

For Health Professionals

Health Alerts

Health Advisory #67 - Manufacturer's Recall of Nasal Spray Contaminated with *Burkholderia cepacia* Complex - March 25, 2004

Clinicians should be aware that the Centers for Disease Control and Prevention (CDC) has been notified of a voluntary recall of over-the-counter oxymetazoline HCL 0.05% nasal spray because of intrinsic contamination with *B. cepacia* complex. The nasal spray is available over the counter and is distributed as: "Major Twice-A-Day 12 Hour Nasal Spray". Patients with underlying lung disease (especially cystic fibrosis) may be at increased risk for severe infections with *B. cepacia* complex.

The manufacturer, Propharma Inc., has recalled lot# K4496 released 11/03 with an expiration date of 10/06. Preliminary molecular epidemiology indicates that isolates related to the strain found in the nasal spray have been recovered from patients in multiple states.

CDC is assisting the state of Missouri, investigating several cases of *B. cepacia* that have been identified in one hospital, to examine the impact of the recalled product on patient safety and the potential spread of *B. cepacia* within the healthcare setting.

Disease symptoms and characteristics:

B. cepacia is a multidrug-resistant organism and management of patients with these bacteria should be in accordance with hospital policy for infection control and isolation precautions. *B. cepacia* poses very little medical risks to healthy people; however, people whose health is otherwise compromised may be more susceptible. If individuals have used this product and are concerned they should contact their healthcare provider.

B. cepacia consists of several species, or a complex, of bacteria, that are found in the natural environment. Some of these species threaten the health of individuals with cystic fibrosis (CF). It is important to note that in general, the species that colonize the lungs of people with CF differ from most of those found in the natural environment. However, all species of *B. cepacia* have been recovered from the sputum of people with CF; these bacteria were only first reported in people with CF in the 1970s.

B. cepacia bacteria are able to survive in the environment or in the lungs of a person with CF. They are resistant to most common cleaning disinfectants and to many antibiotics, which makes them difficult to treat once they infect the lungs. However, some species may be successfully treated with combinations of antibiotics. Standard health precautions greatly reduce the risk of infection.

Cases of *B. cepacia* complex infection or colonization associated with use of this product should be reported to the Erie County Department of Health at 716- 858-7698 (Monday - Friday, 8:30

AM - 4:30 PM) or 716- 898-4225 (evenings, weekends, and holidays) and CDC at (800) 893-0485.