Medical Device Incident Investigations: Recommendations

Adverse Reaction to CIDEX OPA Instrument Grade Disinfectant Solution: New Contraindication

DIR 14303

Problem

The UK Medicines and Healthcare products Regulatory Agency and Johnson and Johnson Medical have issued a safety alert about sensitisation to CIDEX OPA with repeated exposure. In rare instances CIDEX OPA solution has been associated with anaphylaxis-like reactions in bladder cancer patients undergoing repeated cystoscopies. Bladder cancer is associated with reaction to CIDEX OPA, but this is likely to be due to repeated cystoscopy, rather than a risk factor per se. Bladder cancer is not associated with increased susceptibility to allergic disease.

The manufacturer carried out post-market surveillance and found that since the introduction of this product in 1999 there have been 24 patients who have had anaphylaxis-type reactions after repeated cystoscopies. The reactions generally occurred after 4–9 treatments. The symptoms reported included nausea, penile swelling, hypotension, vomiting, breathing difficulty, wheezing, rash, hives, eye irritation, dizziness and anaphylactic shock. In all of the cases the instruments used had been processed manually. The manufacturer, Advanced Sterilization Products, has updated its product information and is including contraindicating the use of CIDEX OPA solution for the reprocessing of any urological instruments to be used on patients with a history of bladder cancer.

Recommendations

- Do not use CIDEX OPA to process urological instruments for use on patients with bladder cancer.
- Follow the manufacturer's instructions for use when cleaning and rinsing instruments in CIDEX OPA solution.
- Ensure nursing and admission staff are aware of this problem when admitting patients for repeat cystoscopies.

Hand-held Peak Expiratory Flow Meters (PFMs) for the Assessment of Pulmonary Function and the Self-management of Asthma

This paper has been adapted from a Medical Devices Agency Notice
Ref. MDA/2004/025
Issued: 11 June 2004

Problem

Peak Flow Meters manufactured to the new European Standard EN 13826 are being introduced. They will replace the traditional Wright scale and Drug Tariff specification 51, which have been available since the 1990s. The new standard is based on absolute flow and should produce peak flow measurements similar to those obtained by conventional spirometry, and a more accurate assessment of peak flow across the entire measurement range.

It has been known for some time that the Wright scale is non-linear and can over-read in the mid-range by up to 30%. This scale has been used for the diagnosis and management of asthma in the UK and Europe since 1959. The non-linearity has not generally caused clinical problems, although in some cases the over-reading of the Wright scale may have falsely reassured patients and their healthcare professionals, so that corticosteroid therapy, while appropriate, was not prescribed. This has been the main clinical driver behind the introduction of the new scales and EN 13826.

The new PFMs will be CE-marked and identified as complying with EN 13826, ie they may be labelled "EN 13826" or "EU scale". Single-patient-use devices will be available in Europe from 1 September 2004. Multi-patient-use PFMs, with appropriate cleaning instructions, will also be available.

Practitioners should note that EN 13826 specifies one measurement range from 60 l/min to 800 l/min, which should be suitable for all users. However, low range models may also be available. The diagnosis of asthma is a clinical judgement based on various symptoms including wheeze, shortness of breath, chest tightness or cough. These tend to be variable, intermittent, worse at night or provoked by triggers including exercise. Variability of peak expiratory flow is also a characteristic of asthma. There are various methods used for assessing the variability.

For further information see:

"British Guideline on the Management of Asthma" by the British Thoracic Society, Revised edition April 2004. <http://www.brit-thoracic.org.uk/sign/index.htm>

"Peak expiratory flow meter scale changes: implications for patients and health professionals" by Martin R Miller, The Airways Journal 2004; 2 (2): 80-2. <http://www.airwaysextra.com>

BS EN 13826:2003 Peak expiratory flow meters. Available from BSI. <http://www.bsonline.techindex.co.uk>

Recommendations

Healthcare professionals should be aware that:

- PFMs manufactured to EN 13826 will be available from 1 September 2004 and these may be available in Australia soon.
- These new PFMs read accurately across the entire measurement range and may give different results to traditional Wright PFMs.
- This change has the potential to cause confusion in the interpretation of results by all users, and is particularly relevant for patients who have their asthma treated solely on the basis of peak flow measurement.
- Patients with a personalised asthma action plan will need their personal best peak flow re-assessed and their action levels re-calculated when issued with a new EN 13826 PFM. It is recommended that EN 13826 is then recorded on the action plan for reference.
- The Nunn and Gregg patient nomograms (predictive peak flow values) are based on the Wright scale and should not be used with the new EN 13826 PFMs. However, it is expected that new revised predictions will become available.
- PFMs do not need to be changed immediately; a gradual replacement program is recommended—for example when the PFM needs replacing or at the patient's next assessment.
- Computer software packages for patient management that contain asthma templates and prescribing information may require updating to reflect the change in PFM scales.

Patient Lifters: Need for Routine Inspection, Repair, Maintenance and Testing and Careful Use

ODI 10151

Problem

The TGA recently received a report concerning failure of locking pins in a Patient Rehab Lifter. The exact cause of the failure could not be determined, but it became obvious during the investigation of the incident that the lifter had not been maintained in accordance with the Instruction Manual. The manufacturer claimed that they could not be held responsible for the failure of a device that had not been correctly maintained. There was also some evidence that the failure of the locking pin and other parts may have been due to abnormal loading of the Rehab Lifter. A patient rehabilitation lifter is only designed to assist a patient to stand from a sitting position and is not designed to lift the full weight of a patient.

Another report received from an overseas regulatory agency relates to incidents of patient lifters tipping over during use. The analysis by the manufacturer indicated that in the majority of the incidents the instructions for use were not being followed. The patients were not being positioned correctly on the lifter and the safety belt was not being used. If the belt is not used, any movement by the patient while on the lifter may cause it to tip over.

Recommendations

- All load-bearing devices such as Patient Lifters, Rehab Lifters etc should be regularly inspected, repaired and maintained in accordance with the manufacturer's Instructions for Use.
- A Major Service performed by an authorised service agent may be necessary to ensure the equipment is in good working order or continues to meet the requirements of the appropriate Australian or International Standards. All load-bearing devices such as Patient Lifters, Rehab Lifters etc should be load tested at regular intervals as part of a Major Service.
- All lifting devices should only be used within their design limits and this information should be clearly displayed and understood by staff using the device.
- Even simple devices such as patient lifters rely on adherence to the manufacturer's instructions. Failure to follow the manufacturer's instructions when using patient lifters has been known to lead to injuries to both patients and assisting clinical personnel. When using patient lifters, please ensure that the patient is positioned on the lifter correctly and that all safety belts and restraints supplied with the device are used properly.

MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME (IRIS) STATISTICS REPORT
01/04/2004 to 30/06/2004
Total Number Received: 146

Cause of Problem[1]	
Biocompatibility	4
Component Failure	45
Contamination	3
Design	11
Diagnostic Inaccuracy	1
Electrical	2
Inadequate Instructions	4
Labelling	3
Maintenance	4
Manufacture	7
Material/Formulation Deficiency	13
Mechanical	12
Not applicable—ADR	1
Not Device Related	25
Other	9
Packaging/Sterility	3
Quality Assurance	4
Unknown	13
Wear/Deterioration	3

Effect	
Death	7
Serious Injury	17
Temporary Injury	31
No Injury	91

Source Category	
Medical Administrator	1
Specialist	14
General Practitioner	2
Coroner	2
Nurse	11
Blood Bank	4
Hospital Supply Service	17
Other	25
Sponsor	56
Overseas Advice	7
Biomed Engineer	4
Para Medical	2

Result of Investigation	
TGA News article	2
Compliance Testing	1
No Further Action	58
Not Investigated[2]	43
Other	1
Problem Not Confirmed	3
Product Improvement	9
Recall/Hazard Alert	18
Refer to GMP	4
Safety Alert	3
User Education	10

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.