G36 Biomedical Engineering in Root Cause Analysis – Example: Assessing Infant Apnea-Related Deaths

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After attending this presentation, attendees will gain a better understanding by example of how Biomedical Engineering can assist in root cause analysis by examining how testing of subject apnea monitors and analyses of downloaded patient data can be useful in determining device failure versus human error.

This presentation will impact the forensic community by demonstrating how Biomedical Engineering analysis can shed light on important information involving medical devices. In this example, testing of subject apnea monitors and analyses of downloaded patient data can be useful in determining whether such devices have failed, or whether other factors (including human error) led to infant deaths.

Infants (primarily those of low birth weight) who are at risk for Sudden Infant Death Syndrome (SIDS) are often prescribed apnea monitors for at-home use. Infant apnea monitors are designed to alert caregivers if a child has become apneic and/or has heart rate changes outside of the preset limits. These monitors are not fool proof, however, and every year some children who are being monitored die. When this happens, it is the responsibility of the Medical Examiner to ascertain why the death occurred. Biomedical Engineers trained in this technology can play a vital role in these death investigations.

Apnea in neonates and infants occurs most likely because of immaturity of their respiratory and neurologic systems. Though it is common for infants to pause in their breathing for short periods, pauses lasting longer than 20 seconds are cause for concern, as are pauses of shorter duration accompanied by decreased heart rate. Infant apnea monitors are designed to detect increases and decreases in heart rate along with pauses in breathing, and sound an alarm if they occur. This is accomplished by attaching a belt with a series of electrodes around the infant's chest. The electrodes are attached to the monitoring unit itself. Monitors should have a battery backup, a remote alarm, a power loss alarm, a battery charge or AC power indicator, a sibling alarm as well as an internal memory for event and physiological data storage.

In cases where a child monitored with one of these devices has unexpectedly expired, a technical analysis should be performed by a trained Biomedical Engineer. A physical examination of the monitor itself should be conducted, along with an assessment of the electrical circuitry and analysis of monitor-downloaded data. A combination of downloaded patient and monitoring compliance data from the apnea monitor memory can be cross-correlated with events, such as feeding schedules or EMS run sheets. Deaths of monitored infants have been related to such issues as monitor hardware and software failures, obstructive apnea (often not detected), parental monitoring compliance, inability to hear the alarms, cardiac artifact in the transthoracic impedance signal, or electromagnetic interference, to name a few. If an apnea monitor is sent to the Medical Examiner's office along with an infant who has expired, it should be maintained as evidence, and the stored data downloaded and analyzed along with statements of the caregivers.

Case material corresponding to several of these failure-related issues will be presented to illustrate how a root cause approach can assist in making sense of why such tragic events may have occurred.

Biomedical Engineering, Infant Apnea Monitor, Sudden Infant Death Syndrome (SIDS)

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