Press Release

Date: Tuesday 28 February 2012
Time: 11:00
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MHRA UPDATES ADVICE FOR METAL-ON-METAL HIP REPLACEMENTS

The Medicines and Healthcare products Regulatory Agency (MHRA) today issued updated advice to surgeons that patients with a particular type of metal-on-metal hip replacement should be monitored annually for the life of the hip replacement. This updates previous advice from April 2010 that patients with this type of hip replacement need only be monitored for a minimum of five years after their operation.

The updated advice is included in a new MHRA Medical Device Alert that has been issued to clinicians today for the management of patients with these hip implants to minimise the risk of having to undergo further surgery to correct complications.

An expert advisory group was set up by the MHRA to look at the management of patients with soft tissue swelling associated with metal-on-metal hip implants. This group meets regularly to evaluate new scientific advice and observations from clinicians. This updated advice is based on updated evidence that patients with hip replacements with head diameter of 36 millimetres or more need to be monitored every year.

Dr Susanne Ludgate, Clinical Director of the MHRA, said:

“Clinical evidence shows that patients have a small risk of suffering complications from having metal-on-metal hip implants. These implants have in most cases completely transformed the lives of patients who in the past were subject to increasingly severe pain and progressive lack of mobility.

“As a precautionary measure, we have today issued updated patient management and monitoring advice to surgeons and doctors that they should annually monitor patients for the lifetime of their metal-on-metal total hip replacements that are sized 36 millimetres or more because this particular type of hip replacement has a small risk of causing complications in patients. This updates previous advice that patients with this type of hip replacement need

only be monitored for a minimum of five years after their operation. By monitoring patients every year, any complications will get picked up earlier and more complex surgery on the patient can be avoided.

“The MHRA was the first regulatory agency in the world to issue advice to clinicians about metal-on-metal hip implants in April 2010 and we, in combination with our expert advisory group, are continuing to closely monitor all the latest evidence about these devices. If patients have any questions, they should speak to their orthopaedic surgeon or doctor.”

Joe Dias, President of the British Orthopaedic Association (BOA), said:

"The safety of our patients is always our first concern. The British Orthopaedic Association welcomes the publication of this updated advice from the MHRA. We will continue to work closely with the MHRA to provide further advice on this matter as new information becomes available."

Ends

Notes to Editor

1. The MHRA takes its post-market surveillance role very seriously and works with other Member States to ensure that only compliant medical devices are placed on the market. Following reports of problems with large metal-on-metal hip replacement/resurfacing in the late 1990s the National Joint Registry, the British Orthopaedic Association, the British Hip Society and the MHRA formed a close working relationship as an expert advisory committee to investigate the possibility of potential problems associated with some of these types of joint replacements. Whilst there had been reports from other countries, the UK was the first in the world to issue guidance through its regulatory authority the MHRA as a result of these closer working practices. Other counties have now followed this lead.

2. The MHRA is the government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe. No product is risk-free. Underpinning all our work lie robust and fact-based judgements to ensure that the benefits to patients and the public justify the risks. We keep watch over medicines and devices, and take any necessary action to protect the public promptly if there is a problem. We encourage everyone – the public and healthcare professionals as well as the industry – to tell us about any problems with a medicine or medical device, so that we can investigate and take any necessary action. www.mhra.gov.uk