Executive Summary of the American Association of Clinical Chemistry Laboratory Medicine Practice Guideline: Using Clinical Laboratory Tests to Monitor Drug Therapy in Pain Management Patients

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Guest: Dr. Paul Jannetto is a consultant at the Mayo Clinic in Rochester, Minnesota, where he serves as co-director of the Clinical Mass Spectrometry Clinical and Forensic Toxicology and the Metals Laboratories. Dr. Jannetto is also a Guest Editor of the JALM January 2018 special issue on Laboratory Support of Pain Management.

Randye Kaye: Hello, and welcome to this edition of "JALM Talk" from *The Journal of Applied Laboratory Medicine*, a publication of the American Association for Clinical Chemistry. I'm your host, Randye Kaye.

Laboratory Medicine Practice Guidelines, published by the American Association for Clinical Chemistry, recommend best practices for clinical laboratories in a number of different areas of patient testing. These guidelines are formed via a systematic review of published literature and the consensus of experts in the field with the goal of optimizing patient care.

Recently, a review of the pain management literature was undertaken in order to produce laboratory practice guidelines in this subject area.

Pain management is a complex topic involving a number of stakeholders including patients, clinicians, the clinical laboratory, and others. A major component of pain management is monitoring a patient's compliance with taking their prescribed medication, making sure patients are not diverting this medication, and also making sure patients are not taking medications that they are not prescribed.

Given that the magnitude of prescription opioid abuse has grown significantly over the past 10 years and that opioid-induced deaths have also increased dramatically, assessing risk and documenting responsible care when prescribing such drugs is at the forefront of clinicians' minds.

An "Executive Summary of the American Association of Clinical Chemistry Laboratory Medicine Practice Guideline: Using Clinical Laboratory Tests to Monitor Drug Therapy in Pain Management Patients" is published in the January 2018 special issue of JALM on Laboratory Support of Pain Management.

The first author of this summary is Dr. Paul Jannetto, a consultant at the Mayo Clinic in Rochester, Minnesota, where he serves as co-director of the Clinical Mass Spectrometry Clinical and Forensic Toxicology and the Metals Laboratories. Dr. Jannetto is also a Guest Editor of the JALM January 2018 special issue on Laboratory Support of Pain Management, and he is our guest for today's podcast.

Welcome Dr. Jannetto. First question, what is the purpose and target audience of the Laboratory Medicine Practice Guideline (LMPG): Using Clinical Laboratory Tests to Monitor Drug Therapy in Pain Management Patients?

Dr. Paul Jannetto: The purpose of this LMPG was to provide clinical and laboratory practice recommendations to address specific questions regarding the appropriate use of diagnostic tests to monitor adherence or compliance to controlled substances in the pain management population.

Ultimately, this guideline produced 26 evidence-based and seven consensus-based recommendations on the use of laboratory and point of care tests to monitor the use of controlled substances in pain patients. The goal of this LMPG was to address many of the issues and challenges faced by clinical laboratories, practicing pain management clinicians, policy makers, regulatory bodies, and health insurance companies surrounding urine drug testing in pain management patients, including, how to determine what types the laboratory tests are appropriate and what specific analytes should be tested for.

Randye Kaye: How does this LMPG differ from the CDC guidelines for prescribing opioids for chronic pain and other clinical practice guidelines which state that urine drug testing should be performed?

Dr. Paul Jannetto: The CDC and other clinical practice guidelines only provide a general recommendation stating that urine drug testing should be performed in chronic pain patients who are prescribed opioids or other controlled substances to see if they are actually taking the prescribed medications or illicit drugs.

However, this LMPG addressed more of the details around what type of testing, for example, immunoassay screening versus definitive tests, the role of genetic testing in this population, and the role of quantitative urine drug testing. In the end, this guideline provides more specific details around laboratory diagnostic tests, while also identifying and pointing out the gaps where evidence is lacking in the literature.

Randye Kaye: I see. Can you tell me some of the key messages and evidence-based recommendations for clinicians and payers and laboratories who perform urine drug testing?

Dr. Paul Jannetto: One of the key evidence-based recommendations is that first-line definitive testing, either qualitative or quantitative, is recommended for detecting the use of relevant over the counter medications, prescribed and non-prescribed drugs, and illicit substances in pain management patients.

In addition, specimen validity testing, for example, pH testing, is recommended since it is an effective tool to ensure that laboratory test results are correctly interpreted in pain management patients.

Specimen validity testing determines the suitability of the urine specimen collected and received, which directly affects the ability to correctly identify the medications, both prescribed and non-prescribed, as well as illicit substances used by pain management patients.

Randye Kaye: There's a lot of literature surrounding the use of laboratory tests to monitor drug therapy in pain management patients. Did you identify any gaps in that literature, and what are they?

Dr. Paul Jannetto: Additional studies are needed to examine the true cost effectiveness of different types of diagnostic assays and determine what is the required turnaround time for urine drug testing to reduce or prevent negative outcomes in patient care.

The current evidence in the literature also did not support using specific patterns of conjugated and unconjugated drug and drug metabolites to define a patient's metabolic phenotype. And there was insufficient evidence to support the practice of normalizing quantitative results, to creatinine or specific gravity or that doing so was an effective means of detecting compliance.

Randye Kaye: So, what effect do you think this guideline is going to have on the current opioid epidemic in the U.S.?

Dr. Paul Jannetto: In the end, I hope this LMPG provides some guidance for laboratorians and clinicians to minimize unnecessary and costly testing and lead to more appropriate laboratory test utilizations, so providers get the required information they need in a simplified format to verify adherence to controlled substances in their pain management patients.

Randye Kaye: That was Dr. Paul Jannetto from the Mayo Clinic talking about the JALM "Executive Summary of the American Association of Clinical Chemistry Laboratory Medicine

Practice Guideline: Using Clinical Laboratory Tests to Monitor Drug Therapy in Pain Management Patients" for this podcast.

Thanks for tuning in for JALM Talk. See you next time and don't forget to submit something for us to talk about.