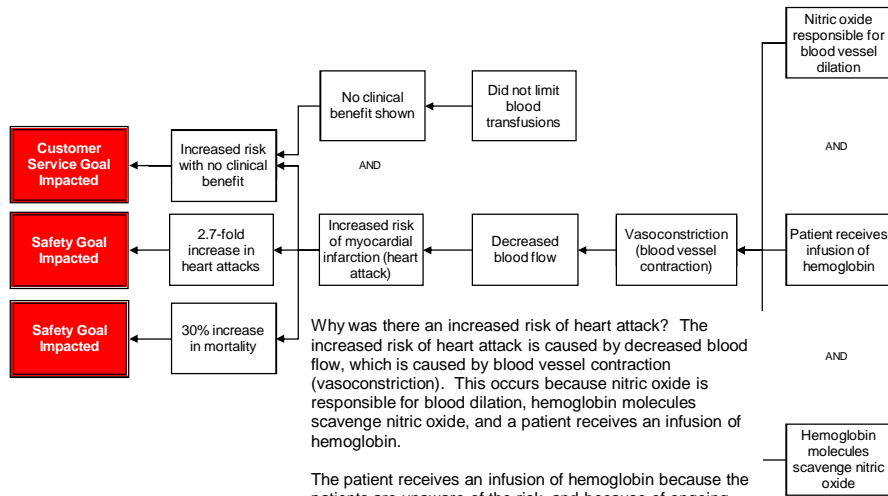


Increased risk from hemoglobin-based blood substitute clinical trials, U.S. A., 2008

A study recently published by the Journal of the American Medical Association presented a review of clinical trials of hemoglobin-based blood substitutes. This study showed that the clinical trials resulted in increased risk of heart attack and death for the patients being studied with no clinical benefit. We will examine this issue using the Cause Mapping process. A thorough root cause analysis built as a Cause Map can capture all of the causes in a simple, intuitive format that fits on one page.

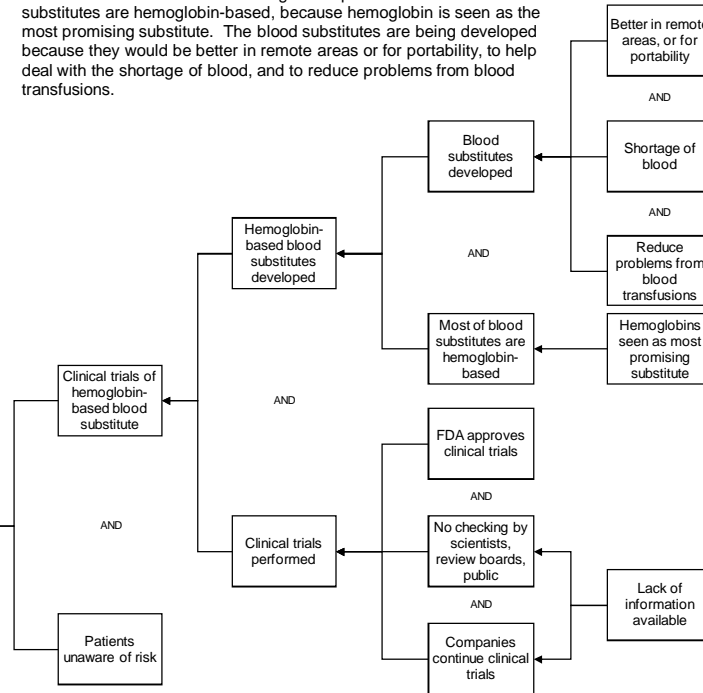
In clinical trials one of the overall goals is to have zero injuries. The blood substitute trials led to a 30% increased risk of death, and a 2.7-fold increase in heart attack, causing increased risk with no clinical benefit. The two goals that are impacted in the blood substitute example are the safety goal and the customer service goal.

In this example all of our impacts to the goals are caused by the increased risk of heart attack (myocardial infarction). Additionally, there was no clinical benefit shown because the use of blood substitutes did not limit blood transfusions.



The patient receives an infusion of hemoglobin because the patients are unaware of the risk, and because of ongoing clinical trials of hemoglobin-based blood substitutes. These trials are ongoing because hemoglobin-based blood substitutes have been developed and because clinical trials are being performed.

The hemoglobin-based blood substitutes have been developed because blood substitutes are being developed and most of the blood substitutes are hemoglobin-based, because hemoglobin is seen as the most promising substitute. The blood substitutes are being developed because they would be better in remote areas or for portability, to help deal with the shortage of blood, and to reduce problems from blood transfusions.



The clinical trials were performed because they were approved by the FDA; there was no checking by scientists, review boards, or the public; and the companies continued clinical trials. There was no checking, and the companies continued the trials, because there was a lack of information available.

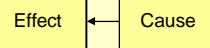
The FDA and the blood companies are still trying to figure out how to go forward based on these new results. Because of the potential usefulness of blood substitutes, especially in military applications, it's likely we'll continue to see progress on this issue.

Cause Map Detail Level



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Why?



NOTE: Read the Cause Map from left to right with the phrase "Was Caused By" in place of each arrow.