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Meeting the demands of on-going metal-on-metal hip surveillance through nurse led services

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Abstract This paper discusses the implications following a recall of all metal-on-metal hip replacements by the Medicines and Healthcare products regulatory Agency (MHRA). Issues identified were the release of metal ions from the metal implants. These ions were found to seep into local tissues and cause reactions that destroyed muscle and bone leaving some patients with long term disability. At the centre surveillance was monitored by an extension of the current Nurse Led services using existing staff and resources. There were a significant number of patients that required monitoring and there were difficulties contacting these patients and ensuring that they understood the importance of attending a clinic.

Editor comments
The recall of metal of metal-on-metal hip replacements has created a significant challenge to orthopaedic services internationally and resulted in patients and their families feeling anxious about the possibility of metallosis. This paper presents a useful insight into how a nurse led service in the UK has provided on-going support for patients through surveillance and advice within existing resources. Since the authors wrote this paper the Medicines and Healthcare products Regulatory Agency have issued

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a further medical device alert on 25th June 2015 regarding Smith & Nephew Orthopaedics Birmingham Hip Resurfacing (BHR) system due to higher than expected revision rates for certain groups of patients, requiring annual surveillance of patients for the life of the implant including assessment of symptoms, monitoring serum cobalt and chromium levels and MARS MRI or ultra sound scanning of the hip/s. For further detail please access web link https://www.gov.uk/drug-device-alerts/metal-on-metal-mom-hip-replacements-guidance-on-implantation
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Introduction

Hip replacement surgery has transformed the lives of many patients over the years. Cobalt chrome metal hip implants were first used in the 1930s (Bannister, 2012). In 1953 George McKee began using metal-on-metal (MoM) as a bearing surface for total hip Arthroplasty. Poor early results and the introduction of Sir John Charnley's metal on Polyethylene cemented low friction Arthroplasty meant that the use of MoM was abandoned in the 1970s. The primary driver behind the more recent return to metal on metal was the need for surgery in younger more active patients and that by preserving femoral bone stock this procedure was deemed less invasive than a total arthroplasty. Other purported advantages were that this approach reduced stress; there was minimal risk of dislocation, improved range of movement and easier revision (Macpherson and Breusch, 2011).

MoM total hip replacement has become popular over the past decade and accounts for around 14% of hip replacements in the United Kingdom (Smith et al., 2012). There have been issues raised which has led to an extension of the existing Nurse Led Clinics.

Background

Unfortunately there has been a steady decline in the past 3 years because all MoM devices have been found to wear at an accelerated rate in some patients, potentially causing damage and deterioration in the bone and tissues around the hip (NHS Choices, 2014) and the National Joint Registry (NJR) was showing a 5 year revision rate in 6.2% of patients who had received MoM prosthesis (Sedrakyan, 2012). Cobalt chromium implants are known to release metal ions, but some metal-on-metal prostheses do so on a much greater scale than previously thought. These ions can seep into local tissues causing reactions that destroy muscle and bone leaving some patients with long term disability (Cohen, 2012). In August 2010 an urgent field safety notice was issued by the prosthesis manufacturers, DePuy, relating to implants known as the ASR (Articular surface replacement) and ASR XL Acetabular systems. The notice stated that as part of their ongoing surveillance of its products, they had received unpublished data from the NJR that the 5 year revision rate for the ASR hip resurfacing was 12% and 13% for the ASR XL Acetabular system. This was higher than expected and was shown to be highest in those with an ASR head size below 50 mm in diameter and in females. As a result DePuy was issuing a voluntary recall of all ASR products.

Medicines and Healthcare products regulatory Agency (MHRA) directive

In September 2010 the MHRA issued a medical device alert asking that no DePuy ASR hip replacements were implanted and that all patients that had had an ASR implanted were to be informed about this recall and to be seen in a clinic. In June 2012 the MHRA issued an updated notice asking that all MoM hip replacement patients were contacted as there was a chance that they could develop progressive soft tissue reactions as a result of debris associated with MoM articulations.

The recommendations for any patient presenting with symptoms of abnormal pain, limping, swelling around the hip or deteriorating hip function were to carry out the following investigations:

- X-ray hip Anterior and posterior views and compare with previous films
- Measure cobalt and chromium ion levels
- Cross sectional imaging including MRI or Ultrasound scan
- If MRI OR Ultrasound scan reveals soft tissue reactions, fluid collections or tissue masses then to consider revision surgery.
- Monitor annually for the life of the implant

The National Joint Registry

The South West London Elective Orthopaedic Centre (SWLEOC) in Epsom Surrey has been operational since