USE OF NON-STERILE PRODUCT CAUSES PATIENT HEALTH ISSUES

Cause Map

Intravenous product meant for training only

A non-sterile product that was meant for clinical simulation (training) only was administered intravenously to at least 40 patients, one of whom died and at least 17 of whom became seriously ill.

"It seems like it's not just one single mistake. There could have been instances where ordering was done by office staff who didn't know the difference, as well as instances where the right product was ordered but they received the wrong stuff."
- Dr. Alexander J. Kallen, medical officer at the Centers for Disease Control and Prevention (CDC)

1 Problem

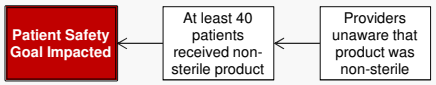
What	Problem(s)	Saline solution recalled; deaths/ injuries from use
When	Date	January 7, 2015
	Time	N/A
	Different, unusual, unique	Facilities unaware that products were for simulation only
Where	Facility, site	Florida, Georgia, Idaho, Louisiana, North Carolina, New York, and Colorado
	Unit, area, equipment	Simulated intravenous (IV) saline products
	Task being performed	Given via IV to patients

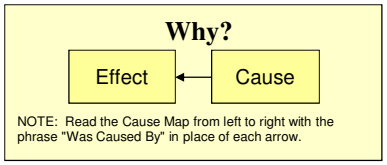
Impact to the Goals

Patient Safety	1 patient killed; at least 17 ill
Employee Safety	?
Environmental	?
Compliance	?
Patient Services	>40 patients received non-sterile products
Schedule/ Operations	?
Property/ Equipment	Bags with saline and distilled water recalled
Labor/ Time	Investigation

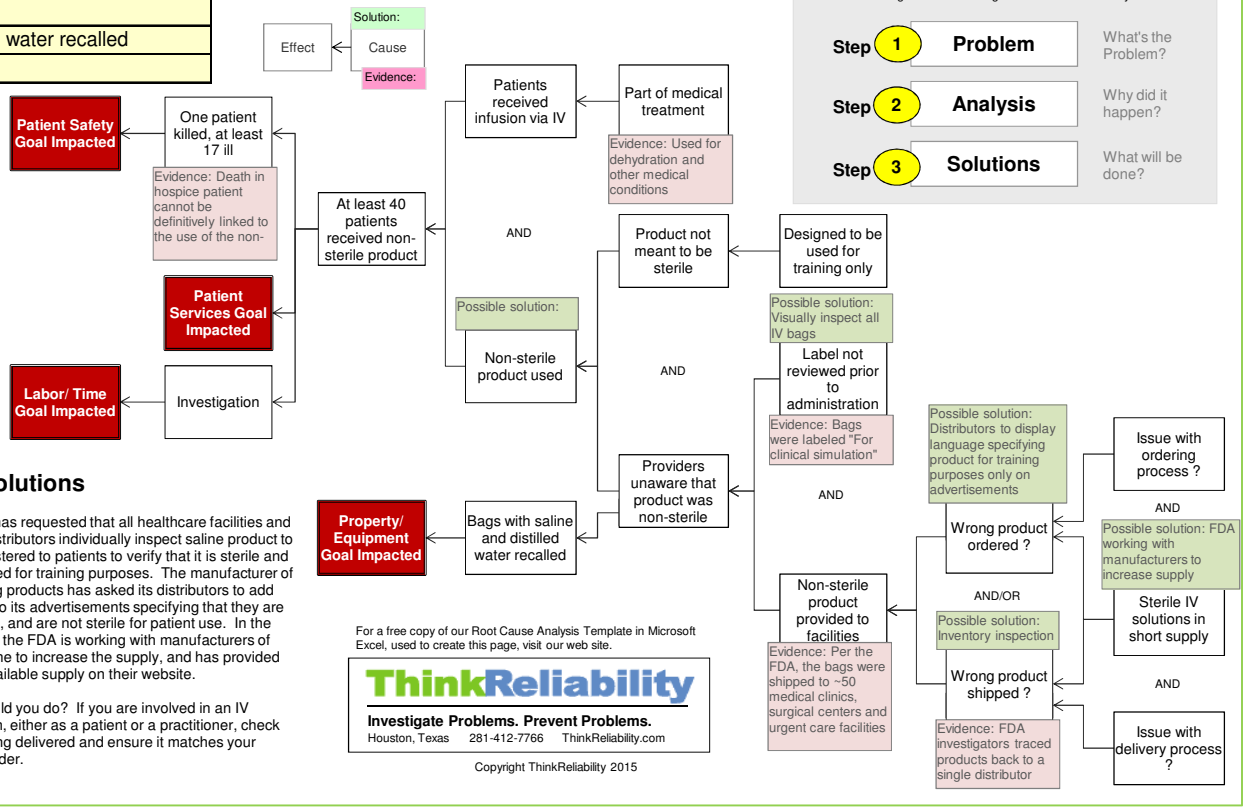
2 Analysis

Basic Level Cause Map Start with simple Why questions.





More Detailed Cause Map
Add detail as information becomes available.



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?

3 Solutions

The FDA has requested that all healthcare facilities and product distributors individually inspect saline product to be administered to patients to verify that it is sterile and not intended for training purposes. The manufacturer of the training products has asked its distributors to add language to its advertisements specifying that they are for training, and are not sterile for patient use. In the meantime, the FDA is working with manufacturers of sterile saline to increase the supply, and has provided links to available supply on their website.

What should you do? If you are involved in an IV transfusion, either as a patient or a practitioner, check what's being delivered and ensure it matches your doctor's order.

Timeline

Date	Description
May 22, 2014	Company begins shipping saline labeled "for clinical simulation"
December 30, 2014	FDA alert to healthcare professionals regarding potential use of non-sterile IV solutions
January 7, 2015	Manufacturer of training IV bags initiates recall
January 15, 2015	FDA says one person died and 17 were sickened in seven states due to the use of non-sterile solutions
January 16, 2015	FDA opens investigation

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