

Patient Deaths Caused by Defective Defibrillator Wires

US
April 2012

A recent study (link to study) determined that at least 20 patients have died as a result of defective defibrillator wires. The wires, also called leads, connect the defibrillator to the heart to both monitor heart rhythms and deliver electric shock if needed. Defective defibrillator wires have the potential to affect many people since more than 79,000 in the United States and 49,000 abroad have the implants.

Step 1 - Create the Outline

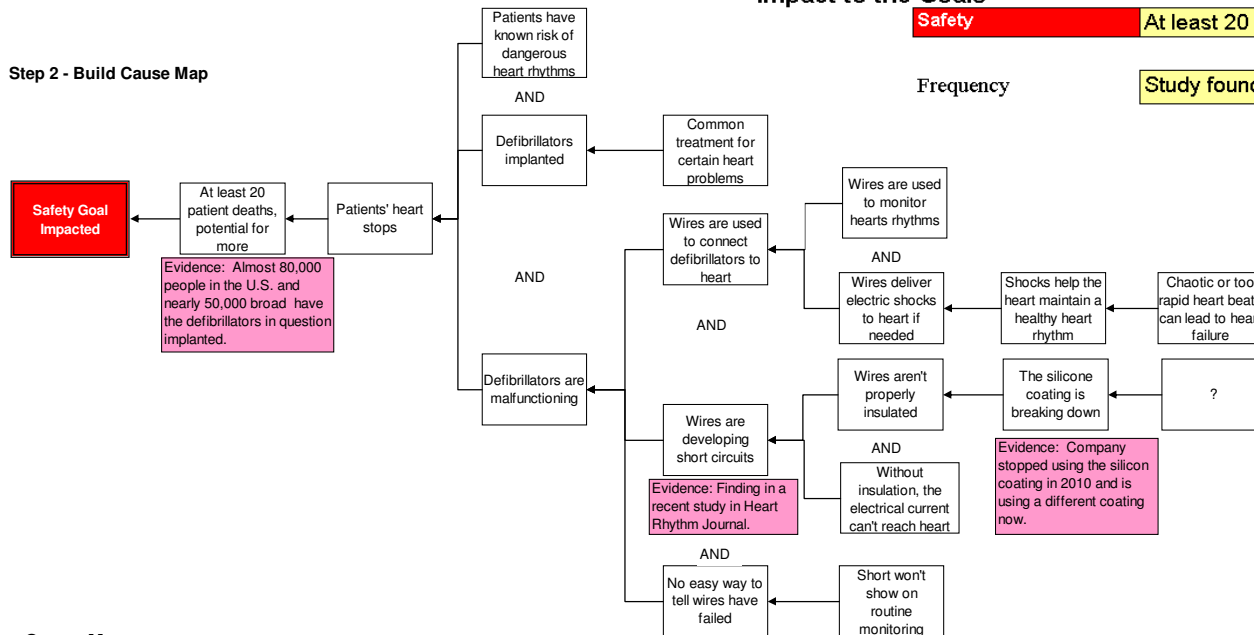
Step 1. Outline the Problem

What	Problem(s)	Patients' deaths, defective defibrillator wires
When	Date	2011
	Differences	Purchased from same supplier
Where	Physical Location	Wires made by same company
	Task being performed	Defibrillators monitoring and regulating heart beats

Impact to the Goals

Safety	At least 20 patient deaths, potential for more	This incident ??
Frequency	Study found 22 deaths	Annual Total ??

Step 2 - Build Cause Map



In this case, the patients died because their heart stopped. The heart stopped because the patients were at risk of heart issues, had defibrillators implanted and the defibrillators malfunctioned. Implanting defibrillators is a common treatment for certain heart conditions and many people have them.

The defibrillators malfunctioned because the wires used to connect the defibrillator to the hearts weren't properly insulated and a short circuit developed, preventing the defibrillator from shocking the heart when it was needed. The wires aren't properly insulated because the silicone coating on the wires is breaking down over time. The defibrillators are also malfunctioning because the issue with the wires isn't one that can be found by routine monitoring so the problem isn't identified until it's too late.

The company that makes the wires is questioning the findings of the study and says that the information used was incomplete.

It's also not clear at this time what the best course of action is at this time based on the information used.

Cause Map High Level



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