

SURGICAL TOOL MAY SPREAD CANCER

Cause Map

FDA to determine future of the morcellator

"There is at present no safe way to offer laparoscopic power morcellation as part of any minimally invasive surgery."

- Dr. Craig Shriver, surgical oncologist, Walter Reed National Military Medical Center

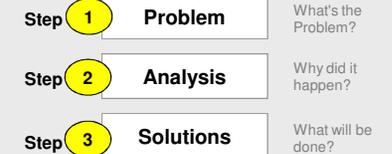
"I don't know that necessarily morcellation should be banned. But this data is important to allow people to make decisions."

- Dr. Jason D. Wright, lead author, Journal of the American Medical Association study regarding morcellators

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



1 Problem	What	Problem(s)	FDA discourages use of morcellators
	When	Date	April 17, 2014
		Different, unusual, unique	Prevalence of uterine cancer higher in women who undergo hysterectomies to treat benign conditions; no pre-operative test that reliably tests for uterine sarcoma
Where	Facility, site	Healthcare facilities	
	Unit, area, equipment	Laparoscopic power morcellator	
	Task being performed	Minimally invasive hysterectomy	

Impact to the Goals	
Patient Safety	Risk for spreading cancer
Employee Safety	?
Environmental	?
Compliance	?
Patient Services	Delay in identifying risk from product use
Schedule/ Operations	Sales of morcellators stopped
Property/ Equipment	Use of morcellators questioned
Labor/ Time	?

Frequency	Procedure performed on about 50,000 women per year; 1 in 368 found to have uterine cancer
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2 Analysis

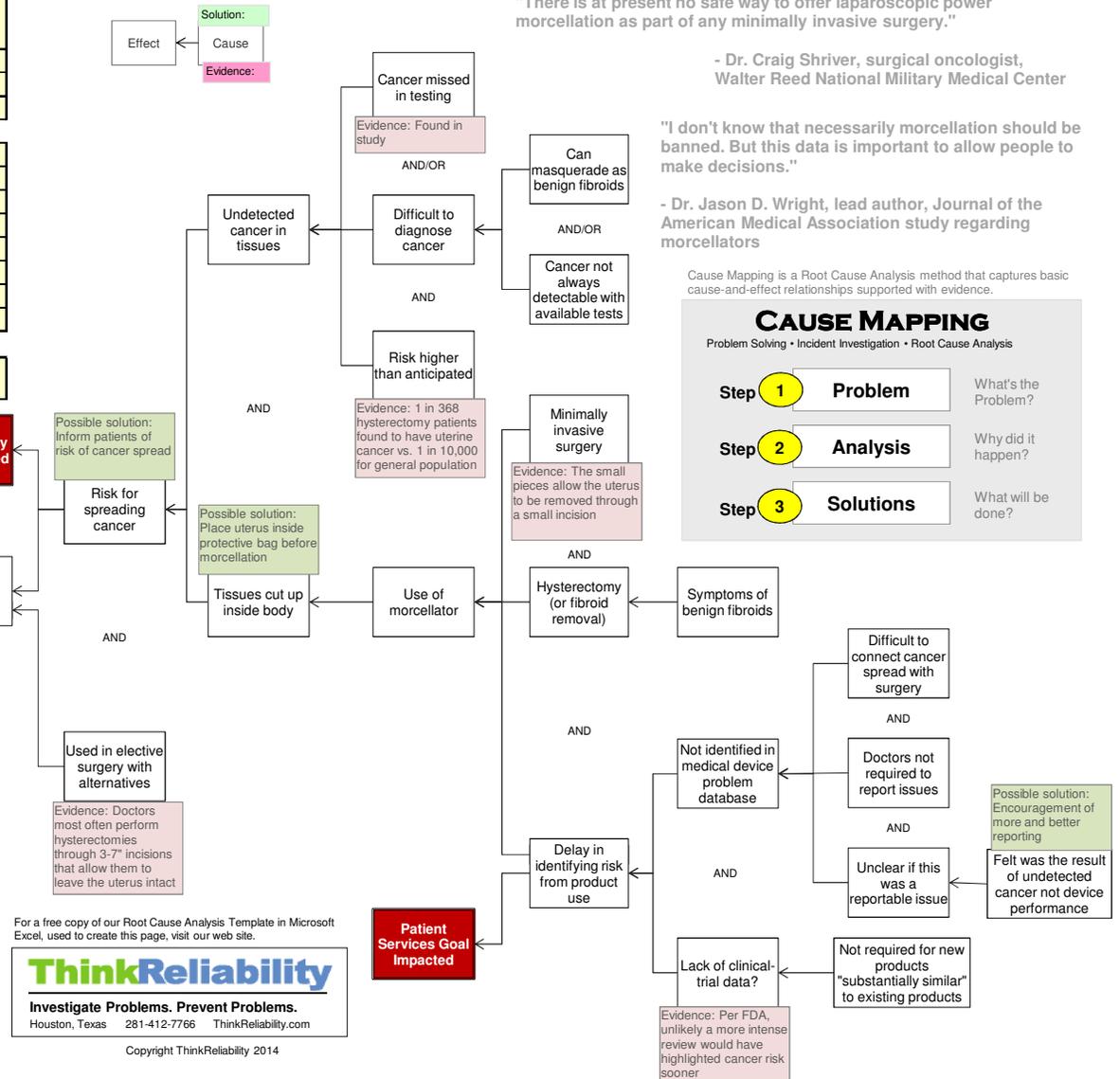
More Detailed Cause Map - Add detail as information becomes available.

3 Solutions

The FDA is working to determine what - if any - restrictions will be placed on morcellator use. It's pretty clear to some, especially given that this treatment for fibroids is considered elective and there are alternatives, including a traditional hysterectomy. Says Dr. Craig Shriver, surgical oncologist at Walter Reed National Military Medical Center, "There is at present no safe way to offer laparoscopic power morcellation as part of any minimally invasive surgery."

However, others think the tool still has a place for minimally invasive surgery and that patients should be able to determine for themselves if the risk is worth taking. According to Dr. Jason D. Wright, the lead author of a study regarding morcellators published in the Journal of the American Medical Association study, "I don't know that necessarily morcellation should be banned. But this data is important to allow people to make decisions."

In the meantime, some facilities are attempting to enclose the uterus in a protective bag before morcellation to minimize the risk of tissue remaining in the body, but there is no evidence that this reduces the risk of cancer spread. Until the FDA's final decision, each patient and healthcare facility will have to do their own risk assessment to determine whether or not the tool should be used.



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