BE 4775 / BE 5775 MEDICAL DEVICES - Lecture 02

Fall 2014

Introduction of the Case Studies

Case 1. This involves medical device design, medical device standards, off-label use, anesthesia, patient monitoring, use of CPR, physician training and credentialing, cause of patient death. The layout as to where this information is to be found will be provided as a start.

Ota v. British Oxygen - a dermatologist who has no surgical privileges and practices out of his office decides to offer liposuction surgery. He takes a one-day course and sets up an outpatient facility. His second patient, a 40 year old woman arrests on the table, has CPR and dies 3 days later. The doctor claims that BOC connected his dental analgesia machine with oxygen and nitrous oxide backward. Issues include medical device design for anesthesia, vital sign monitoring to detect patient status including impending hypoxia, defibrillation, physician training, off-label use of a medical device, CPR, NFPA 99 medical gas standards, breathing circuits, physician training and credentialing, and liability assessment for the death amongst the physician, the medical device manufactures and the nurse anesthetist. The students will be given the case summary and made aware of case related and general resources they will need to determine the root cause of the death and who is most responsible (as determined by a jury).

Case 2. A woman in her 40's was undergoing a lymph node surgical procedure. There was a fire and she was badly burned in the head and neck leaving permanent scars and injury. The students will be asked to investigate the root cause of the fire, along with the related issues of the fire triangle, medical device design (for anesthesia, surgical sterile field, electrosurgery, operative technique, hospital standards and medical and clinical staff training.) Issues will include the flammability standards of drapes, the nature of electrosurgery delivery of energy to the patient (CUT, COAG, power levels technique as fulguration, etc.) , physician training and communication, hospital standards, medical device labels and warnings. Students will be asked to investigate the OR fire to determine the root cause and form opinions on fault, and what can be done to prevent another surgery.

Case 3. An orthopedic surgeon sells himself to a 50 bed hospital to be one of the very best, most modern spinal surgeons in the United States. He is granted privileges. He operations on about 100 patients performing nontraditional, spinal procedures using three medical technologies for the spine or bone – all off label and in combination. In addition to his unique surgery on the spine, he also performs traditional spine surgery. Most all the patients become permanently disabled. The issues here include biomechanics of the spine,

normal spine procedures with normal, FDA cleared technologies, study of other FDA cleared medical technology for orthopedics including electrical bone growth stimulators, cadaver based bone replacement materials with advanced growth enhancers, hospital credentialing standards, issues of medical device off-label use, patient informed consent, and an objective look at what the surgeon in question was trying to accomplish for biomechanical stability of the spine for his patients.

Case 4. A 30-year old woman who is diabetic was given and MRI examination. Afterward, she went home and was discovered later unconscious with a life-threatening hypoglycemic condition that resulted in brain damage. Her external insulin pump appeared to have over-dosed her. This case involves medical device design and design philosophy, medical device safety, instructions for use, warnings, hospital patient care policies, medical device testing, incident simulation, field investigation technique, and utilization of experts. The students will be given the necessary direction to investigate insulin pumps, MRIs, magnetic field management, insulin pump programming, FDA 510(k) clearances, medical device FDA reporting, FDA required FMEA tables, management of medical device complaint files and the role of FDA required Corrective Action Preventive Action (CAPA) procedures.

Case 5. A male patient has an implanted pacemaker/defibrillator. He is suing because the device fired and he fell on a sidewalk and injured his coccyx, then a few weeks later, as he was pulling in to his garage, the device fired and he drove in to the back wall of the garage, and then again a few weeks later, he was sitting on the couch and it fired and he sprung off the couch and received a rug burn. This issue is to determine why the internal defibrillator fires. Issues include device design, analysis of the downloaded data from the device, patient education, the role of ambient electrical interference, the utilization of leadwires, sensing and interpretation of the ECG, FDA related reports of similar incidents, issues of heat fibrillation and defibrillation, and forming opinions on the root cause of the shocks.