

1 Problem

COUNTERFEIT DRUGS SOLD IN US

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

Step 1. Outline the Problem

What	Problem(s)	Counterfeit drug sold
When	Date	2011
	Differences	Purchased from same supplier
Where	Physical Location	In the US, most cases in California
	Task being performed	Cancer treatment
Impact to the Goals		
	Safety	Risk that patients could receive drugs
		This incident
	Frequency	19 known cases in 2011

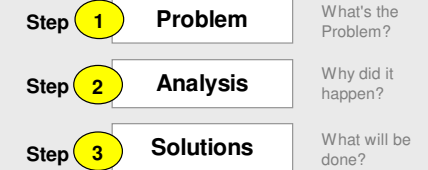
Cause Map

A counterfeit version of Avastin, a cancer treatment drug, was purchased by as many as 19 U.S. oncology practices last year.

"Right now you have a situation where one shady wholesaler can introduce something and that can then pass through multiple actors in the system," - said Allen Coukell, director of medical programs at the Pew Health Group and co-author of the report on counterfeit medicines.

CAUSE MAPPING

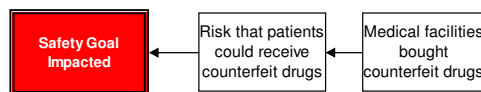
Problem Solving • Incident Investigation • Root Cause Analysis



2 Analysis

Basic Level Cause Map - Start with simple Why questions.

Basic Cause-and-Effect



Many medical facilities bought counterfeit Avastin last year without realizing the drugs were not legitimate. There are no reported cases of the drugs being given to patients, but the potential was there.

More Detailed Cause-and-Effect

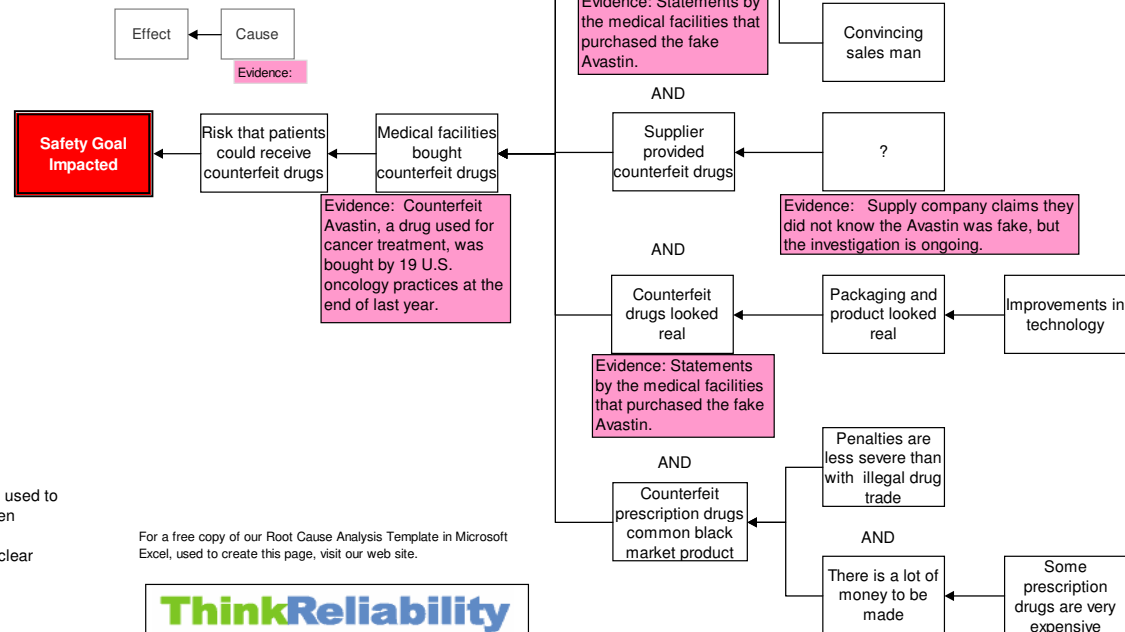
Many factors led to the oncology practices purchasing the fake Avastin. The supplier offered the lowest price for the drug, about \$400 less than the manufacturer's price. Additionally, the supplier appeared to be legitimate and had a very convincing salesman working for them. The supplier appeared to have both US phone number and offices in the US. In reality, the US number phones were being automatically routed to an overseas number, but this process was transparent to the medical practices. The counterfeit drugs themselves also appeared to be authentic. As technology improves it is becoming more difficult to spot the fakes.

At this point in the investigation it's not clear whether the supplier knew the drugs were fakes. The company claims it had no knowledge that the counterfeit product. One thing that is clear is why counterfeit drugs appear in the supply. There is a lot of money to be made. Some prescription drugs are extremely expensive and selling fakes can be very profitable. The drug in this case, Avastin, sells for more than \$2,000 for a 400-milligram vial. There are also generally less severe punishments for crimes associated with prescription drugs compared with the illegal drug trade.

It is estimated that less than one percent of the drug supply is counterfeit in developed nations, but counterfeit drugs are a huge issue in developing countries. Even a small amount of counterfeit prescription drugs has the potential for a large impact on peoples' health.

More Detailed Cause Map -

Add detail as information becomes available.



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 final step of the Cause Mapping process is to come up with potential solutions that could be used to prevent the problem from reoccurring. There are a number of solutions to this issue that have been suggested. The US Senate has recently passed a bill that pushes for stronger punishments for counterfeit drug trafficking and calls for a universal system to track prescription drugs, but it's unclear how this might be adopted into law.