-RCT This was included in our evidence summary This was included in our evidence summary Would be excluded as non-RCT Would be excluded as non-RCT This was included in our evidence summary This was included as non-RCT Thank you for highlighting this study. We originally excluded this study as the abstract did not provide sufficient detail. We have now included this in our evidence summary for completeness and it does not impact the decision to not update recommendation 1.6.7. This was included in our evidence summary This was included as non-RCT This was included in our evidence summary for completeness and it does not impact the decision to not update recommendation 1.6.7. This was included in our evidence summary This was included in our evidence summary
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		 intertrochanteric hip fractures. J Orthop Trauma; 29(12):538-43. 12. Suh YS, Nho JH, Kim SM, et al. 2015. Clinical and radiographic outcomes among bipolar hemiarthroplasty, compression hip screw and proximal femur nail antirotation in treating comminuted intertrochanteric fractures. Hip Pelvis; 27(1):30-5. 13. Wang Q, Yang X, He HZ, et al. 2014. Comparative study of InterTAN and dynamic hip screw in treatment of femoral intertrochanteric injury and wound. Int J Clin Exp Med; 7(12):5578-82. 14. Guerra MT, Pasqualin S, Souza MP, et al. 2014. Functional recovery of elderly patients with surgically-treated intertrochanteric fractures: preliminary results of a randomised trial comparing the dynamic hip screw and proximal femoral nail techniques. Injury; 45 Suppl 5:S26-31. 15. Haq RU, Manhas V, Pankaj A, et al. 2014. Proximal femoral nails compared with reverse distal femoral locking plates in intertrochanteric fractures with a compromised lateral wall; a randomised controlled trial. Int Orthop; 38(7):1443-9. 	 12. Would be excluded as non-RCT 13. Would be excluded as non-RCT 14. This was included in our evidence summary 15. This was included in our evidence summary
The Royal Osteoporosis Society	No	The context in regard to the numbers of current exponential increase of hip fractures needs updating	Thank you for your response. The ongoing <u>NIHR Cochrane reviews</u> and the <u>WHITE4</u> study looking at sliding hip screw versus X-Bolt Dynamic Plating System for trochanteric fractures which is also in preparation for publication could potentially affect several recommendations within section 1.6. To ensure efficiencies in the update process these studies will be assessed as soon as possible and their impact on section 1.6 will be considered. When the guideline is updated the team who undertake the guideline development will consider the need to update the context section of the guideline, including numbers of hip fractures.

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Public Health England	Neither agree nor disagree	No additional comments	Thank you for your response.
Royal College of Nursing (RCN)	No response	The Royal College of Nursing shared the consultation with colleagues who care for people with Hip Fracture to review the draft consultation document, however we did not receive any comments. Thank you for the opportunity to comment on this.	Thank you for your response.
Royal College of Anaesthetists	No response	 The Royal College of Anaesthetists has reviewed the above guidance and feels that there is appropriate emphasis on: patient/carer choice and involvement in care patient/carer involvement in decision making patient/carer information including guidance on topics this should include individual patient needs, preferences and values working with the patient/carer to ensure treatment is holistic with appropriate account taken of their individual circumstances. The Lay Committee feels unable to comment specifically on principles 3, 4 and 5 but state that principles 1, 2 and 6 are relevant and noted that multi-disciplinary working always bring clinical and process benefits. 	Thank you for your response and support for the guidelines appropriate emphasis on patient/carer choice and shared decision making.
2. Do you have ar	ny comments on are	as excluded from the scope of the guideline?	
Stakeholder	Overall response	Comments	NICE response
The Society & College of Radiographers	No	No additional comments	Thank you for your response.

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Bone, Joint and Muscle Trauma Cochrane Review Group (BJMT)	 Direct medical costs HRQoL Blood transfusion 	 Useful data to inform future HE analyses are in preparation from the WHiTE cohort and have been submitted to Bone Joint Research. Png et al. Utilisation and costs of formal and informal care, home adaptations and physiotherapy among older patients with hip fracture. Submitted 2019 BJR WHITE is now being published. Papers are in submission with various Journals. Data can be shared with NICE to inform HE modelling if required. The planned date of publication of 2022 is likely to be an overestimate – reports are expected to be published in 2019. The suite of reviews conducted by BJMT will include an overview on blood management. Expected publication date Oct 2020. It is likely that this Review could help NICE give guidance about transfusion and a wider group of interventions in the management of perioperative anaemia in the next update. Consider adding this to the scope in future surveillance decisions. 	Thank you for your response and highlighting these studies and reviews. The ongoing <u>NIHR Cochrane reviews</u> and the <u>WHiTE4</u> study looking at sliding hip screw versus X-Bolt Dynamic Plating System for trochanteric fractures which is also in preparation for publication could potentially affect several recommendations within section 1.6. To ensure efficiencies in the update process these studies will be assessed as soon as possible and their impact on section 1.6 will be considered.
NHS England/Improvement	Yes	Cemented implants. Patient Safety have ongoing concerns regards intraoperative death or severe harm due to bone cement implantation syndrome and regularly still see such events reported to the National Reporting and Learning System first discussed https://bmjopen.bmj.com/content/4/6/e004853 . Whilst the studies reviewed report statistically significant benefit of patient outcomes in terms of mobility and pain, there is little published evidence describing intra/perioperative morbidity associated with the use of hip cement. The	Thank you for your response. The issue of the safety of cemented implants was considered during the 2017 update of the guideline. At that time the committee felt it appropriate to still recommend cemented implants but added a footnote to highlight a guideline[1] on how to reduce the risk from cemented hemiarthroplasty. As noted, NICE are aware of the World hip trauma evaluation five study[2] and will be tracking this study to ensure it is considered as soon as possible after publication.

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		review does mention an as yet unpublished study (due 2021) that may potentially have an impact on future advice https://doi.org/10.1186/ISRCTN18393176	 [1] The Association of Anaesthetists of Great Britain and Ireland, British Orthopaedic Association and British Geriatric Society have produced a safety guideline on reducing the risk from cemented hemiarthroplasty for hip fracture (2015). This safety guideline is not NICE accredited. [2] World hip trauma evaluation five: a randomised controlled trial comparing cemented and uncemented implants for the treatment of displaced intracapsular hip fractures. ISRCTN18393176
The Chartered Society of Physiotherapy	No	No additional comments	Thank you for being involved as a stakeholder.
Smith & Nephew UK Limited	Not answered	N/A	Thank you for being involved as a stakeholder.
The Royal Osteoporosis Society	Yes	The multi-disciplinary 1.8 and particularly 1.8.1 discusses liaison and integration there could be greater emphasis on the importance of secondary fracture prevention. Delirium has a section for tasks to be considered, this could be applied for secondary fracture prevention treatments or link to osteoporosis guidance tools. The White study (yet to be published) looks at patient centred outcomes post hip fracture were falls and bone health assessment is a significant outcome measure post hip fracture.	 Thank you for your response. The surveillance process did not identify any new evidence that would change recommendations in section 1.8. NICE has a guideline on <u>Delirium</u> (CG103). NICE is aware of the WHITE studies and is tracking the following studies to ensure they can be considered as soon as possible after publication: World hip trauma evaluation five: a randomised controlled trial comparing cemented and uncemented implants for the treatment of displaced intracapsular hip fractures. ISRCTN18393176 World hip trauma evaluation four. ISRCTN92825709

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Public Health England	No	Section 1.9 Patient and carer information currently has no requirement to inform regarding secondary fracture prevention, this needs updating. As osteoporosis has a strong genetic link particularly with an indicator of hip fracture this is an opportunity to improve knowledge of bone health for prevention of future hip fractures with other generations. A review of the rehabilitation for hip fracture to improve outcomes is required. The implementation section could be strengthened with a review and more advice that is specific to hip fracture e.g. publish a baseline assessment. There is also an opportunity to include scoring systems.	The surveillance process did not identify any new evidence that would change recommendations in section 1.9. Secondary prevention related to osteoporosis was out of scope for this guideline but NICE has a guideline on <u>Osteoporosis: assessing the</u> <u>risk of fragility fracture</u> (CG146), which is currently identified for update. The surveillance process also did not identify any new evidence that would change recommendations on rehabilitation. The implementation section of the guideline 'putting this guideline into practice' is a standard part of NICE clinical guidelines. NICE also produced <u>tools and resources</u> . When the guideline is updated the committee can consider implementation issues and update during that process.		
Royal College of Nursing (RCN)	No response	No additional comments	Thank you for participating as a stakeholder.		
Royal College of Anaesthetists	No response	No additional comments	Thank you for participating as a stakeholder.		
1. Do you have ar	1. Do you have any comments on equality issues?				
Stakeholder	Overall response	Comments	NICE response		
The Society & College of Radiographers	No	No additional comments	Thank you for your response.		

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Bone, Joint and Muscle Trauma Cochrane Review Group (BJMT)	No	No additional comments	Thank you for your response.
NHS England/Improvement	No	No additional comments	Thank you for your response.
The Chartered Society of Physiotherapy	No	No additional comments	Thank you for your response.
Smith & Nephew UK Limited	Not answered	N/A	Thank you for participating as a stakeholder.
The Royal Osteoporosis Society	No	No additional comments	Thank you for your response.
Public Health England	No	No additional comments	Thank you for your response.
Royal College of Nursing (RCN)	No response	No additional comments	Thank you for participating as a stakeholder.
Royal College of Anaesthetists	No response	No additional comments	Thank you for participating as a stakeholder.

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- 2. Recommendation 1.6.4 suggests using a proven femoral stem design rather than Austin Moore or Thompson stems. New evidence indicates that the older Thompson hemiarthroplasty may be clinically equivalent to the Exeter/unitrax stem and head. This new evidence contradicts the current guideline recommendation 1.6.4 and as such an update is proposed.
- a. Is there any other new evidence we need to be aware of in relation to this recommendation?
- b. Are there any issues for clinical practice with this current recommendation that need to be considered alongside the evidence?

Stakeholder	Overall response	Comments	NICE response
The Society & College of Radiographers	4a – No 4b - No	4a. No additional comments 4b. No additional comments	Thank you for your response and agreement that there is no additional evidence or issues for clinical practice that we need to consider.
Bone, Joint and Muscle Trauma Cochrane Review Group (BJMT)	4a - No 4b - No	4a. No additional comments 4b. No additional comments	Thank you for your response and agreement that there is no additional evidence or issues for clinical practice that we need to consider.
NHS England/Improvement	Not answered	No additional comments	Thank you for your response and agreement that there is no additional evidence or issues for clinical practice that we need to consider.
The Chartered Society of Physiotherapy	4a - No 4b - No	4 a. No additional comments 4b. Need to support prompt mobilisation	Thank you for your response and agreement that there is no additional evidence or issues for clinical practice that we need to consider. With regards to needing to support prompt mobilisation, recommendation 1.7.1 currently states 'Offer patients a physiotherapy assessment and, unless medically or surgically contraindicated, mobilisation on the day after surgery.'
Smith & Nephew UK Limited	Not answered	N/A	Thank you for participating as a stakeholder.

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The Royal Osteoporosis Society	Not answered	No comments	Thank you for participating as a stakeholder.
Public Health England	Not answered	No comments	Thank you for participating as a stakeholder.
Royal College of Nursing (RCN)	No response	No additional comments	Thank you for participating as a stakeholder.
Royal College of Anaesthetists	No response	No additional comments	Thank you for participating as a stakeholder.

3. Recommendation 1.6.2 and 1.6.3 provide advice on total hip replacements. New evidence from 2 small RCTs indicates that total hip replacement and hemiarthroplasty may be equivalent. This new evidence does not appear sufficient to change recommendations 1.6.2 and 1.6.3 and as such no update is proposed.

a. Is there any other new evidence we need to be aware of in relation to these recommendations?

b. Are there any issues for clinical practice with these current recommendations that need to be considered alongside the evidence?

Stakeholder	Overall response	Comments	NICE response
The Society & College of Radiographers	5a – No 5b - No	5a. No additional comments 5b. No additional comments	Thank you for your response and agreement that there is no additional evidence or issues for clinical practice that we need to consider.
Bone, Joint and Muscle Trauma Cochrane Review Group (BJMT)	5a – Yes 5b - No	 5a - HEALTH is likely to be the definitive trial to address this question and any updates prior to this study reporting will likely be very rapidly superseded. 5b - No additional comments 	Thank you for your agreement that there are no additional issues for clinical practice that we need to consider. With regards to the HEALTH trial, NICE are aware of this trial and are tracking it to ensure it can be considered as soon as possible after publication.

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			Comparing total hip arthroplasty and hemi-arthroplasty on revision surgery and quality of life in adults with displaced hip fractures: the <u>HEALTH study</u> . ISRCTN59890378
NHS England/Improvement	Not answered	No additional comments	Thank you for participating as a stakeholder.
The Chartered Society of Physiotherapy	5a – No 5b - No	5a. Need to support prompt mobilisation 5b. Need to support prompt mobilisation	Thank you for your agreement that there is no additional evidence or issues for clinical practice that we need to consider
Smith & Nephew UK Limited	Not answered	N/A	Thank you for participating as a stakeholder.
The Royal Osteoporosis Society	Not answered	No comments	Thank you for participating as a stakeholder.
Public Health England	Not answered	5a. – No comments 5b How could NICE guidance can be systematically implemented to improve the outcomes of people with hip fracture	Thank you for your response and agreement that there is no additional evidence that we need to consider. With regards to implementation, NICE provides <u>tool and resources</u> to support implementation of NICE guidance.
Royal College of Nursing (RCN)	No response	No additional comments	Thank you for participating as a stakeholder.
Royal College of Anaesthetists	No response	No additional comments	Thank you for participating as a stakeholder.

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