Guidance on the vigilance system for CE-marked medical devices

Artificial heart valves

VG02

November 2008
First published 1998

website document
Contents

1 Introduction .......................................................................................................................... 3
2 Why report? ......................................................................................................................... 3
3 What should be reported? .................................................................................................... 3
4 Adverse incidents generally not reportable ........................................................................ 4
5 Are reoperations reportable? ............................................................................................ 5
6 References ......................................................................................................................... 5
1 Introduction

This guidance document gives advice to manufacturers on the notification of adverse incidents involving artificial heart valves under the medical devices vigilance system. It is intended to facilitate the uniform application and implementation of the Medical Devices Directive 93/42/EEC. It is supplementary to, and should be read in conjunction with, the European Commission guidelines on a medical devices vigilance system [2], and MHRA Directives Bulletin 3 - Guidance on the operation of the EU vigilance system in the UK [3].

This guidance sets out the Medicines and Healthcare products Regulatory Agency’s (MHRA) views on the interpretation of the medical devices regulations. It should not be considered to be an authoritative statement of the law in any particular case as it is intended as guidance only. Manufacturers and others should consult the legislation referred to, making their own decisions on matters affecting them in conjunction with their lawyers and other professional advisers. The MHRA does not accept liability for any errors, omissions, misleading or other statements in the guidance whether negligent or otherwise. An authoritative statement could be given only by the courts.

2 Why report?

To obtain information on device related incidents, the Medical Devices Directive [1] requires manufacturers to have procedures in place for systematic review of experience gained from device usage in the post-production phase. These review systems are particularly important in helping to ensure the continuing safety of artificial heart valves, because their long term performance cannot reliably be predicted from information obtained from pre-market clinical investigations or short term use.

3 What should be reported?

The Medical Devices Directive [1], through the relevant national regulations [4], requires manufacturers to notify the relevant Competent Authority (MHRA in the UK) if:

- they know of any artificial heart valve deterioration or malfunction, or any inadequacy in instructions for use which has led, or might lead, to the death of a patient or serious deterioration in their state of health. This would include circumstances where:
  - an artificial heart valve related problem results in prolonged surgical time, and includes extended periods on bypass or the need for the surgeon to re-open the heart,
  - the cause of the artificial valve replacement or incident is not well defined or involves a number of aetiological factors, and the manufacturer is unable to obtain further clarification within the reporting timescale.
- the artificial heart valve has been subject to a Field Safety Corrective Action [2].

Most adverse incidents associated with heart valves will be reportable under the vigilance system. The following examples are for illustrative purposes only and do not constitute an exhaustive list. It is the manufacturer's responsibility to judge each
incident on its own merit, and to ensure compliance with the statutory reporting requirements contained within the relevant national regulations [4] implementing the Medical Devices Directive [1].

- Housing ring/stent fracture.
- Separation of sewing cuff from housing/stent.
- Valve replacement due to severe haemolysis (in the absence of paravalvular leak, or contributing patient factors such as haemolytic disease).
- Transient ischaemic attack or cerebrovascular accident.
- Valve thrombus (in the absence of a clotting disorder or noncompliance with/inadequate anticoagulation therapy).
- Leaflet/ocluder fracture or escape.
- Structural deterioration e.g. wear damage, hinge damage.
- Tissue failure such as tear or perforation within 7 years of implant (in the absence of calcification, endocarditis or pannus overgrowth).
- Tissue failure within 7 years of implantation, due to calcification in patients over 65 years of age at implantation.
- Incidents relating to accessories or instrument failure.
- User error resulting in death or serious injury.
- Unexpected degree of pannus overgrowth.
- Paravalvular leak.

4 Adverse incidents generally not reportable

Some expected and foreseeable side effects can be considered as not reportable. These must all be clearly identified in the manufacturer’s labelling, clinically well recognised and quantifiably predictable, well documented in the device master record with an appropriate risk assessment, and clinically acceptable in terms of individual patient benefit. All such incidents should, however, be subject to trend analysis as part of the manufacturer’s wider post-market surveillance process. The expected prevalence or rate of such events should be specified, and if an adverse trend emerges, this should trigger a vigilance report by the manufacturer to the relevant Competent Authority.

Adverse incidents that are generally not reportable include:
- endocarditis
- myocardial infarction
- haemorrhage or complications relating to anti-coagulation/clotting disorder
- arrhythmia
- overall mortality rate of valve population.
5 Are reoperations reportable?

Explantation and replacement of an artificial heart valve 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 [2]. Local or systemic changes that may be related to the artificial heart valve should be reported.

Elective replacement resulting from a Field Safety Corrective Action is not reportable unless the investigation of the explanted device identifies a malfunction which could have led to the death, or serious deterioration in the health of the patient. In this case, reporting would take place when the malfunction has been identified.

6 References


   http://ec.europa.eu/enterprise/medical_devices/meddev/

3. Directives Bulletin 3 - Guidance on the operation of the EU vigilance system in the UK.


© Crown Copyright 2008
Published by the Medicines and Healthcare products Regulatory Agency