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Canadian Adverse Reaction Newsletter

1991 – 2011 20th anniversary

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www.health.gc.ca/carn

In this issue

Scope

This quarterly publication alerts health professionals to potential signals detected through the review of case reports submitted to Health Canada. It is a useful mechanism to stimulate adverse reaction reporting as well as to disseminate information on suspected adverse reactions to health products occurring in humans before comprehensive risk–benefit evaluations and regulatory decisions are undertaken. The continuous evaluation of health product safety profiles depends on the quality of your reports.

Reporting Adverse Reactions

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Custom-Pak Ophthalmic Surgery Procedure Pack: contamination with foreign bodies and risk of related complications

Key points

- Health Canada received 28 reports of incidents suspected of being associated with contamination of the surgical pack with lint, fibre or particles.
- Fourteen patients required removal of fibre particles from their eye by a surgeon.
- Health professionals are reminded to examine the pack and its contents before use.

The Custom-Pak Ophthalmic Surgery Procedure Pack is a surgical tray consisting of single-use devices and accessories for specific ophthalmic procedures such as cataract surgery. It is regulated as a class IV medical device (highest risk class). Its licence was first issued in Canada in October 1999. The pack is customized for each type of procedure to meet the specific needs of the surgeon and the facility.[1] The contents of the pack are grouped based on their intended use and include components such as procedure cassettes and accessories, barrier products, plastics, gloves, knives, sutures, absorbing products, self-adhesive products, eye protection products and electrosurgical devices. Once assembled, the packs are placed in plastic pouches with a content label and sealed. The pouches are sterilized and then placed in cardboard shipping boxes.

As of Apr. 30, 2011, Health Canada received 28 reports of incidents suspected of being associated with the contamination of the surgical pack with lint, fibre or particles. The foreign bodies were either discovered in the packs or found by the surgeon during surgery or the postoperative examination of the patient's eye. In 14 cases, the reporter described that the foreign body was removed by the surgeon. In 10 of these cases, a second surgery was required to do this, and in 3 cases the surgeon removed the foreign body from the eye during the initial surgery (information not specified in 1 report). In several of the reports, physicians expressed a concern for the potential risk of infection. Also, in many of these reports, the exact source of the foreign body could not be conclusively determined.

Some of the reports described that the manufacturer had identified the particles as cotton, polyethylene, paper, polyurethane foam, polyester fibre, polystyrene, poly 3-methylcaprolactam and cardboard. It was also reported that the particles may have originated from

the components of the surgical pack itself. The cardboard particles may have entered the product at the supplier's, in the Custom-Pak warehouse or during the assembly process.

Any foreign substance has the potential to induce an inflammatory response.[2] In cases where a foreign body, such as a cotton fibre, has been inadvertently implanted inside the eye during surgery and left there, the evidence relating to the long-term clinical consequences is limited.[3] A foreign body that penetrates the eye as a result of an ocular trauma can cause infection, among other complications. In such cases, prompt diagnosis and appropriate treatment, including antimicrobial therapy, can help prevent the risk of infection and endophthalmitis.[4]

Health professionals are reminded to examine the Custom-Pak Ophthalmic Surgery Procedure Pack and its contents before use. Health Canada continues to monitor adverse incidents suspected of being associated with this product and is working with the manufacturer to update the product label.

Ilhemme Djelouah, RPh, BScPhm, DIS Medical Biology (University of Paris V), Health Canada

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Case presentation

Recent Canadian cases are selected based on their seriousness, frequency of occurrence or the fact that the reactions are unexpected. Case presentations are considered suspicions and are presented to stimulate reporting of similar suspected adverse reactions.

Dental/surgical rotary handpieces and patient burns

Rotary handpieces used in dental and surgical procedures consist primarily of an engine and a chuck mechanism that secures burs (drill bits) into place. Handpieces may be classified as either pneumatic (use of a turbine driven by compressed air) or electric (powered by an electric motor).[1] These devices are used to cut, shape, drill, abrade, burnish, finish and polish tissue and restorative materials. In Canada, surgical rotary handpieces are typically regulated as class II medical devices (IV being the highest risk class).

Health Canada received a report of a patient who experienced a burn to the cheek area during restorative work on an upper tooth with a dental handpiece. As a result, there was pain and swelling in the area and the patient was prescribed an analgesic. After 2 weeks, some scarring was noted at the burn site. Post-incident analysis by the manufacturer revealed that the handpiece in question had worn bearings and had been inadequately maintained overall. This possibly contributed to increased internal friction and heat production. Furthermore, the reported use of the back of the head of the handpiece as a cheek retractor, and the presence of a dent along the back cap edge of the device, may have also affected the operation of the handpiece and contributed to the device overheating. Health Canada has received similar reports of patient burns involving different handpiece models from several device manufacturers.

Health Canada encourages the reporting of patient burns and other adverse incidents suspected of being associated with the use of dental or surgical handpieces to the Health Products and Food Branch Inspectorate through the toll free hotline (1-800-267-9675).

Reference

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CARN's 20th anniversary

Celebrating a milestone anniversary is an opportunity to remember what has been accomplished in past years and to look ahead to new challenges. The *Canadian Adverse Reaction Newsletter* (*CARN*) was first published in 1991. Although its appearance and Editorial Team have changed over the last 20 years, its primary goal remains the same: to be a reliable source of information on adverse reactions (ARs) suspected of being associated with health products in Canada.

CARN is an example of an early-stage risk communication tool, one of many risk communication vehicles that Health Canada uses to issue health product safety information.[1] It features articles and data related to serious or unexpected adverse reactions (ARs) reported to Health Canada by industry, health professionals and consumers. Spontaneous AR reports continue to be an important component in monitoring the safety of health products.[2] These reports provide the backbone of *CARN* and make it relevant to the reader. Its intent is not only to raise awareness, but also to stimulate reporting of similar ARs by health professionals and consumers.

The information published in *CARN* about Canadian AR reports can enhance the global understanding of a health product safety issue. For example, in a recent review of the interaction between rosiglitazone and fenofibrate published in *Endocrine Practice*,[3] an AR report from the July 2005 issue of *CARN*[4] was included as evidence in the clinical understanding of the interaction. In April 2011, *CARN* published an update on rosiglitazone–fenofibrate interactions, with details of the most recent Canadian cases reported to Health Canada.[5] This is not the only time *CARN* has been cited in the literature. The Editorial Team conducted an analysis of the number of citations to *CARN* in the scientific literature as an indirect measure of its impact. As of Mar. 31, 2011, there have been 140 citations in more than 70 journals internationally.

The Editorial Team would like to take this opportunity to thank its readers for their continued interest.

CARN Editorial Team

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Editor's note

After 20 years, *CARN* will be undergoing changes to its Editorial Team. I am pleased to introduce the new Editor-in-Chief, Patricia Carruthers-Czyzewski.

I have had the privilege of serving as Editor-in-Chief since 1996. I have witnessed first-hand how AR reports published in *CARN* contributed to the understanding of emerging safety issues. This underscores the vital role you play in reporting ARs that you witness in your professional practice. It also highlights the importance of promoting a reporting culture where health professionals, consumers and industry have a shared responsibility. I am convinced that *CARN* will continue to disseminate this valuable information. The challenge for *CARN* over the next decade will be to leverage the reach of new tools such as social media to further its goal of prompting AR reporting and increasing awareness.

Ann Sztuke-Fournier, BPharm,
Former Editor-in-Chief

Did you know? Medical devices and incidents

This issue of the *Canadian Adverse Reaction Newsletter* is dedicated to incidents with medical devices.

The term "medical device" covers a wide range of products used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition. In Canada, all medical devices are categorized into 4 classes based on the level of risk associated with their use:

Class I: Lowest risk (e.g., reusable surgical scalpel, bandages, culture media)
Class II: Low risk (e.g., contact lenses, epidural catheters, pregnancy test kits)
Class III: Moderate risk (e.g., orthopedic implants, glucose monitors, dental implants)
Class IV: High risk (e.g., HIV test kits, pacemakers, angioplasty catheters)

Health Canada encourages health professionals and the general public to report incidents suspected of being associated with medical devices to the Health Products and Food Branch Inspectorate through the toll free hotline (1-800-267-9675). Additional information on incident reporting can be found on the Health Canada Web site at www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui-0060_prob-rpt_doc-eng.php.

Quarterly summary of health professional and consumer advisories

(posted on Health Canada's Web site: May 21, 2011 – Aug. 22, 2011)

Date*	Product	Subject
Aug 17	Products from Ben Venue Laboratories Inc.	Potential supply shortage
Aug 4	Sandoz products	Possible fading of the expiry date and lot number
Aug 4	Propecia & Proscar (finasteride)	Potential rare risk of breast cancer in men
July 22	Centrum Materna Prenatal Multivitamins	Unidentified capsules found in one bottle
July 21 & 29, Aug 4	Multaq (dronedarone)	Potential of an increased risk of cardiovascular events
July 20	Calcium Gluconate Injection 10%	Important information concerning the presence of aluminum
July 20	Metoclopramide	Stronger warnings on risk of abnormal muscle movements
July 13	Procter & Gamble mouthwash	Recall: possible microbial contamination
July 8	Valproate products	Risks to children when taken by mothers during pregnancy
July 4	Man Up Now	Removed from sale due to undeclared sildenafil
June 27	Champix (varenicline tartrate)	Potential risk of heart problems in patients with heart disease
June 21	Level 1 Normothermic IV Fluid Administration Sets	Withdrawal of products equipped with F-50 gas vent filter assembly
June 21	Cialis	Seizure of counterfeit Cialis in the Greater Toronto Area
June 17	Actos (pioglitazone)	Potential risk of bladder cancer
June 15	Antipsychotic drugs	Labelling update: risk of abnormal muscle movements and withdrawal symptoms in newborns exposed during pregnancy
June 14, July 6 & 25	Unauthorized products	Removed from sale at Burnaby and Richmond stores due to possible serious health risks
June 7	Junior (160 mg) and children's (80 mg) strength acetaminophen tablets	Recall: faulty child resistant packaging
June 7	Yaz and Yasmin (drospirenone-containing oral contraceptives)	Potential for an increased risk of venous thromboembolism
June 3	Docusate sodium capsules USP, 100 mg	Recall of lot 31040225: possible bacterial contamination
June 2 & 7	Rituxan (rituximab)	Fatal infusion related reactions in patients with rheumatoid arthritis
May 3	Boston Scientific devices	Risk of infection with non-sterile devices stolen
May 21 to Aug 22	Foreign products	9 Foreign Product Alerts (FPAs) were posted on the Health Canada Web site during this period; FPAs are available online (www.hc-sc.gc.ca/ahc-asc/media/index-eng.php) or upon request

Advisories are available at www.health.gc.ca/medeffect.

*Date of issuance. This date may differ from the posting date on Health Canada's Web site.

Canadian Adverse Reaction Newsletter

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Suggestions?

Your comments are important to us. Let us know what you think by reaching us at mhpd_dpsc@hc-sc.gc.ca

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Adverse reactions (ARs) to health products are considered to be suspicions, as a definite causal association often cannot be determined.
Spontaneous reports of ARs cannot be used to estimate the incidence of ARs because ARs remain underreported and patient exposure is unknown.