

# 1 Problem

<b>What</b>	Problem(s)	Fungal meningitis outbreak
<b>When</b>	Date	See timeline
	Different, unusual, unique	Contaminated with Aspergillus fungus
<b>Where</b>	State, city	Massachusetts
	Facility, site	Compounding Center
	Unit, area, equipment	Methylprednisolone acetate
	Task being performed	Lumbar epidural steroid injection for back pain

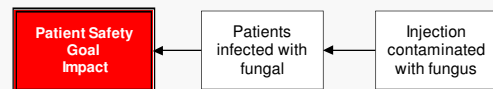
## Impact to the Goals

<b>Patient Safety</b>	5 patients killed
	>30 patients sickened
<b>Employee Impact</b>	?
<b>Compliance</b>	Voluntary surrender of license
<b>Organization</b>	Recall of 3 lots of drug
<b>Patient Services</b>	Difficult treatment required
<b>Environmental</b>	Injection contaminated with fungus
<b>Property, Equip, Mtls</b>	Recall of 3 lots of drug
<b>Labor, Time</b>	Difficult treatment required

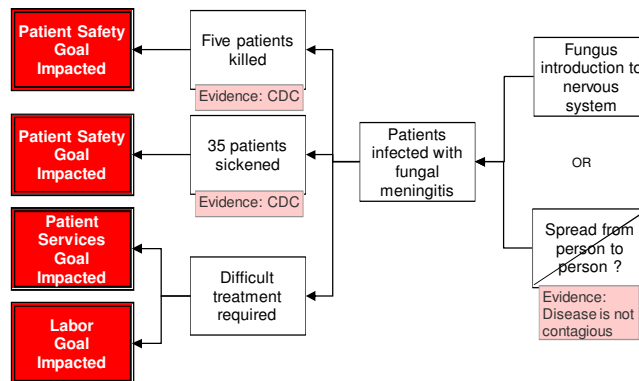
Frequency: At least 35 in 6 states affected  
 Annualized Cost ?

# 2 Analysis

**Basic Level Cause Map** - Start with simple Why questions.



**More Detailed Cause Map** - Add detail as information becomes available.



# FUNGAL MENINGITIS

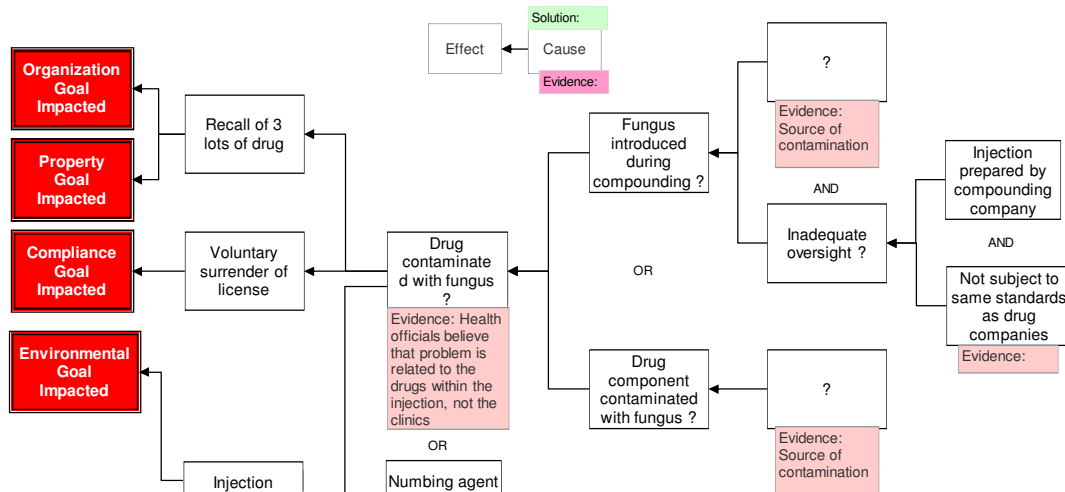
## Cause Map

### Contaminated injections kill

At least 5 patients have been killed, and more than 35 sickened, by fungal meningitis, a very rare, serious, and difficult to treat disease. Compounded steroid epidural injections are believed to have been contaminated with the fungus.

"When it became clear that the infection control practices at the clinic were up to par, the steroid medication became implicated."

William Shaffner  
 Chair of Vanderbilt Department of Preventive Medicine



Cause Mapping is a Root Cause Analysis method that captures basic cause-and-effect relationships supported with evidence.

## CAUSE MAPPING

Problem Solving • Incident Investigation • Root Cause Analysis

- Step 1 Problem** - What's the Problem?
- Step 2 Analysis** - Why did it happen?
- Step 3 Solutions** - What will be done?

## Timeline

Date	Description
September 23, 2004	Compounding company inspected by FDA
January 19, 2005	Inspection completed
December 4, 2006	Letter from FDA to compounding company regarding concerns resulting from inspection
July 1, 2012	Beginning of use of drugs from infected lots
July 30, 2012	Beginning of use of drugs from infected lots at neurosurgery clinic in Tennessee
September 18, 2012	Dr. Pettit of Vanderbilt diagnoses the first case of the fungal meningitis
September 20, 2012	Neurosurgery clinic in Tennessee closes down
September 26, 2012	Compounding company told of issue with injections
	Compounding company voluntarily recalled 3 lots
October 3, 2012	North Carolina suspended compounding company's license to do business in the state

For a free copy of our Root Cause Analysis Template in Microsoft Excel, used to create this page, visit our web site.

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