

Domain 5: Optimize Human and Environmental Factors
Story of Ben Kolb

The setting

Ben required ear surgery following two other episodes of ear surgery at two and five years of age. On December 15, 1995, he was admitted to hospital (Martin Memorial Hospital in Florida,) and was a bit scared. His mom Tammy stayed with him, talked about soccer (he was captain of his team) and Christmas (he was going to sing in the yearly pageant at school. An orderly came to wheel him into the operating room and his mom waved ‘goodbye’.

Ben was given general anaesthesia and twenty minutes later the surgeon injected local anaesthetic (lidocaine) into four quadrants surrounding his ear. The scrub technician felt Ben’s chest pounding through the surgical drapes and the certified registered nurse anaesthetist saw significant changes in the blood pressure on pulse. The supervising anaesthesiologist was called to the operating room and managed the hypertension and tachycardia which stabilized within minutes. He asked the scrub technician to save the syringes thinking this was an unusual reaction to lidocaine 1% with epinephrine 1:100,000. Nine minutes later, Ben experienced a cardiac arrest. Resuscitation efforts went on for an hour and 40 minutes. A pacemaker was inserted. Ben finally left the operating room in a profound coma and on a ventilator.

The risk manager was called to the operating room and an investigation was begun immediately.

The surgeon and anaesthesiologist went to meet the mother Tammy Kolb and explained how Ben’s heart had stopped, how difficult it was to restart and explained that Ben was in a deep coma and may not be able to wake up. She responded, “I know he will get better. I have seen this on TV.”

The operating room was left undisturbed and the risk manager and director of surgical services reviewed the details of the case. The syringes of lidocaine with epinephrine, the original vial and the bottle of topical adrenaline and the one other vial in each box, i.e. two syringes and four vials, were retained and taken directly to the pharmacist who initiated a product recall for the same lot numbers and sent an alert through the U. S. Pharmacopoeia. Samples were sent to the University of Georgia for analysis.

Ben had been transferred to a tertiary care centre, but died the following day (brain death.) The risk manager informed the defense counsel, the insurer, the Board and the Senior Management and the coroner. An investigation was begun and individual meetings were held with every person who entered the O.R. suite during the procedure.

Drawings were made of the location of all equipment and people, and a pharmacist was assigned to the investigation.

Procedurally, the only variation was a failure to label the syringes of lidocaine. The risk manager called the family again, the anesthesiologist attended the funeral home viewing and the surgeon attended the funeral.

During a routine sentinel event meeting, the details of the event were described by the CRNA, the anaesthesiologist and the surgeon. Also present was the Chief of Anaesthesia, Chief of Surgery, Vice President Medical Affairs, Position Chair of the Quality Committee, the President of the Medical Staff and the Risk Manager. The Chief of Anaesthesia identified a similar incident he had seen in Miami years ago where concentrated adrenaline was used instead of the lidocaine with adrenaline.

The risk manager pursued this line of inquiry with the nursing staff and scrub techs who believed they had followed procedure and that this could not have happened*.

On December 19th, the University of Georgia said they were unable to identify the contents of the vials and asked for additional sample, which was sent. On January 2nd, the University of Georgia reported that they were running tests for the topical adrenaline properties.

The risk manager and the team continued to identify steps in the process and found one unnecessary step in the commonly accepted process for transferring medications to the sterile operating room environment. The step was the use of intermediate containers. Pharmaceuticals were transferred to small plastic and stainless steel containers on the operating room table using sterile technique by pouring or use of a syringe. The circulating nurse and scrub technician verified visually and audibly the contents and expiration dates. The intermediate containers had been labelled by the scrub tech during set up. The scrub tech then finished the preparation by withdrawing the injectable pharmaceutical into a syringe. The syringe should have been labelled. The topical solution was poured on cotton pellets to dab on bleeders during the procedure. As the tech finished, the circulating nurse would finish the room set up and bring the patient to the O.R. The investigating team recommended the use of a filter straw or spike for the scrub tech to attach a labelled syringe to and intermediate containers were eliminated. The risk manager, pharmacist and team decided to engage a crisis management firm and located a second lab with different testing methods and 0.25 cc of the substance that remained in the syringe that had been used on Ben was sent to the National Medical Services in Willow Grove, Pennsylvania. It was confirmed that the syringes thought to contain lidocaine actually contained topical adrenaline.

The risk manager phoned the family and the following day they were told of the error. The risk manager explained how and why the two medicines are used in surgery, how the samples had been saved and sent for testing and that the hospital accepted full

responsibility. This was the hospital's error and no one else's. They were working to make the process safer so this never happened again. She told them that they were very, very sorry.

That evening the Kolb family, their attorney, the risk manager and the hospital attorney reached a confidential settlement. The risk manager was very concerned that this was an error that could be repeated in other places and therefore she wrote an article for an O.R. management journal describing the error and the procedural changes that were developed to keep this type of error from occurring.

In October 1996, Ben's story was told to the First Annenburg Conference on Medical Error to 300+ researchers, clinicians and concerned citizens.

Other cases in the U.S. were found in children age four to seven who did not survive.

References: The Patient Safety Handbook by Barbara J. Youngberg, Martin J. Hatlie. "Moving Beyond Blame to Create an Environment that Rewards Reporting," by Doni Hass, PP. 415-421. Published by Jones and Bartlett Publishers 2003.

Health Care Industry, Heal Thyself by Lisa Belkin in The Orlando Sentinel July 27,1997