MHRA comments on the Assessment Report - Hip replacement (total) and resurfacing arthroplasty [ID540]

Section	Text	Comments
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**.
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 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**.
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**)…
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**
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 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.
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).
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 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.*	Please Note: Large diameter heads are also known to be less susceptible to dislocation.
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*	It is the metal ion levels that need to be measured. Suggested change: The MHRA recommendation states that patients with MoM

	radiographic assessment to exclude adverse local tissue reactions as the source of pain.	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.
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.
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 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.*	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 than a certain diameter of head to clarify this point.
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.