MHRA			
Page	Text	Com Comment	AR Comment
2.1. Background – page 18	*However, in June 2012 advice about follow-up of patients receiving a MoM articulation changed as a result of research on complications. The Medicines and Healthcare products Regulatory Agency (MHRA) issued a medical device alert and recommended that clinicians should perform appropriate follow-up.*	Suggested changes to improve accuracy as follows: The Medicines and Healthcare products Regulatory Agency (MHRA) issued a medical device alert **in June 2012, updating its original patient follow –up advice of April 2010**.	Suggested change made – please see erratum document
2.4.2.2 RS vs.THR- page 22	*Category A: CePoM (Cemented-cemented with a polyethylene-metal articulation) (125,285 patients)* *• Category B: CeLPoM (Cementless-cementless with a polyethylene-metal articulation) (37,874 patients)* *• Category C: CeLCoC (Cementless-cementless with a ceramic-ceramic articulation) (34,754 patients)* *• Category D: HyPoM (Hybrid (cementless-cemented) with a polyethylene-metal articulation) (28,471 patients) and* *• Category E: CePoC (Cemented-cemented with a polyethylene-ceramic articulation) (12,075 patients)*	Current conventional description of the type of the THRs is head material/cup, not the other way around. Therefore suggested changes as follows (These need to be changed in thought out this document.): Category A: Ce**MoP** (Cemented-cemented with a **metal on polyethylene** articulation) (125,285 patients) • Category B: CeL**MoP** (Cementless-cementless with a **metal on polyethylene** articulation) (37,874 patients) • Category C: CeLCoC (Cementless-cementless with a ceramic **on** ceramic articulation) (34,754 patients) • Category D: Hy**MoP** (Hybrid (cementless-cemented) with **a metal on polyethylene** articulation) (28,471 patients) and • Category E: Ce**CoP** (Cemented-cemented with a	We did not follow convention; we think the system used is easily comprehensible

		ceramic **on** polyethylene articulation) (12,075 patients)	
3.1.4.2. Summary of NICE TA44…- page 34	*However, in June 2012 advice about follow-up of patients receiving a MoM articulation changed*	Perhaps it needs to reference original MHRA advice. Therefore : However, in June 2012 advice about follow-up of patients receiving a MoM articulation **updated from the original advice of April 2010**.	Suggested change made – please see erratum document
3.1.4.2. Summary of NICE TA44… - page 34	*Follow-up, if indicated, should consist of both imaging (MRI or ultrasound) and blood metal ion tests (ion level >7 parts per billion (PPB) indicates potential for soft tissue reaction). Then revision should be considered if imaging was abnormal and/or blood metal ion levels were rising.*	The correct units are as follows: ….tests (ion level >7 parts per billion (**ppb**)…	Suggested change made – please see erratum document
3.1.4.3. Summary of MHRA alert advice – pages 34 and 35	*Asymptomatic: follow-up according to local protocols - no need for investigations unless cause for concern about implant*	It would be more accurate if modify as follows: Asymptomatic: follow-up according to local protocols - no need for investigations unless cause for concern about **cohort or patient becomes symptomatic**	Suggested change made – please see erratum document
3.2.1.3 Hip replacement – page 41	*Cemented prostheses are held in place with bone cement and generally consist of three components, a femoral stem, a femoral head (modular) and an acetabular cup.*	Some cemented acetabular cups have a metal backing/shell. Suggested change: Cemented prostheses are held in place with bone cement and generally consist	Suggested change made – please see erratum document

		of three components, a femoral stem, a femoral head (modular) and an acetabular cup, **which may consist of two parts, an external metal shell and a liner**.	
3.2.1.4. Hip replacement with components made of different materials – page 43	*Table 1. THR and RS articulation and fixation type combinations*	Table 1 needs to have consistent terminology for both THR and RS. The materials for head, cup and shell liner are shown. For instance, for THR, the first four boxes under "Acetabular cup shell" may say "metal" for all four cases and under "Accetabular liner"may say "Polyethylene", "Ceramic" or "Metal". For the RS, material for heads, acetabular cup shell and liner need to be shown.	Suggested change made – please see erratum document
3.2.1.4 as above – page 48	*MoM articulations provide a hard bearing surface, however due to their reportedly high revision rate they are no longer recommended by the MHRA for use in the UK (reference MDA/2012/036) (see Figure 7).*	This statement is incorrect. MHRA has not made any recommendations about the use of these devices, it has only provided advice on patient follow up. We would suggest: MoM articulations provide a hard bearing surface, however due to their reportedly high revision rate, **the MHRA has made recommendations for following up patients implanted with such devices** (reference MDA/2012/036) (see Figure 7).	Change made Please see amended text in erratum document
As above – page 49	*Head size is important because in simulator tests larger head sizes give lower wear due to the boundary lubrication regime becoming more favorable.[54] Therefore, implantation of large diameter MoM bearing surfaces on stemmed prostheses became*	Please Note: Large diameter heads are also known to be less susceptible to dislocation.	We were not able to include head size in our analysis - this was not part of our scope

	popular on the basis of such evidence which suggested that they should result in less wear and thus lower failure rates. They seemed particularly appropriate for younger, more active patients.		
As above- page 50	*The MHRA recommendation states that patients with MoM bearings and a painful hip joint should have yearly measurements of serum ion concentrations and radiographic assessment to exclude adverse local tissue reactions as the source of pain.*	It is the metal ion levels that need to be measured. Suggested change: The MHRA recommendation states that patients with MoM bearings and a painful hip joint should have yearly measurements of **whole blood metal** ion concentrations and radiographic assessment to exclude adverse local tissue reactions as the source of pain.	Suggested change made – please see erratum document
3.2.2 Summary of hip resurfacing - page 51	*According to clinical advice, in NHS practice the metal cup is generally cementless and the femoral metal head can be cemented or cementless.*	Perhaps need to have reference on this clinical advice for cementless implantation.	We refer to the options very clearly in our background section. Our comparative data show that a number of different types of combination are used in NHS practice
As above- page 52	*Johnson and colleagues reported 100% implant survivorship at five-years follow-up in 93 patients having RS identified using narrow selection criteria.*[72] *The selection criteria*	It is not clear what is meant by "large femoral head" here, as RS is normally associated with large femoral heads. Perhaps need to add larger	This query should be referred to Johnson and

	included avoiding RS in patients with large femoral head or neck cysts, ensuring proper seating of the femoral component band ensuring an optimal thickness of the cement mantle.	than a certain diameter of head to clarify this point.	colleagues
5.2. Summary of national registries – page 65	*The three national registries report long term data with compliance proportions of 83.2% (NJR), 98.5% (SHAR) and 93.9% (AOANJRR). Revision rates are reported as 88.6%, 95% and 95% at nine, 10 and 10 years respectively.*	Clarity is needed on the annual report year for compliance and if revision rates are for THR, RS or overall and annual report year.	Suggested change made – please see erratum document
Johnson & Johnson			
	Johnson & Johnson is encouraged by the level of similarity of the findings of the work undertaken by the Assessment Group and the findings of our own modelling presented in our manufacturer submission, namely that THR is a cost effective intervention which dominates hip resurfacing and is associated with significant, sustained quality of life benefits.		No comment required
	It is felt that the overall findings of the assessment report are strengthened by the level of corroboration achieved when		No comment required

	compared to the work undertaken for our submission and model, despite some differences in modelling approaches, data sources and assumptions.		
	We are therefore in broad agreement with the Assessment Group's findings; specifically the overarching conclusion that while there is confidence that THR dominates hip resurfacing in all circumstances, a high level of uncertainty around comparisons between classes or categories of THR, such as type of fixation or bearing, make the validity of such comparisons questionable. This is primarily due to the high level of uncertainty around cost-input parameters between categories and the QALY-gains being largely the same in each case.		No comment required
	It is our belief that NHS reference cost data lacks validity when used in the base-case analysis and the use of manufacturer list prices (per NICE protocol) and costs gleaned from NHS Supply Chain underestimate the significant discounts available to the NHS, consequently overestimating the		No comment required

	cost of prostheses overall and should not be used in the base-case.		
	We question the validity of using NHS Supply Chain in the base case analysis. According to information supplied to us by NHS Supply Chain directly, it is their belief that only around 1 in 5 of hip prostheses sold in England is procured through them. We know that for some implants this would be well under 1 in 10 procured through that route. As a result, the cost estimates are biased towards implants with a higher share of the market and cannot be relied upon to make any robust conclusions on prostheses costs.		Considerable effort was made to establish reliable costing and NICE technical staff advised during this process. The over-riding difficulty is that Trusts negotiate individually with device providers so that an analysis of cost data from many different Centres would be required, this has never been done as far as we are aware and would require considerable time to accomplish. A further difficulty is that manufacturers consider such information to be

			confidential (CIC).
	It is important to recognize the total cost of intervention is much broader than simply device (prosthesis cost). Indeed, the total procedure cost comprises theatre time, staff costs, and ward stay, in addition to the cost of the device and additional consumables.		No comment required
	Based upon the results of the DePuy Synthes time-in-motion study, a significant degree of variability was observed across the parameters that have a direct impact on procedure times for prostheses implants. This finding highlights an overarching issue inherent in extrapolating micro-level data, in order to reach macro-level conclusions. This was particularly true for the time-in-motion study (see DePuy Synthes submission, Appendix H, pgs. 233-235), which demonstrated that a wide range of factors beyond prostheses selection had a significant impact on procedure times and thus, costs incurred by the Trust.		The study was listed as AIC so we were unable to reference it in our report/model
Wright Medical Technology, Inc.			

	If RCTs with less than 100 patients and cohort studies were included, it is possible that the results would be different.		No comment required
	The Assessment Report further reports that "Using the NJR data, we found that 97% of those undergoing THR had remained without a revision by 9 years, whereas only 89% of those undergoing RS had not had a revision by the same stage." It is likely that all RS designs were included in this calculation. It is also likely that the survival value would be higher if recalled RS designs were excluded from the survival calculation.		Please see Assessment Group addendum document for assessment of impact of the recalled RS design and of the Wright RS design
British Orthopaedic Association Patient Liaison Group			
	We would like to extend our congratulations to the authors for the thoroughness of the MTA		Thank you
	is there an opportunity for a Patient Version (much reduced and similar to the NJR's version) as there are now many well informed patients ?		NICE will produce this document
18 objectives	The objectives are quite precise:- - The main aim was to undertake a clinical and cost-effectiveness		The follow up treatments, such as provision of

	analysis of different types of THR and RS for the treatment of pain and disability in people with end stage arthritis of the hip. Specific objectives were the following: - To compare the clinical and cost-effectiveness of: - Different types of primary THR compared with RS for people in whom both procedures are suitable - Different types of primary THR compared with each other for people who are not suitable for hip RS Given these objectives, it's not surprising the full patient journey has been omitted and the focus is just on the replacement operation as it's unlikely these would vary according to whether RS or THR is the intervention or according to type of prosthesis. However it's likely that the provision – or lack – of physio, during and after stay in hospital, pre-op advice and preparation etc. can make a lot of difference to outcomes. So if there is an opportunity to state on behalf of patients that research has indicated that these additional interventions can contribute		physiotherapy, may affect the future requirements for revision. Unfortunately this data is not recorded within the NJR and so could not be incorporated into the present analyses

	considerably to outcomes, reduce length of stay and the focus on types of prosthesis is missing an important aspect of the intervention (in the section Recommendations for Research – page 335).		
224 and F economic assessment	The models are a very thorough piece of work and it is great that the NJR and PROMS data make the modelling work possible. The many and varied analyses are very useful and informative. However, it appears that not as much effort has been put into costing out the operations and hospital stays. They concentrate on one main cost variable – namely the cost of the prostheses. There are many other high cost items for both THR RS as an intervention and including these may well change the results for some of the cost effectiveness analyses and outcomes.		Considerable effort was made to establish reliable costing and NICE technical staff advised during this process. This effort may not be reflected in the report. The over-riding difficulty is that Trusts negotiate individually with device providers so that an analysis of cost data from many different centres would be required, this has never been done as far as we are aware

			and would require considerable time to accomplish. A further difficulty is that manufacturers consider such information as commercially confidential
	Cost of the surgery for both THR and RS (ref Table 76 and associated text) is taken from standard sources. There is a body of literature that states with good evidence that the NHS tariff and standard sources of the cost of the surgery itself is not a reasonable representation of the cost of THR. The evaluation has used costs that are easy to access may not be entirely appropriate; surgical time can vary up to 20 minutes or so for cemented vs. cementless operations. There may also be other factors associated with the type of primary and revision replacement operation used and prosthesis used that will impact and cause variation in (costly) theatre time.		Information for the separate categories A to E is not available; while these may classified into a cemented and uncemented groups, we are not sure if the generic costs mentioned would be appropriate
	Furthermore, it is believed that it is relatively easy to get data on theatre time for the operations and a standard cost for		As mentioned above, considerable effort was made to

	theatre time by the minute. Even if primary data are not available to the Warwick team, they should use sensitivity analysis to test the relative impact of a variety of the costs on the analysis. Varying theatre time (e.g. 20 minutes) for the different operations would test the impact of this. Given the immense effort spent on the modelling and analysis of NJR data, it was surprising to see the very limited attention to resource use and costs used in the evaluations and limited sensitivity analysis using some informed assumptions.		establish reliable costing and NICE technical staff advised during this process. This effort may not be reflected in the report. The over-riding difficulty is that Trusts negotiate individually with device providers so that an analysis of cost data from many different centres would be required, this has never been done as far as we are aware and would require considerable time to accomplish. A further difficulty is that manufacturers consider such information as commercially confidential

	Length of stay is another variable that did not seem to have been explored - it may be that the mean/median is standard no matter what operation and would have no significant impact on the comparison between the different operations/prostheses. But this was not discussed in the report and there was no sensitivity analysis.		This would have required specific primary data collection by THR category and RS which was not possible in the time available
	Is there a case for RS evaluations being a preferred intervention for a certain type of patient, despite the outcomes of these analyses?		This is certainly a possibility but was beyond our remit; and will be discussed by NICE at the committee meeting. Finding the effectiveness of the best performing RS types when used in the best responding patients (e.g. young active males?) might reveal the patient subgroup(s) and RS prosthesis in which RS competed with THR

			prostheses in a cost effective way. This would best be done in an RCT because of the strong selection biases for intervention that are inherent in the NJR database
335 research recommendations	There is a difficulty in doing such trials under Recommendation No. 1 because manufacturers are constant in their striving to modify devices driven by competition and need to increase prices - long term studies are unlikely to be achievable and useful.		Nevertheless they remain desirable
	Why are so many devices not supported by ODEP ratings?		Question for the ODEP rating agency
	From the long -term results, is it possible to make the common cemented stem and poly cup the default for patients aged 80+? This may limit surgeon choice but may shift the emphasis onto the young adult for good clinical evidence.		This is certainly a possibility but was beyond our remit; and may be discussed by NICE at the committee meeting
Colin R Howie Cons Orth Surgeon			

Vice Pres elect **British Orthopaedic Association**			
	As ever NICE (and specifically the team undertaking this analysis) are to be congratulated on the thorough and detailed work that has taken place in this assessment. An enormous amount of excellent analysis has been carried out, any subsequent comments below should be taken as such; are meant to be helpful; and not direct criticism.		Thank you
introductory section.	The description of the patient group is apt but underlies fundamental problems in diagnosing "osteoarthritis" which is, as noted briefly, a collection of end state symptoms, signs and disparate pathological features that are not caused by a currently diagnosable inflammatory disorder (rheumatoid, itself defined by a committee) and in many cases may be due to a variety of as yet unidentified genetic metabolic traumatic or mechanical issues. Perhaps the wording on page 28 goes some way to trying to tease this out yet somehow manages to imply that it is one, understood,		We recognized that OA as a diagnosis of exclusion (as described by this commentator) is problematic

	condition. An understandable but misleading overstatement. This is further highlighted when the difficulties of correlating the radiographic appearances with symptoms severity of symptoms and the benign effects of age are discussed. Though not formally part of this assessment I would suggest a little more is written in this section, there is a widespread belief that radiographs are the arbiters of benefit. Management based on radiograph alone is not supported in the NICE document on OA hip, this paragraph could do with a little expansion from the previous guidance.		
31	penultimate paragraph the cost of conservative treatment is mentioned.		No comment required
Page 35 3.1.4.4	second paragraph again mentions opiates however I believe this relates to codeine type opiates not buprenorphine and other highly addictive narcotics recently available for home use specifically for the management of patients with severe pain secondary to terminal cancer. This is an important distinction, few patients come off these strong opiate		Interesting point thank you

	drugs after successful hip replacement removes their reason for pain. When using very strong opiate analgesics for benign pain this is now known to create dependency and increase attendance at GP surgeries with several recent reviews on their use for pain from a benign condition which in this case is reversible. I am not aware of proper papers on the use of strong opiates for the longer term management of single joint arthritis (which is reversible by surgery). Yet there use has become widespread. This is neither the subject of this assessment nor is their sufficient evidence at present to give definite advice however the use of the word "opiate" could be taken to construe that the use of buprenorphine etc. should be tried before surgery, this would be a derogation from evidence based medicine. Indeed there is current advice that they are avoided as they are known to increase visits to the general practitioner and have considerable side effects with concerns about driving ability. Could I suggest that the word opiate is		

	modified to minor opiate (personally I would suggest that patients are referred for surgery before they are considered for strong opiates for isolated joint disease…. But then I have an inherent bias!		
Figure 1	algorithm looks satisfactory however I would suggest in box 1b simple analgesia. Actually the evidence for this is thin and the evidence for strong opiates thinner.		Useful comment - thank you
Figure 2	most patients are followed up at 6 weeks then 1 year around the country, very few are reviewed at day 10 as noted here. After subsequent review at one year most units only follow patients at 5 yearly intervals unless there are problems such as the MoM recall. After a certain age follow up is often discontinued (around75) as the patient is likely to have increasing difficulty attending and less likelihood of revision. There is considerable variation around the country with many commissioners only allowing one postoperative visit.		Useful comment – thank you
Section 3.2.1.5	this section is surprisingly short and fails to mention the problems of the		We made a decision not to include head

	interaction between the head size sliding distance (volumetric wear) and thickness of bearing surface all of which interact an d cause problems. This section needs expanded. In the evidence section table page 164 there is reference to bigger heads causing more wear from the English NJR. (Haven't checked may refer to MoM only). Appreciate that head is a confounding factor in most if not all studies however it should perhaps be mentioned that patients come in many sizes with outside cup diameters from 38 to 60+ and that this places practical constraints on the size of head that can be inserted and the type of bearing surface available (in the smaller cup sizes only polyethylene may be available and head size may be as little as 22 mm for practical limitations.		size in our comparison as were interested in RS as a whole group. The commentator might be interested in the Smith paper published in the Lancet in 2012 which covered this topic
Section 3.2.3.1	dislocation first paragraph needs a range of dislocation rates for revision.		In the time available we were not able to extract these data from the NJR
	Second paragraph the most common cause for early dislocation is mal-positioning, late dislocation wear and soft tissue problems become more		Useful comment – thank you

	common.		
Section 3.2.4	one other reason for increased revision rates is the metal on metal problem, this should be highlighted. Perhaps the significant increase in overall numbers is due to catch up on waiting lists and a short comment on the overall rate of hip replacement compared with other European countries should be made.		As mentioned above, in the time available we were not able to extract these data from the NJR
Section 3.4	again OA is what is left after the inflammatory arthropathies have been removed. It is really an end stage pathological state rather than a diagnosis (feel free to ignore this comment).		See comment above regarding problems with OA diagnosis
National registry	The sections based on national registry results are a welcome feature as it moves the information from full randomized trial ***efficacy*** to real world ***effect***. The data has been used well and effectively recognizing its limitations and accepting the undoubted knowledge they impart.		Thank you
Page 186	the deviation from scope is entirely appropriate.		Thank you
Method	The methodology is beyond my personal		No comment

	knowledge but seems overall appropriate the assumptions reasonable and the various categories sensible (with the caveat about head size mentioned earlier).		required
General	The Industry responses are interestingly variable but understandable.		No comment required
General	The DePuy paper comes to the same overall conclusions however they support a variety of implants in their model. We should not be surprised and they do make several valid points about the learning curve (surgeon's abilities) and the patient groupings are homogeneous. That it can be criticized is perhaps a reflection of the smaller amounts spent on implants compared to drug marketing.		The NJR does provide information regarding grade of surgeon but this is essentially dichotomous whereas surgeons experience will be more continuous. Smith (Lancet 2012) found no difference in outcome when using the limited NJR information about different surgeons
General	The issue raised by DePuy (the effect of surgeon's skills) raises questions recently considered in papers from the Australian register about how many of		These issues are clearly valid, however analyses are limited by the

	one particular procedure needs to be done before competence is gained. There are many surgeons who do relatively few procedures extremely well but stick to one implant. There are some high volume surgeons who have not made a good implant selection so their results are less than would be expected. Surely we can say that most surgeons should stick to one implant.		lack of information in the NJR (see response above)
General	As there is little clinical difference between groups (other than resurfacing) and that the advice is made on economic grounds between the THR groups (and the differences in cost are less than the use of LMWH as prophylaxis) there will inevitably be continuing debate. However the lack of clinical difference actually makes the point that a surgeon should stick to one particular implant.		This will be a decision for the NICE committee to consider
Comments on Technical Content by James Richardson RJAH Orthopaedic Hospital/Keele University			
	It is a difficult problem to use observational data to come to an accurate conclusion of what is best implant.		We agree and recommend that an RCT is desirable. We consider that

			appropriate caveats in this respect are included in the report.
2.1 Background	IA group of patients require repeated revision surgery and this becomes increasingly demanding of expertise, equipment and higher cost. Also complications such as fracture around the stems of hip replacements in the elderly is a difficult complication to manage with generally longer in-patient stay and medical care. Likewise the costs of treating infection can be high. These different problems steadily increase for patients who have a hip replacement initially at a young age. Some patients are left with disability following failed hip revision that can require high cost maintenance. Additionally, even patients of high activity levels will be selected for different prostheses irrespective of age. Age is not therefore a complete control for activity level which correlates with wear rates and subsequent failure. These younger patients therefore often seek an innovative solution that may improve long term outcome. The surgeon is also seeking a better solution and will likely be less experienced with the innovative		We agree that age is not a complete proxy for activity and that this is an issue particularly for the comparison of RS with THR using the NJR observational data. The amount of use the hip replacement receives is an unknown quantity; the NJR data on BMI, that might be a useful surrogate for activity, was so incomplete it did not offer a usable alternative. There is considerable complication inferred in the

	design, and so the learning curve of the surgeon also contributes to a higher failure rate. Inherently this group of active and motivated patients have a high mileage and therefore higher wear and so a high failure rate. Thus innovative designs suffer from an 'innovation bias'. Patients want good function from their hip. This is crucial. A well functioning hip will wear faster than one that has restricted use. The age of a second-hand car is not necessarily a reflection of the mileage it has done. Our UK Joint Registry does not collect data on the amount of use a particular patient has had from their hip.		proposal / concept that a well-functioning hip will wear faster since it implies that, all other things being equal, earlier revision is an indicator of a superior implant
Page 21 2.4.2 Cost Effectiveness Results 2.4.2.2 RS vs THR	This comparison appears to miss some of the complexities of costings. Theatre time and in-patient stay vary between RS/THR and Revision THR as well as the cost of prostheses. Generally revision following THR requires a revision prosthesis (more expensive in terms of theatre time and implant cost) whereas following RS requires a primary THR. Has this difference been included in the analysis? The 3 factors of implant, in-patient stay and theatre time each comprise about a third of the cost of a joint replacement. Theatre time and in-patient stay vary quite widely		Thank you for this comment. We were unable to collect costing data in more detail

	between institutions and also over time as new techniques of rapid rehabilitation have come into effect. (need to find a reference to support this)		
Page 2.4.2.3 THR vs THR	One Category that is missing and is important is the cementless stem with a cemented polythene/ceramic articulation. This is known as a reverse hybrid and in some studies gives particularly good results, for example the Norwegian Registry.		We have included reference to the reverse hybrid hip in our background and systematic review. The categories we investigated further were based on frequency of use
Page 32 3.1.3.3 Variation in services and uncertainty about best practice	Unfortunately, inaccuracies in data collection can lead to the quoted low price of £560 in Tower Hamlets. For example reporting of reduction of a hip dislocation as a hip revision in some units. Also, patients having hemi-arthroplasty for hip fracture may have a very low cost implant (less than £200) but be coded as total hip replacement. This will contribute to the apparent significant range in cost.		Thank you for this useful comment
Page 44 Table 3 Combination of bearing/articulation surface and fixation method by	Table 3 appears to omit the reverse hybrid of a cementless stem on a cemented cup. This table does not recognise the variations between different designs of the same fixation method. This table fails to account		As mentioned above, we have included reference to the reverse

frequency as reported in NJR 2010-11	for the introduction of cross-linked polythene designs as a separate group despite evidence for there being less wear with cross-linked polythene **(TO INSERT REF)**		hybrid hip in our background and systematic review. The categories we investigated further were based on frequency of use
Page 49 Paragraph 4	Are metal on metal prostheses included as a separate group in this report? In view of the fact that the ASR implant has been removed both as a resurfacing and as a total hip replacement due to its poor results have their results been removed from these relevant groups? I found no evidence in the report that this is the case.		The RS ASR were included in the RS population. Please see addendum
Page 52	There is a wide variation in outcome depending on patient factors, surgical factors, centre factors and implant itself. These interactions are complex. It would be difficult to predict the outcome of a unit changing from an implant they have become accustomed to using. A different implant would not necessarily give the results achieved by others.		No comment required
Page 83	Harris hip scores and WOMAC function scores do not differ with cup designs nor the use of cross-linked polythene. There is widespread adoption of these new polythenes and an improved survival is		Interesting additional comments thank you. However is 'The

	predicted in the long term from the reduction in wear rates, but this is unlikely to be seen before 10 years of use. In ceramic on polythene for the younger patient 9 year follow up is relatively short and so the importance of a non-scratchable surface may become evident many years later. Implant dislocation is particularly troublesome for patients as it destroys confidence in their hip replacement and greatly limits their activities. This aspect is little studied. The benefit of cemented over cementless cups is therefore important even if it has little effect on revision rates and cost. Wear becomes important in the younger patient if it leads to osteolysis. Bone loss limits the options for revision and re-revision become more difficult and more costly usually with lower levels of function. (Lower function actually improves survival of the implant). Eventually loss of bone that is either major on the acetabular or femoral side will lead to a situation where hip revision becomes impossible.		benefit of cemented over cementless cups is therefore important even if it has little effect on revision rates and cost.' An evidence based comment?
6.2.4	This good randomised controlled trial found reduced osteolysis with ceramic on ceramic		We agree that good RCT evidence is

	and better survival with use of cementless fixation of cup and stem. This is strong evidence as it requires a randomised trial to avoid the error of National Registries in being only an observational report and affected by the 'innovation bias' in younger/active patients.		important and is relatively lacking in this field
6.2.6	There is evidence in a paper from Bristol on mortality *BMJ* 2012;344:e2383 doi: 10.1136/bmj.e2383 (Published 3 April 2012) I draw attention to the paper from the Netherlands demonstrating that the main cost driver was not just the cost of implants, but also in-patient stay and ward costs. Rapid rehabilitation techniques have halved in-patient stay in recent years but this is likely to be independent of all hip designs.		We briefly have examined the potential usefulness of the "*BMJ* 2012;344:e2383 doi: 10.1136/bmj.e2383 (Published 3 April 2012)" data for cost effectiveness analysis. After considering this we think that the uncontrolled strong patient selection biases probably lead to unreliable mortality estimates; please see addendum
161	In paragraph two the finding that cementless stems and cups are at a significantly lower risk of revision than cemented is a consistent finding in Finland.		Thank you for this useful comment

	In Sweden the opposite is found but it should be noted that Sweden has a long history of focussing on the skills of cementing and has never had a significant proportion of patients being treated with cementless hip replacement. The different findings from different Registries probably reflect the pattern of skill development in the two different countries.		
172	In the last paragraph what is missing in this discussion is the place of cross-linked polythene. This has been shown in this report to have lower wear rates and would benefit from separate analysis to see whether the extra costs of those implants is reflected in appropriate cost effectiveness.		As mentioned above, we have included reference to the reverse hybrid hip in our background and systematic review. The categories we investigated further were based on frequency of use
176	The idea of using propensity scoring to construct a matched sample of THR patients that can be compared to RS patients is good. However, why was the propensity score based on age and gender only? A surgeon may base the choice between RS and THr on many things that are not captured by age and gender alone. The idea of propensity scoring is to account for many covariates, not just two, and the		Age and gender were chosen because analyses indicated that they both affected revision rates. There were indeed very many co-variates in the NJR

	NJR contains many covariates that would be useful. For instance, BMI and surgeon grade. By using the many covariates reported in the NJR, a better matching cohort would be constructed.		however their influence on revision was uncertain and their exploration could have been almost limitless and inclusion of more would reduce the yield of matched populations. The NJR data for BMI was very incomplete rendering it unusable, while Smith (Lancet) used the NJR information about surgeons and found this had little affect on outcome
186	Our joint registry identifies the surgeon as one of the larges factors in predicting outcome following hip replacement. This is a combination of the infection rate in the centres used by that surgeon, the implants available, the rehabilitation team, the pattern of referral and the skill of that surgeon. This study fails an opportunity to use this predictor in matching patients.		Please see comment above. Many factors may be potentially important; the time constraints for the report did not allow a fully systematic exploration if these.

	Each innovative design of implant has a period of interest and high use which later settles to an appropriate level. RS is no longer a widely used option, as stated in the report. Of great interest to patients and surgeons are the groups C, D, E and the two groups of similar numbers to E but unidentified in this report. It is therefore innapropriate to pool these THR groups together, and also a lost opportunity.		The A-E categories were not pooled except for the comparison with "generic" RS. Since each of the categories differed little from each other in revision rates it appeared logical to combine for the THR versus RS comparison
192	Most hip surgeons would be interested in analysis of patients under the age of 50. This is the group that is most demanding in terms of having high activity and also having longest life expectancy. This group will not simply have one revision in their lifetime, but probably several. The committee may consider advising that all patients under 50 years be invited to join a randomised trial where a new design is to be compared to the 'best alternative' in the practice of that surgeon. The national joint Registry could be charged with the duty of providing the outcomes for these patients, and so allowing a large number and low cost study.		See AG addendum for results for a population aged 50 years. We agree strongly with the suggestion that "*all patients under 50 years be invited to join a randomised trial where a new design is to be compared to the 'best alternative' in the practice of that surgeon*."

	Figure 39 It is difficult to predict the future. The Warwick Evidence prediction of 20 years survival for a total hip replacement is of a 12.9% revision rate with age averaging around 60 (Fig. 36). This seems very unlikely considering the long term results are already known for Sweden and presented in Table 72 where in the 50 to 59 age group the revision rates are 30%. In the Swedish graph the third phase of the bathtub can be seen with a steepening of most curves around 8 years. UK data does not allow this third phase to be identified and so the extrapolations of the current UK data are likely to be inaccurate.		Fig 36 shows the "observed" (i.e. KM analysis) of revision for propensity matched populations. The average age is 60 but this is not a prediction and the data only goes to 10 years. Fig 38 shows predicted revision at 20 years is about 12.9%. We assume "Table 72 refers to Figure 72. The Swedish registry (Fig 72 in the report and reproduced below) does indeed show that revision rates increase after the NJR observation period and this is why we fitted a bath tub model. It is true that with 20 years of data, the

			extrapolation would be more reliable; however it is worth pointing to the consultee's comment about innovative advancement in the context of the Swedish data which includes older generation / less innovative devices than does the NJR and so we might expect better performance from the latter
Summary	It may help the Committee to understand this particularly high rate of failure among younger patients who are otherwise fit and well. This is shown in Figure 72 (page 301) from the Swedish data. For this reason patients and surgeons are seeking advice on which implants are best used in the younger patient. This was a significant reason for surgeons choosing the resurfacing in the younger patient as evidenced in the 14 year age difference beween RS and THR in Table 58, page		Thank you for this comment

	196. In the past it was also a reason for surgeons trying the uncemented stems in younger patients. Due to Registries having no control of allocation of choice of implant this has led significant bias through all Registries. Newer implants are used for the younger patients, but then appear to have a correlation with more rapid failure.		