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NOTICE TO HOSPITALS

**from the Marketed Health Products Directorate, Therapeutic Products Directorate,
and the Health Products and Food Branch Inspectorate**

July 29, 2002

To: Hospitals Chief of Medical Staff

Please forward to the relevant Departments of Surgery; Otolaryngology; Pediatrics; Geriatrics; Internal Medicine; Intensive Care Units; Infection Control; Emergency and involved professional staff and **post this NOTICE** in your institution.

Cochlear Implant Recipients may be at Greater Risk for Meningitis

Health Canada has become aware of information issued by the US-FDA concerning a possible association between cochlear implants and the occurrence of bacterial meningitis. It was stated in the FDA Public Health Web Notification on July 24/2002 (<http://www.fda.gov/cdrh/safety/cochlear.html>).

“At least 25 cases of meningitis have been diagnosed worldwide in children and adults ranging in age from 21 months to 63 years who have undergone cochlear implantation for severe to profound deafness. A total of 9 known deaths resulted from these cases. At this time, 2 out of 3 companies have reported cases of bacterial meningitis in patients who have been implanted.

Cerebrospinal fluid culture results are available in 11 cases. Seven have grown *Pneumococcus* and four have grown Diplococci (most likely *Pneumococcus*). The vaccination history against *Pneumococcus* was available in 5 cases and none had been vaccinated. The onset of meningitis symptoms ranged from less than 24 hours to greater than 5 years from time of implant.”

In Canada, one case of meningitis (not resulting in death) has been reported in a patient with cochlear implant. Health Canada is following up with all the manufacturers of cochlear implants distributed in Canada. Health Canada is also conducting an investigation to determine if there are other cases of meningitis associated with cochlear implants in Canada.

What are Cochlear Implants?

Cochlear implants are devices containing electrodes which are positioned in the cochlea (inner ear) to activate auditory nerve fibers allowing for transmission of sound signals to the brain. Approximately 60,000 implantations have been performed worldwide to date.

Meningitis

Meningitis is an inflammation of the lining of the surface of the brain which is often the result of a bacterial or viral infection. Early symptoms of meningitis include fever, irritability, lethargy and loss of appetite in infants and young children. Older children and adults may also manifest headache, stiff neck, photophobia, nausea and vomiting, and confusion or alteration in consciousness. Physicians are encouraged to consider a diagnosis of meningitis in cochlear implant patients when such symptoms exist and to begin appropriate diagnosis and treatment as soon as possible. Children < 2 years of age have the highest risk of developing meningitis.

Predisposition to Meningitis

A small percentage of deaf patients may have congenital abnormalities of the inner ear which predispose them to meningitis even prior to implantation. Other predisposing factors may include otitis media, immunodeficiency status, prior history of meningitis, or neuro-surgical intervention. The cochlear implant, because it is a foreign body, may act as a nidus for infection when patients have bacterial illnesses.

Cochlear Implants and Otitis Media

In some of the reported cases of meningitis in cochlear implant recipients, patients may have had overt or sub-clinical otitis media prior to surgery or before the meningitis developed. Physicians are encouraged to consider prophylactic antibiotic treatment prior to implantation, as appropriate, and to diagnose and treat otitis media promptly in patients with cochlear implants.

Cochlear Implants and Vaccination

Cochlear implant candidates, as well as those individuals who have already received the implant, may benefit from immunizations against organisms that commonly cause bacterial meningitis, particularly *Streptococcus pneumoniae*. All candidates for and recipients of cochlear implants should be up-to-date with their immunizations.

The National Advisory Committee on Immunization (NACI) recommends the following:

Pneumococcal vaccines

- Heptavalent pneumococcal conjugate vaccine (PCV7) be routinely given to all children ≤ 23 months of age starting at 2 months of age and to all children 24 to 59 months of age at high risk for invasive pneumococcal disease.
- The 23-valent pneumococcal polysaccharide vaccines be given routinely to all adults 65 years of age and older and to persons aged 2 to 64 years at high risk for invasive pneumococcal disease.

Haemophilus vaccines

- Haemophilus influenzae b conjugate vaccine be routinely given to infants starting at 2 months of age and to children up to 59 months of age.

Meningococcal vaccines

- Meningococcal C conjugate vaccine be routinely given to infants starting at 2 months of age and be given to children 1 to 4 years, adolescents and adults.
- Quadrivalent (A, C, Y, W135) meningococcal vaccine be given routinely to individuals > 2 years of age at high risk for invasive meningococcal disease.

For more details re: scheduling of doses and risk factor information, please consult the Canadian Immunization Guide, 6th edition, 2002 (www.hc-sc.gc.ca/pphb-dgspsp/publicat/cig-gci/) or your local Medical Officer of Health.

Reporting Cases of Meningitis in Cochlear Implant Recipients

As a reminder, all cases of bacterial meningitis are notifiable and should be promptly reported to your local Medical Officer of Health. Also, please report cases of meningitis in cochlear implant recipients directly to the device manufacturer or to Health Canada/ Health Products and Food Branch Inspectorate at the Operational Centre closest to you:

HEALTH PRODUCTS AND FOOD BRANCH INSPECTORATE OPERATIONAL CENTRES

Atlantic

Suite 1625, 1505 Barrington St.
Halifax, Nova Scotia
B3J 3Y6
Tel: (902) 426-5350
Fax: (902) 426-6676

Manitoba and Saskatchewan

510 Lagimodière Blvd.
Winnipeg, Manitoba
R2J 3Y1
Tel: (204) 983-5453
Fax: (204) 984-2155

Québec

1001 ouest, rue St-Laurent
Longueuil, Québec
J4K 1C7
Tel: (450) 646-1353, ext. 232
Fax: (450) 928-4455

Western

3155 Willingdon Green
Burnaby, BC
V5G 4P2
Tel: (604) 666-3704
Fax: (604) 666-3149

Ontario

2301 Midland Avenue
Scarborough, Ontario
M1P 4R7
Tel: (416) 973-1466
Fax: (416) 973-1954