The Scottish Government

**CEL 23 (2012)**

**29 June 2012**

Dear Colleague

## METAL ON METAL HIP REPLACEMENTS – MONITORING ARRANGEMENTS

### Summary

1. This letter sets out the arrangements that must be followed for all patients with metal on metal hip replacements (MoM) and outlines the monitoring arrangements that are required.

### Background

2. A medical device alert was published on 25 June 2012 (updating the alert published on 28 February 2012) by the Medicines and Healthcare products Regulatory Agency (MHRA) (MDA/2012/008), making recommendations about the management and monitoring of patients with MoM prostheses (**Annex A**).
http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON155761?tabName=Scotland

3. Research evidence has been published in the Lancet[1] about the performance of stemmed large head MoM implants, giving recommendations about their use in the future. The relevant specialist associations are advising members to take into account this new evidence before reaching appropriate clinical decisions. The British Hip Society provided clear professional guidance on 1st March 2012 that stemmed, large diameter metal on metal primary total hip replacements using bearing of 36mm or above should only be performed in properly conducted and ethically approved research studies.
http://www.britishhipsociety.com/MoM%20Update.htm

**Addresses**

For action
Chief Executives, NHS Boards
Chief Executive, National Waiting Times Centre

For information
Chief Executive, NHS: NSS
General Medical Practitioners

**Enquiries to:**
**Monitoring Returns**
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**CNORIS**
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[1] *A Blom et al: FAILURE RATES OF STEMMED METAL-ON-METAL HIP REPLACEMENTS: Analysis of data from the National Joint Registry of England and Wales 2012*

## Current Activities

4. NHS Boards have worked hard to contact and provide support to their patients during this period of public concern and scrutiny by monitoring those at risk, over 4,000 patients have been identified Scotland wide who have received metal on metal hip replacements (resurfacing and total joint replacements), fortunately not all require detailed review although all do require identification. The cumulative data from all NHS Boards on a Board of treatment basis will be shared clinically with the relevant specialist society-the Scottish Consultants in Orthopaedics and Trauma- to support ongoing improvement efforts.

5. The MHRA published specific Medical Device Alerts (MDA) on the 2nd April 2012 on the MITCH TRH acetabular cups / MITCH TRH modular heads (Finsbury Orthopaedics) when implanted with uncemented Accolade femoral stems (Stryker Orthopaedics). http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON149600

   and on the 25 June 2012 the metal liner component of the R3 acetabular system manufactured by Smith & Nephew Orthopaedics Limited.

   http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON155749?tabName=Scotland

## Clinical governance

6. NHS Boards remain responsible for their patients, including those managed in the independent sector under contract from the NHS, as well as those treated under the waiting times guarantee. This is set out in the HDL (2005) 41, (**Annex A**). Where necessary, data should be forwarded to CNORIS, confirming that risks have been minimised by conforming to the recommended care pathways for patients with metal on metal bearings.

## Joint Replacement information systems

7. NHSScotland has a successful Arthroplasty Project (SAP) established in 1999 with the aims of instigating change through continual feedback; setting individual results in a local and national context; using outcomes which the public could identify with. SAP is now recognised worldwide for its close interaction with surgeons and its ability to change behaviour. There is some evidence that Scottish patients have not been as exposed to the metal on metal problems as those in other parts of the UK.

8. In recent years NHS Scotland has invested in a solution to support Operating Theatre Management (OPERA) and is currently in use in 60-70% of Scotland. The new theatre system has the facility to include implant and associated data such as the operation type, the surgeon, the assistant, the anaesthetist, the anaesthetic type etc. A collaboration approach is to be taken forward between the SAP and NHS Boards to deliver the requirement to monitor all implanted devices allowing management to discharge its responsibilities to our patients with much less effort.

**Action required**

9. **To ensure where possible every patient still resident in NHSScotland is traced, monitored and treated in accordance with the current guidance and to monitor the workload on scanning and laboratory testing facilities, Chief Executives are asked to ensure that:**

    1. **this CEL is copied to all relevant clinicians, including for information to General Medical Practitioners;**

    2. **all Orthopaedic Departments have systems in place to implement MHRA MDA/2012/008;**

    3. **NHS Boards share good practice in patient surveys and database systems for follow-up and recall of patients with MoM hip replacements; and**

    4. **NHS Boards provide six monthly reports to James White using the template shown in Annex B. The first report is due in September 2012.**

Yours sincerely

**SIR HARRY BURNS**
**Chief Medical Officer**

**ANNEX A**

## MHRA guidance on metal on metal hip replacements

MHRA 25 June 2012
MOM framework.pdf

www.mhra.gov.uk/home/groups/dts-bs/documents/medicaldevicealert/con155767.pdf

## HDL (2005) 41 Quality of clinical services provided by the independent healthcare sector on behalf of the NHS

HDL2005_41[1].pdf

http://www.sehd.scot.nhs.uk/mels/HDL2005_41.pdf

**ANNEX B**

**Reporting Template 30 September and 31 March reports to**

James H White, Policy Officer, Directorate for Health Finance and Information| Capital and Facilities Division,

James.White@scotland.gsi.gov.uk

| NHS Board name | MoM hip resurfacing (no stem) | Number of MOM hip resurfacing patients completed follow-up according to MHRA protocol | DePuy ASR™ hip replacements (all types) | Other large head (femoral head diameter ≥36mm) MoM total hip replacements (Including Stryker: add as subgroup please) | Smith & Nephew Orthopaedics Ltd R3 acetabular system | All other metal on metal bearings |
|---|---|---|---|---|---|---|
| Number of resident patients Identified for follow-up 2003-2011 | | | | | | |
| Non residents | | | | | | |
| Number of resident patients completed life of implant follow-up or revised (revision numbers separately here please) | | | | | | |
| Non residents | | | | | | |
| Number of new resident patients operated 2012 | | | | | | |
| Non residents | | | | | | |