

# 1 Problem

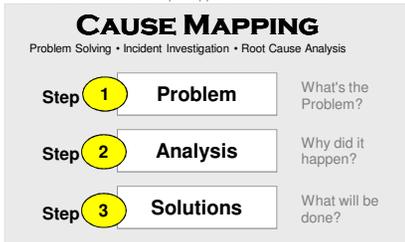
<b>What</b>	Problem(s)	Patient deaths, infection
<b>When</b>	Date	November 8, 2014
	Time	N/A
<b>Where</b>	Different, unusual, unique	Potential issues with drugs, surgery
	Facility, site	Chhattisgarh, India
	Unit, area, equipment	Institute of Medical Sciences
	Task being performed	Mass sterilization operations

## Impact to the Goals

<b>Patient Safety</b>	13 women died
<b>Compliance</b>	Surgeon arrested
	Drug manufacturing staff arrested
<b>Patient Services</b>	Post-surgical infection

Frequency	4.5 million women sterilized in a year
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Cause Mapping is a Root Cause Analysis method that captures basic cause-and-effect relationships supported with evidence.



Although there is currently limited information on what exactly led to the death of these women, an analysis of those things that went wrong can still be useful to look for solutions. (Each possible cause (which indicates that more evidence is needed) can be developed with additional detail when more information is available.)

Post-mortem inspection of the women who were killed indicated that their deaths were due to septic shock from severe infections. The infections were believed to have been obtained during the surgery due to dirty tools or poor conditions. (It's not surprising that a clinic with limited resources known for having substandard cleanliness would struggle to ensure clean equipment for 83 surgeries in 6 hours.) If the antibiotic they were given in order to fight potential infection was adulterated (and not providing the desired active ingredients, or too little of them to be effective), it would decrease the women's ability to fight off the infection.

The potential poisoning (supported by sickness of others who received medication from the same batch) is believed to be due to counterfeit or adulterated medication. Preliminary testing showed the presence of a chemical used in rat poison within the medication. Counterfeit and adulterated drugs are both a problem in India; the World Health Organization (WHO) estimates that as many as 1 in 5 drugs made in India are fake. The US FDA prevents the importation of the antibiotic used at the clinic from India. Drug inspectors in the area indicate that about 25% are of substandard quality due to poor manufacturing practices. Enforcement of drug quality is limited in the area, and issues with medication are seen frequently.

Both the surgeon and the owners of the pharmaceutical manufacturing facility have been arrested. Both sterilizations and the use of certain drugs have been limited in the area until the causes resulting in the women's deaths have been determined. What hasn't happened (yet) is a serious look at the country's method of family planning in hopes that these types of tragedies never happen again.

# 13 WOMEN DIE AFTER PAID STERILIZATION SURGERY

Cause Map

## Sub-standard surgical conditions, adulterated drugs may be responsible

The deaths of 13 women after they underwent tubal ligation (female sterilization surgery) at a government-run clinic has resulted in outrage and arrests, but few answers. It is known that shortly after one of these mass sterilizations on November 8th at a mobile clinic, the women became ill and died. The cleanliness of the tools used for the surgeries as well as of the clinic itself are believed to have caused infections that led to severe septic shock that resulted in these deaths. However, over the next few days, patients from different clinics who had taken antibiotics from the same batch used at the sterilization clinic also became ill, raising the question of contaminated - or outright counterfeit - drugs. The signs of poisoning and septic shock can be similar, so additional testing is needed. Either way, it's clear that the care these women received was substandard. Not only are the condition of the clinics and medication in question, but the use of these surgeries as a form of family planning, common in the area.

"It was almost inevitable, given the unsafe, unethical and unhygienic conditions that persist throughout India in these camps."

- Kerry McBroom, Human Rights Law Network advocate

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# 2 Analysis

Detailed Cause Map - Add detail as information becomes available.

