Effective Health Care

Metal-on-metal Total Hip Arthroplasties
Nomination Summary Document

Results of Topic Selection Process & Next Steps

- The topic, *Metal-on-metal total hip arthroplasties,* was found to be addressed by a systematic literature review that was prepared for the Food and Drug Administration (FDA) Orthopaedic and Rehabilitation Devices Advisory Panel. Given that the existing review covers this nomination, no further activity will be undertaken on this topic.
  - FDA Executive summary memorandum. Metal-on-Metal Hip Implant Systems. Prepared for the June 27-28, 2012 Meeting of the Orthopaedic and Rehabilitation Devices Advisory Panel, Gaithersburg, MD. Available at: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel/ucm309184.htm

Topic Description

Nominator(s): Individual

Nomination Summary: The nominator is concerned that there have been "recalled" medical devices used for total hip replacement, specifically those with metal-on-metal (MoM) bearings. The nominator wishes to know what treatment exists for cobalt and chromium in the blood stream resulting from the use of MoM hip implants. For this nomination, we expanded the search parameters to include the severity and occurrence of adverse events that might be caused by raised metal ion levels as well as serum ion levels or related debris for hip implants made of other material.

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Population(s): Individuals with metal-on-metal total hip arthroplasty

Intervention(s): Metal-on-metal hip implants

Comparator(s): Other hip implants, including metal-on-polyethylene; ceramic-on-ceramic; ceramic-on-polyethylene; ceramic-on-metal

Outcome(s): Ion serum or debris levels, occurrence of adverse events, hip prosthesis longevity, need of revision / resurfacing surgery

Key Questions from Nominator:
What is the severity of adverse events from metal ion toxicity?
Are there effective treatments for metal ion (or other debris) toxicity?
If revision or resurfacing surgery is recommended, what are some alternative comparators to MoM?

Considerations

- The topic meets EHC Program appropriateness and importance criteria. (For more information, see http://effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/how-are-research-topics-chosen/.)
- Rates of total hip arthroplasty (THA) have increased over the last 2-3 decades. With aging of the population and increased longevity, the number of THAs is projected to increase further.
- There are increasing concerns over adverse events associated with early failure of MoM hip systems including the potential need for revision surgery. This topic was found to be addressed by a systematic review that was prepared for the FDA's Orthopedic and Rehabilitation Devices Advisory Panel, which met in June 2012 to seek expert scientific and clinical opinion on the benefits and risks of MoM hip implants This panel examined failure rates and modes, metal ion testing, imaging methods, local and systemic complications, patient risk factors; and considerations for post-surgery follow-up. There does not appear to be sufficient new information from literature published since the systematic review for the FDA was conducted to warrant an AHRQ review at this time.