

1 Problem

RECALLED CONTACTS CAUSE ISSUES

Step 1. Outline the Problem

What	Problem(s)	Contacts causing eye problems
When	Date	Summer 2011
	Differences	Residue on contacts, recall
Where	Physical Location	Product distributed worldwide
Impact to the Goals	Safety	Dozens of customers report eye problems
	Customer Service	Negative publicity about product
	Production-Schedule	Man hours spent and revenue lost because of recall
	Frequency	1x
		This incident ??
		Annual Total ??

Cause Map

Dozens complained about eye issues ranging from blurry vision to torn corneas after wearing recalled contact lenses. Many didn't even know that their contacts had been recalled.

This situation "can only be described as a stealth recall" .

- Phyllis Entir, author of blog eFoodAlert.

Cause Mapping is a Root Cause Analysis method that captures basic cause-and-effect relationships supported with evidence.

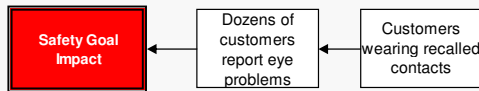
CAUSE MAPPING

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?

2 Analysis

Basic Level Cause Map - Start with simple Why questions.



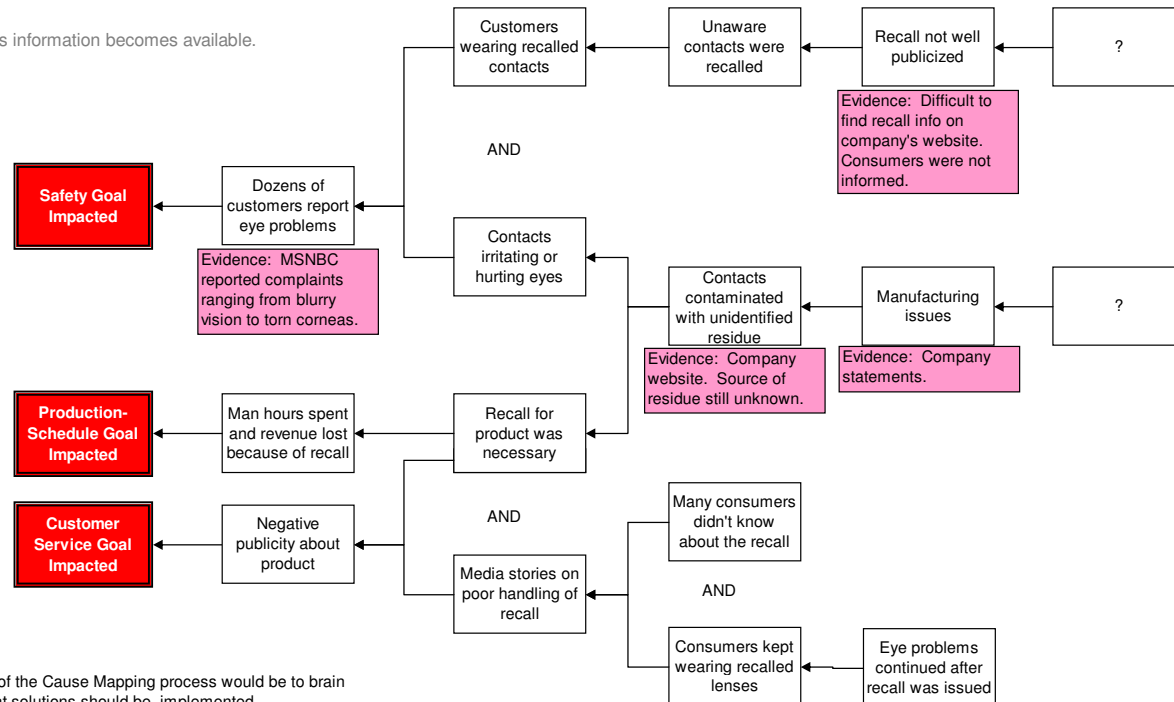
Basic Cause-and-Effect

Consumers experienced a number of eye problems from a residue on their contact lenses. The company has stated that a manufacturing error led to the residue.

More Detailed Cause-and-Effect

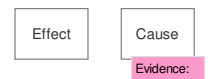
Avaira Toric contact lenses, manufactured by CooperVision Inc, were voluntarily recalled on August 19, 2011. The recall occurred after dozens of consumers complained about eye problems including impaired vision, eye pain and torn corneas. According to a company statement, a manufacturing error resulted in a silicone oil residue on some contacts. More than 8 million lenses were affected worldwide by the recall, but only about 780,000 of these contact lenses were distributed in the USA.

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



The company has received a large amount of negative media attention following the recall. News articles and blogs have claimed that CooperVision was purposely downplaying the recall, resulting in many consumers being unaware that their lenses had been recalled. Unaware of the potential danger, consumers continued to wear their lenses and continued to have eye problems as a result. The FDA publicly threatened to independently inform consumers of the risk associated with these contact lenses if the manufacturer didn't better publicize the recall.

Following the media attention, the company has increased efforts to notify consumers about the recall. The FDA has also posted a notice on their website of this recall, identifying it as a Class I recall, the most serious class of recall. The FDA has said that the company's actions are now consistent with what would be expected with a Class I recall.



3 Solutions

After the investigation is complete, the final step of the Cause Mapping process would be to brainstorm possible solutions and then determine what solutions should be implemented.

In this example, part of the solution must include how to better inform consumers about product

For a free copy of our Root Cause Analysis Template in Microsoft Excel, used to create this page, visit our web site.

ThinkReliability
 Investigate Problems. Prevent Problems.
 Houston, Texas 281-412-7766 ThinkReliability.com