Medical Device Incident Investigations: Recommendations

Reprocessing phaco-emulisfying handpieces

The TGA Incident Report Investigation Scheme (IRIS) has received several reports in recent times about concerns with cleaning and sterilising reusable phacoemulsion handpieces used in eye surgeries.

Concerns from theatre staff and sterilising managers relate more specifically to the perceived lack of manufacturers' instructions on how to reprocess these devices if used on patients suspected of having Creutzfekdt-Jakob Disease (CJD) or when used in high risk infectivity sites such as specific parts of the eye. (See Department of Health and Ageing 2004, *Infection control guidelines for the prevention of transmission of infectious diseases in the health care setting* <http://www.health.gov.au/internet/main/publishing.nsf/Content/icg-guidelines-index.htm>).

Recommendation

The TGA recommends that if hospital staff suspect that a patient may be infected with a prion-type disease, those responsible for ensuring the safe reprocessing of such devices should firstly contact the sponsor of the device to obtain appropriate manufacturer's reprocessing instructions.

If these instructions are not sufficient to meet the requirements of the healthcare facility's policy and procedures, it is recommended that the healthcare facility then follow local or national guidelines on how to manage these instruments.

MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME (IRIS) STATISTICS REPORT 01/07/2008 to 30/09/2008
Total Number Received: 397

Cause of Problem[1]	
Component Failure	16
Contamination	4
Design	14
Electrical	41
Inadequate Instructions	6
Labelling	6
Maintenance	4
Manufacture	12
Material/Formulation Deficiency	20
Mechanical	169
Not Device Related	59
Other	13
Packaging/Sterility	2
Quality Assurance	10
Unknown	40
Wear/Deterioration	8

Effect	
Death	8
Serious Injury	123
Temporary Injury	90
No Injury	176

Source Category	
Medical Administrator	15
Specialist	7
General Practitioner	1
Nurse	27
Blood Bank	1
Hospital Supply Service	10
Other	6
Sponsor	306
Overseas Advice	2
Biomed Engineer	12
Para Medical	5
Patient/User	4
Dentist	1
Coroner	0

Result of Investigation	
Bulletin Article	1
Company Warned	2
No Further Action	89
Not Investigated[3]	271
Other	42
Problem Not Confirmed	6
Product Improvement	22
Recall/Hazard Alert	5
Safety Alert	4
User Education	11

Notes:

1. The problem causes are not mutually exclusive. For example, a material deficiency may have led to a mechanical malfunction or a biocompatibility problem.
2. Every report received by IRIS receives a risk analysis by the Scheme Coordinator and is discussed by a panel of technical and clinical professionals. In the case of reports that are "Not Investigated" the panel has made a decision that further investigation of the particular event is not necessary at that time. However, these reports are logged into the database for future reference and the trend of reports is monitored. In making their decision, the panel considers whether any similar reports have been received previously.