

Our reference: CEM/CMO/2012/07
Gateway: 17352

12 March 2012

*Richmond House
79 Whitehall
London
SW1A 2NS*

*Tel: +44 (0)20 7210 4850
Fax: +44 (0)20 7210 5952
www.dh.gov.uk*

To:
Cluster SHA Medical Directors in England
Primary Care Trusts in England (Chief Executives)
NHS trusts in England (Chief Executives)
Hospitals in the independent sector registered with CQC
Independent treatment centres registered with CQC
NHS Foundation Trusts in England (Chief Executives)

For Information:
Care Quality Commission (CQC) (Headquarters)
General Practitioners

Dear Colleagues

Metal on Metal Hip Replacements

You will know there has been considerable public discussion recently about the safety and performance of metal on metal (MoM) hip replacements. A medical device alert was published on 28 February 2012 by the MHRA (MDA/2012/008), making recommendations about the management and monitoring of patients with these prostheses. Research evidence has also now been published in the *Lancet*¹ about the performance of large stemmed MoM implants, giving recommendations about their use in the future. The England and Wales National Joint Registry has contributed to both pieces of work. For some time the National Joint Registry has been drawing the attention of the clinical community to the performance of various types of MoM hip replacements. In addition, the relevant specialist associations are now also advising members to take into account the new evidence before reaching appropriate clinical decisions.

In the light of the accumulating evidence, we would like to be confident that all those who commission, organise and provide orthopaedic services – in particular for the NHS – can satisfy themselves that appropriate decisions about choice of implant are being

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*

taken. Decisions should be based on the research evidence, the medical device alert issued by the MHRA, and NJR data as presented in its last annual report. For this reason, we are asking the Executive Teams of healthcare providers across the UK to make sure you have effective local governance of the purchasing decisions and surgical choices made about the type of hip replacements or resurfacing offered to patients with pain and disability from arthritis. For many providers, such governance already exists.

We remind you that participation in the National Joint Registry has been a condition of the standard contracts for NHS-funded care in England since April 2011. We need to ensure that future decisions about risk can be made on the basis of a full dataset as we go forward.

We endorse the MHRA conclusion, recorded in its Medical Device Alert, that the majority of patients with MoM hip replacements have well functioning hips and are thought to be at a low risk of developing serious problems. We also share the MHRA conclusion that the difference in expected performance between certain types of these implants is of concern. In addition, a small number of patients with these implanted hips may develop progressive soft tissue reactions to the wear debris of MoM articulations. This has led to the requirement recorded in the Medical Device Alert that some groups of patients with MoM implants should be reviewed annually for at least five years or even for life. An Annex that sets out the updated management required for different types of MOM implant patients is attached to the latest MDA.

We think it essential that orthopaedic surgical teams are asked to lead the process of choosing the implants offered and to ensure that these choices reflect current evidence. As a matter of clinical and financial governance, we recommend that senior managers are asked to confirm to you that satisfactory procedures are in place for the oversight and regular review of decisions about the purchasing, implantation and surveillance (through participation in the National Joint Registry) of the performance of these devices, and of the quality and duration of outcomes for patients (recorded through Patient Recorded Outcomes Measures). In particular, we are asking you to make sure that the advice published by the MHRA in its Medical Device Alerts about MoM hip replacements is followed for all patients.

We emphasise that decisions on the clinical effectiveness of specific treatments and interventions must take account of a patient's individual circumstances; that different interventions will provide different levels of benefit depending on the individual; and that the relative value an individual will receive from a treatment (compared to alternatives or receiving no treatment) is the primary and legitimate consideration.

For these reasons, we suggest that any decision to restrict access to a particular treatment or intervention must be able to be justified, be based on good evidence and take individual circumstances into account; and that any individual affected must be able to be challenge such decisions through a review process. We would also like to be clear that we are not suggesting any restrictions to fair access to services, or about any change to the appropriate local prioritisation of services offered to both individual patients and the population as a whole. This letter refers to the technical decisions about the choice of implant, made within the offer of those services.

Our colleagues in the other devolved administrations are writing to the providers within their jurisdiction in similar terms.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Sally C Davies', written in a cursive style.

**PROFESSOR DAME SALLY C DAVIES
CHIEF MEDICAL OFFICER
CHIEF SCIENTIFIC ADVISER**

A handwritten signature in black ink, appearing to read 'Bruce Keogh', written in a cursive style with a horizontal line underneath.

**SIR BRUCE KEOGH
MEDICAL DIRECTOR FOR NHS ENGLAND**