National Institute for Health and Clinical Excellence

Multiple Technology Appraisal (MTA)
Total hip replacement and resurfacing arthroplasty for the treatment of pain or disability resulting from end stage arthritis of the hip (review of TA2 and TA44)

Response to consultee and commentator comments on draft scope

Section	Consultees	Comments	Action
Background information	The Association for Perioperative Practice (AFPP)	1. On the whole, description is accurate; however believe to the non-professional reader descriptions of types of operations available may be confusing. Page 2/6 para 1 – appendix A Using the National Joint Register definitions may be more appropriate Primary Total Prosthetic Replacement using cement Primary Total Prosthetic Replacement not using cement Primary Resurfacing Arthroplasty of Joint Primary Total Prosthetic Replacement not classified elsewhere (e.g. HYBRID) * Only one implant Cup or Stem may be cemented. A simple statement: A Hip replacement replaces the acetabular surface: • With either a single plastic cemented cup Or a two piece cup made of an outer metal shell into which is placed a plastic or ceramic liner. Metal acetabular liners are under the spot light! And replaces the proximal femur:	Comments noted. Page 2/6 para 1 has been amended so the procedures are described using the National Joint Register definitions; resurfacing has been amended to resurfacing arthroplasty. It is indicated in paragraph 4 that total hip replacement may be called total prosthetic replacement (as per NJR definitions) however, for consistency with TA 2, total hip replacement has been used in the scope. The comments advising how to describe the structure of and the materials used for the prostheses have been incorporated into the technology section alongside those of other the consultees.

Section	Consultees	Comments	Action

		• With a Monobloc (Single piece) metal stem
		• A two piece femoral component made of a metal stem
		• To which is attached a metal or ceramic head to articulate with acetabular implant(s)
		• These may be uncemented or cemented into position
		
		2. Same paragraph – Hip Resurfacing comments:
		  • Strong bone, younger and active
		  • Research has shown that patient needs to be MALE. MOM hips fail in menopausal females!
		3. Revision rates – Why not quotes leading world register – www.njrcentre.org.uk, patient are encouraged to access this site for information?
		4. Para 3 – MoM confusing gives the impression that chunks of metal are falling off implants, which is clearly not the case?
			Comments noted on hip resurfacing arthroplasty. For people for whom resurfacing arthroplasty is not suitable, primary total hip replacement shall be compared to non-surgical management.
			Data from the National Joint Registry has been reported in the background section.
			Paragraph 3 used the wording of the MHRA alert.

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	British Orthopaedic Association Patient Liaison Group (BOAPL)	Top of page 2 of Appendix A "Surgeons may use combinations of cups and stems made by different manufacturers." 1) There is little clinical evidence to support many of these device combinations. 2) There is a severe liability on the Consultant/Trust/Independent provider should a replacement go wrong. 3) The manufacturer would, in no circumstances, recommend the use of a device with another manufacturer's device. There is a loss of control over function. 4) Training material including workshops do not support this use. 5) Change Paragraph 5 to; Currently artificial hip joints last on average at least 10 to 15 years, some considerably longer..	The statement "Surgeons may use combinations of cups and stems made by different manufacturers" has been removed from the background section of the scope. The technologies will only be appraised in line with the indication as described in their CE mark. The sentence describing the lifespan of artificial hip joints has been amended to include "some considerably longer".

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	Corin Group PLC	Broadly in agreement with this. We would emphasise that resurfacing is a more bone conserving procedure than THR. Although resurfacing devices currently on the market are metal-on-metal, several manufacturers are developing and trialling alternative bearing materials.	The background section has been amended so that the sentence beginning "Hip resurfacing is less invasive than a total hip replacement …" now reads "Hip resurfacing arthroplasty conserves more femoral bone than total hip replacement…" To avoid repetition the sentence "One of the claimed advantages of the technique is that it preserves femoral bone and therefore the outcome of future replacements may be improved" has been removed from the technology section. The multiple technology appraisal process can only make recommendations for prostheses that have a CE mark at the time of appraisal.

Section	Consultees	Comments	Action
	DH	Good	Comment noted.

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	DuPuy Synthes, Johnson and Johnson	BACKGROUND: We suggest that the text is amended as follows: *Arthritis is a group of diseases that affect joints, leading to pain and disability. Osteoarthritis is the most common form of arthritis, where there is loss of cartilage ~~at the end of the joints and accompanying changes in the end of the bone~~* ***within the joint and accompanying changes in the underlying bone.*** We suggest the addition of the following text as follows: *In 2011 there were 57,745 hip procedures carried out in the NHS in England and Wales, with a further 25,138 carried out in independent hospitals****. In 2011, 93% of primary hip replacements were of hips affected by osteoarthritis (OA) and 1% with inflammatory arthrothopy such as Rheumatoid Arthritis (RA) (1).*** *1. The NRR Centre Hemel Hempstead. National Joint Registry for England and Wales Annual Report 2011. Available URL: http://www new.njrcentre.org.uk/njrcenre/Default.aspx Accessed 27/02/12* We suggest the addition/ amendment of the text as follows: *People with arthritic damage to their hip may receive total replacement of the damaged hip with a metal alloy ~~or ceramic~~* ***prosthesis, which may include ceramic parts or a polyethylene component. It*** *may be fixed in position using cement, be cementless or be a hybrid where one component of the prosthesis requires cement but the other does not. Surgeons use combinations of cups and stems made by different manufacturers. Alternatively, patients may receive hip resurfacing which involves removing damaged surfaces of the bones inside the hip joint and replacement with a metal surface. Hip resurfacing* ***removes less bone*** *~~is less invasive~~ than a total hip replacement and can result in a greater range of movement after surgery, but requires the patient to have relatively strong bones, therefore tends to be used in younger, more active patients.*	The wording has been amended to "within the joint and accompanying changes to the associated bone". This section has been amended to read "In 2011, 57,745 hip procedures were carried out in the NHS in England and Wales, with a further 25, 138 carried out in independent hospitals and 93% of primary hip replacements were or hips that were affected by osteoarthritis". Page 2/6 para 1 has been amended so the procedures are described using the National Joint Register definitions. To avoid repetition in the scope, the structure of and the materials used for the prostheses are now described in the technology section only. The comments relating to the structure of and the materials used for the prostheses have been incorporated into the technology section alongside those of other the consultees.

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		We suggest the addition of the following text as follows: ***The life of current hip joints has been shown to vary by age. The long term data for the Swedish Hip Arthroplasty Register shows that for younger patients aged less than 50****, the success rate at 17 years was only 66%. However, in older patients aged greater than 75, the success rate was 94% at 17 years.* ~~*Currently artificial hip joints last on average for 10 to 15 years. Some hip replacements require revision surgery because of loosening of the joint, wear and tear, pain and dislocation.*~~ ***The worst results for younger patients in Sweden were due to revision following wear of the polyethylene component and this was the driver for the development of hard wearing bearings such as ceramic on ceramic and metal and metal as well as the development of cross-linked polys****. Current NICE guidance says that the best prostheses should demonstrate a 'benchmark' revision rate of 10% or less at 10 years or, as a minimum, a three year revision rate consistent with this benchmark.* *In June 2012, the Medicines and Healthcare Regulatory Agency (MHRA) released an updated alert that Metal on Metal (MoM) implants (total hip replacements or resurfacing) may wear* ~~*down*~~ *at an accelerated rate in some people.*	The Consultees' comments on the lifespan of prostheses have been noted. The background section is intended to give a brief overview. It is anticipated that the lifespan or revision rates of different prosthesis will be considered during the appraisal. The word "down" has been removed from the section describing the MHRA alert.
	Healthcare Improvement Scotland	Page 2, para 1: Hip resurfacing is not less invasive than total hip replacement. It is true to say that in hip resurfacing less bone is removed on the femoral side. On the acetabular side, some authors have published that more bone may need to be removed, although this is not widely accepted. On the other hand, the soft tissue exposure required for a successful hip resurfacing usually is more invasive than that required for a total hip replacement and thus the statement that hip resurfacing is less invasive should be altered as it is misleading.	The background section has been amended so that the sentence beginning "Hip resurfacing is less invasive than a total hip replacement …" now reads "Hip resurfacing arthroplasty conserves more femoral bone than total hip replacement".

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	MHRA	• The background data on the number of procedures etc seem to be rather not up to date, ideally should be within the last year or two. • MHRA's guidance of June 2012, recommended whole blood ion metal measurement, not just blood metal measurement	The 2006 figures on the proportion of people who received a primary hip replacement of a hip affected by osteoarthritis have been updated with 2011 figures from the National Joint Registry. The wording in the scope "blood metal measurement" has been replaced with "whole blood ion measurement".

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	NHS supply chain (ODEP)	We feel that the background information lacks conviction. There are several comments which are not up to date including statement that a cemented hip system is the most commonly used implant system. There is concern over the generic diagnosis of what causes hip disease. We suggest that the British Hip Society re-writes the introduction ensuring it is current and factually correct. There is disappointment that the scope makes no mention of the existence of the Orthopaedic Data Evaluation Panel and its role in the implementation of the previous NICE Guidance for Hip Replacement. ODEP has moved the original set of guidelines on because the original guidelines were not adequate for the job	During consultation the comments from all consultees are taken into account and necessary amendments are made to the scope accordingly. The background introduction of total hip replacement and resurfacing arthroplasty has been amended to give a briefer top level description of hip replacement procedures using NJR definitions. The materials used in and the structure of prostheses are described in greater detail in the technologies section. The remit for this appraisal says that THR and resurfacing arthroplasty will be appraised for use by people with end stage arthritis of the hip. There are other causes of hip disease other than arthritis, however, this appraisal will only appraise indications specified in the remit. A description of ODEPs role in the implementation of NICE TA 2 and TA 44 has been added to the background section of the scope.

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	Royal College of Nurses (RCN)	The back ground information looks comprehensive although 2006 figures seems quite old. It would have been good to have more up to date figures. The joint registry is a mandatory requirement but this is not clear here. We suggest that the final paragraph should state that the National Joint Register is a mandatory requirement. Do Advancing Quality and Enhanced Recovery pathways need to be mentioned? Suggest the footer be revised to state…..for the treatment of pain and/or disability resulting from end stage arthritis...	The 2006 figures on the proportion of people who received a primary hip replacement of a hip affected by osteoarthritis have been updated with 2011 figures from the National Joint Registry. The final paragraph has been amended to state that the data collection for National Joint Registry is a mandatory requirement for NHS organisations. The background section is intended to give a brief overview. The implementation of the recommendations that arise from this appraisal will be discussed in the Technology Appraisal document. The Department of Health has agreed a change to the wording of the remit to include people with pain or disability resulting from end stage arthritis of the hip.

Section	Consultees	Comments	Action
	Smith and Nephew	We would like to draw attention to the statement, "Surgeons may use combinations of cups and stems made by different manufacturers". Smith & Nephew prostheses are not designed, tested or validated to accommodate this use. The practice of mixing and matching components from different manufacturers should be specifically addressed during the review.	The statement "Surgeons may use combinations of cups and stems made by different manufacturers" has been removed from the background section of the scope. The technologies will only be appraised in line with the indication as described in their CE mark.
	Stryker UK Ltd	**Appraisal objective/remit** Clarification that this scope only includes Primary Hip Replacements and should also cover indications of disability as well as pain.	This multiple technology appraisal updates TA 2, which appraised primary total hip replacements. The intervention has been specified as 'primary total hip replacement' (See table). The Department of Health has agreed a change to the wording of the remit to include people with pain or disability resulting from end stage arthritis of the hip.

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	Warwick Evidence	• More explicit statement on what are the first line treatment options for patients with osteoarthritis and rheumatoid arthritis of the hip is required. Exercise, manual therapy, and pain management are listed as first line treatments, is this list exhaustive? • Resurfacing is actually more invasive in terms of the surgical exposure and there is some evidence that ROM after resurfacing is actually worse - however, the overall review is both topical and pertinent.	The background section is intended to give a brief overview. It is anticipated that the non-surgical management will be defined further after systematic review. Functional result is listed as an outcome in the scope.

Section	Consultees	Comments	Action
The technology/ intervention	Association of British Healthcare Industries (ABHI)	**Title/ Remit** We would like clarification that this appraisal should focus purely on primary procedures. Given the complexity of revision hip arthroplasty, it should be the subject of its own appraisal, should this be deemed appropriate. We would like disability to be added as an indication for hip arthroplasty. In most cases the main indication for hip arthroplasty is pain although other symptoms could deem patients as eligible candidates for total joint replacement. In TA2, guidance on the Selection of Prostheses for Primary Total Hip Replacement (1) NICE state that Elective THR should be carried out to relieve discomfort and disability caused by arthropathies (including osteoarthritis and rheumatoid arthritis) of the hip. We would therefore urge NICE to remove the term "end stage" arthritis. Recent research has suggested that those who have early surgery have better outcomes than those who have later surgery when they are older with more severe symptoms (3) NICE Guidance CG59 on the care and management of osteoarthritis in adults indicates that referral for joint surgery should be before there is "prolonged and established functional limitation and severe pain" (2) 1) *TA2: NICE Technology Appraisal 02. Guidance on the Selection of Prostheses for Primary Total Hip Replacement. NICE. Issue date: April 2000. Developed by the National Clinical Guideline Centre.* 2) *NICE Clinical Guideline 59: The care and management of osteoarthritis in adults. NICE. Issue date: June 2009. Developed by the National Clinical Guideline Centre.* 3) *Hajat S, Fitzpatrick R, Morris R et al. Does waiting for total hip replacement matter? Prospective cohort study. J Health Serv Res Policy 2002;17:19–25.*	During the exploratory workshop which was held when a review of TA 2 and TA 44 were being considered the consultees agreed that the remit should be restricted to prostheses for primary hip surgery because the correct choice of the primary THR would necessarily reduce the number of revisions. Although the remit does not specify primary procedures, the population for this appraisal is defined as those with end stage arthritis (for which non-surgical management has failed). Therefore this population will not have received prior prostheses. For clarity the description of the interventions have been amended to specify primary total hip replacements and primary hip resurfacing arthroplasty. During the exploratory workshop "end stage" was defined as arthritis for which non-surgical management had failed. The scope outlines the referral criteria of CG 59.

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	The Association for Perioperative Practice (AFPP)	See comments above re description of operations.	Comments noted.

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	British Orthopaedic Association Patient Liaison Group (BOAPL)	Total hip replacement (THR) and resurfacing (HR) are different technologies and should not be considered in the same paper. THR is widely understood with 30+ years of peer review research behind it. The evolving metal on metal issues surrounding HR should not be underestimated. Already the MHRA have agreed a different follow up regime for metal on metal patients involving metal ions etc. As such two separate papers should be produced.	Total hip replacement and resurfacing have been referred to be reviewed through the Multiple Technology Appraisal process. The MTA process is designed to appraise single or multiple products, devices or other technologies, with one or more indications. During an exploratory workshop held when TA2 and TA 44 were being considered for review consultees said that at the time of TA44 surface replacement was considered to be appropriate for a subpopulation of people for whom total hip replacements were appropriate (that is people who are younger and more active) and in practice THR and surface replacement devices are used in the same population. The consultees also said that there may be a separate population for whom THR but not surface replacement is appropriate (such as women of childbearing age) and this group should be considered separately.This is reflected in the listed comparators.

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	Corin Group PLC	The description of the technologies currently approved for use is accurate but as stated above alternative bearing materials are currently being developed and trialling with the intention of removing the problems associated with metal on metal articulations.	The multiple technology appraisal process can only make recommendations for prostheses that have a CE mark at the time of appraisal.
	DH	Good	Comment noted
	Depuy Synthes, Johnson and Johnson	**THE TECHNOLOGY:** We suggest the addition/ amendment of the text as follows: *(2) a metal stem which is inserted into the femur, and (3) ~~a plastic, metal or ceramic cup~~ a solid or modular cup which is inserted in the acetabulum (hip socket of the pelvis).* *Hip resurfacing involves removal and replacement of the surface of the femoral head with a metal hollow hemisphere, which fits into a metal cup which locates in the acetabulum. ~~One of the claimed advantages of the technique is that it preserves femoral bone and therefore the outcome of future replacements may be improved.~~* ***One of the claimed advantages of newer techniques and devices both in THR and Resurfacing is that they preserve femoral bone and therefore the outcome of future replacements may be improved following future revision procedures.*** Please note that THR manufacturers should not include Finsbury, who have been acquired by DePuy.	The technology section has been amended to reflect the suggested descriptions of the technologies from the AFPP, DePuy Sythes,Johnson and Johnson, Healthcare improvement Scotland and Smith and Nephew, particularly to emphasise that both cup and femoral components can be modular or monoblock. Finsbury has been removed from list of THR manufacturers.

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	Healthcare Improvement Scotland	Hip replacement consists of 2-5 parts: Monoblock stems and polyethylene sockets is the usual 2 part combination. Stems may be modular consisting of 2 or 3 parts (stem, neck and head). The head may be metal or ceramic and of varying diameters. The sockets may be monoblock polyethylene, metal or metal-backed polyethylene or may be modular with a metal backing and a polyethylene, ceramic or metal bearing liner.	The technology section has been amended to reflect the suggested descriptions of the technologies from the AFPP, DePuy Sythes,Johnson and Johnson, Healthcare improvement Scotland and Smith and Nephew, particularly to emphasise that both cup and femoral components can be modular or monoblock.

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	MHRA	• Total hip replacement is carried out to relieve "pain" rather discomfort. • The femoral head of a hip replacement prosthesis is either a continuation of the metal stem or it is firmly attached to it (or its parts) via a taper connector. As such it does not "sits" on the top of the metal stem, but perhaps it is "fitted/connected" to/with the femoral stem. • Comis Orthopaedics and Finsbury Instruments no longer exist.	Comments noted. The scope has been amended to say "total hip replacement is carried out to relieve pain and disability caused by arthritis of the hip". The technology section has been amended. The description of the femoral component of a hip replacement prosthesis now reads "A monoblock (single piece) metal stem with a metal, ceramic or ceramicised metal head is inserted into the proximal femur (top of thigh bone) in order for the prosthesis head to articulate with the cup". Comis orthopaedics and Finsbury Instruments have been removed from the scope and the matrix.

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	NHS Supply chain (ODEP)	No, we recommend that NICE liaise with the British hip society to review the statements provided. Examples include statement that the proximal femur is replaced during a hip replacement, it is not replaced, in a hip replacement implants either fit on (surface replacement) or inside the bony canal of the proximal femur. There are also inaccuracies in the supplier list e.g. Symbios and JRI are not manufactures of hip resurfacing products, it should also be note that Finsbury is no longer an active organisation.	During consultation the comments from all consultees are taken into account and any necessary amendments made to the scope accordingly. The description of total hip replacement has been amended to read: The acetabulum (hip socket of the pelvis) is replaced with either a cup made from a single material or a two piece (modular) cup made of an outer metal shell into which a polyethylene, ceramic or metal bearing liner is placed. A monoblock (single piece) metal stem and head or a two piece (modular) femoral component consisting of a metal stem with a metal, ceramic or ceramicised metal head is inserted into the proximal femur (top of the thigh bone) in order for the prosthesis head to articulate with the cup.

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			Symbios SA and JRI have been removed from the list of primary resurfacing head and cup manufacturers. Finsbury has been removed from the list of total hip replacement manufacturers.
	Royal College of Nurses (RCN)	The description of the technology seems accurate.	Comment noted.
	Smith and Nephew	Smith & Nephew recommends amendment to paragraph 1 to include "(1) a metal, ceramic or ***ceramicised metal (OXINIUM)*** ball that replaces …." Append paragraph 1 with "but may comprise of more components to accommodate modularity". Advances in technology have provided various modularity options for both femoral neck and acetabular components. Smith & Nephew recommends corrosion at taper junction interfaces of each is included in the review.	The technology section has been amended to reflect the suggested descriptions of the technologies from the AFPP, DePuy Sythes,Johnson and Johnson, Healthcare improvement Scotland and Smith and Nephew, particularly to emphasise that both cup and femoral components can be modular or monoblock. Ceramicised metal has been added to the description of the technology.
	Styker UK Ltd	Stryker are not actively marketing a resurfacing product.	Comment noted. Stryker have been removed from the list of resurfacing head and cup manufacturers.

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	Warwick Evidence	• Specify that this review considers the effects of primary total hip replacement/hip resurfacing procedures only by excluding the effects of secondary procedures (i.e., second hip replacement, hip replacement after failed hip resurface)? • Highlight whether its focus is restricted to only total hip replacement or it may also include the effects of half replacement (hemiarthroplasty)? Further specification needed as to whether the review should focus on unilateral, bilateral, or both types of total hip replacement	During the exploratory workshop which was held when a review of TA 2 and TA 44 were being considered the consultees agreed that the remit should be restricted to prostheses for primary hip surgery because the correct choice of the primary THR would necessarily reduce the number of revisions. Although the remit does not specify primary procedures, the population for this appraisal is defined as those with end stage arthritis for which non-surgical management has failed. Therefore this population will not have received prior prostheses. For clarity the description of the interventions have been amended to specify primary total hip replacements and primary hip resurfacing arthroplasty. Hemiarthroplasty is outside of the remit for this MTA. The comment on unilateral and bilateral operations is noted. All elective total hip replacement operations are to be considered. No changes

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			required to scope.
Population	The Association for Perioperative Practice (AFPP)	Yes	Comment noted.
	Corin Group PLC	In terms of defining the population, surface replacement should be considered separately. Surfacing replacement is not used in the same population as total hip replacement. Specific indications recognising the, now well documented, risk factors for the success of the surface replacement should be considered.	Participants at the exploratory workshop held when TA2 and TA44 were being considered for review agreed that the two technologies should be appraised together. For subpopulations for whom one of the technologies is not appropriate or contraindicated the comparator will be non-surgical management.
	DH	Good	Comment noted.

Section	Consultees	Comments	Action
	DePuy, Johnson and Johnson	**THE POPULATION:** We suggest that the population is amended as follows: *People with pain **and disability** **(I)** resulting from ~~end stage~~ **(II)** arthritis of the hip for which **non-surgical management** has failed*. **(I)** Addition of "disability" When considering THR surgery, decision making should be multi-factorial and driven by the overall health of a patient undergoing a surgical procedure. In most cases the main indication for hip arthroplasty is pain although other symptoms could deem patients as eligible candidates for total joint replacement. In their paper "The operation of the century: total hip replacement", Learmonth et al (2007) stated that "Today, young patients present for hip-replacement surgery hoping to restore their quality of life, which typically includes physically demanding activities"(2). In TA2: Guidance on the Selection of Prostheses for Primary Total Hip Replacement (1) NICE state that Elective THR should be carried out to relieve discomfort and disability caused by arthropathies (including osteoarthritis and rheumatoid arthritis) of the hip. 1. *TA2: NICE Technology Appraisal 02. Guidance on the Selection of Prostheses for Primary Total Hip Replacement. NICE. Issue date: April 2000. Developed by the National Clinical Guideline Centre.* 2. *"Learmonth I, Young C. The operation of the century: total hip replacement. Lancet 2007; 370: 1508–19*	The Department of Health has agreed a change to the wording of the remit to include people with pain or disability resulting from end stage arthritis of the hip.

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		(II & III) "End stage" and "Non Surgical Management" The use of the terms 'non-surgical management' and 'best supportive care' appear to be used intermittently by NICE throughout the draft scope, which can be confusing. A more consistent approach would be to adopt one of these phrases and continue use of it throughout. 'Non-Surgical Management' would be preferential and seem more appropriate than 'best supportive care'. 'Best supportive care' infers an aspirational 'best in class' definition of non-surgical management that in reality may vary considerably across different geographies. Further clarification on how non-surgical management is defined and furthermore what constitutes 'failure' of non-surgical management is required if it is to define the population of interest in this appraisal. Best supportive care may consist of a range of different possible therapies including exercise, pharmaceuticals, aids and devices and other therapies such as electrotherapy and acupuncture. This treatment should be tailored to individual patient needs and consequently we consider that it would be very difficult to define best supportive care as a single treatment with a known outcome. NICE Guidance CG59 on the care and management of osteoarthritis in adults indicates that referral for joint surgery should be before where there is "prolonged and established functional limitation and severe pain". (1) Therefore, it is unlikely that there is a body of prospective evidence comparing best supportive care with joint replacement, as it is unlikely that patients would be willing to be allocated to non surgical treatment. This poses a question regarding the suitability of best supportive care as a comparator on the basis that it is not currently recommended by NICE as a treatment for patients with chronic osteoarthritis who are fit enough for joint replacement. 1. *CG59: NICE Clinical Guidance 59. Guidance on the care and management of osteoarthritis in adults. NICE. Issue date: April 2003. Developed by the National Clinical Guideline Centre.*	The scope has been amended so that "non-surgical management "rather than best supportive care is the comparator for people for whom resurfacing arthroplasty is not appropriate.

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	Exactech UK Ltd	The defined population may exclude other common indications for total hip replacement, such as: femoral neck fracture, AVN, and congenital hip dysplasia.	The remit for this appraisal says that the population is people with end stage arthritis.
	MHRA	• Presumably the Hip resurfacing is also "elective". We would suggest to remove the word "elective". • We would suggest modifying the populations as follows: People with pain or decreased mobility resulting predominately from end stage arthritis of the hip for which non-surgical management has failed.	Comments noted. "Elective" has been removed. The population needs to be in line with the remit. The Department of Health has agreed a change to the wording of the remit to include people with pain or disability resulting from end stage arthritis of the hip.
	NHS supply chain (ODEP)	Not as well as it could be. Take for example the fact that surface replacement in small women, women over 50 and people with osteoporosis is contra indicated, with latest studies suggesting it may well be shown that it is contra indicated for all females.	For those people for whom surface replacement is not suitable or contraindicated, primary total hip replacement shall be compared to non-surgical management.
	Royal College of Nurses (RCN)	Population seems appropriate although there is no indication here that this surgery may be required at a very young age for this type of disease. We would suggest that this is better reflected in the statement made in the technology section 'carried out to relieve discomfort and disability' rather than 'people with pain'	Comment noted no changes required to the scope. The Department of Health has agreed a change to the wording of the remit to include people with pain or disability resulting from end stage arthritis of the hip.

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	Smith and Nephew	We recommend that consideration should also be given to other indications for use as stated in approved product labelling (e.g. trauma, avascular necrosis of the femoral head, etc.)	The remit for this appraisal says that the population is people with end stage arthritis.
	Stryker UK Ltd	The population defined should be those with discomfort or disability caused by arthropathies.	The remit for this appraisal says that the population is people with end stage arthritis. The Department of Health has agreed a change to the wording of the remit to include people with pain or disability resulting from end stage arthritis of the hip.
	Warwick Evidence	• Query as to whether this review will include or exclude patients with indications other than osteoarthritis or rheumatoid arthritis of the hip? For example, patients with femoral fractures due to mechanical trauma • A priori subgroups can be defined by age (young vs. elderly), gender (male vs. female), severity score of an underlying condition, other patient-level baseline characteristics. *More detail is provided in other considerations*	The remit for this appraisal says that the population is people with end stage arthritis. This review will not include populations that have other indications for hip resurfacing arthroplasty or total hip replacement. The comments on subgroup are noted. The subgroups in the scope should not be defined by protected characteristics outlined in equality legislation.

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Comparators	Association of British Healthcare Industries (ABHI)	The use of the terms 'non-surgical management' and 'best supportive care' appear to be used intermittently by NICE throughout the draft scope, which can be confusing. A more consistent approach would be to adopt one of these phrases and continue use of it throughout. 'Non-Surgical Management' would be preferential and seem more appropriate than 'best supportive care'. 'Best supportive care' infers an aspirational 'best in class' definition of non-surgical management that in reality, may vary considerably across different geographies. Furthermore, non-surgical management may consist of a range of different possible therapies that are tailored to individual patient needs, consequently making it difficult to define best supportive care as a comparative single treatment with a known outcome	Comments noted. The scope has been amended so that "non-surgical management" rather than best supportive care is the comparator for people for whom hip resurfacing arthroplasty is not suitable.
	The Association for Perioperative Practice (AFPP)	Yes	Comment noted.
	Corin Group PLC	As above, the technologies should be considered separately. They are used in different populations.	Participants at the exploratory workshop held when TA2 and TA44 were being considered for review, agreed that the two technologies should be appraised together. For subpopulations for whom one of the technologies is not appropriate or contraindicated the comparator will be non-surgical management.
	DH	Yes. The case for a non-operative treatment is difficult and follow-up would need to be certain this was not a delay to joint replacement rather than an alternative.	Comments noted. No changes required to the scope.

Section	Consultees	Comments	Action
	DePuy, Johnson and Johnson	**COMPARATORS:** The use of the terms 'non-surgical management' and 'best supportive care' appear to be used intermittently by NICE throughout the draft scope, which can be confusing. A more consistent approach would be to adopt one of these phrases and continue use of it throughout. 'Non-Surgical Management' would be preferential and seem more appropriate than 'best supportive care'. 'Best supportive care' infers an aspirational 'best in class' definition of non-surgical management that in reality may vary considerably across different geographies. Further clarification on how non-surgical management is defined and furthermore what constitutes 'failure' of non-surgical management is required if it is to define the population of interest in this appraisal. Best supportive care may consist of a range of different possible therapies including exercise, pharmaceuticals, aids and devices and other therapies such as electrotherapy and acupuncture. This treatment should be tailored to individual patient needs and consequently we consider that it would be very difficult to define best supportive care as a single treatment with a known outcome. NICE Guidance CG59 on the care and management of osteoarthritis in adults indicates that referral for joint surgery should be before there is "prolonged and established functional limitation and severe pain". Therefore, it is unlikely that there is a body of prospective evidence comparing best supportive care with joint replacement, as it is unlikely that patients would be willing to be allocated to non surgical treatment. This poses a question regarding the suitability of best supportive care as a comparator on the basis that it is not currently recommended by NICE as a treatment for patients with chronic osteoarthritis who are fit enough for joint replacement. Other important considerations are the potential consequences of not having surgery; patient reported quality of life can often deteriorate over time without surgical intervention. Intervention could in some severe cases prevent further deterioration of the disease (1). In addition avoidance of medication for increasing levels of pain and symptom relief, mobility aids and supportive care services is an important consideration. For example, Devlin et al (2009) showed that problems with anxiety/depression are very commonly reported by	Comments noted. The scope has been amended so that "non-surgical management "is the comparator for people for whom surface replacement arthroplasty is not appropriate. The comments on the definition of best supportive care and the appropriateness of best supportive care (replaced by non-surgical management) as a comparator for people for whom surface replacement arthroplasty is not appropriate have been noted. For this population, who would be eligible for total hip replacement, non –surgical management was considered the only possible comparator.

Section	Consultees	Comments	Action
		those awaiting hip replacement, and that alleviating this is also an important source of improvement in quality of life following surgery. Resurfacing should be considered as a standalone intervention alongside THR. The current wording is misleading and should be readdressed to allow independent consideration. We advocate that suitability of either option should be based on individual patient characteristics and should be clinically guided. *(1)Buckwalter JA, M. H. (1998). Articular cartilage: degeneration and osteoarthritis, repair, regeneration, and transplantation.* *(2) Devlin N J; Parkin D; Browne J: Using the EQ-5D as a performance measurement tool in the NHS. Department of Economics, Discussion Paper Series No. 09/03*	
	MHRA	No comment	Comment noted.
	NHS supply chain (ODEP)	Hip replacement including resurfacing replacement where appropriate for end stage arthritis of the hip. It is used when all conservative measures have failed. The comparators including arthrodesis osteotomy are no longer undertaken except in unusual circumstances as they fall a long way short of patient expectations. The NJR holds data relating to the performance of many varying component combinations i.e. articulation material (metal, poly, ceramic), size and fixation method. It is not good enough to just compare resurfacing and total hips. Large head metal on metal total hips have been proof of this recently.	Other surgical interventions such as arthrodesis or osteotomy are not listed as comparators in the scope. The scope says under 'Other Considerations' that if evidence allows different types of hip prostheses will be considered separately.

Section	Consultees	Comments	Action
	Royal College of Nurses (RCN)	This is the standard treatment but there should be comparators with those who cannot have a hip replacement and those who have had replacements but not tolerated them. Best supportive care will need to be defined as stated further on in the document. It should be a comparator	The remit for this appraisal says that the population is people with end stage arthritis for whom non surgical management has failed. Therefore these people would be receiving their first (primary) prosthesis. Revision rates are a listed outcome measure. This appraisal will only consider populations who are eligible for total hip replacement and/or resurfacing arthroplasty. The comparator for people for whom THR but not hip resurfacing arthroplasty is suitable has been changed to non-surgical management.

Section	Consultees	Comments	Action
	Smith and Nephew	The scope document lists standard treatments as exercise, manual therapy and pain management. We recommend inclusion of FAI, PAO, hip arthroscopy, visco-supplementation and hemi-arthroplasty, placingTHA on the spectrum of care for osteoarthritis.TA44 We recommend that consideration be given to design related variability within the re-surfacing class in any comparison with THA.	Surgical treatments performed on the hip other than total hip replacement or surface replacement arthroplasty are outside the remit of this appraisal. The other considerations section of the scope says that if evidence allows different types of hip prostheses shall be considered separately. No changes required to the scope
	Stryker UK Ltd	Elective total hip replacement and Hip Resurfacing are alternative procedures for treating people with discomfort or disability caused by arthropathies, and the comparator should therefore be the same for both procedures. TA 44 states "MoM hip resurfacing is recommended as an option for people with advanced hip disease who would otherwise receive a conventional primary total hip replacement (THR) and are likely to live longer than the device is likely to last" – this should therefore not be considered as the primary option for people but as an alternative treatment for primary total hip replacement.	Elective hip replacement and hip resurfacing arthroplasty are alternative treatments and the scope says that they will be compared with each other. However it is recognised that there may be some people who are not suitable for hip resurfacing arthroplasty but are suitable for total hip replacement, a separate comparator of non-surgical management care has been given for this population.

Section	Consultees	Comments	Action
	Warwick Evidence	Specific research questions 1. In patients eligible for either hip replacement or hip surface replacement, what is the clinical and cost effectiveness of total hip replacement compared to hip surface replacement 2. In patients eligible for hip replacement but ineligible for hip surface replacement what is the clinical and cost effectiveness of hip replacement in comparison to best supportive or standard care • If the comparator population is "people who are not suitable for hip resurfacing" then the correct intervention population would be a subgroup of "total hip replacement" recipients who have been excluded from consideration for resurfacing. This subpopulation would be difficult to identify in practice	Comments noted. No changes required to the scope.
Outcomes	Association of British Healthcare Industries	Improvements in total hip arthroplasty implant design have resulted in more total hip arthroplasty procedures being performed in young and more active patients. A recent study by The Work Foundation showed that in 2009 in the region of 11,000 people in England and Wales were enabled to return to work by a hip replacement surgery, saving the UK welfare system £37.4 million each year of their working lives. We would urge NICE to consider the wider societal benefits of joint replacement beyond the perimeter of health budgets as not having the intervention is often 'more of a cost' to patients, the health care system and the society. (1) Hip replacement has transformed the lives of hundreds of thousands of people with arthritis of the hip regardless of their ability to work. To avoid discrimination against the patient sub-population that aren't in active employment, return to normal activity/ daily living and where applicable, work, should all be captured as outcomes. *(1) Bevan S, Zheltoukhova K, McGee R. Adding Value: The Economic and Societal Benefits of Medical Technology. The Work Foundation 2011*	The NICE reference case says that the perspective on outcomes should be all direct health effects, whether for patients or, when relevant, other people (principally carers). The perspectives adopted on costs should be that of the NHS and Personal Social Services (PSS). Changes in mobility, self care, pain and ability to perform daily activities are expected to be captured in the utility measures.

Section	Consultees	Comments	Action
	The Association for Perioperative Practice (AFPP)	Believe early infection rates: Hospital Acquired Infections (HIA's) as described by Health Protection Agency's – Surgical Site Surveillance programme is a key indicators as to the functioning of the Consultant led extended surgical team (May involve advanced perioperative practitioners – Surgical Care Practitioners undertaking surgical interventions, including wound closures of joint replacements which are part of this consultation) & Our association members who are operating theatre staff: • Supporting the above surgical team in providing appropriate sterile surgical instrumentation • In an appropriate safe clinical environment • Ensure correct size implants are used • Support patients during surgery to ensure all risks are accounted for. Infection rate a key outcome for patient surgical episodes.	Comments noted. No changes required to the scope.
	Corin Group PLC	Metal degradation is discussed but other particle debris should be considered from ceramics, polyethylene debris, PMMA particles.	Comment noted. Wear of prostheses is anticipated to be reflected in revision rates of prostheses with different bearing surfaces. The scope has been amended so that outcome measures to be considered includes adverse effects of treatment (peri- and post- procedural), including degradation products where appropriate.

Section	Consultees	Comments	Action
	DH	For completeness, dislocation rates of the prosthetic joint and infection rates should be recorded in the follow-up.	Comment noted. Dislocation rates have been added to the outcomes. Infection would be considered under adverse events.
	DePuy, Johnson and Johnson	**OUTCOMES:** Total hip replacement is one of the most successful and cost effective interventions in medicine (2, 3). It offers reliable relief of pain and considerable improvement in function in patients suffering with osteoarthritis or inflammatory arthritis of the hip sustainable over the long-term (3-8). Improvements in total hip arthroplasty implant design and advances in bearing materials, including modern surface arthroplasty, have resulted in more THR procedures being performed in young and more active patients. We would urge NICE to consider the wider societal benefits of joint replacement beyond the perimeter of health budgets. A recent study by The Work Foundation showed that interventions such as total joint replacement involving medical technologies may help those individuals regain active employment status, thus contributing to the retention of skills and improved societal productivity, while reducing the demand for the government to make payments to those individuals in the form of welfare benefits. In 2009 in the region of 11,000 people in England and Wales were enabled to return to work by a hip replacement surgery, saving the UK welfare system £37.4 million each year of their working lives. Not having the intervention is often 'more of a cost' to patients, the health care system and the society. (1)	Comments noted. The NICE reference case says that the perspective on outcomes should be all direct health effects, whether for patients or, when relevant, other people (principally carers). The perspectives adopted on costs should be that of the NHS and Personal Social Services (PSS). Changes in mobility, self care, pain and ability to perform daily activities are expected to be captured in the utility measures.

Section	Consultees	Comments	Action
		Nunley et al (2011), conducted a multicenter telephone survey on 943 patients	

Section	Consultees	Comments	Action
		younger than 60 years with a University of California, Los Angeles (UCLA) activity score of 6 or higher (which indicates that the patient regularly participates in moderate activities) who underwent hip arthroplasty surgery between 2005 and 2007 at a minimum of 1 year after surgery. They found that most young, active patients employed before surgery can expect to return to work (90.4%), with the vast majority returning to their preoperative occupation, and very few (2.3%) were limited in their ability to return to work because of their operative hip. (9) Hip replacement has transformed the lives of hundreds of thousands of people with arthritis of the hip regardless of their ability to work. To avoid discrimination against the patient sub-population that aren't in active employment, return to normal activity/ daily living and where applicable, work, should all be captured as relevant outcomes. References: OUTCOMES: *(1) Bevan S, Zheltoukhova K, McGee R. Adding Value: The Economic and Societal Benefits of Medical Technology. The Work Foundation 2011* *(2) Liang M, Cullen K, Larson M, Thompson M, Schwartz J, Fossel A. Cost effectiveness of total joint arthroplasty in osteoarthritis. Arthritis Rheum 1986;29:937-43.* *(3) Jonsson B, Larsson S. Functional improvements and costs of hip and knee arthroplasty in destructive rheumatoid arthritis. Scand J Rheumatol 1991; 20:351-7.* *(4) Rissanen P, Aro S, Slatis P, Sintonen H, Paavolainen P. Health and quality of life before and after hip or knee arthroplasty. J Arthroplasty 1995;10:169-75.* *(5) Wiklunch I, Romanus B. A comparison of quality of life before and after arthroplasty in Paitents who had arthrosis of the hip joint. J Bone Joint Surg 1991;73A:765-9.* *(6) Laupacis A, Bourne R, Rorrabeck C, Feeny D,Wong C,Tugwell P, et al. The effect of elective total hip replacement on health related quality of life. J Bone Joint Surg 1993;75A:1619-26.* *(7) Ritter M, Albohm M, Keating M, Faris P, Meding J. Comparative outcomes of total joint arthroplasty. J Arthroplasty 1995;10:737-41* *(8) McGuigan F, Hozack W, Moriarty L, Eng K, Rotham R. Predicting qualityof- life outcomes following total joint arthroplasty. J Arthroplasty 1995;10:742-7.* *(9) Nunley RM, Ruh EL, Zhang Q, Della Valle CJ, Engh CA Jr, Berend ME, Parvizi J, Clohisy JC, Barrack RL. Do patients return to work after hip arthroplasty surgery. Washington University/Barnes-Jewish Hospital, Department of Orthopaedics, Saint Louis, Missouri 63110, USA. J Arthroplasty. 2011 Sep;26(6 Suppl):92-98.e1-3. Epub 2011 May 23*	

Section	Consultees	Comments	Action
	Health Improvement Scotland	Outcomes: Validated outcome measures such as the Harris Hip Score and the Oxford Hip Score may be used.	Comment noted. A NICE scope does not specify the instrument to be used for measuring a particular outcome.
	MHRA	• The methodology of assessment should be separated from the health benefits : o reduced pain o no adverse effects from treatment o bone conservation if possible o improve range of movement and quality of life o long lasting term implant life.	Comment noted. The outcomes listed in the scope include pain, adverse effects of treatment, bone conservation, Health-related quality of life, functional result and revision rates. No changes required to the scope.
	NHS Supply chain (ODEP)	ODEP is always looking at the outcomes. Companies have to submit data on a regular basis to maintain their ODEP rating. ODEP recommend that the outcomes to be considered are pain relief, mobility, PROMS and NJR data.	Pain and functional result are listed as outcomes in the scope. PROMs data collected for people having a hip replacement include QOL measures EQ 5D, patient reported function and patient reported health.
	Royal College of Nurses (RCN)	What will 'adverse effects of treatment' include? Should mortality be included?	Mortality has been added to the scope.

Section	Consultees	Comments	Action
	Smith and Nephew	We recommend that consideration be given to differentiate between prospective and retrospective clinical trials and registry data. Revision rates should not in isolation be the principal outcome end-point and must be balanced against the adjusted mortality rate especially when comparing resurfacing with THA.	The methods guide for technology appraisals says that during the systematic review any potential bias arising from the design of the studies used in the assessment should be explored and documented. Mortality has been added to the scope.
	Stryker UK Ltd	Regarding Bone Conservation outcome – it would be useful to define how this will be measured	A NICE scope is not intended to specify the instrument to be used for collecting a particular outcome.

Section	Consultees	Comments	Action
	Warwick Evidence	**Efficacy outcomes** • Ideally, the specified efficacy outcomes should be divided by patient-oriented (disability, ADL, range of movement, function, pain, revision rates, time to revision, patient satisfaction, and quality of life) and surrogate/clinical outcomes (bone conservation, radiosteriometric analysis, metal degradation products) • **Note** that the draft scope does not mention mortality as an outcome. The review needs to assess at least all cause mortality/survival rates **Adverse events/harms** • Suggest to divide/differentiate adverse vents into two groups: Peri-procedural complications and Post-procedural events (adverse events)	Comments noted on the outcomes noted. No changes required to the scope. Mortality has been added to the scope The scope has been amended so in the outcomes section "adverse events of treatments (peri- and post-procedural)" is listed.

Section	Consultees	Comments	Action
Economic analysis	The Association for Perioperative Practice (AFPP)	Aspects are appropriate. However do not understand why NICE needs to replicate work already being done by orthopaedic surgeons & academic departments. i.e. Recent ground breaking publication: The economic benefit of hip replacement: a 5-year follow-up of costs and outcomes in the Exeter Primary Outcomes Study Richard Fordham, Jane Skinner, Xia Wang, John Nolan and the Exeter Primary Outcome Study Group "EPOS") BMJ Open (2012;2:e000752. doi:10.1136/ bmjopen-2011-000752)	Comments noted. For a multiple technology appraisal the assessment group prepares an assessment report which is an analysis of the clinical and cost effectiveness of the technology and is based on a systematic review of the literature, examination of submissions (from consultees), and advice from clinical advisers. Relevant published literature and unpublished data will be incorporated in the assessment report. NICE produces national guidance and should NICE recommend the use of a technology within the NHS, commissioners are legally required to make funds available to pay for the technology.
	Corin Group PLC	The costs of revision should be considered within the QALY assessment. Guidance needs to given on the acceptance of costs of QUALY and the comparison of surface replacement and total hip replacement.	Revision rates are listed as an outcome. It is anticipated that the costs of revision would be incorporated in the economic model. No changes are required to the scope.

Section	Consultees	Comments	Action
	DePuy Johnson and Johnson	**ECONOMIC ANALYSIS:** We agree that the timeline needs to be sufficiently long to enable assessment of long-term revision rates. This would be consistent with the approach used by Briggs et al in the NICE Guidance on the selection of prosthesis for primary total hip replacement (1). Patients were able to move through different states via a Markov structure if their hip replacement failed (e.g. due to infection or loosening) and they then required a revision. As some patients may now require more than one revision operation in a lifetime, it should be possible to move through these states more than once. We would therefore advocate that the patient lifetime would be the most appropriate measure. *(1) TA2: NICE Technology Appraisal 02. Guidance on the Selection of Prostheses for Primary Total Hip Replacement. NICE. Issue date: April 2000. Developed by the National Clinical Guideline Centre.*	Comments noted.
	Health Improvement Scotland	For patients in the workforce it will be useful to use return to work (and level, i.e. same work, reduced hours, lighter duties) as a measure of cost effectiveness to society.	The NICE reference case says that perspectives adopted on costs should be that of the NHS and Personal Social Services (PSS).
	MHRA	No comment	n/a
	NHS supply chain	Are costs of the respective interventions going to be compared with each other? ODEP recommend that the new guidance would require an extension from the current 10 year benchmark out to include guidance at 15 and 20 years.	The costs and clinical effects of the interventions will be compared with each other. Reference to revision rates and benchmarks are now included in the scope.
	Royal College of Nurses (RCN)	This seems difficult as the time horizon is long i.e. 20 years plus.	Comment noted

Section	Consultees	Comments	Action
	Smith and Nephew	We recommend that NICE consider the total activity based cost of care identified over patients lifetimes with a minimum 3-10 year time horizon for data analysis and extrapolation. A clear indication of the perspectives of society, the NHS or patients as stakeholders must be specified.	Comment on time horizon noted. The NICE reference case says that perspectives adopted on costs should be that of the NHS and Personal Social Services (PSS).
	Stryker UK Ltd	NICE should consider the wider economic and societal benefits of Total Hip Replacement in its evaluation	The NICE reference case says that perspectives adopted on costs should be that of the NHS and Personal Social Services (PSS).
	Warwick Evidence	Study design • Suggest to a priori identify study designs to be eligible for the cost effectiveness review separately Type of analysis • Time horizon - the mean life time of a single intervention episode is probably the most sensible time horizon in addition to the usual NICE lifetime horizon	The NICE methods guide lists appropriate study designs for cost effectiveness analysis. The protocol for the systematic review will define study inclusion and exclusion criteria. This does not need to be specified in the scope. Comments on time horizon noted, no changes required to the scope.

Section	Consultees	Comments	Action
Equality and Diversity	Association of British Healthcare Industries	Rates of total joint surgery (TJR) vary by age, gender, ethnicity, socio-economic status and patient characteristics, despite there being no evidence that such factors affect outcome (1-4, 5) There is evidence to suggest that there is a historic unmet need for treatment of severe joint pain, as well as substantial variability in access across different groups and an increasing number of older people in which joint pain is more prevalent. These are all factors that should be considered when updating guidance on how to diagnose, when to refer and commissioning of treatments for severe hip pain. When considering THR surgery, decision making should be multi-factorial and driven by the overall health of a patient undergoing a surgical procedure, rather than their chronological age. (6, 7, 8) This is consistent with NICE's recent guidance on the treatment of patients with a fractured neck of femur. Rather than apply an upper chronological age threshold, NICE has recommended that a THR is offered to patients with; a displaced intracapsular fracture who are able to walk independently and are not cognitively impaired and are medically fit for anaesthesia and the procedure (9). Current evidence in joint replacement surgery from the national and international registries and peer reviewed studies support the current recommendation from NICE stating that patient-specific factors should not be barriers to referral for surgery. In the example of obese patients, denying joint replacement surgery, is therefore not justified and is creating inequity of access to care to people who have often put on weight as their OA has increased their disability and restricted their ability to maintain appropriate activity levels. *(1) Dieppe P, Basler H-D, Chard J et al. Knee replacement surgery for osteoarthritis: effectiveness, practice variations, indications and possible determinants of utililization. Rheumatology 1999;38:73–83.* *(2) Hawker GA, Wright JG, Coyte PC et al. Differences between men and women in the rate of use of hip and knee arthroplasty. N Engl J Med 2000;342:1016–22.* *(3) Hudak PL, Clark JP, Hawker GA et al. 'You're perfect for the procedure! Why don't you want it?' Elderly arthritis patients' unwillingness to consider total joint arthroplasty surgery: a qualitative study. Med Dec Making 2002;22:272–8.* *(4) Katz BP, Freund DA, Heck DA, Dittus RS, Paul JE, Wright JG. Demographic variation in the rate of knee replacement: a multi-year analysis. Health Serv Res 1996;31:125–40.* *(5)* Scott CE, Bugler KE, Clement ND, Macdonald D, Howie CR, Biant LC. Patient expectations of arthroplasty of the hip and knee. Bone Joint Surg Br. 2012 Jul;94(7):974-81. *(6) 74 Sanders C, Donovan J, Dieppe P. The significance and consequences of having painful and disabled joints in older age: co-existing accounts of normal and disrupted biographies. Sociol Health Illn 2002;24:227-53.*	Most of these comments relate to implementation issues. The implementation of the guidance will be discussed in the appraisal documents. In line with NICE's published principles of social value judgements NICE guidance should refer to age only when one or more of the following apply. There is evidence that age is a good indicator for some aspect of patients' health status and/or the likelihood of adverse effects of the treatment. There is no practical way of identifying patients other than by their age (for example, there is no test available to measure their state of health in another way). There is good evidence or good grounds for believing that because of their age patients will respond differently to the treatment in question.

Section	Consultees	Comments	Action
		(7) Beadling, Lee; "TKA can be an option for the young active patient." Orthopedics Today: Vol. 23 No. 10. October 2003 (Page 43). *(8) BJ Cole and CD Harner "Degenerative arthritis of the knee in active patients: evaluation and management" J. Am. Acad. Ortho. Surg., Nov 1999; 7: 389 - 402.* *(9)* Davis W, Porteous M. Joint Replacement in the Overweight Patient: A Logical Approach or New Form of Rationing? Ann R Coll Surg Engl. 2007 April; 89(3): 203–206	

Section	Consultees	Comments	Action
	The Association for Perioperative Practice (AFPP)	Rationing as current economic status affects waiting lists. Business needs leading clinical decision making "you cannot use that implant! It is too expensive?" Ageism: Age related discretion in an ageing society	Comments noted. Age is not listed as a determinant of eligibility in the scope. No changes are required to the scope.
	Corin Group PLC	Age is a factor to consider Equality should be given to patients when receiving an advanced bearing and older patients should not be discriminated against	Comments noted. Age is not listed as a determinant of eligibility in the scope. No changes are required to the scope.

Section	Consultees	Comments	Action
	DePuy Johnson and Johnson	**EQUALITY:** . I. Introduction II. The Unmet Need for Total Joint Replacement (TJR) III. Inequity of Access to Intervention Based on Age IV. Inequity of Access to Intervention Based on BMI I. Introduction Joint replacement is a common elective procedure that makes a substantial contribution to public health and is, therefore, an important equity indicator (1). However, recent reviews have highlighted variations in surgical activity at both national (2) and international levels (3), with the USA, for example, having much higher rates of total knee replacement (TKR) than the UK. There is evidence of perceived barriers to treatment at three levels; in studies controlling for patients' willingness to seek treatment, a resistance to referral at primary care and a reluctance to provide intervention at secondary care level (1-3). I. The Unmet Need for Total Joint Replacement (TJR) Rates of total joint surgery (TJR) vary by age, gender, ethnicity, socio-economic status and patient characteristics, despite there being no evidence that such factors affect outcome (4-7, 23). Judge et al (2010), performed analysis combining small area estimates on the need for and surgical provision of hip and knee replacement surgery to explore evidence of inequity in access to care. They found that there is strong evidence of under provision of hip and knee replacement relative to need in England, with inequity by age, sex, deprivation, rurality, and ethnicity. This varied by geography and neither hospital or distance variables explained the evidence of the observed inequities.	These are all implementation issues, but will be presented to Committee for information.

Section	Consultees	Comments	Action
		Studies by Juni, Yong, Steel, Judge and Peters all found that, older people, women and the less wealthy had a greater need for joint replacement (36, 37, 38, 39, 40, 41). People in the North of England, women and the poorest had the greatest disparity between those in need and those receiving joint replacement mainly because of the impact of treatment on their personal lives (36, 43, 44). These population-based surveys appear to indicate that there are large numbers of people in the UK in need of joint replacement who are not currently being treated. The willingness for surgery may be influenced by factors such as increasing age, female gender, and lower wealth. People in these groups may have less positive expectations of surgery and be more prepared to accept coping strategies, creating inequalities in access to treatment (40, 41). In those candidates not treated with surgery it is also unclear whether they are receiving appropriate care (37). There is evidence to suggest that there is a historic unmet need for treatment of severe joint pain, and information indicating whether this is being addressed by current levels of surgery is limited. Additionally, there is substantial variability in access across different groups and an increasing number of older people in which joint pain is more prevalent. These are all factors that should be considered when updating guidance on how to diagnose, when to refer and commissioning of treatments for severe hip pain. I. Inequity of Access to Intervention Based on Age Sanders et al (2004) found that patients are reporting that General Practitioners (GPs) are creating barriers to both younger and older groups of patients (9). Older patients are not being deemed suitable for referral as their symptoms are viewed as inevitable with age and untreatable or they aren't sufficiently disabled (3, 9, 10, 11). Conversely younger people also find themselves discriminated against by some GPs, who think they are either not sufficiently disabled (1) or too young for an operation and should wait until they are older (9, 10). Younger patients however, seem much more determined to get the treatment they feel is necessary. This has been demonstrated in	

Section	Consultees	Comments	Action
		requests for private referrals (9). The question about appropriate age for surgery is important because recent research has suggested that those who have early surgery have better outcomes than those who have later surgery when they are older with more severe symptoms (8). Once reserved for elderly patients, total joint replacement surgery is becoming more common in the younger, active population and the benefits of performing total knee replacement surgery in younger patients may outweigh the risks of future revision surgery. The benefits are primarily quality of life, pain reduction, and maintaining proper fitness. By accomplishing these goals, patients may also reduce the risk of developing other problems associated with poor fitness such as cardiovascular disease (12, 13, 14). It is important for policy makers to consider that the next generation of older people might be more demanding and have greater expectations of their right to surgery and this may bring with it greater demand for surgery. There is no upper chronological age beyond which patients should not be considered for total hip replacement (21). As patients get older, care needs to be taken to properly determine those patients who can tolerate the surgery and the recovery. Elderly patients with adequate preparation can safely undergo arthroplasty and achieve improvements in hip or knee scores that are comparable to younger patients (15-20). Shah et al (2004) looked specifically at frail elderly patients undergoing Total Hip Replacement (THR) surgery and found excellent outcomes with low mortality (15). When considering THR surgery, decision making should be multi-factorial and driven by the overall health of a patient undergoing a surgical procedure, rather than their chronological age. (12, 13, 14) This is consistent with NICE's recent guidance on the treatment of patients with a fractured neck of femur. Rather than apply an upper chronological age threshold, NICE has recommended that a THR is offered to patients with; a displaced intracapsular fracture who are able to walk independently and are not cognitively impaired and are medically fit for anaesthesia and the procedure (24).	

Section	Consultees	Comments	Action
		IV. Inequity of Access to Intervention Based on BMI We are aware of published reports that some Primary Care Trusts (PCTs) are seeking to restrict access to joint replacement based on patient specific factors (26). It is important that any barriers to treatment based on patient specific factors are evidenced based and robustly demonstrable. Current evidence in joint replacement surgery from the national and international registries and peer reviewed studies support the current recommendation from NICE stating that patient-specific factors should not be barriers to referral for surgery. When investigating the impact of a funding restriction for Total Joint Replacement (TJR), introduced to those with a body mass index (BMI) of less than 30 kg/m2, Davis et al extrapolated local data to incorporate numbers that would be affected if this policy was instituted in their local PCT and nation-wide based on data from the National Joint Registry of England and Wales. They also examined the available literature to discover if there is any evidence that obesity affects outcome in hip and knee replacement surgery. (31) They found that 24% of the population undergoing total hip replacement and 38.5% of patients undergoing total knee replacement in the test population were classified as obese, so denying joint replacement to patients with a BMI > 30 kg/m2 would have represented a significant cost saving to a purchasing authority. However, they concluded that this would be done at the expense of an increase in suffering in those patients denied surgery. They could find no convincing evidence in the literature to support the policy of denying anyone a hip replacement on the grounds of obesity and that the policy they were testing discriminated not just against the overweight, but also has a greater impact on women than men. They concluded that if this policy were to be adopted nation-wide, it would lead to unnecessary suffering in over 20,000 people every year. Ten-year survivorship figures following total joint replacement have been found to be comparable for both obese and non-obese patients (32) and there is evidence to show that joint replacements do not wear out sooner in obese patients (33). A poorer outcome is not the same as a poor outcome (27, 28). A benefit can still be substantial from the patients point of view even if it is not the maximum achievable, and it will be easier to exercise when the new joint	

Section	Consultees	Comments	Action
		has been received due to improved mobility and decreased pain. (29) A systematic review to determine how patient characteristics influence the outcomes of hip and knee arthroplasty considered 500 patients with osteoarthritis. It was shown that all subgroups derived benefit from total joint arthroplasty and that in no specific subgroup of patients did total joint arthroplasty appear contraindicated, suggesting that surgeons should not restrict access to these procedures based on patient characteristics (34). Denying joint replacement surgery to obese patients, in a short term attempt to save money is not justified and is creating inequity of access to care to people who have often put on weight as their OA has increased their disability and restricted their ability to maintain appropriate activity levels. References: EQUALITY: *(1) Judge A, Welton N, Sandhu J, Ben-Shiomo Y. Equity in access to total joint replacement of the hip and knee in England: cross sectional study. BMJ 2010;341:c4092doi:10.1136/bmj.c4092* *(2) Williams MH, Frankel S, Nanchahal K, Coast J, Donovan J. Total hip replacement. In: Stevens A, Raftery J, eds. Health care needs assessment. Oxford: Radcliffe Medical Press, 1994:448–523.* *(3) Dieppe P, Basler H-D, Chard J et al. Knee replacement surgery for osteoarthritis: effectiveness, practice variations, indications and possible determinants of utililization. Rheumatology 1999;38:73–83.* *(4) Hawker GA, Wright JG, Coyte PC et al. Differences between men and women in the rate of use of hip and knee arthroplasty. N Engl J Med 2000;342:1016–22.* *(5) Hudak PL, Clark JP, Hawker GA et al. 'You're perfect for the procedure! Why don't you want it?' Elderly arthritis patients' unwillingness to consider total joint arthroplasty surgery: a qualitative study. Med Dec Making 2002;22:272–8.* *(6) Katz BP, Freund DA, Heck DA, Dittus RS, Paul JE, Wright JG. Demographic variation in the rate of knee replacement: a multi-year analysis. Health Serv Res 1996;31:125–40.* *(7) Chaturvedi N, Ben-Shlomo Y. From the surgery to the surgeon: does deprivation influence consultation and operation rates? Br J Gen Pract1995;45:127–31.* *(8) Hajat S, Fitzpatrick R, Morris R et al. Does waiting for total hip replacement matter? Prospective cohort study. J Health Serv Res Policy 2002;17:19–25.* *(9) C. Sanders, J. L. Donovan1 and P. A. Dieppe. Unmet need for joint replacement: a qualitative investigation of barriers to treatment among individuals with severe pain and disability of the hip and knee. Rheumatology 2004;43:353–357 doi:10.1093/rheumatology/keh044 Advance Access publication 17 November 2003.* *(10) Gignac MA, Davis AM, Hawker G, Wright JG, Mahomed N, Fortin PR, et al. "What do you expect? You're just getting older": a comparisonof perceived osteoarthritis-related and aging-related health experiences in middle- and older-age adults. Arthritis Rheum 2006;55:905-12.* *(11) 74 Sanders C, Donovan J, Dieppe P. The significance and consequences of having painful and disabled joints in older age: co-existing accounts of normal and disrupted biographies. Sociol Health Illn 2002;24:227-53.*	

Section	Consultees	Comments	Action
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Section	Consultees	Comments	Action
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Section	Consultees	Comments	Action
	MHRA	No comment	N/a

Section	Consultees	Comments	Action
	Smith and Nephew	We recommend NICE consider the effect of high and low volume surgical users, particularly with respect to hip resurfacing. We recommend that these surgeon and centre effects related to geographical access to best care be examined.	Comment noted. No changes to the scope required.
	Stryker UK Ltd	There are currently unjustified access restrictions imposed locally for people requiring total hip replacements and differences on technology access depending on geographical locations (postal code bias). So, it would be desirable that NICE stress the need to reinforce the importance of equity of provision by Commissioners to this treatment.	Comment noted. If NICE recommends a technology, commissioners within the NHS are legally required to make funds available to pay for the technology.
	Warwick Evidence	Age related hip replacement policies (e.g. by NHS Commissioning or providing organisations)may be important to consider in this respect	Comment noted. NICE do not take into account NHS commission policies unless they affect the clinical and cost effectiveness.
Innovation	The Association for Perioperative Practice (AFPP)	*Do you consider the technology to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?* Yes	Comment noted.
	Corin Group PLC	*Do you consider the technology to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?* Not truly innovative. Total hip replacement is a successful treatment option and incremental innovation provides small improvements which may be significant particularly in the younger, more active group.	Comment noted.

Section	Consultees	Comments	Action
	DH	*Do you consider the technology to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?* This question needs to be addressed yes.	Comment noted.
	Depuy, Johnson and Johnson	Do you consider the technology to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)? We are in agreement that innovation such as big heads and conservative stems, cementless technology and materials are presented as sub groups rather than as part of the main question. The decision to proceed on any of these groups will be driven by data availability	Comment noted.
	MHRA	*Do you consider the technology to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?* • Generally is not, there are some examples notably metal on ceramic.	Comment noted.
	Smith and Nephew	The principal paradigm shift in the management of these indications was made decades ago when THA was first introduced. Incremental benefits in design and material iterations have subsequently improved implant performance modestly. However, the introduction of the ceramicised metal femoral heads and highly cross-linked polyethylene cups has led to a step change in implant survivorship.	Comments noted.

Section	Consultees	Comments	Action
	Warwick Evidence	*Do you consider the technology to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?* • This technology considerably improves the management options of the condition	Comment noted.
Other considerations	Association of British Healthcare Industries	We agree with the proposal to perform subgroup analysis by type of hip prosthesis and patient activity level. We also agree that, where the availability of data allows, that it may be appropriate to extend the sub grouping. However, it is important that analysis of performance by prosthesis type should be by construct to allow for the complexity that comes with the numerous combinations of available devices as well as potential associations between different subgroups of designs that could influence outcomes, such use of bearing materials and method of fixation. The use of worldwide registry data should be a key consideration within their analysis.	Comments noted.
	The Association for Perioperative Practice (AFPP)	Clinical scoring systems to assess need for surgical intervention.	Comment noted.
	Corin Group PLC	As previous comments: • Surface replacement does not cover the same indications as total hip replacement. • There will also be a move to an alternative bearing for surface replacement.	Comments noted

Section	Consultees	Comments	Action
	DH	There is a need to clarify for metal ion measurement what cohort you are measuring in. I suggest all patients, but particularly those with metal on metal bearing surface (all implant combinations have at least one metal on metal bearing).	The MHRA recommendations are that metal ion measurements should be made in symptomatic patients, and in all patients who have receive large head metal on metal THR or DePuy ASR implants.

Section	Consultees	Comments	Action
	DePuy, Johnson and Johnson	Are the subgroups in other considerations appropriate? We agree with the proposal to perform subgroup analysis by patient activity level and type of hip prosthesis. Some designs may be used more frequently in more active patients (1) and this should be accounted for in the analysis. Additionally, there are potential associations between different subgroups of designs that could influence outcomes, such use of bearing materials and method of fixation. Internal data at DePuy indicates that metal on metal bearings are more likely to be used with cementless devices. Where evidence allows, analysis of performance by prosthesis type should be by construct to reduce the risk of this type of confounding. For example cementless total hip replacement with ceramic on ceramic bearings should be considered separately from cementless total hip replacement with other bearing designs. We also agree that it may be appropriate to extend the subgrouping to different head sizes, or groups of head sizes, where possible. *(1) The NRR Centre Hemel Hempstead. National Joint Registry for England and Wales Annual Report 2011. Available URL: http://www new.njrcentre.org.uk/njrcenre/Default.aspx Accessed 27/02/12* If included as a comparator, how should management without the use of hip replacement or resurfacing (best supportive care) be defined? The use of the terms 'non-surgical management' and 'best supportive care' appear to be used intermittently by NICE throughout the draft scope, which can be confusing. A more consistent approach would be to adopt one of these phrases and continue use of it throughout. 'Non-Surgical Management' would be preferential and seem more appropriate than 'best supportive care'. 'Best supportive care' infers an aspirational 'best in class' definition of non-surgical management that in reality may vary considerably across different geographies.	Comments noted. This information will be presented to the Committee for information. The scope has been amended so that non-surgical management is used consistently throughout the document. The comments on subgroup analysis have been noted. No changes required to the scope.

Section	Consultees	Comments	Action
		Further clarification on how non-surgical management is defined and furthermore what constitutes 'failure' of non-surgical management is required if it is to define the population of interest in this appraisal. Best supportive care may consist of a range of different possible therapies including exercise, pharmaceuticals, aids and devices and other therapies such as electrotherapy and acupuncture. This treatment should be tailored to individual patient needs and consequently we consider that it would be very difficult to define best supportive care as a single treatment with a known outcome. NICE Guidance CG59 on the care and management of osteoarthritis in adults indicates that referral for joint surgery should be before there is "prolonged and established functional limitation and severe pain" (2). Therefore, it is unlikely that there is a body of prospective evidence comparing best supportive care with joint replacement, as it is unlikely that patients would be willing to be allocated to non surgical treatment. There poses a question regarding the suitability of best supportive care as a comparator on the basis that it is not currently recommended by NICE as a treatment for patients with chronic osteoarthritis who are fit enough for joint replacement. 1. *Gignac M, Davis A, Hawker G, Wright J, Mahomed N, Fortin P, Badley E. "What Do You Expect? You're Just Getting Older": A Comparison of Perceived Osteoarthritis-Related and Aging-Related Health Experiences in Middle- and Older-Age Adults. Arthritis & Rheumatism (Arthritis Care & Research) Vol. 55, No. 6, December 15, 2006, pp 905–912* 2. *CG59: NICE Clinical Guidance 59. Guidance on the care and management of osteoarthritis in adults. NICE. Issue date: April 2003. Developed by the National Clinical Guideline Centre.*	

Section	Consultees	Comments	Action
		Should different types or brands of hip prostheses be considered separately? If so, how should different types of prostheses be grouped? We agree with the proposal to perform subgroup analysis by type of hip prosthesis and patient activity level. We also agree that, where the availability of data allows, that it may be appropriate to extend the sub grouping. However, it is important that analysis of performance by prosthesis type should be by construct to allow for the complexity that comes with the numerous combinations of available devices as well as potential associations between different subgroups of designs that could influence outcomes, such use of bearing materials and method of fixation.	
	Healthcare Improvement Scotland	There have been some reports regarding survivorship differences following total hip replacement vs hip resurfacing based on data from the National Joint Registry of England and Wales. The report should touch on this and shed some more light to this issue.	Mortality has been included as an outcome as has revision rates which will reflect the lifespan of a prosthesis.
	MHRA	Modular stem prostheses can also be considered	Comment noted.

Section	Consultees	Comments	Action
	NHS supply chain (ODEP)	An analysis of the economic and health consequences of delayed referral should be considered i.e. if the patient is kept in primary care to delay addition to a waiting list then, as the condition is generally progressive, the intervention will be more complex when the patient presents for surgery. How do you propose to implement the outcome of the review? Publishing and expecting ODEP to catch the fallout without formal endorsement would not be acceptable.	Comments noted. It is stated under Other Considerations that "if the recommendations remain based on long (term performance) revision rates, the collection and monitoring of performance data and arrangements for the effective implementation of such recommendations should be considered". The Institute will consider implementation of the guidance.
	Smith and Nephew	The scope document describes THA as "thetechnology." We recommend that consideration be given to intra-class technology and design-related variability of implant components, such as monolithic or modular stems and monoblock or modular cups. When comparing component materials ceramicised metal should be included in the assessment as a distinct bearing surface material. We recommend consideration of the following as independent risk factors for implant survivorship: • Implant design. • prosthetic femoral head size • cemented, uncemented or hybrid implant systems • gender • age • body mass index • surgeon training and experience • surgical centre procedure volume	The 'Other Considerations' section of the scope now states that 'If the evidence allows different types of hip prostheses will be considered separately such as: Hip replacements with components made from different materials (metal, ceramic, polyethylene, ceramicised metal). Cemented, cementless or hybrid prostheses. Prostheses with differing femoral head size. Prostheses with differing revision rates, for example ODEP ratings.

Section	Consultees	Comments	Action
	Stryker UK Ltd	The matrix of the wide variety of products that are planned for consideration will be very complex and may result in unclear results. Clear presentation of the TA results might lead to wider adoption	Comment noted

Section	Consultees	Comments	Action
	Warwick Evidence	Patient-level subgroups • Age is a characteristic which will require consideration as it may affect resurfacing eligibility • Sub groups are essentially defined by which replacement they have e.g. only younger more active patients are generally considered for Resurfacing or MoM hip replacement. Patients could be divided by chronological age e.g. above and below 65yrs - this is a clinically relevant/recognised cut-off but people will still argue about physiologically young 70 year old patients Intervention-related factors • There are only a limited number of bearing combinations which are actually used in practice MoM, CoC and MoP - the latter initial denoting the acetabular bearing. Cementation of each component (or not) remains a source of debate, as does head size - less than or equal to 28mm being 'small' anything bigger 'large' - with particular reference to rate of dislocation. These could be the sub-types of prosthesis • Operator's experience • Caregiver's (physiotherapists, occupational therapists) experience • Post-procedural rehabilitation factors • Other treatment-level factors (type, brand, standard vs. mini incision techniques). It will be very difficult and contentious to compare brands Long-term revision rates • Observational studies (controlled or uncontrolled) or hip registers may be needed to investigate long-term revision rates of hip replacement from	Comments noted. It is not possible to make recommendations for subgroups based on age or gender. The scope states that consideration should be given to differing head size (see 'Other Considerations').

Section	Consultees	Comments	Action
Questions for consultation	The Association for Perioperative Practice (AFPP)	*Do you consider the technology to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?* Yes *Do you consider that the use of the technology can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?* See above article – Yes *Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits* National Joint Registers – www.njrcentre.org.uk Health Protection Agency – www.hpa.org.uk *Please answer any of the questions for consultation if not covered in the above sections. If appropriate, please include comments on the proposed process this appraisal will follow (please note any changes made to the process are likely to result in changes to the planned time lines).* Nil to note	Comments noted.

Section	Consultees	Comments	Action
	Corin Group PLC	*Do you consider that the use of the technology can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?* • No *Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits* • Peer reviewed publications • Global registries • Post market surveillance data • FDA IDE panel reviews *Please answer any of the questions for consultation if not covered in the above sections. If appropriate, please include comments on the proposed process this appraisal will follow (please note any changes made to the process are likely to result in changes to the planned time lines).* • Surface replacement does not cover the same indications as total hip replacement and therefore the two technologies should be considered separately.	Comments noted. The technologies will be considered separately, for the populations for which they are indicated.
	DH	*Do you consider that the use of the technology can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?* There may well be a significant impact on QALYS (perhaps detrimental)	Comment noted.

Section	Consultees	Comments	Action
	DePuy, Johnson and Johnson	Do you consider that the use of the technology can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation? (Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits) Total hip replacement is one of the most successful and cost effective interventions in medicine (2, 3). It offers reliable relief of pain and considerable improvement in function in patients suffering with osteoarthritis or inflammatory arthritis of the hip sustainable over the long-term (3-8). Improvements in total hip arthroplasty implant design and advances in bearing materials, including modern surface arthroplasty, have resulted in more THR procedures being performed in young and more active patients. *Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits* We would urge NICE to consider the wider societal benefits of joint replacement beyond the perimeter of health budgets. A recent study by The Work Foundation showed that interventions such as total joint replacement involving medical technologies may help those individuals regain active employment status, thus contributing to the retention of skills and improved societal productivity, while reducing the demand for the government to make payments to those individuals in the form of welfare benefits. In 2009 in the region of 11,000 people in England and Wales were enabled to return to work by a hip replacement surgery, saving the UK welfare system £37.4 million each year of their working lives. Not having the intervention is often 'more of a cost' to patients, the health care system and the society. (1) Nunley et al (2011), conducted a multicenter telephone survey on 943 patients younger than 60 years with a University of California, Los Angeles (UCLA) activity score of 6 or higher (which indicates that the patient regularly	Comments noted. The NICE reference case says that outcomes and costs should be considered from a NHS and PSS perspective only.

Section	Consultees	Comments	Action
		participates in moderate activities) who underwent hip arthroplasty surgery between 2005 and 2007 at a minimum of 1 year after surgery. They found that most young, active patients employed before surgery can expect to return to work (90.4%), with the vast majority returning to their preoperative occupation, and very few (2.3%) were limited in their ability to return to work because of their operative hip. (9) Hip replacement has transformed the lives of hundreds of thousands of people with arthritis of the hip regardless of their ability to work. To avoid discrimination against the patient sub-population that aren't in active employment, return to normal activity/ daily living and where applicable, work, should all be captured as outcomes. *(1) Bevan S, Zheltoukhova K, McGee R. Adding Value: The Economic and Societal Benefits of Medical Technology. The Work Foundation 2011* *(2) Liang M, Cullen K, Larson M, Thompson M, Schwartz J, Fossel A. Cost effectiveness of total joint arthroplasty in osteoarthritis. Arthritis Rheum 1986;29:937-43.* *(3) Jonsson B, Larsson S. Functional improvements and costs of hip and knee arthroplasty in destructive rheumatoid arthritis. Scand J Rheumatol 1991; 20:351-7.* *(4) Rissanen P, Aro S, Slatis P, Sintonen H, Paavolainen P. Health and quality of life before and after hip or knee arthroplasty. J Arthroplasty 1995;10:169-75.* *(5) Wiklunch I, Romanus B. A comparison of quality of life before and after arthroplasty in Paitents who had arthrosis of the hip joint. J Bone Joint Surg 1991;73A:765-9.* *(6) Laupacis A, Bourne R, Rorrabeck C, Feeny D,Wong C,Tugwell P, et al. The effect of elective total hip replacement on health related quality of life. J Bone Joint Surg 1993;75A:1619-26.* *(7) Ritter M, Albohm M, Keating M, Faris P, Meding J. Comparative outcomes of total joint arthroplasty. J Arthroplasty 1995;10:737-41.* *(8) McGuigan F, Hozack W, Moriarty L, Eng K, Rotham R. Predicting qualityof- life outcomes following total joint arthroplasty. J Arthroplasty 1995;10:742-7.* *(9) Nunley RM, Ruh EL, Zhang Q, Della Valle CJ, Engh CA Jr, Berend ME, Parvizi J, Clohisy JC, Barrack RL. Do patients return to work after hip arthroplasty surgery. Washington University/Barnes-Jewish Hospital, Department of Orthopaedics, Saint Louis, Missouri 63110, USA. J Arthroplasty. 2011 Sep;26(6 Suppl):92-98.e1-3. Epub 2011 May 23*	

Section	Consultees	Comments	Action
	MHRA	*Do you consider that the use of the technology can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?* • No comment *Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits* • Data from registries (National Joint and Australian Registries, Manufacturers postmaket data, ODEP ratings *Please answer any of the questions for consultation if not covered in the above sections. If appropriate, please include comments on the proposed process this appraisal will follow (please note any changes made to the process are likely to result in changes to the planned time lines).* • There should be a single guidance document for hip arthroplasty looking at the benefits of resurfacing and total hip arthroplasties • Is the current 90% survivorship at 10 years appropriate based on current knowledge?	Comments noted.
	NHS supply chain	Total hip replacement is a fantastic operation when performed by properly trained surgeons on patients where the indications for surgery are fulfilled.	Comments noted.

Section	Consultees	Comments	Action
	Smith and Nephew	*Do you consider that the use of the technology can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?* Ceramicised metal femoral heads may better meet current needs.as demonstrated by revision rate reduction and the opportunity for use in patients with suspected or known metal sensitivity. The combination of ceramicised metal femoral heads and highly cross-linked polyethylene cups is expected to offer additional reductions revision rates. *Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits* Data demonstrating the health related benefits of these technologies are available from retrospective and prospective clinical trial publications and a variety of joint replacement registries. *Please answer any of the questions for consultation if not covered in the above sections* TA44 We recommend that bone conserving mid-head femoral resection techniques be considered in the same category as femoral head resurfacing techniques.	Comments noted.
	Stryker UK Ltd	*Do you consider that the use of the technology can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?* Hip replacement also has an impact on the wider economic and societal benefits eg return to work, reduced welfare costs, reduced carer burden, therefore wider societal impact should be considered in the Appraisal's Scope. *Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits* The Work Foundation Report "Adding Value – The Economic and Societal Benefits of Medical Technology" (copy attached)	The NICE reference case says that perspectives adopted on costs should be that of the NHS and Personal Social Services (PSS).

Section	Consultees	Comments	Action
	Warwick Evidence	*Please answer any of the questions for consultation if not covered in the above sections. If appropriate, please include comments on the proposed process this appraisal will follow (please note any changes made to the process are likely to result in changes to the planned time lines).* • The 'best non-operative treatment' is very difficult to define. Similarly, indications for surgery are very difficult to pin down. Clinical experts have suggested that potentially the easiest and most useful comparison is between types of hip and bearing surface for those patients who are having a replacement hip i.e. avoid the non-op issue altogether	This appraisal shall compare THR to resurfacing arthroplasty. Non-surgical management is the comparator for people for whom THR but not resurfacing arthroplasty is appropriate.
Additional comments on the draft scope.	The Association for Perioperative Practice (AFPP)	1. A significant number of our members will be involved in joint replacement operations that involve very young patients – Rheumatoid Arthritis, young adults 17 years to 30 years. 2. Will this age range be included in this study as your title parameters are "Pain" and "End Stage". 3. Who / How will age parameters be set? 4. Health Protection Agency not on list – Important for wound site surveillance data following joint replacements. Each orthopaedic dept in U.K has to undertake statutory surveillance on hip replacements for at least one calendar quarter.	The appraisal will not make any restrictions to the recommendations based on age. The Health Protection Agency has been added to the matrix.

Section	Consultees	Comments	Action
	DePuy, Johnson and Johnson	**TITLE:** *Total hip replacement and surface replacement for the treatment of pain resulting from end stage arthritis of the hip (Review of technology appraisal guidance 2 and 44)* We suggest that the title is amended as follows: **Primary (I)** total hip replacement and surface replacement for the treatment of pain **and disability (II**) resulting from ~~end stage~~ **(III)** arthritis of the hip. I) Addition of "Primary" Revision hip arthroplasty is a very variable intervention due to the wide variety of boney deficits on the femoral and acetabular sides that need to be addressed. Any such appraisal of revision technologies should be the subject of a separate appraisal, should this be deemed appropriate. II) Addition of "disability" When considering THR surgery, decision making should be multi-factorial and driven by the overall health of a patient undergoing a surgical procedure. In most cases the main indication for hip arthroplasty is pain although other symptoms could deem patients as eligible candidates for total joint replacement. In their paper "The operation of the century: total hip replacement", Learmonth et al (2007) stated that "Today, young patients present for hip-replacement surgery hoping to restore their quality of life, which typically includes physically demanding activities"(2). In TA2: Guidance on the Selection of Prostheses for Primary Total Hip Replacement (1) NICE state that Elective THR should be carried out to relieve discomfort and disability caused by arthropathies (including osteoarthritis and rheumatoid arthritis) of the hip.	Comments noted. These have been raised by DePuy, Johnson and Johnson in earlier sections where they have been addressed. The Department of Health has agreed a change to the wording of the remit to include people with pain or disability resulting from end stage arthritis of the hip.

Section	Consultees	Comments	Action
		(1) *TA2: NICE Technology Appraisal 02. Guidance on the Selection of Prostheses for Primary Total Hip Replacement. NICE. Issue date: April 2000. Developed by the National Clinical Guideline Centre* (2) *"Learmonth I, Young C. The operation of the century: total hip replacement. Lancet 2007; 370: 1508–19* III) Deletion of "end-stage" arthritis NICE Guidance CG59 on the care and management of osteoarthritis in adults indicates that referral for joint surgery should therefore, be before there is "prolonged and established functional limitation and severe pain" (1). The scope specifies "end stage" arthritis, however the question of the appropriate timing for surgery is important because recent research has suggested that those who have early surgery have better outcomes than those who have later surgery when they are older with more severe symptoms (2). Hajat et al undertook a prospective cohort study to assess the impact on the outcome of total hip replacement of the length of timing spent waiting for surgery and found that waiting for surgery is associated with worse outcomes 12 months later. (2) Those patients who started with a worse Oxford Hip Score before the operation tended to remain worse after the operation. Worse pre-operative score was associated with an increased length of either outpatient or inpatient wait, and this trend remained after the operation. The relationship between waiting time and outcome remained after adjustment for possible confounding variables. We would urge NICE to consider that, in some cases, health care has, as its principal goal not the improvement in health, but rather the slowing down of the rate of disease and degradation in quality of life, or the avoidance of a future health problem. For example, Devlin et al (2009) showed that problems with anxiety/depression are very commonly reported by those awaiting hip replacement, and that alleviating this is also an important source of improvement in quality of life following surgery (3). This could be true in the case of the extent of osteoarthritis and could in turn inform the appropriate	

Section	Consultees	Comments	Action
		timing of Total Hip Replacement (THR). The degeneration of articular cartilage as part of the clinical syndrome of osteoarthritis is one of the most common causes of pain and disability in middle-aged and older people. The strong correlation between increasing age and the prevalence of osteoarthritis, and recent evidence of important age-related changes in the function of chondrocytes, suggest that age- related changes in articular cartilage can contribute to the development and progression of osteoarthritis over time(4). *(1) NICE Clinical Guideline 59: The care and management of osteoarthritis in adults. NICE. Issue date: June 2009. Developed by the National Clinical Guideline Centre.* *(2) Hajat S, Fitzpatrick R, Morris R et al. Does waiting for total hip replacement matter? Prospective cohort study. J Health Serv Res Policy 2002;17:19–25.* *(3) Devlin N J; Parkin D; Browne J: Using the EQ-5D as a performance measurement tool in the NHS. Department of Economics, Discussion Paper Series No. 09/03* *(4) Buckwalter JA, M. H. (1998). Articular cartilage: degeneration and osteoarthritis, repair, regeneration, and transplantation.* **APPRAISAL/ OBJECTIVES REMIT:** *To appraise the clinical and cost effectiveness of total hip replacement and surface replacement within their CE marked indications for the treatment of pain resulting from end stage arthritis of the hip*.* We suggest the addition of "**primary**" total hip replacement.	The intervention has been specified as primary total hip replacement' (See table).
	MHRA	None	Comment noted.
	Stryker UK Ltd	Any additional comments on the draft scope The comparator definition is undefined and may be better as "non surgical management" which should be consistent throughout the guidance.	The comparator for people who are suitable for THR but not resurfacing arthroplasty has been amended to non-surgical management.

Section	Consultees	Comments	Action
	Warwick Evidence	• Appendix A mentions that: " National Joint Registry was set up by the Department of Health and Welsh Assembly Government to collect information on all hip, knee, ankle, elbow and shoulder replacement operations and to monitor the performance of joint replacement implants". This resource has not been given a bibliographic reference, however it is very likely to represent the best source of patient level information that can be used to address this technology assessment	Comment noted. Scopes for technology appraisals do not contain a bibliography.

The following consultees/commentators indicated that they had no comments on the draft remit and/or the draft scope

None

NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

Health Technology Appraisal

Total hip replacement and resurfacing arthroplasty for the treatment of pain or disability resulting from end stage arthritis of the hip (Review of technology appraisal guidance 2 and 44)

Response to consultee and commentator comments on the provisional matrix of consultees and commentators

	Proposed consultee:	**Proposal made by:**	**Action taken:**	**Justification:**
1.	**Arthroplasty Care Practitioners Association** The Arthroplasty Care Practitioner Association is not listed:acpa-uk.net	**Association for Perioperative Practice**	Added	This group meets the criteria for inclusion.

2.	**Health Protection Agency** Health Protection Agency not on list – Important for wound site surveillance data following joint replacements. Each orthopaedic dept in U.K has to undertake statutory surveillance on hip replacements for at least one calendar quarter.	**Association for Perioperative Practice**	Added	This organisation meets the criteria for inclusion.
3.	Will patient liaison groups that exist within some of the large professional groups be consulted?	**Association for Perioperative Practice**	n/a	NICE consults with the parent organisations. Where we are aware of a patient liaison group we will try to ensure that they are aware of the appraisal
4.	**Comis Orthopaedics and Finsbury Instruments** These companies no longer exist	**Medicines and Healthcare products Regulatory Agency**	Removed	