Medical Device Incident Investigations: Recommendations

Sleep apnoea (CPAP and VPAP) devices being used as ventilators

The Therapeutic Goods Administration continues to receive reports that CPAP and VPAP devices are being used as life support units, especially for elderly patients. In one reported case, a patient was "turning blue and nearly died" when their VPAP device stopped when it over heated. The over heat alarm was triggered. Another report concerns a patient who was totally dependent on the device complaining about the lack of a power backup system in case of power failure. The patient claims that he would die if the machine stopped. A third report was about a hospital using one of these devices as a life support patient ventilator when it stopped working due to a motor bearing failure. In that case, the patient was hand ventilated until replacement unit was obtained.

The CPAP and VPAP devices manufactured by several manufacturers are non-continuous ventilators intended to augment the ventilation of patients who have restrictive or obstructive respiratory disorders and require non-continuous ventilator support. Examples of such respiratory disorders are obstructive sleep apnoea, chronic obstructive pulmonary disease, neuromuscular and chest wall diseases.

The Clinical and Operating Manuals state that these devices are not intended to be used as life support ventilators. They may stop operating due to a power failure or if a fault occurs in the product.

Recommendations:

The TGA emphasises that the use of CPAP and VPAP ventilators for life support is in breach of the manufacturers' intended purpose and may lead to a serious adverse event. The units lack appropriate alarms and backup modes normally required for life supporting patient ventilators.

MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME (IRIS) STATISTICS REPORT
01/04/2007 to 30/06/2007

Total number received: 280
Total number of investigations completed: 238

Cause of Problem[1]	
Component Failure	21
Contamination	10
Design	11
Electrical	16
Inadequate Instructions	3
Labelling	2
Maintenance	2
Manufacture	18
Material/Formulation Deficiency	12
Mechanical	20
Not Device Related	33
Other	26
Packaging/Sterility	2
Quality Assurance	6
Unknown	77
Wear/Deterioration	9

Effect	
Death	9
Serious Injury	55
Temporary Injury	64
No Injury	110

Source Category	
Medical Administrator	4
Specialist	13
Nurse	8
Blood Bank	1
Hospital Supply Service	16
Other	2
Sponsor	181
Overseas Advice	2
Biomed Engineer	5
Para Medical	1
Patient/user	22
Dentist	0
Coroner	1

Result of Investigation	
Bulletin Article	2
Company Warned	1
Compliance Testing	1
No Further Action	43
Not Investigated[2]	152
Other	7
Problem Not Confirmed	12
Product Improvement	13
Recall/Hazard Alert	7
Safety Alert	6
User Education	3

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.