New Hampshire Health Alert Network
Health.Alert@nh.gov

Status:	Actual
Message Type:	Alert
Severity:	Severe
Sensitive:	Not Sensitive
Message Identifier:	NH-HAN #20121101 Fungal Meningitis
Delivery Time:	12 hours
Acknowledgement:	No
Originating Agency:	NH Department of Health and Human Services, Division of Public Health Services

DATE: November 1, 2012 **TIME:** 1600 EDT

TO: Physicians, Physician Assistants, Nurses, Infection Control Practitioners, Infectious Disease Specialists, Hospital Emergency Departments, Hospital CEOs, Laboratory Response Network, Manchester Health Department, Nashua Health Department, NHHA, NH School Nurses and Administrators, Community Health Centers, DHHS Outbreak Team, DPHS Investigation Team, Ambulatory Surgical Centers**,** Public Health Network, and DPHS Management Team

FROM: Sharon Alroy-Preis MD, State Epidemiologist

SUBJECT: Update #6 on Fungal Meningitis Outbreak

New Hampshire DHHS, Division of Public Health Service (NH DPHS) recommends:

- Awareness of newly noted bacterial growth in previously recalled NECC products.
- Awareness of the FDA Press Release regarding national Ameridose recall.
- Discontinue use of all Ameridose products and return them to the firm.
- Timely reporting of human illness suspected to be related to NECC or Ameridose products to DPHS and FDA Med Watch.

National and Local Outbreak Update:
The national case count as of October 31, 2012, related to this outbreak is 377 cases in 19 states including 28 deaths. In New Hampshire there are currently 11 cases meeting CDC case definition, including 8 cases of meningitis and 3 cases of arthritis.

New CDC/FDA Laboratory Findings from NECC Product Testing
FDA and CDC have announced today that they have identified bacterial growth in two additional NECC products. These two products, betamethasone and cardioplegic solution, were previously recalled. Three lots of the betamethasone and one lot of the cardioplegic solution are growing various bacillus species, a gram positive rod. This is the first documented bacterial growth from unsealed vials, in addition to documented fungal growth from the recalled methylprednisolone acetate lots.

The growth is concerning, but the clinical and epidemiologic significance is not yet clear. No *Bacillus* infections have been identified in this outbreak to date. However, these infections can be difficult to diagnose because gram positive rods are frequently dismissed as laboratory contaminants. DPHS recommends providers to broaden their differential to consider the possibility of fungal or bacterial infection in those who received NECC products after May 21st and to report to NH DPHS any *Bacillus* cultures from sterile sites. We will be recommending surveillance with the laboratories in the NH Laboratory Response Network (LRN) to identify *Bacillus* infections from sterile sites that were detected over the past several months and on an ongoing basis.

Recommendations for Providers for New NECC Product Bacterial Growth:

1. Consider fungal and bacterial infections in patients with symptoms after receipt of NECC products, especially betamethasone and cardioplegic solution.
2. If any patients exposed to NECC products since May 21st had gram positive rods isolated from sterile sites, please report this to NH DPHS at the contact information below.

Ameridose Recall

The U.S. Food and Drug Administration (FDA) announced on Oct 31, 2012 that Ameridose, LLC, based in Westborough, Mass., is voluntarily recalling all of its unexpired products in circulation (a full list of products can be found at www.ameridose.com).

Ameridose, LLC has been under FDA investigation as part of the fungal meningitis investigation of the New England Compounding Center (NECC) due to shared management of the two firms. Preliminary findings from the inspection conducted at the Ameridose facility have raised concerns about the lack of sterility assurance for products produced at and distributed by this facility. Human illness has not been reported but FDA is cautioning providers that the use of injectable Ameridose products can represent a serious hazard to health that could lead to life-threatening injuries. Ameridose entered into a voluntary agreement with the Massachusetts Board of Registration in Pharmacy to cease all pharmacy and manufacturing operations starting on Oct. 10, 2012.

At this point, DPHS does not have a list of facilities or providers in NH that received Ameridose products but we will continue to send information as it becomes available in this rapidly developing situation.

Drug Shortage Considerations

FDA has identified six Ameridose products that currently are on the critical drug shortage list. These products were in shortage before the Ameridose recall, but supplies may be further affected as a result of the Ameridose recall. FDA is taking a number of actions, including working with alternate manufacturers of approved products to maintain supplies of these six life-saving drugs, listed below:

1. Sodium Bicarbonate Injection
2. Succinylcholine Injection
3. Atropine Sulfate Injection
4. Bupivacaine Hydrochloride Injection
5. Lidocaine Hydrochloride Injection
6. Furosemide Injection

Recommendations for Providers and Facilities for Ameridose Recall:

1. Discontinue the use of all Ameridose products.
2. Coordinate return of the products to Ameridose (1-888-820-0622).
3. At this time health care professionals do **not** need to contact or follow up with patients who received Ameridose products. However, have some level of clinical suspicion for the potential of human illness associated with the receipt of Ameridose products (particularly injectable products).
4. Report any patients whose symptoms may be related to the use of Ameridose products or unusual findings associated with those products to DPHS (603-271-4496, or after hours: 603-271-5300 asking to page the public health nurse on call) and to the FDA MedWatch program at www.fda.gov/medwatch

Additional Resources:

1) Health care professionals and patients may dial the FDA's Drug Information Line at 855-543-DRUG (3784) and press * to get the most recent information regarding the Ameridose recall and speak directly to a pharmacist.

2) The full FDA announcement can be accessed at: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm326361.htm

3) Refer to the FDA's Drug Shortage website for information on availability of drugs currently in shortage.

4) CDC is in the process of writing health advisory messages for clinicians specific to the Ameridose recall and the newly noted bacterial contamination. Once these are complete, they will be posted to their website at http://www.cdc.gov/HAI/outbreaks/meningitis.html

For any questions regarding the contents of this message, or to report cases, please contact NH DHHS Infectious Disease Investigation and Surveillance Sections at 603-271-4496. After hours or toll free (In NH) at 800-852-3345, ext. 4496 or 603-271-5300 and ask for the public health professional on call.

DEFINITION OF TERMS AND ALERTING VOCABULARY

Message Type

Alert:	Original alert
Update:	Prior alert has been updated and superseded
Cancel:	Prior alert has been cancelled
Error:	Prior alert has been retracted

Status

Actual:	Refers to a live event
Exercise:	Designated recipients must respond to the communication or alert
Test:	Related to a technical and/or system test

Severity

Extreme:	Extraordinary threat to life or property
Severe:	Significant threat to life or property
Moderate:	Possible threat to life or property
Minor:	Minimal threat to life or property
Unknown:	Unknown threat to life or property

Sensitive

Sensitive:	Indicates the alert contains sensitive content
Not Sensitive:	Indicates non-sensitive content

Message Identifier A unique alert identifier that is generated upon alert activation

Delivery Time Indicates the time frame for the delivery of the alert

Acknowledgement Indicates whether an acknowledgement on the part of the recipient is required to confirm that the alert was received, and the time frame in which a response is required.

Originating Agency A guaranteed unique identifier for the agency originating the alert.

Alerting Program The program sending the alert or engaging in alerts and communications using PHIN Communication and Alerting (PCA) as a vehicle for their delivery.

You have received this message based upon the information contained within our emergency notification database.

If you have a different or additional e-mail or fax address that you would prefer to be used, please contact:

Denise M. Krol, MS
NH HAN Coordinator
Denise.Krol@dhhs.state.nh.us

Business Hours: 8 AM – 4 PM
Tel: 603-271-4596
Fax: 603-271-0545