Problem 1 Problem(s) Saline solution recalled; deaths/ injuries from use What Date January 7, 2015 When N/A Time Different, unusual, unique Facilities unaware that products were for simulation Facility, site Florida, Georgia, Idaho, Louisiana, North Carolina, Where 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 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 nvestigation **Analysis** 2 Patient Safety Basic Level Cause Map Start with simple Why guestions. At least 40 Providers **Patient Safety** patients unaware that received nonproduct was sterile product non-sterile

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

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

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."

Part of medical

treatment

Evidence: Used for

Product not

meant to be

sterile

AND

Providers

unaware that

product was

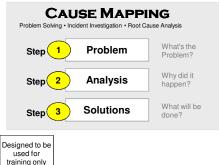
non-sterile

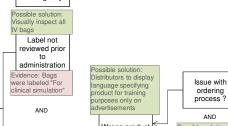
dehydration and

other medical conditions

- Dr. Alexander J. Kallen, medical officer at the Centers for Disease Control and Prevention (CDC)







Wrong product Possible solution: FDA ordered? working with manufacturers to ncrease supply Non-sterile AND/OR product Sterile IV provided to solutions in Possible solution: facilities nventory inspection short supply

FDA, the bags were shipped to ~50 medical clinics, surgical centers and rgent care facilities

Wrong product AND shipped? Issue with nvestigators traced livery process products back to a single distributor

Solutions

links to available supply on their website

Timeline

Date Description

Company begins shipping saline labeled "for clinical May 22, 2014

Effect

simulation"

FDA alert to healthcare professionals regarding potential use December 30, 2014

Why?

NOTE: Read the Cause Map from left to right with the

phrase "Was Caused By" in place of each arrow

Cause

of non-sterile IV solutions

January 7, 2015 Manufacturer of training IV bags initiates recall FDA says one person died and 17 were sickened in seven

January 15, 2015 states due to the use of non-sterile solutions

January 16, 2015 FDA opens investigation More Detailed Cause Map Add detail as information becomes available. Solution:

Cause

Evidence

Property/

Equipment

Patients

received

nfusion via IV

AND

Possible solution

Non-sterile

product used

Bags with saline

and distilled

water recalled

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Excel, used to create this page, visit our web site.

Effect One patient killed, at least 17 ill

Evidence: Death in nospice patient cannot be

At least 40 definitively linked to patients the use of the nonreceived non sterile product

Impacted

Patient

ervices Goa

Labor/ Time Investigation Goal Impacte