

Pain Management Testing by Liquid Chromatography Tandem Mass Spectrometry

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KEYWORDS

- Opiates • Opioids • Pain medication • LC-MSMS • Liquid chromatography
- Tandem mass spectrometry

KEY POINTS

- Opioid pain medications cause severe social and financial burden because of their severe side effects.
- Addiction prevention requires accurate and sensitive testing for monitoring patient compliance with prescriptions.
- Testing must include opiates, synthetic opioids, illicit drugs, and prescription drugs with abuse potential.
- The commercially available opiate immunoassays cannot fulfill the requirements of pain medication monitoring.
- Liquid chromatography tandem mass spectrometry methods are ideal for pain medication monitoring, but require careful method development, validation, and result interpretation.

INTRODUCTION

Opioids, chemicals that bind to tissue opioid receptors, have gained much attention in recent years owing to their increasing impact on public and individual's health. Opioid prescribing trends have been increasing from 1999 through 2016, the last year for which complete statistics are available, bringing with it the unprecedented increase in opioid overdoses and related deaths.¹ By the end of 2015, 63% of all drug overdose-related deaths were due to opioids, surpassing 33,000 lethal cases that year. The highest number of deaths were due to fentanyl and its analogs (20,100 deaths), followed by heroin and prescription opioids (15,400 and 14,400 deaths, respectively). The number of opioid related deaths has surpassed that of cocaine or

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methamphetamine^{1,2} and exceeded that of deaths related to human immunodeficiency virus infection in its peak year.

This increase is largely due to opioid use to alleviation of chronic, nonmalignant pain, in contrast with earlier practice of opioid use at the end of life and for malignant pain treatment. The proportion of visits to medical providers for nonmalignant pain has shown an approximately 26% increase in the United States from 2000 to 2010. The proportion of visits with provider-diagnosed pain has increased by approximately 50%,³ whereas the proportion of visits when opioids were prescribed more than doubled.³

The economic burden to US society was estimated to be \$78 billion in 2013,⁴ but the revised cost by The Council of Economic Advisers projected \$500 billion just 2 years later.⁵ This substantial increase is attributed to the increasing number of opioid overdose-related cases within the time the studies were conducted and to the fact that the paper by Florence and colleagues⁴ only calculated health care-related cost, whereas the report by the Council of Economic Advisers estimated all cost to society. Regardless of accounting practices, the opioid epidemic is a serious burden on US society and must be dealt with. For successful intervention, appropriate tools must be applied before remedies can be offered to the individual and the community.

THE NEED FOR OPIOID TESTING

Opioids are very effective pain killers, but have side effects ranging from nausea, vomiting, and miosis to coma or severe respiratory depression, leading to death. Uncommon side effects include confusion, hallucinations, delirium, muscle rigidity, myoclonus, and opioid-induced hyperalgesia during cessation of drug administration.

The most severe side effects—namely, tolerance, dependence, and addiction—belong to the group of reinforcement disorders. Tolerance, which requires successively larger doses of the drug to achieve the same medical effect, can develop with even short-term opioid use. Tolerance can be also lost when the patient has no access to opioids for a while, as during incarceration. Regaining access to opioids again, the person restarts his or her drug intake at the previous doses and the lost tolerance leads to a severe outcome.^{6,7} Dependence, a change in the individual's metabolism, forces the patient to continue use of the drugs beyond the cessation of pain. Addiction, the most severe side effect of opioid use, is composed of physiologic and behavioral changes that lead to drug-seeking behavior, often via criminal means. The side effects of withdrawal force the patient back to repeat drug use, or when prescription is no longer available, to obtain the opioid via illegal means.

The combination of tolerance, dependence, and addiction can turn the patient toward readily available illicit opioids such as heroin, illegal versions of the prescription drugs such black market methadone or fentanyl, or designer opioids such fentanyl analogs or Krokodil (desomorphine). Diverting legally obtained opioids, that is, selling the prescription medication on the streets is another aberrant behavior that is often associated with sample adulteration in the form of “spiking” the sample with the prescribed drug to mask lack of use.

Patients on chronic opioid therapy are required to sign a medical agreement or contract that stipulates conditions for participation in the treatment. By signing, the patient agrees that all controlled substances come from prescription by a medical provider; the patient will inform the prescriber of any change in his or her medication, health status, or the presence of side effects; that he or she will not share or allow the use of his or her medication by another person; and he or she submits to random urine drug tests.

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