CONCERNS OVER FAULTY IMPLANTS

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?

1 Problem

Step 1. Outline the Problem

What	Problem(s)	Women received faulty breast implants
When	Date	2001-2010
	Differences	All implants from same company
Where	Physical Location	Manufactured in France, exported to many countries
	Work Being Done	Breast implant surgery
Impact to the Goals		
	Safety	Health risks to thousands of women
		This incident ??
	Frequency	Thousands of woman affected
		Annual Total ??

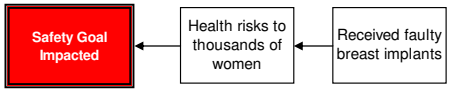
Cause Map

Thousands of women received faulty breast implants that are both filled with substandard silicone and rupturing at twice the industry average. Nations are scrambling to determine the best course of action to deal with this issue.

"In case of rupture, you'd have a dangerous quantity of silicone in your body,"
- Laurent Lantieri, a plastic surgeon at a hospital near Paris.

2 Analysis

Basic Level Cause Map - Start with simple Why questions.



Basic Cause-and-Effect

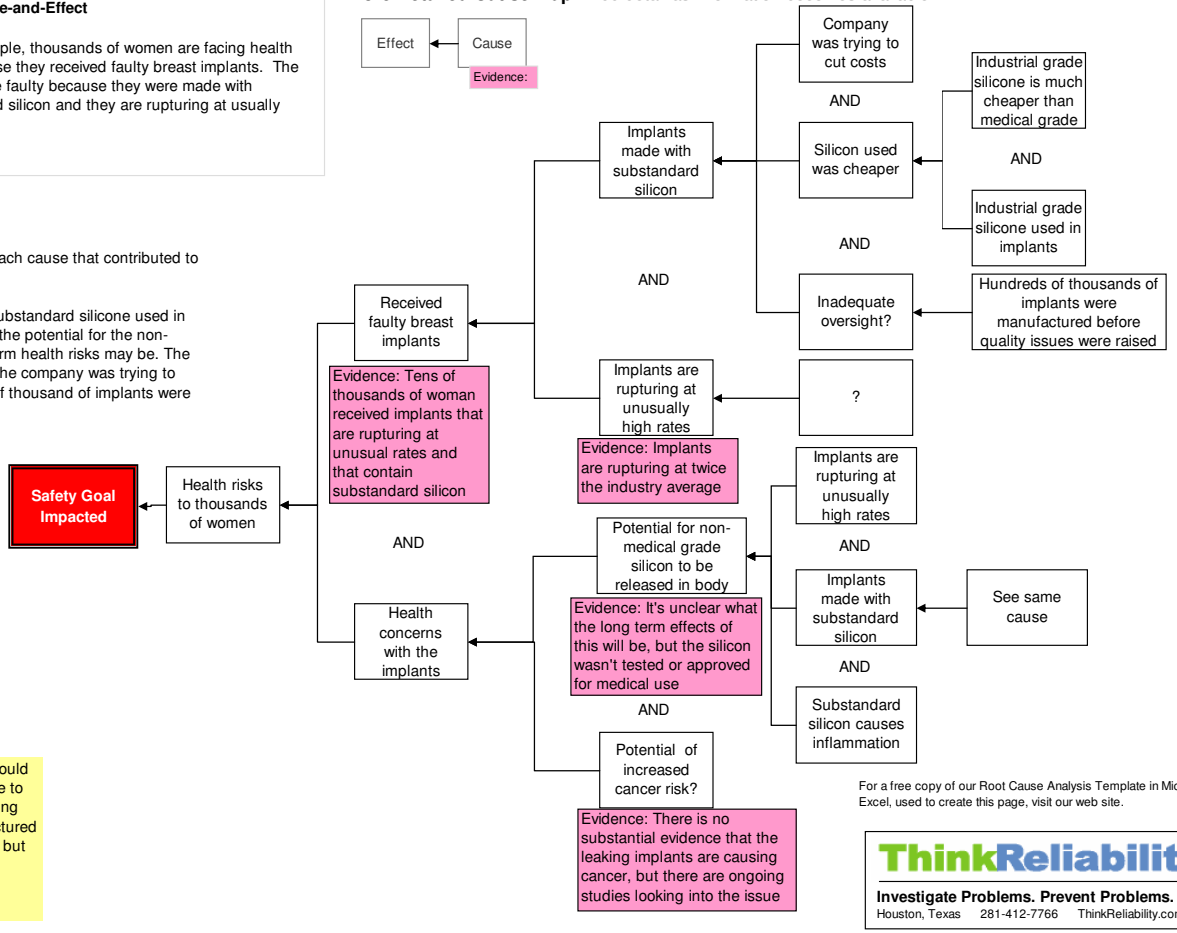
In this example, thousands of women are facing health risks because they received faulty breast implants. The implants are faulty because they were made with substandard silicon and they are rupturing at usually high rates.

More Detailed Cause-and-Effect

The Cause Map is built by continuing to ask "why" questions and adding boxes with each cause that contributed to this issue.

In this example, woman are facing health risks because of the risks associated with substandard silicone used in breast implants. The implants are rupturing at twice the industrial average, adding to the potential for the non-medical silicone to be released into the body. No one knows for sure what the long term health risks may be. The substandard silicon was used in the faulty breast implants because it is cheaper and the company was trying to minimize costs. There may also have been inadequate oversight because hundreds of thousand of implants were manufactured before any quality issues were raised.

More Detailed Cause Map - Add detail as information becomes available.



3 Solutions

The final step of the Cause Mapping process is to come up with potential solutions that could be used to prevent the problem from reoccurring. In this example, work is still being done to determine the long term health risks. Officials are attempting to weigh the risks of removing the implants with the potential risks of leaving them in place. The company that manufactured the implants has gone out of business and is no longer manufacturing medical products, but the French government is working to determine if changes are necessary to the approval process for medical devices to ensure no similar incidents occur in the future.

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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