

## Device-specific guidance for manufacturers on reporting adverse incidents under the vigilance system

### Joint replacement implants

To be read in conjunction with the guidelines on a medical devices vigilance system [MEDDEV 2.12/1 which sets out the general adverse incident reporting obligations on all manufacturers of medical devices including joint replacement implants.](#) [1]

#### 1. Are revisions reportable?

There are a number of reasons why joint replacement implants are revised. These include, but are not limited to:

- infection of the operation site (septic loosening)
- malpositioning or misalignment of one or more of the implant components during implantation
- mechanical failure of one or more of the implant components e.g. fracture of hip stems or knee tibial trays, excessive wear of hip acetabular cups or knee tibial components etc.
- aseptic loosening of one or more of the implant components
- associated anomalous soft tissue changes [2].

Revision of a joint replacement implant is considered to be a serious deterioration in a patient's state of health since it necessarily requires surgical intervention to prevent permanent impairment of body function or permanent damage to body structure [1].

However, only revisions where there has been an implant failure or deterioration of the implant, or anomalous local or systemic changes which may be related to the implant are reportable.

#### What should be reported?

##### 1.1 Infection / misalignment / malpositioning

Revisions carried out primarily because of infection or misalignment / malpositioning during implantation are not generally considered to be malfunction or deterioration of the implant and are not therefore usually considered to be reportable under the Vigilance system. Misalignment / malpositioning are however reportable if they are considered to have occurred as a direct consequence of the design of the implant or of the design of the instrumentation intended to be used in conjunction with the implant.

## **1.2 Mechanical failure**

Revisions carried out secondary to mechanical failure of the implant (however long it has been implanted) are considered to be a malfunction or deterioration of the implant and are therefore reportable unless there is clear evidence that the main cause of failure was not implant related. Examples of potentially non-reportable cases include, but are not limited to:

- inappropriate implant selection
- misalignment / malpositioning during implantation (unless such misalignment / malpositioning resulted as a direct consequence of the implant's design)
- failure of the cement to bone interface in cemented implants (this should be reported by the cement manufacturer).

## **1.3 Aseptic loosening**

Revisions carried out primarily because of aseptic loosening within the expected life of the implant (as specified in the information supplied with the implant by the manufacturer) are considered to be a malfunction or deterioration of the implant and are reportable. If the expected life of the implant is not specified, revisions due to aseptic loosening within 10 years of primary implantation should be reported.

## **1.3 Associated anomalous soft tissue changes**

Revisions carried out where there are surrounding anomalous soft tissue changes, including soft tissue necrosis, pseudotumours or pathological changes typical of hypersensitivity, should be reported, regardless of whether or not the implant is considered to be misaligned / malpositioned. There is presently an unestablished cause/effect relationship between these changes and joint failure and the MHRA thus considers them to be a malfunction of the implant for the purpose of vigilance [2].

## **1.4 Reason for revision not clear**

In some cases, the reason for revision may not be well defined, may involve a number of aetiologies, or may present novel or previously unrecognised factors. Under these circumstances, the incident should be reported [2].

## **2. Blood metal ions and systemic changes**

There is a paucity of evidence concerning the relationship between blood metal ion concentrations and systemic changes or genotoxicity. Therefore, all systemic side effects associated with high blood metal ion concentrations, including those related to birth defects and malignancy should be reported for the purpose of vigilance. High blood metal ion concentrations in the absence of side effects or revision surgery need not be reported.

## **References**

1 [Guidelines on a Medical Device Vigilance System, MEDDEV 2.12-1](#)

2 [Advice from the MHRA Expert Advisory Group](#) on the biological effects of metal wear debris generated from hip implants.