Medical Device Alert

Ref: MDA/2012/036 Issued: 25 June 2012 at 11:00

Device

All metal-on-metal (MoM) hip replacements

Problem

The MHRA is issuing updated information and advice about the follow-up of patients implanted with metal-on-metal (MoM) hip replacements.

Action by

- Medical directors.
- Orthopaedic departments.
- Orthopaedic surgeons.
- Staff involved in the management of patients with joint replacement implants.

CAS deadlines

Action underway: 25 July 2012

Action complete: 28 August 2012

Action

Put **updated** systems in place for the follow-up and investigation of patients implanted with MoM hip replacements (see appendix).

Note: The recommendations in this Medical Device Alert (MDA) replace the advice previously given in MDA/2010/033, MDA/2010/069 and MDA/2012/008.

Problem

The majority of patients implanted with MoM hip replacements have well functioning hips and are thought to be at a low risk of developing serious problems.

A small number of patients implanted with these hips may, however, develop progressive soft tissue reactions to the wear debris associated with MoM articulations. The debris can cause soft tissue necrosis and adversely affect the results of revision surgery. The MHRA's clinical orthopaedic experts are of the opinion that early revision of poorly performing MoM hip replacements should give a better revision outcome.

Following extensive consultation with the MHRA's clinical orthopaedic experts, the MHRA is issuing this **updated** advice to healthcare professionals involved in the management of patients implanted with MoM hip replacements. This advice updates the recommendations for patient follow-up previously given in MDA/2010/033, MDA/2010/069 and MDA/2012/008. In particular it incorporates updated advice on the duration of follow-up of symptomatic patients implanted with:

- MoM hip resurfacing (no stem)
- stemmed MoM total hip replacements that have a femoral head diameter <36mm.

The MHRA is continuing to monitor the situation in consultation with orthopaedic experts and may issue further advice.

Action

Follow the advice given in the table in the appendix for the management of patients implanted with MoM hip replacements.

The table in the appendix identifies four groups of MoM hip replacements:

- MoM hip resurfacing implants
- MoM total hip replacements with a head diameter <36mm
- MoM total hip replacements with a head diameter ≥36mm
- DePuy ASR™ hip replacements comprising:
    - ASR™ acetabular cups for hip resurfacing arthroplasty or total hip replacement
    - ASR™ surface replacement heads for hip resurfacing arthroplasty
    - ASR™ XL femoral heads for total hip replacement.

The table provides recommendations for follow-up of both symptomatic and asymptomatic patients implanted with MoM hip replacements in each of the above four groups. These include advice on appropriate imaging (Metal Artefact Reduction Sequence (MARS) MRI / ultrasound), blood metal ion levels and situations where revision may need to be considered.

Measurements of cobalt or chromium ions should be carried out:

- in England, Northern Ireland or Wales, by laboratories participating in the Trace Elements External Quality Assessment Scheme (TEQAS) - http://www.sas-centre.org/home.html
- in Scotland, by the Scottish Trace Element and Micronutrient Reference Laboratories - Scottish Trace Element and Micronutrient Reference Laboratory - http://www.trace-elements.co.uk/

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- Local authorities in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (Chief Executives)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Clinical governance leads
- Medical directors
- Nursing executive directors
- Orthopaedic departments
- Orthopaedic outpatient clinics
- Orthopaedic surgeons
- Outpatient theatre nurses
- Pathologists
- Radiology departments
- Radiology directors
- Risk managers
- Theatre managers

Primary care trusts

CAS liaison officers for onward distribution to all relevant staff including:

- Directors of public health
- General practitioners (for information only)
- NHS walk-in centres (for information only)

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2012/036** or **2010/004/019/291/007**

Technical aspects

Miss Feza Haque or Dr Crina Cacou
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7066 / 7338
Fax: 020 8754 3965
Email: feza.haque@mhra.gsi.gov.uk
crina.cacou@mhra.gsi.gov.uk

Clinical aspects
Dr Susanne Ludgate
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 6800
Fax: 020 8754 3965

Email: susanne.ludgate@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website http://www.mhra.gov.uk

Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group
Room 17
Annex 6
Castle Buildings
Stormont Estate
Dundonald BT4 3SQ

Tel: 02890 523 704
Fax: 02890 523 900

Email: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic

Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB

Tel: 0131 275 7575
Fax: 0131 314 0722

Email: nss.iric@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:
Improving Patient Safety Team
Medical Directorate
Welsh Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk

Appendix

Management recommendations for patients with metal-on-metal hip replacement implants

	MoM hip resurfacing (no stem)		**Stemmed MoM total hip replacements – femoral head diameter <36mm**		**Stemmed MoM total hip replacements – femoral head diameter ≥36mm**		**DePuy ASR™ hip replacements (all types)**	
	Symptomatic patients	**Asymptomatic patients**	**Symptomatic patients**	**Asymptomatic patients**	**Symptomatic patients**	**Asymptomatic patients**	**Symptomatic Patients**	**Asymptomatic patients**
Patient follow-up	Annually for the life of the implant	According to local protocols	Annually for the life of the implant	According to local protocols	Annually for the life of the implant	Annually for the life of the implant	Annually for the life of the implant	Annually for the life of the implant
Imaging: MARS MRI or ultrasound	Recommended in all cases	**No** - unless concern exists for cohort or patient becomes symptomatic	Recommended in all cases	**No** - unless concern exists for cohort or patient becomes symptomatic	Recommended in all cases	Recommended if blood metal ion levels rising	Recommended in all cases	Recommended in all cases
1st blood metal ion level test	**Yes**	**No** - unless concern exists for cohort or patient becomes symptomatic	**Yes**	**No** - unless concern exists for cohort or patient becomes symptomatic	**Yes**	**Yes**	**Yes**	**Yes**
Results of 1st blood metal ion level test	*Blood metal ion level >7ppb indicates potential for soft tissue reaction*		*Blood metal ion level >7ppb indicates potential for soft tissue reaction*		*Blood metal ion level >7ppb indicates potential for soft tissue reaction*	*If blood metal ion level >7ppb then second blood test required 3 months later*	*Blood metal ion level >7ppb indicates potential for soft tissue reaction*	*If blood metal ion level >7ppb then second blood test required 3 months later*
2nd blood metal ion level test	**Yes** - 3 months after 1st blood test if result was >7ppb		**Yes** - 3 months after 1st blood test if result was >7ppb		**Yes** - 3 months after 1st blood test if result was >7ppb	**Yes** - 3 months after 1st blood test if result was >7ppb	**Yes** - 3 months after 1st blood test if result was >7ppb	**Yes** - 3 months after 1st blood test if result was >7ppb
Results of 2nd blood metal ion level test	*Blood metal ion level >7ppb indicates potential for soft tissue reaction especially if greater than previously*		*Blood metal ion level >7ppb indicates potential for soft tissue reaction especially if greater than previously*		*Blood metal ion level >7ppb indicates potential for soft tissue reaction especially if greater than previously*	*If blood metal ion levels rising - further investigation required including imaging*	*Blood metal ion level >7ppb indicates potential for soft tissue reaction especially if greater than previously*	*Blood metal ion level rising indicates potential for soft tissue reaction*
Consider need for revision	If imaging is abnormal and/or blood metal ion levels rising		If imaging is abnormal and/or blood metal ion levels rising		If imaging is abnormal and/or blood metal ion levels rising	If imaging is abnormal and/or blood metal ion levels rising	If imaging is abnormal and/or blood metal ion levels rising	If imaging is abnormal and/or blood metal ion levels rising

Notes and guidance on next page

Appendix

Table footnotes:

- Blood metal ion testing to be in whole blood
- 7 parts per billion (ppb) equals 119 nmol/L cobalt or 134.5 nmol/L chromium

Guidance notes

- On the basis of current knowledge, this chart has been produced as a guide to the management of these patients. It will not necessarily cover all clinical situations and each patient must be judged individually.
- MARS MRI scans (or ultrasound scans) should carry more weight in decision making than blood ion levels alone.
- Patients with muscle or bone damage on MARS MRI are those of most concern. A fluid collection alone around the joint in an asymptomatic patient, unless it is very large can be safely observed with interval scanning.
- Local symptoms include pain and limping.