

## Lifelong checks for metal hip implant patients

## March 1 2012

The UK government's health regulator has advised new checks for patients who have undergone large head metal-on-metal hip replacements, following a major investigation by Newcastle University engineers.

The new advice follows a report triggered by the work of Newcastle University expert Dr Tom Joyce who first exposed the problems associated with the implanted devices.

All-metal hips have a high failure rate and rubbing between the ball and cup can cause metal to break off, seeping into tissue and causing complications.

But despite the fact that the risks posed by these minute pieces of metal have been known and well documented for decades, <u>patients</u> have been kept in the dark.

The new claims could mean that more people are affected by the dangers of metal hip replacements than suffered in the recent PIP breast implant scandal. It means 49,000 people will now need annual tests to check their blood ion levels.

The joint investigation by the *British Medical Journal* (BMJ) and BBC Newsnight showed how metal ions can seep into the tissues of patients with metal-on-metal hip implants, causing reactions that destroy muscle and bone, and leaving some patients with long term disability.



Newcastle University's bioengineering team led by Dr Joyce began investigating the problem of metal hips as far back as 2008 and raised concerns about the health risks to patients.

Criticising the Medicines and Healthcare products Regulatory Agency (MHRA), Dr Joyce said it took the <u>health</u> regulator four years to recall from the market articular surface replacement (ASR) hips following mounting evidence about the dangers posed to patients. ASRs were eventually recalled in 2010.

Dr Joyce said: "The MHRA are meant to be on the side of patients but they have not been neutral and have had too cosy a relationship with the notifying bodies and manufacturers.

"The MHRA seem to have tried to shy away from the issue – why have they not felt in a position to do anything?

"Since the replacement hips were withdrawn in 2010 nothing has changed and the entire system has seriously failed patients. There needs to be a lot more transparency in the system."

Hip implants, like breast implants, did not have to pass any clinical trials before they were put into patients.

The report tells how the implants' metal ions can seep into the bloodstream, spreading to the lymph nodes, spleen, liver and kidneys, before leaving the body as urine. Concern has also been raised about damage to chromosomes, leading to genetic changes.

Their investigation also shows how companies have changed the design of their metal hips over the last decade in a bid to prevent dislocation and increase movement, without conducting new trials to demonstrate their safety.



New guidance was issued yesterday by the MHRA over metal implants, and patients who have undergone large head metal-on-metal hip replacements should be monitored annually for life. The MHRA said there was a "small risk" the implants could cause complications in patients.

It means some 49,000 people in the UK whose hip replacements have a head diameter of 36 millimetres or more will now need annual tests to check their blood ion levels.

Dr Susanne Ludgate, Clinical Director of the MHRA, said in a statement: "Clinical evidence shows that patients have a small risk of suffering complications from having metal-on-metal hip implants.

"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 <a href="https://nicensess.com/hip replacement">hip replacement</a> has a small risk of causing complications in patients."

## Provided by Newcastle University

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