

Root Cause Analysis Cases Studies with Causal Tree Analysis

TRAINING SEMINAR Medical Device Adverse Event Investigation and Management 2013

The reference materials on Root Cause Analysis (RCA) from ECRI's Healthcare Risk Control describe a variety of analytic techniques for performing an RCA. One common technique is shown here using <u>causal tree analysis</u> (CTA). Following is a case study of a potentially serious injury from a surgical pneumatic tourniquet. The cause of the adverse event was related to errors on the part of several members of the surgical team. Accompanying this first case is a completed CTA diagram. Such diagrams on RCA applied to healthcare technology adverse events are useful in examining the underlying causes of an incident. The causal analysis was performed using the coding and descriptors in the modified Eindhoven Classification Model (ECM) causal coding system (Battles and Shea 2001¹).

The applicable excerpts from the modified ECM are described in a key at the bottom of the diagrams to assist in interpretation of the CTA (also frequently referred to as a fault tree analysis) that follows the tourniquet case abstract. For self-education or training in filling out a CTA, causal tree diagrams are included for the other cases presented in this section. Such analyses could also be pursued with the numerous case studies presented in other handouts.

CTA involves reasoning from the general to the specific by working backward through time to examine preceding events leading to an incident. This method studies potential system failures. It allows for analysis of situations in which a negative event will not occur unless several subevents occur first. Relationships between events that have an interaction with each other can be more clearly shown. CTA is considered proactive RCA because the process seeks to identify the origin(s) of possible direct proximate causes for an incident and, once this is accomplished, to find ways to avoid these origin(s). A fault tree is a graphic model that displays the combination of equipment failures, human errors, and/or management system failures that result in an incident. The tree starts with an undesired top event (i.e., accident, incident, management system failure) and is subsequently broken down into contributory events. A fault tree uses logic symbols to find the basic events that will cause the incident to occur.

^{1.} Battles JB, Shea CE. A system of analyzing medical errors to improve GME curricula and programs. *Acad Med* 2001 Feb;76(2):125-33.



Case 1: Surgery for Traumatic Amputation

A patient underwent emergency surgery at a tertiary care teaching hospital for arm revascularization following traumatic amputation. The 13-hour procedure was performed by an emergency replantation team that had been established by the hospital for such emergencies. Team members included six surgeons, two anesthesiologists, four scrub nurses, three circulating nurses, and two surgical technicians. Members of this team had worked together in smaller groups on nonemergent surgical procedures for several years but rarely worked as an assembled emergency trauma surgery team.

After autologous vein harvesting from one of the patient's legs for use in revascularization of the arm, the microprocessor-controlled pneumatic leg tourniquet was not deflated despite an order by the vascular surgeon to do so. At that time, the tourniquet had been inflated for 25 minutes at a pressure of 250 mm Hg. An hour later, when the vascular surgeon checked the closure of the vein-harvesting incision site, she saw that the leg was still exsanguinated and discovered that the tourniquet was still inflated. The tourniquet had remained inflated for more than 90 minutes. Although the 60-minute alarm on the tourniquet triggered, it was not heard because the volume was adjusted below an audible level.

In general surgery at this hospital, the anesthesiologist is responsible for tourniquet inflation and deflation and for monitoring the inflation time. In emergency trauma surgery, these tourniquet responsibilities are delegated to a circulating nurse. Although the nurse knew her duties for the surgical tourniquets in this case and had heard the request for the tourniquet to be deflated, that duty was not routine for her and was not carried out in the rush of the first three hours of the surgery. The tourniquet was removed, and the leg was allowed to passively perfuse. Despite concerns over the potential for development of compartment syndrome, the affected leg recovered and was not harmed. The event was reported as an incident by the circulating nurse. Initial suspicions that the tourniquet had malfunctioned proved incorrect during subsequent investigation. This is classified as a close-call event because the patient's leg would have been seriously injured or lost if the tourniquet remained inflated for the duration of the long procedure.



Case 1 Causal Tree Analysis No-harm Event



HSS = Active Errors, Skills-based Behavior, Slip

HRC = Active Errors, Rule-based Behavior

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TD = Latent Errors, Technical, Design

HRM = Active Errors, Rule-based Behavior, Monitoring

(See Battles and Shea 2001 for detailed descriptions.)

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Case 2: Air Embolism During Apheresis

An on-call physician was preparing an apheresis machine in an intensive care unit to perform plasma exchange (PE) therapy on a critically ill patient. Plasma exchange was performed at the hospital only several times per year. The patient was to undergo plasma exchange with human albumin solution (HAS) over the course of a 90 minute treatment, with 3 L of plasma to be removed and replaced with 2.5 L of HAS. As nursing staff was in short supply, the physician was aided by a medical resident physician. The resident had no experience with PE therapy or apheresis equipment. A dual lumen catheter was placed in the femoral vein to provide the ports for the blood supply and return tubing that lead to and from the machine. A central venous line had been inserted via the right jugular vein, but was capped with a stopcock.

The patient was anxious and was fidgeting with and tugging on the femoral blood lines leading to and from the machine. In the haste to begin therapy, a second check of the blood lines and connectors was not performed.

Just as treatment began, the blood level in drip chamber of the tubing set on the machine dropped and triggered an alarm that stopped the treatment. The physician raised the blood level in the drip chamber by pulling back on a 50cc syringe attached to one of the chamber's ports. As the blood level rose to an appropriate level, the machine automatically resumed treatment at which time a large bolus of air was seen moving toward the patient in the blood return line. During treatment, segments of air bubbles were seen in the venous PE line that was returning blood to the patient by the treating physician and by an attending nurse. This air was then seen entering the patient.

About two minutes later, she went into respiratory arrest, and cardiopulmonary resuscitation (CPR) was initiated. During CPR, air was reportedly again seen in the venous blood line. Despite the resuscitation attempts, the patient died. Postmortem examination indicated that the patient died of a fatal venous air embolus, probably of a volume greater than 250 ml. Air was determined to be in the brachiocephalic veins, superior vena cava, inferior vena cava, and the right ventricle. At the time of the treatment, the patient was in a semireclining position with the back of the bed raised to about 40° . It was also found that the patient had inadvertently dislodged the return line from a safety clamp on the machine.



Case 2 Causal Tree Analysis Near Miss Event



HRC = Active Errors, Rule-based Behavior

TD = Latent Errors, Technical, Design

HRM = Active Errors, Rule-based Behavior, Monitoring

(See Battles and Shea 2001 for detailed descriptions.)

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Case 3: Fetal Monitoring

A patient in labor at a small rural hospital was being monitored with an ultrasonic fetal monitor for a number of hours before delivery of the baby girl in the early hours of the morning. The fetal monitoring strip showed no signs of fetal distress before delivery as judged by the resident obstetrician. The patient was the only one in the hospital's labor and delivery ward that night and was closely monitored by the resident.

At delivery, having been delivered with a tight (nuchal) cord the baby was determined to be compromised with Apgar scores of 2,5, 5. The infant recovered well very soon after delivery and was diagnosed as healthy upon discharge the following day. Immediately subsequent to delivery, the fetal monitor continued to print out a fetal heart rate tracing for approximately two minutes, until it was turned off. Based on the lack of any evident fetal distress before delivery and upon the subsequent tracing of the fetal monitor after delivery, it was questioned whether the fetal monitor was working properly.

Review of the fetal monitoring strips found them to the reasonably unremarkable with just a few decelerations with compensatory accelerations. Subsequent testing of the monitor revealed it to be working satisfactorily. The suspicion that the monitor was not working was based on the initially poor fetal Apgar scores and the continuing "fetal tracings" after delivery. It was noted that the post-delivery suspect fetal tracing was at a baseline heart rate of approximately 130 beats per minute. This contrasts with the fetal heart rate of 150 beats per minute that was seen throughout most of the rest of the strip until about 5 minutes before delivery where the rate was approximately 135-140. It was determined that placement of the ultrasonic transducer on the mother's abdomen had not been checked during the later stages of labor. The two minutes of 130 beats per minute heart rate seen on the strip immediately after delivery of the infant, as well as the 135-140 seen just prior to delivery, was the maternal heart rate presented by the mother's pulsing aorta.

The resident obstetrician had not recognized that toward the end of labor that the maternal and fetal heart rates were virtually identical and had not checked the placement of the ultrasonic transducer. Had the fetal distress during delivery been more prolonged, this no-harm event could have had a much more problematic outcome for the child.



Case 4 Causal Tree Analysis No-harm Event



TD = Latent Errors, Technical, Design

HRM = Active Errors, Rule-based Behavior, Monitoring

(See Battles and Shea 2001 for detailed descriptions.)

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