



## Pathology/Biology Section - 2016

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### H73 **Buprenorphine Prevalence in the Office of the Chief Medical Examiner (OCME) Cases Positive for Drugs of Abuse: To Screen or Not to Screen?**

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After attending this presentation, attendees will be aware of the debate on the safety of buprenorphine as it relates to the actual prevalence of use and abuse in a drug-positive population.

This presentation will impact the forensic science community by increasing the awareness of the prevalence of buprenorphine in autopsy cases positive for drugs of abuse in Maryland and provoking thought on the necessity and effect of its inclusion into the initial postmortem toxicology drug screen and its impact on public health.

Buprenorphine is a partial opioid agonist approved by the U.S. Food and Drug Administration in 2002 for use in opioid addiction therapy. Buprenorphine is generally considered to have a more favorable safety profile relative to other opioids due to its ceiling effect and partial agonist effect. In higher doses, buprenorphine may actually block the effects of full opioid agonists and can potentially induce withdrawal in opioid-addicted individuals. Buprenorphine is available as a sole-active ingredient preparation as well as in combination formulations with naloxone to discourage misuse and diversion. Despite this, the drug continues to be misused as a self-medication for opioid withdrawal. Though relatively safe when used appropriately, multiple deaths have been reported due to buprenorphine use and misuse alone or in combination with other drugs. In several of the reported cases, the levels of buprenorphine were not considered toxic; however, since no other identifiable causes of death could be found, buprenorphine toxicity was still listed as contributory to the cause of death. In the majority of these cases, buprenorphine was taken with other drugs. Due to the rising number of individuals in Maryland receiving buprenorphine as part of their substance abuse treatment, the issue of its diversion and misuse in the drug abusing population has been a growing public health concern. There are currently 561 physicians in Maryland that have received waivers to prescribe buprenorphine for opioid addiction therapy. In 2014, there were 252,664 prescriptions written for buprenorphine in Maryland. Therefore, it is important to try to elucidate the drug's possible role in the death of individuals who use and/or misuse it, with or without the concomitant use of abused drugs. The recent increased availability of buprenorphine has fueled concern from certain groups of the possible role of buprenorphine in drug intoxication deaths involving other drugs of abuse. Therefore, the OCME performed buprenorphine screening of blood for cases testing positive for drugs of abuse from December 2013 to July 2014 to determine its prevalence in these cases.

Buprenorphine screening was performed by Enzyme-Linked Immunosorbent Assay (ELISA) with the Immualysis™ Buprenorphine Direct ELISA kit. Screening was performed according to manufacturer's instructions with a blood cutoff concentration of 0.5ng/mL. From December 2013 to July 2014, a total of 2,744 autopsies were performed and 614 cases positive for drugs of abuse were selected for buprenorphine screening. Of the 614, only 30 cases (4.88%) screened positive for buprenorphine in blood. Of the 30 cases, confirmation was completed for five cases, resulting in four positive cases and one negative case. Confirmation in the remaining 25 cases is ongoing. Of the four confirmed positive cases, buprenorphine was a contributing factor in the cause of death in only three. In all three, additional drugs were present in blood, including ethanol, oxycodone, benzodiazepines, quetiapine, zolpidem, and amphetamine.

Given the increasing role of buprenorphine in opioid dependence therapy and the rising increase in the numbers of diverted buprenorphine being seized by law enforcement, concern for its role in the deaths of cases positive for drugs of abuse is expected; however, considering its pharmacological attributes, it is actually much safer in overdose than opioid full agonists. When used in combination with naloxone, it may discourage misuse and diversion. While the use, misuse, and diversion of buprenorphine is on the rise, its low prevalence in autopsy cases positive for drugs of abuse suggests that its actual role in contributing to death in this population may be very small. Its inclusion into initial postmortem toxicology screens may be unwarranted. Medical examiners should use caution in implicating buprenorphine as a cause of death in cases where non-toxic levels are detected in the absence of additional significant toxicological findings and no other cause of death is identified.

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#### **Buprenorphine, Screen, Public Health**

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