

# 1 Problem

What	Problem(s)	Patients infected, killed by superbug, scopes contaminated
When	Date	See timeline
	Different, unusual, unique	Design of device makes cleaning difficult
Where	Facility, site	UCLA Medical Center
	Unit, area, equipment	Duodenoscopes
	Task being performed	Diagnosis/ procedures on digestive system (ERCP)

## Impact to the Goals

Patient Safety	2 patient deaths
Employee Safety	Risk from gas sterilization of scopes
Environmental	CRE contamination of duodenoscopes
Patient Services	7 patients infected with CRE
Property/ Equipment	Difficulty properly cleaning equipment

Frequency	Numerous infection outbreaks from use of duodenoscopes since 1987
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# 2 Analysis

## Cause Map

Add detail as information becomes available.

**The bacteria involved in the outbreak are deadly:** "CRE are nightmare bacteria. Our strongest antibiotics don't work and patients are left with potentially untreatable infections." - Tom Frieden, CDC Director

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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# 3 Solutions

**The FDA is working on label changes for duodenoscopes:** "We are working to expedite modifications to the label. We are also talking about updating the risk information." - FDA Chief Scientist William Maisel

**Some worry that may not be enough:** "The devices need to be designed better, the instructions need to be more clear, the hospitals need better training, and adequate time needs to be given in hospitals to ensure sterility is top notch." - Mary Logan, Association for the Advancement of Medical Instrumentation

**It's all part of a much bigger problem:** "The world will still be at serious peril from a risk we don't take seriously, which is antibiotic resistance. Germs are figuring out how to resist our antibiotics faster than we can make new ones." - David Ropeik, risk perception & communication consultant

# SCOPES CAUSE SUPERBUG OUTBREAK

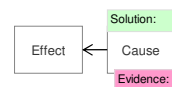
Cause Map

## 7 patients infected, 2 patients killed by contaminated duodenoscopes

"Recent medical publications and adverse event reports associate multidrug-resistant bacterial infections in patients who have undergone ERCP with reprocessed duodenoscopes, even when manufacturer reprocessing instructions are followed correctly. Meticulously cleaning duodenoscopes prior to high-level disinfection should reduce the risk of transmitting infection, but may not entirely eliminate it." - FDA Safety Communication, February 19, 2015

"The devices need to be designed better, the instructions need to be more clear, the hospitals need better training, and adequate time needs to be given to hospitals to ensure sterility is top notch."

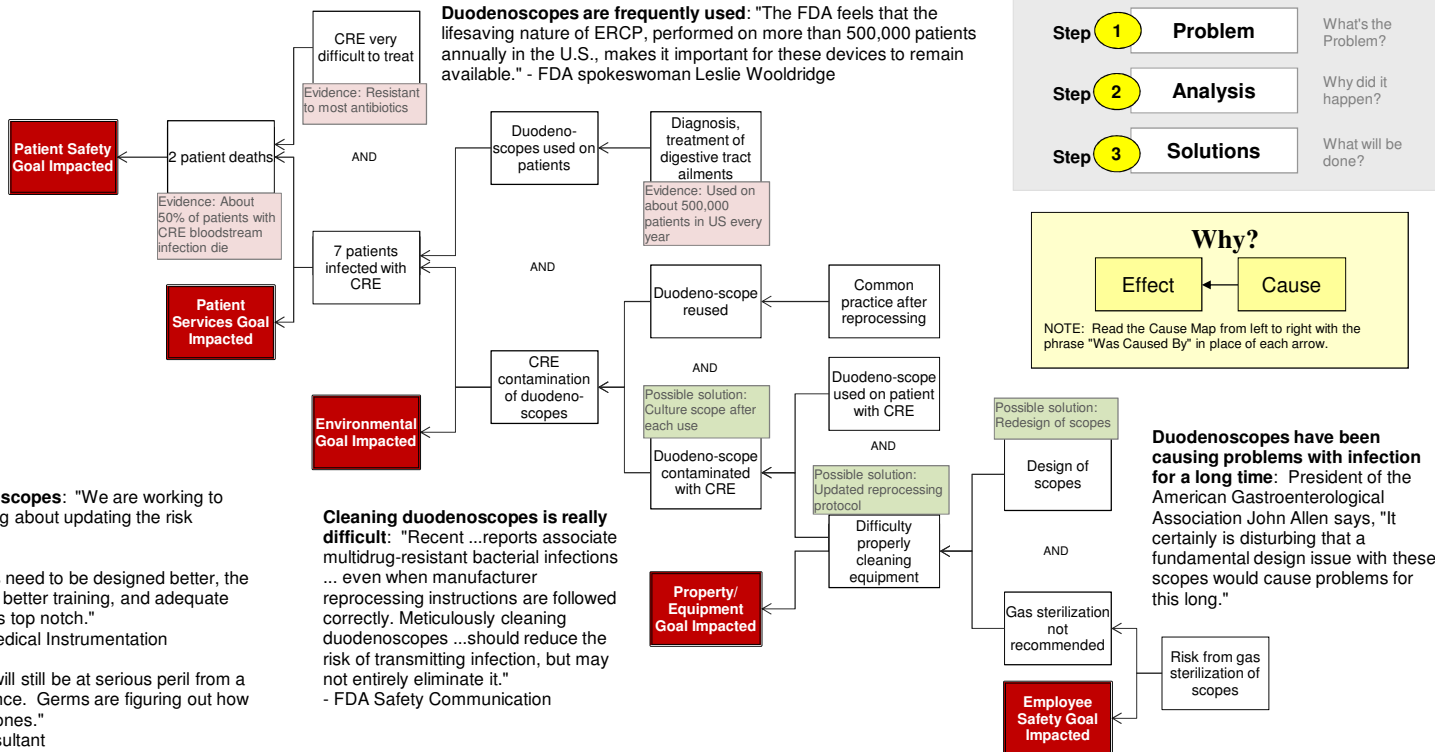
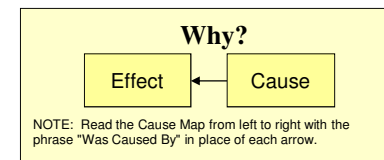
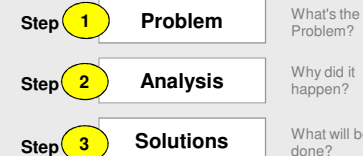
- Mary Logan, Chief Executive, Association for the Advancement of Medical Instrumentation



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



**Duodenoscopes are frequently used:** "The FDA feels that the lifesaving nature of ERCP, performed on more than 500,000 patients annually in the U.S., makes it important for these devices to remain available." - FDA spokeswoman Leslie Wooldrige

**Cleaning duodenoscopes is really difficult:** "Recent ...reports associate multidrug-resistant bacterial infections ... even when manufacturer reprocessing instructions are followed correctly. Meticulously cleaning duodenoscopes ...should reduce the risk of transmitting infection, but may not entirely eliminate it." - FDA Safety Communication

**Duodenoscopes have been causing problems with infection for a long time:** President of the American Gastroenterological Association John Allen says, "It certainly is disturbing that a fundamental design issue with these scopes would cause problems for this long."

