K48 Medical Devices and Their Impact on Death Investigations

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After attending these presentations participants will understand how medical devices such as blood glucose monitors, insulin pumps, patient controlled analgesia, intrathecal pumps, and defibrillators can impact death investigation by providing information about the events surrounding a death.

The presentation will impact the forensic community by providing information about medical devices, their evaluation, and assignment of cause and manner of death.

Introduction: There are a variety of medical conditions in which medical devices including blood glucose monitors, insulin pumps, patient controlled analgesia, intrathecal pumps, and defibrillators are employed and these devices are encountered with increasing frequency in forensic death investigations. Questions concerning the proper operation and potential tampering of these devices as well as historical information contained in them is of concern to a variety of forensic professionals.

Topics Covered: This special session will cover regulatory, pathological, toxicological, and safety issues related to medical devices.

A historical overview of these devices, their in vitro diagnostic evaluation and safety by the Food and Drug Administrations Center for Devices and Radiological Health (CDRH) as well as basic information on device regulation will be discussed. More than 20,000 companies worldwide produce over 80,000 brands and models of medical devices for the U.S. market. These devices rang from contact lenses and blood sugar monitors to implanted hip joints and heart valves. The CDRH makes sure that new medical devices are safe and effective before they are marketed. The center is also responsible for monitoring these devices throughout the product life cycle, collecting, analyzing, and acting on information about injuries and other experiences in the use of medical devices and radiation-emitting electronic products, setting and enforcing good manufacturing practice regulations and performance standards for medical devices, monitoring compliance and surveillance programs for medical devices.

A synopsis of techniques that might be used during autopsy when encountering an in vitro device as well as case studies in which the interaction of pathology and these devices played a role in the death will be included. Special procedures used during and following an autopsy can help with a diagnosis of device performance. These procedures can help when deciding on a cause and manner of death.

Toxicological case studies focused mainly on chronic pain treatment involving fentanyl patches and continuous analgesia infusion devices will be discussed. Aggressive treatment of chronic pain in recent years has lead to an increase in the frequency of cases in which analgesic devices such as fentanyl patches and intrathecal pumps are encountered by forensic professionals. Investigations into the performance of these devices are often requested and the toxicology laboratory is faced with the task of testing the devices and interpreting the results. The case studies will be used to illustrate salient points such as proper storage of the devices, sampling and caution in interpretation.

Finally the session will conclude with a discussion of medical devices related specifically to the treatment of diabetes mellitus and case studies in which these devices played a role in deciding the cause and manner of death. In postmortem death investigation of deaths involving diabetes mellitus, having a record of recent blood glucose measurements can help in determining the level of control the decedent had prior to death and whether or not there were recent difficulties such as abnormally low or high blood glucoses. Diabetic deaths to nonketotic hyperosmolar coma and diabetic ketoacidosis can be diagnosed by high vitreous glucose, disturbances in vitreous electrolytes and the presence of acetone. However, deaths due to insulin overdose are usually a diagnosis of exclusion as methods for measuring postmortem insulin concentrations are not readily available or even reliable. Both traditional blood glucose devices and the new continuous blood glucose monitors can be accessed to provide historical information to aid in this diagnosis. Many insulin pumps also keep a continuous record documenting 7-14 days worth of blood glucose levels, insulin boluses (insulin given in response to a meal, snack or correction of high blood glucose), and total insulin use per day. Instruction on how to access the data these devices contain will be provided.

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