

1 Problem

What	Problem(s)	Contamination found in drugs produced for NIH use
When	Date	Discovered in April 2015
	Different, unusual, unique	?
Where	Facility, site	NIH Clinical Center in Bethesda, MD
	Task being performed	Creation of drugs for clinical studies

Impact to the Goals

Patient Safety	6 unknowingly given potentially contaminated drugs Some knowingly using potentially contaminated drugs
Compliance	Facilities not compliant with standards
Patient Services	Treatment potentially delayed
Schedule/ Operations	Clinical trials potentially delayed
Property/ Equipment	Facility upgrades required
Labor/ Time	Investigation and corrective actions required

CONTAMINATION FOUND IN NIH PHARMACY

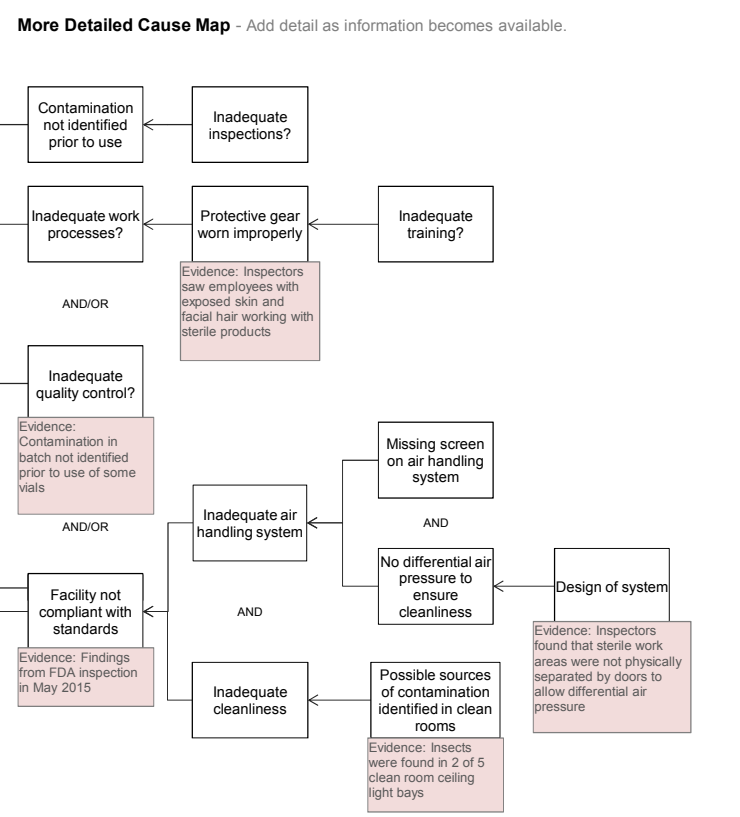
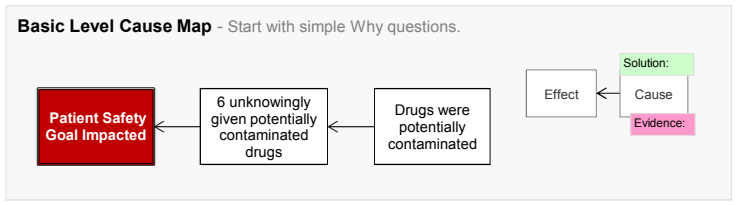
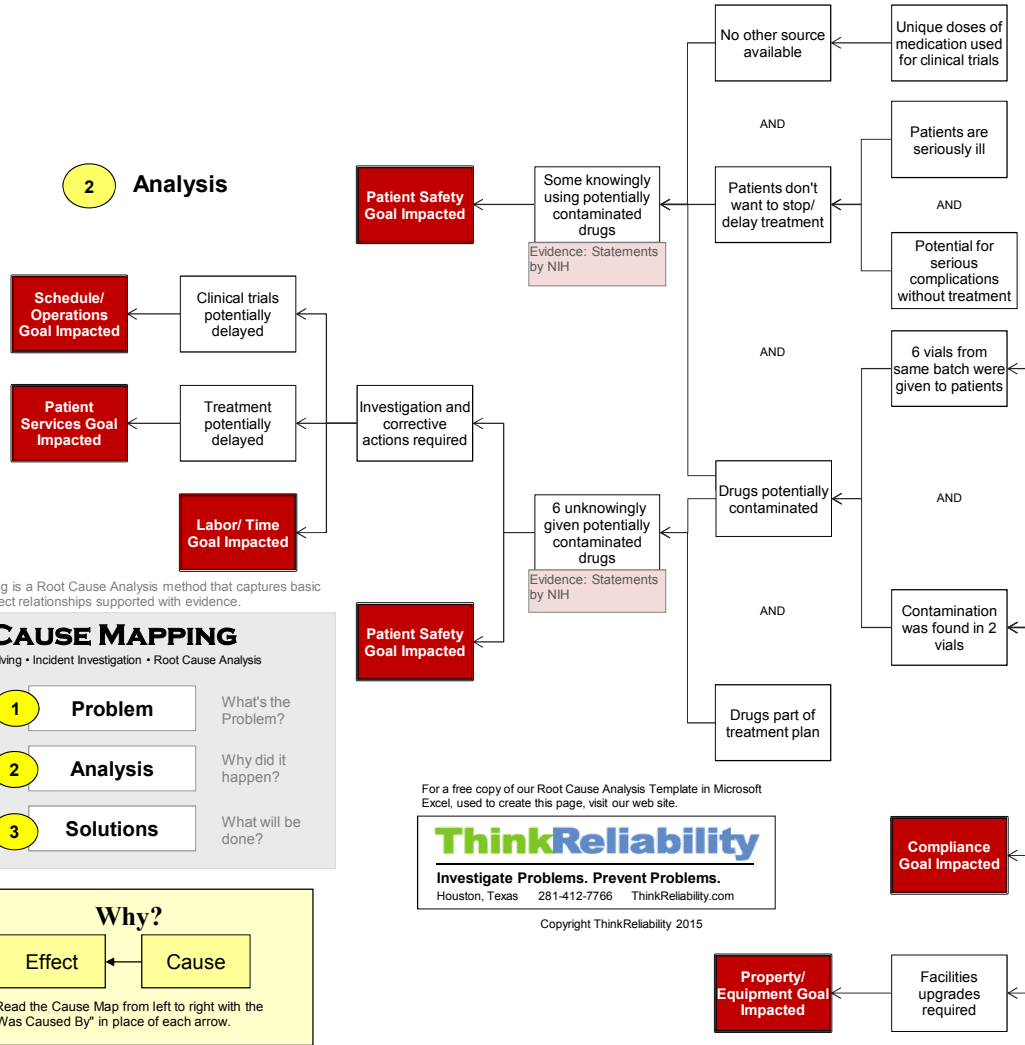
Cause Map

The National Institute of Health (NIH) has announced that production of drugs for use in clinical studies has been suspended after fungal contamination was found in two vials of product. The exact source of the contamination has not been identified, but a recent Food and Drug Administration (FDA) inspection of the facility that prepared the product found multiple deficiencies, including issues with both the facility and the work practices.

"This is a distressing and unacceptable situation. The fact that patients may have been put in harm's way because of a failure to follow standard operating procedures ... is deeply troubling. I will personally oversee the steps to protect the safety of patients and remedy the situation as swiftly as possible."

- NIH Director Francis S. Collins

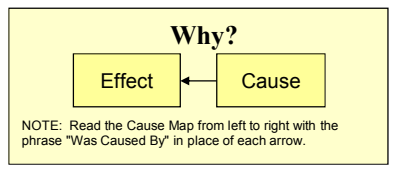
2 Analysis



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?



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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