**Problem**

**What**  
Patients infected, killed by superbug, scopes contaminated

**When**  
Date: See timeline

**Where**  
UCLA Medical Center

**Task being performed**  
Diagnosis/ procedures on digestive system (ERCP)

**Impact to the Goals**

<table>
<thead>
<tr>
<th>Goal</th>
<th>Impacted</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Safety</td>
<td>2 patient deaths</td>
<td>Numerous infection outbreaks from use of duodenoscopes since 1987</td>
</tr>
<tr>
<td>Employee Safety</td>
<td>Risk from gas sterilization of scopes</td>
<td></td>
</tr>
<tr>
<td>Environmental</td>
<td>CRE contamination of duodenoscopes</td>
<td></td>
</tr>
<tr>
<td>Patient Services</td>
<td>7 patients infected with CRE</td>
<td></td>
</tr>
<tr>
<td>Property/Equipment</td>
<td>Difficulty properly cleaning equipment</td>
<td></td>
</tr>
</tbody>
</table>

**Analysis**

**Cause Map**

1. **Patient Safety Goal Impacted**
   - Cause: CRE very difficult to treat
     - Evidence: Resistant to most antibiotics
   - Effect: 2 patient deaths

2. **Patient Services Goal Impacted**
   - Cause: CRE very difficult to treat
     - Evidence: About 50% of patients with CRE bloodstream infection die
   - Effect: 7 patients infected with CRE

3. **Environmental Goal Impacted**
   - Cause: Duodenoscopes used on patients
     - Evidence: Used on about 500,000 patients in US every year
   - Effect: CRE contamination of duodenoscopes

4. **Property: Equipment Goal Impacted**
   - Cause: Difficult properly cleaning equipment
   - Evidence: Common practice after reprocessing

5. **Employee Safety Goal Impacted**
   - Cause: Gas sterilization of scopes
     - Evidence: Recommended but may not be enough
   - Effect: Risk from gas sterilization of scopes

6. **Solution**
   - Possible solution: Culture scope after each use
   - Possible solution: Updated reprocessing protocol

**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 to hospitals to ensure sterility is top notch." - Mary Logan, Chief Executive, 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

**Cause Mapping**

- "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.

**SCOPES CAUSE SUPERBUG OUTBREAK**

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

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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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