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

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.

Issues: What was the role of each member of the team, how was the medication prepared, what was the environment like?

Discuss team roles, competencies and scopes of practice: Domain 2 Work in teams 1.1 and 1.2

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.

Issues: Something had gone dreadfully wrong in a routine operation. What are the next steps? What would your role be?

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

Issues: Could this be an adverse event rather than an unusual reaction to lidocaine? If so what are the steps to follow?

Discuss the importance of immediate recognition of the need for reporting the adverse event and getting a better understanding of the adverse event: Domain 6 Recognize and respond to an adverse event, 4.1 and 4.2

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."

Issues: Telling the family, stress on family and health care team (second victims) and what needs to be done to support them.

Discuss the need for immediate communication to the family and how difficult this is for the mother and the health care team. Domain 6 Mitigate harm and address immediate risks for patients/families and others affected by adverse event 2.1 and 2.3

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.

Issue: Appropriate investigation of possible problems – what samples should be collected and where should they be sent?

Discuss the importance of sample collection and analysis Domain 6, 4.2

Ben was transferred to a tertiary care centre, but died the following day (brain death.) The risk managed 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.

Issues: Careful analysis of event, communication and reporting to those with a need to know

Discuss the importance of detailed event analysis, and each person's role in participating in this analysis Domain 1 Contributing to a culture of safety, 1.6 and 3.3

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.

Issues: Ask what would you have done? Would you have reached out to the family or stayed away 'because this was a coroner's case', 'we are not sure what happened but we feel responsible'. Discuss the importance of maintaining a connection to the family.

Disclosure of adverse event Domain 6 3.1, support for family Domain 6 2.3

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*.

Issues: Openness to learning, sharing experiences, careful investigation

This highlights the importance of shared analysis, taking opportunities to reflect on practice, to learn from others' experiences Domain 1 Culture of safety 1.7, 3.7

** This highlights the importance of the role of attitude and professional culture in clinical practice, and how we need to be aware of the individual and environmental factors that can affect human performance; Domain 5, 1.2*

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.

Issues; Adverse event leading to death, mixing of syringes, failure to label syringes, using an unsafe procedure that was common yet had not been identified as a possible safety risk.

This describes the opportunity to demonstrate a sound process of decision making, understanding where the process can be challenged and corrected Domain 5 Optimizing human and environmental factors 2.3 using critical thinking to improve safety. Human factors discussion: identification of safer procedures 'fail safe' use of solutions.
This can lead into a discussion of common types of cognitive biases Domain 5, 2.1 and the impact of the human/technology interface on safe care-human factors engineering, safe application of technology, safety design and workflow analysis (perfect example in the case here of workflow analysis) Domain 5, 3.1,3.2,3.3, 3.4

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.

Issues: How and what to tell the family, should an apology be given, what are the legal implications?
This can highlight the immediacy of disclosure, use of all elements of disclosure- honest communication, who takes responsibility, the role of expressions of regret and apology, the legal implications Domain 6 Disclose adverse events 3.5, 3.7, 3,8, 3.9, 3.13

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.

Issues: Reporting of adverse events
This demonstrates the significant contribution to disseminating the lessons learned Domain 1 Culture of safety 3.6

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