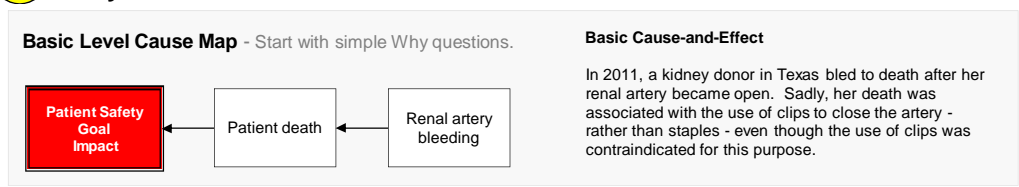


1 Problem

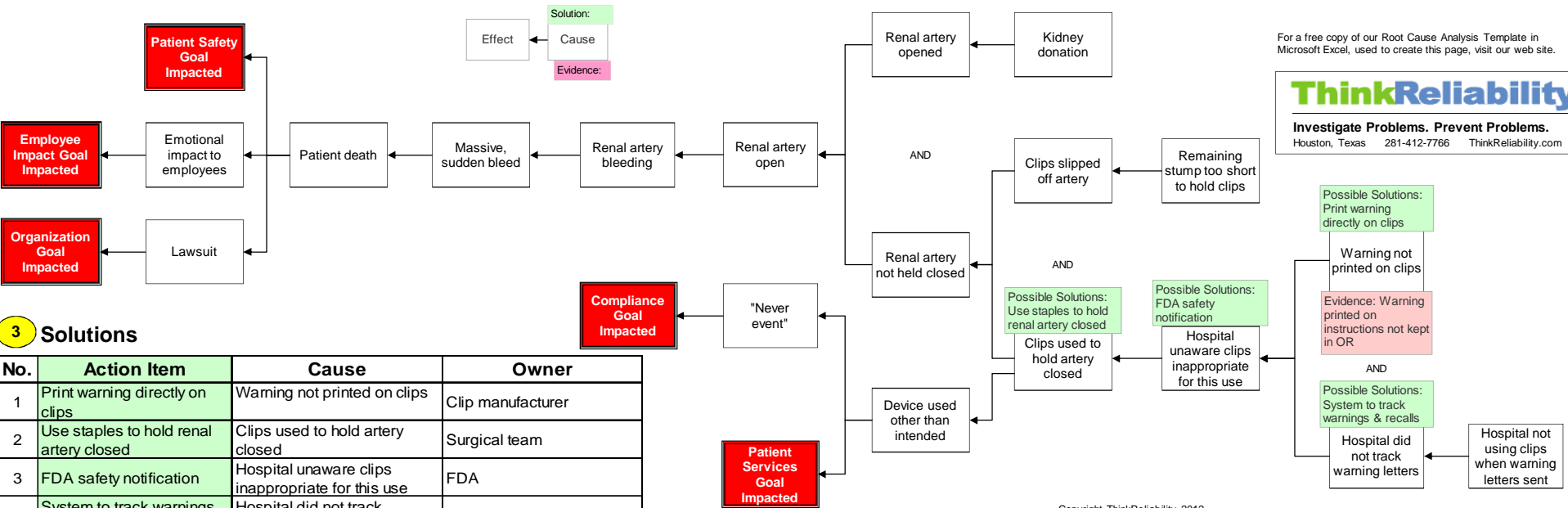
What	Problem(s)	Death of kidney donor
When	Date	2011
	Different, unusual, unique	Use of kidney clip to close renal artery
Where	State, city	Texas
	Facility, site	Medical Center
	Task being performed	Kidney donation
Impact to the Goals		
	Patient Safety	Patient death
	Employee Impact	Emotional impact to employees
	Compliance	"Never event"
	Organization	Lawsuit
	Patient Services	Device used other than intended
	Environmental	N/A
	Property, Equip, Mtls	N/A
	Labor, Time	N/A
		This incident ?
	Frequency	4 deaths from use of clips
		Annualized Cost ?

2 Analysis



More Detailed Cause Map

- Add detail as information becomes available.



3 Solutions

No.	Action Item	Cause	Owner
1	Print warning directly on clips	Warning not printed on clips	Clip manufacturer
2	Use staples to hold renal artery closed	Clips used to hold artery closed	Surgical team
3	FDA safety notification	Hospital unaware clips inappropriate for this use	FDA
4	System to track warnings & recalls	Hospital did not track warning letters	Hospital

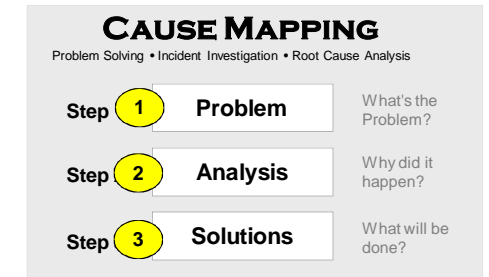
KIDNEY DONOR DEATH

Cause Map

Inappropriate use of tool results in renal artery bleed

"We were just in shock and deep sorrow to learn that our actions thus far and our efforts to try to stop the practice had been ineffective." Dr. Amy Friedman, Director of Transplant Services at Upstate Medical University in New York, who had raised concerns about using clips in kidney donors in 2004

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



More Detailed Cause-and-Effect

The patient died from a massive, sudden bleed caused by the bleeding of the renal artery which was open. The renal artery had been opened as part of the kidney donor surgery, and had been closed using clips that slid off the renal artery. The stump remaining on the renal artery after this kind of surgery is too short to allow the clips adequate purchase, and the clips slid off. The hospital staff was unaware that these clips were contraindicated for this use. Although a warning was placed on the instructions for the clips, these instructions were not kept in the operating room. Additionally, the manufacturer sent out several letters to hospitals warning them not to use these clips for kidney surgery. However, at that time, this hospital was not using the clips, and had forgotten about the letters when the clips were purchased.

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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