Chief Medical Officer Directorate

Scottish Government
Riaghaltas na h-Alba
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Dear Colleague

As you will be aware a Medicines and Healthcare products Regulatory Agency (MHRA) Medical Device Alert (MDA) alert for metal on metal hip replacements (MDA/2012/036) was issued in 2012:

> https://www.gov.uk/drug-device-alerts/medical-device-alert-metal-on-metal-mom-hip-replacements-updated-advice-with-patient-follow-ups.

The MDA was a result of clinical concerns of early failure in a minority of patients, and asked all Health Boards to identify and follow up patients who had been fitted with implants of the type in question.

Since 2012 further evidence has been reviewed, and the MHRA has therefore issued a new MDA, which includes clear, comprehensive, evidence based guidelines, which can be found at the following link:

> https://www.gov.uk/drug-device-alerts/all-metal-on-metal-mom-hip-replacements-updated-advice-for-follow-up-of-patients

In essence, regular long term follow up is required for all patients who have one of the devices concerned, even those with 10A ratings. The follow up frequency, investigations required and actions when results are abnormal are clearly outlined in the new MDA and should be followed. Follow-up is the responsibility of the department and individual who undertook the surgery, as they are able to identify affected patients.

All historical patients prior to 2012 should have been reviewed as part of the 2012 MDA, and recorded at a local level. All patients identified at that time will require further follow up as a result of the new guidance. It is expected that a detailed report of their follow-up be considered by your Health Board's clinical governance and quality assurance mechanisms.

Those centres which have continued to perform metal on metal replacements or resurfacing must identify those additional patients to be identified and followed up as per the new guidance.

From the Chief Medical Officer
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Addresses

For action

Chief Executives, NHS Boards
Medical Directors, NHS Boards

For information

Hannah Cornish Programme Manager
National Coordinating Network for Healthcare and Forensic Medical Services for People in Police Care

Actions required

All Chief Executives should be aware of the issues and requirements and ensure that all actions below have been undertaken.

All Medical Directors should ensure:

1. That the appropriate action is taken for individual patients.

2. That a report is presented through local clinical governance and quality assurance mechanisms to include the minimum data outlined at Point 3, below, and assurance that appropriate enhanced consent has been taken for those operated since 2012.

3. That the data on numbers of patients with a metal on metal implant are recorded by notification to your clinical governance and quality assurance processes using the four categories of device implanted, divided into those before 2012 and those after 2012. Where possible the outcome of surgery and follow up (those revised, those under review and those lost to follow-up after attempts made to contact them) should be notified as a percentage of total carried out.

4. All patients undergoing metal on metal hip replacement since 2012 have had very specific consent taken and recorded, taking into account the additional risks and follow up required.

5. Assurance on the processes being in place and the cumulative data from Point 3 are sent to the medical devices team at the Scottish Government by 10 August 2017 (david.bishop@gov.scot).

All surgeons who undertook or continue to undertake these procedures should:

1. Familiarise themselves with the contents of the MHRA report.

2. Ensure that enhanced consent is taken and that a detailed searchable record of all such future patients is kept to ensure long-term follow up.

3. Initiate appropriate follow up and care.

4. Report to the clinical governance and quality assurance mechanisms locally using at least the minimal data, noted above, as part of a comprehensive audit.

Yours sincerely

Catherine Calderwood

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Chief Medical Officer