

## Medical Error Case Reports and Causal Tree Analyses

For Asian Harmonization Working Party

Sessions on

Medical Device Accident Investigation

28 November 2010

These cases were derived from investigation reports from ECRI's accident and forensic investigation files. Although each case involved an injury or death, it has been rewritten to be a "**near miss**" or "**no-harm**" event while retaining the "latent error" and "active error" components from the original event.

The causal analysis was performed by using the coding and descriptors in the modified Eindhoven Classification Model (ECM) causal coding system described by Battles and Shea (A system of analyzing medical errors to improve GME curricula and programs. Acad. Med. 2001;76:125-33.) The classifications for root causes of medical errors shown in Table 1 of that article will need to be included in the proposal as we will use the related root cause abbreviations in the causal tree analyses below.

Causal analysis has been done for the Case 1. Review of that case and study of the Battles and Shea article (abstract available on the internet at:

<http://www.ncbi.nlm.nih.gov/pubmed/11158830>) is indicated before proceeding with completing the causal analysis tree for the other three cases.

## Case 1: Surgery for Traumatic Amputation

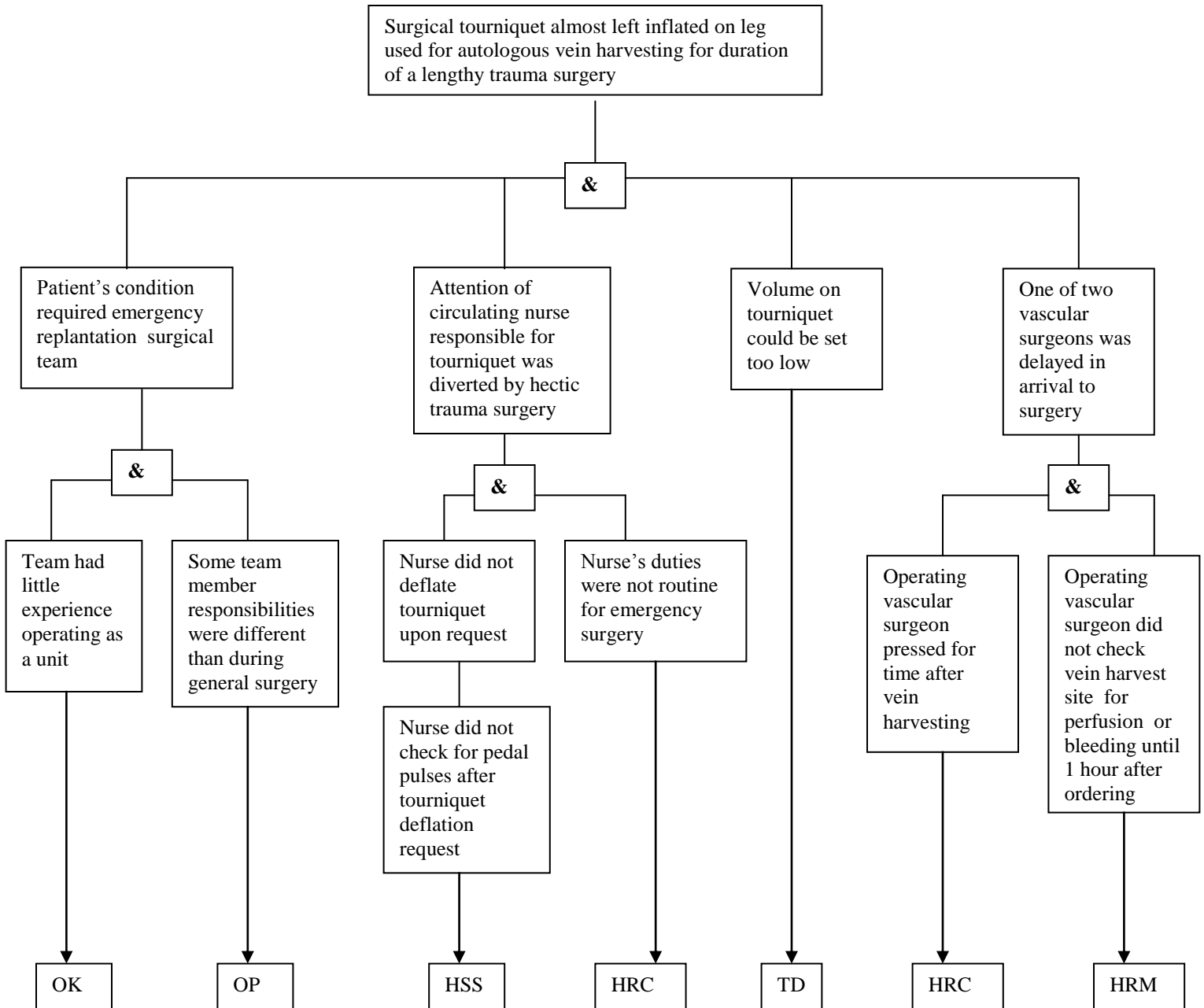
A pediatric patient underwent emergency surgery at a children's hospital for arm revascularization following traumatic amputation. The 13-hour long procedure was performed by an emergency replantation team that had been established by the hospital for such emergencies. Team members included six surgeons, two anesthesiologists, four scrub nurses, three circulating nurses, and two surgical technicians. Members of this team had worked together in smaller groups on non-emergent 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 mmHg.

An hour later, when she checked the closure of the vein harvesting incision site, the vascular surgeon 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 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, deflation, and 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 no-harm event because had the tourniquet remained inflated for the duration of the long procedure, the patient's leg would have been seriously injured or lost.

## Case 1 Causal Tree Analysis

### No-harm Event



OK = Latent Error, Organizational, Transfer of Knowledge

OP = Latent Error, Organizational, Protocols/Procedures

HSS = Active Errors, Skills-based Behavior, Slip

HRC = Active Errors, Rule-based Behavior

TD = Latent Errors, Technical, Design

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(See Battles and Shea 2001 for detailed descriptions.)

## **Case 2: Air Embolism During Apheresis**

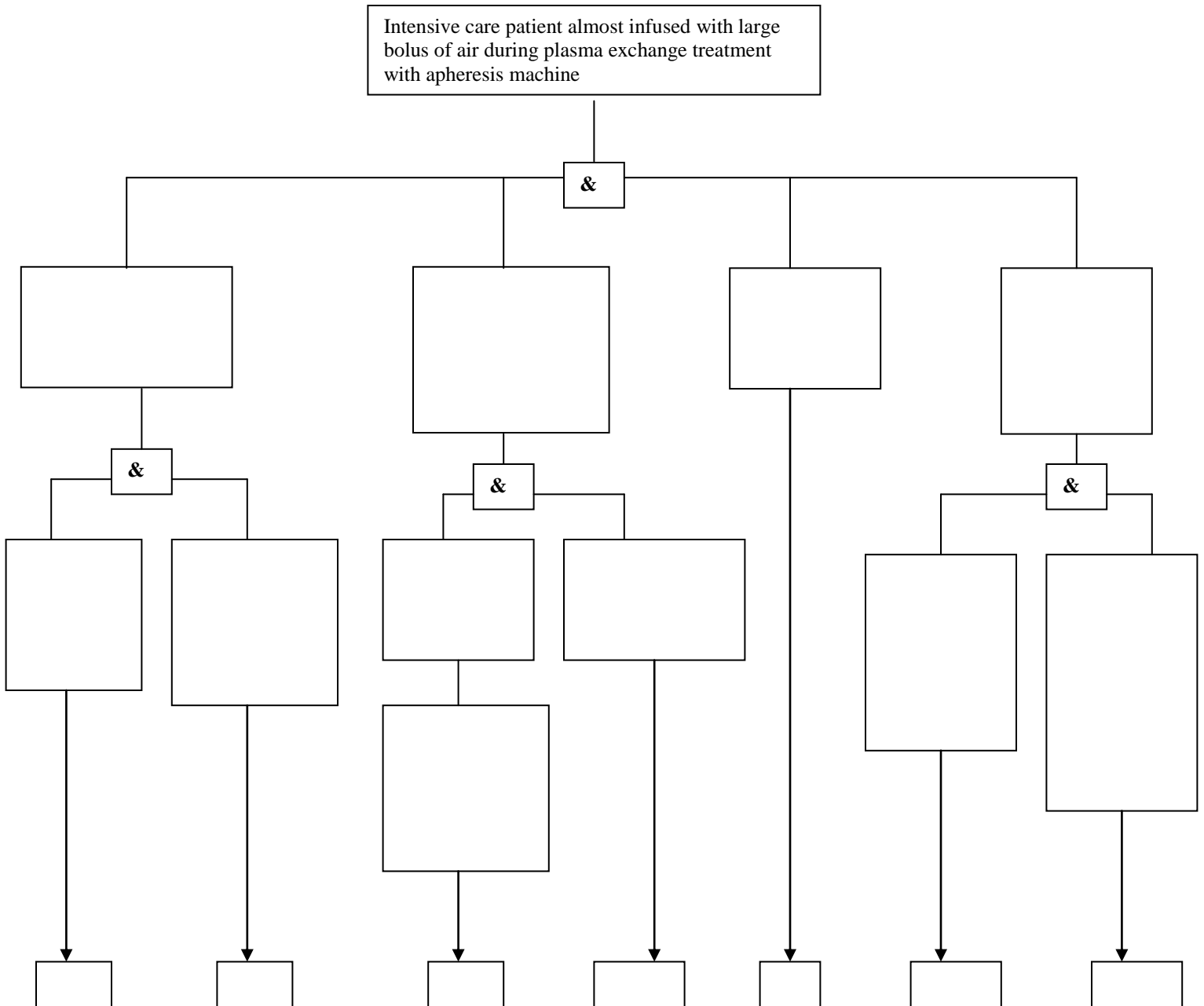
An on-call physician was preparing an apheresis machine in an intensive care unit to perform plasma exchange (PE) therapy on a critically ill patient. Plasma exchange was performed at the hospital only several times per year. The patient was to undergo plasma exchange with human albumin solution (HAS) 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. 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. The physician halted the machine before any air reached the patient. The blood lines were checked for security. It was found that the patient had inadvertently dislodged the return line from a safety clamp on the machine. In addition, the Luer connector at the junction of the blood return line and the femoral catheter was found to be loose and had blood to leak out at the initiation of treatment. This leak also allowed air to be drawn into the return line during drip chamber aspiration.

The air could not have been drawn into the tubing if the tubing was seated in the alarm-activated safety clamp. After checking for security of the tubing and connectors, treatment proceeded uneventfully. The volume of air in the large bore return blood line was approximately 50ml. Had that bolus been introduced into the patient the result of this near miss could have been fatal.

## Case 2 Causal Tree Analysis

### Near Miss Event



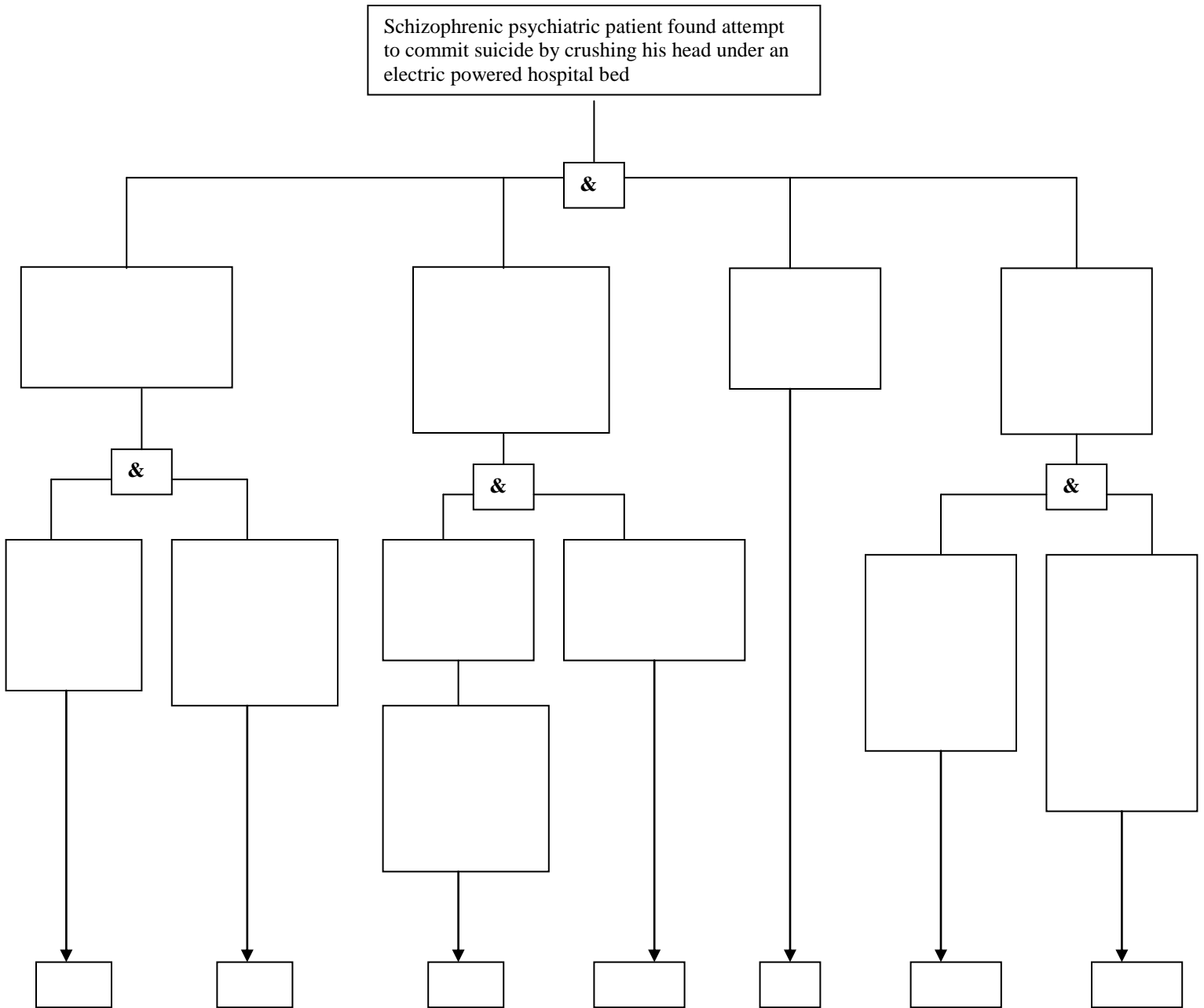
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### **Case 3: Psychiatric Patient Attempted Suicide**

A schizophrenic patient in a physician-owned, private psychiatric hospital was found by the medical staff with his head within the lifting mechanisms underneath the electric bed in his room. When found, he was attempting to activate the electric control switch that lowered the bed. Lowering of the bed in this fashion would have crushed the patient's neck causing suffocation. The electrical lockout controls, intended for use by the nursing staff to disable bed control functions, had not been locked out. The patient injury from this incident occurred. The hospital reviewed their policy for the use of electric beds.

### Case 3 Causal Tree Analysis

#### Near Miss Event



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## Case 4: 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 be reasonably unremarkable with just a few decelerations with compensatory accelerations.

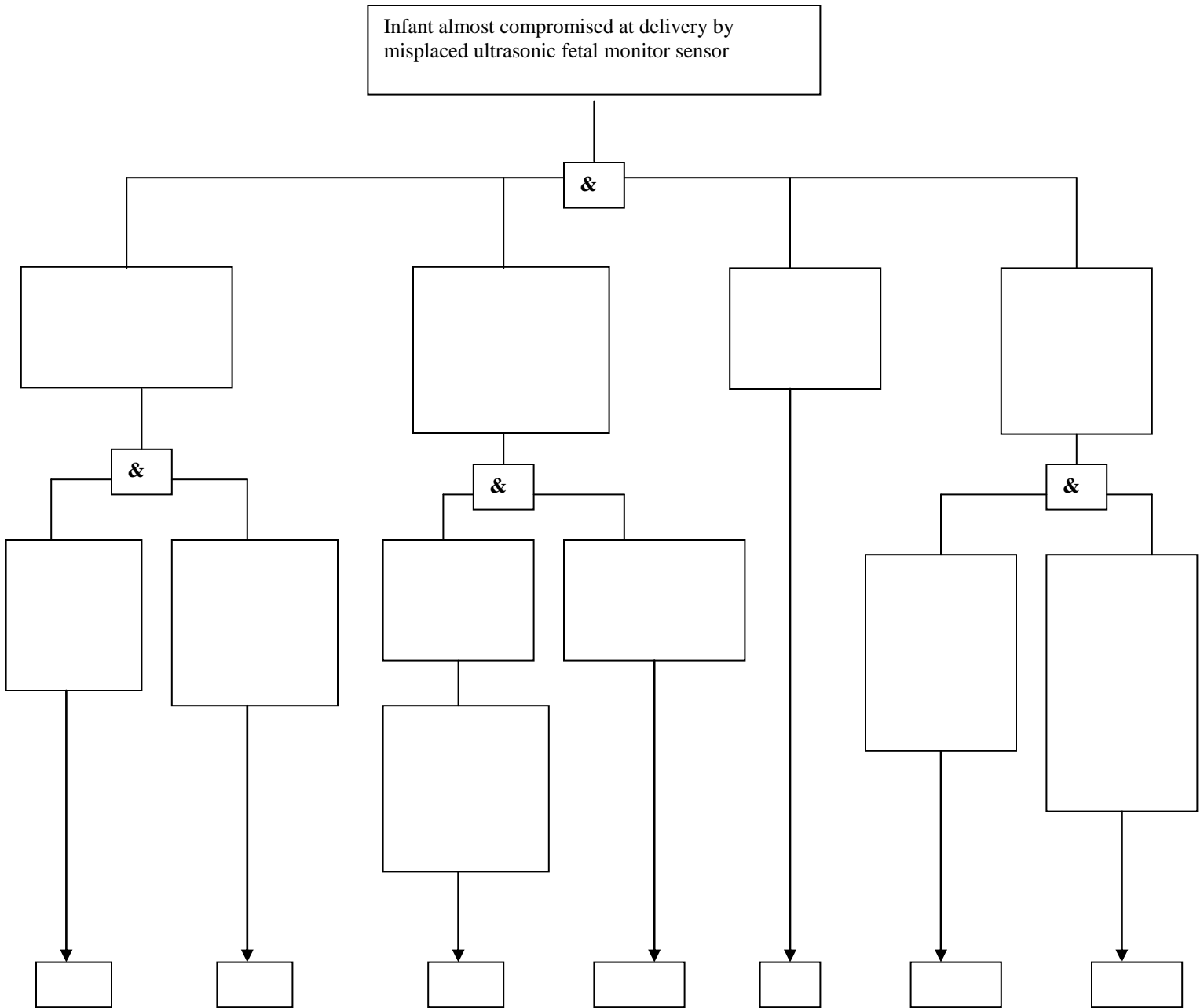
Subsequent testing of the monitor revealed it to be working satisfactorily. The suspicion that the monitor was not working was based on the initially poor fetal Apgar scores and the continuing "fetal tracings" after delivery. It was noted that the post-delivery suspect fetal tracing was at a baseline 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



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