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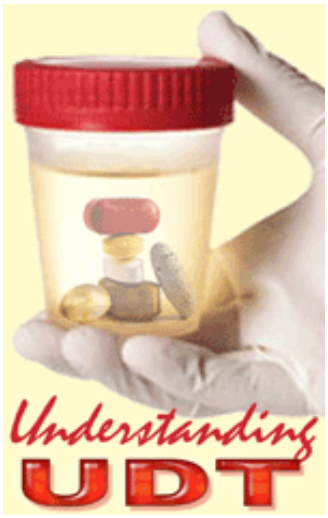
Monday, August 27, 2012

Introducing "Understanding UDT in Pain Care"

Part 1: Clinical Complexities and Medical Mandates

By Stewart B. Leavitt, MA, PhD and Gary M. Reisfield, MD



Urine drug testing, or UDT, is one of the most controversial, yet potentially important, components of effective pain management and pharmacovigilance. However, when UDT is motivated by fear and coercion, rather than diagnostic and therapeutic objectives, it can be offensive or intimidating to patients and misunderstood or misused by practitioners. Yet, UDT is becoming an increasingly accepted and emerging standard of practice that, if done at all, should be done properly. For this, a much better understanding of UDT in clinical pain care is needed.

Successful treatment of an underlying pain disorder is dependent on patient self-reports. But, it is critical that clinicians have objective means of monitoring patients' adherence to prescribed pharmacotherapies for pain and, considering its utility, accuracy, and ease of administration, UDT is an objective measure of choice. Exploring the rationales, applications, benefits, and limitations of UDT for better pain care, while bridging current knowledge gaps, is the mission of this special *Pain-Topics UPDATES* series.

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A Matter of Pharmacovigilance

As readers are no doubt aware, pain has reached pandemic proportions in the United States and worldwide, with an estimated 100 million persons afflicted with chronic pain in the United States alone [IOM 2011]. Pharmacotherapy — particularly, but certainly not exclusively, involving opioid analgesics — remains a central component of many approaches to pain management. Yet, data from various sources have underscored increasing problems associated with the nonmedical use, abuse, and diversion of opioid analgesics by persons of all ages, including alarming rates of opioid addiction, as well as emergency department visits and deaths due, at least in part, to opioid overdose [FDA 2012; Schonwald 2012].

This morbidity and mortality associated with opioid analgesic misuse and abuse focuses negative attention on the dangers of these medications while overshadowing awareness of the very real and important role that they play in improving the quality of life for millions of patients genuinely suffering from chronic pain. As Cheatle and Savage [2012] recently noted:

> *"One of the barriers to effective pain management across the spectrum of pain conditions (acute, chronic noncancer, and cancer pain) is the clinician's fear of prescribing opioids beyond that merited by the actual risks. This has led to the undertreatment of pain, including cancer-related pain. Trepidation regarding the prescription of opioids has been reinforced recently by the rise in the nonmedical use of prescription opioids, resulting in increasing opioid-related harm and deaths, as well as an increased demand for treatment of prescription opioid addiction. It is important to appreciate the actual risks associated with opioids and accommodate these when prescribing, but it is not appropriate to abandon the use of opioids because of misperceptions, as many pain experts agree that opioids remain the most effective analgesics available."*

Simple solutions to the complex problems associated with opioid analgesics are quixotic, and numerous patient assessment and management approaches have been developed in an effort to mitigate risks and ensure that patients with pain have continued access to appropriate treatments, including opioids, to help alleviate suffering. One of the most important approaches incorporates principles of pharmacovigilance [Fishman 2012].

According to the World Health Organization [WHO 2002], pharmacovigilance is the science and activities — including monitoring and testing — related to the detection, assessment, understanding, and prevention of adverse effects or other problems related to medication prescribing and use. The aims of pharmacovigilance are to enhance the care and safety of individual patients while also constituting a broader approach to medical therapy "that contributes to an ethos of safety and serves as an indicator of the standards of clinical care practiced within a country."

Pharmacovigilance is a clinical discipline in its own right, and it is of vital importance for helping to assure effective and safe pain care. Medication monitoring and drug detection via clinical *drug testing* is a key, although not sole, component of pharmacovigilance in pain management.

Some authors have observed that the broad term "drug testing" can be misunderstood or misleading because it implies that a test will detect the presence of *all* controlled medications and other substances of abuse [Gourlay et al. 2010, 2012; SAMHSA 2012]. Similarly, the term "drug screening" can be deceptive when it is thought to encompass all drugs and/or all types of drug tests. Clinical testing usually entails a two-stage process: 1) a preliminary (or presumptive) screening test, and 2) a confirmatory test. Each of these has different levels of accuracy, reliability, specificity, and sensitivity [Leavitt 2005] — topics to be discussed later in this series of *UPDATES*.

The focus here is on Urine Drug Testing, or UDT for short, and sometimes called Urine Drug Monitoring, or UDM, which is the approach most commonly used in everyday clinical practices [Peppin et al. 2012]. Other specimens — such as oral fluid, blood, perspiration/sweat, and hair — also can be used, but they are usually less practical or appropriate even though testing involving any of these serves similar overall purposes and goals.

In concept, UDT involves many of the basic principles of diagnostic testing that clinicians are already familiar with when testing patients to assess, for example, responses to warfarin therapy for atrial fibrillation or insulin for diabetes [Bair and Krebs 2010]. However, to accurately interpret UDT results and understand the role of UDT in pharmacovigilance, clinicians must be familiar with the pharmacokinetics, pharmacodynamics, and pharmacogenetics of the many medications and other drugs that may be involved in pain management. For some clinicians, this may seem daunting, but the educational resources are readily available to provide the necessary

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understanding.

Furthermore, practitioners can and should use additional methods or approaches besides UDT as components of a comprehensive pharmacovigilance approach. These may include [Gourlay et al. 2010; SAMHSA 2012]:

> Data from electronic prescription drug monitoring programs (PDMPs);
> patient history and self-reports;
> pill counts of prescribed medications;
> clinical signs/symptoms of medication effects or substance abuse;
> screening and behavioral assessment questionnaires;
> collateral information from a patients' family (obtained with patient permission);
> the practitioner's clinical judgment.

However, many authors have suggested that these can be variously less objective, helpful, and/or ultimately effective unless they are combined with a consistently implemented program of UDT [Gourlay et al. 2010, 2012; Hammett-Stabler and Webster 2008; Nafziger & Bertino 2009; Reisfield et al. 2007].

Most experts [eg, Peppin et al. 2012; SAMHSA 2012] agree that UDT is the most practical and objective clinical tool available to prescribers for medically assessing *at a given point in time* whether patients are…

a. taking prescribed medications,
b. taking unauthorized controlled medications,
c. using illicit substances, or
d. taking combinations of medications/substances that may induce adverse drug-drug interactions, either pharmacokinetically or pharmacodynamically.

Equipped with the objective documentation of UDT results, pain-care providers can more confidently prescribe pharmacotherapy, including opioids, for patients who may benefit. At the same time, however, it must be noted that UDT also has limitations and can be controversial (discussed below), so practitioners need to weigh the advantages and shortcomings, since when inexpertly used there is a potential for doing harm while incurring added costs in time, effort, and money.

Perspectives on Clinical UDT

UDT in clinical practice emerged from a tradition of forensic

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drug testing in the workplace and the justice system; however, there are some important differences. In forensic testing, urine collection and sample chain of custody are strictly regulated, and results are expected to be *negative* for commonly abused substances of concern, such as amphetamines (including methamphetamine), cocaine, cannabinoids (marijuana), phencyclidine (PCP), opiates (heroin), and MDMA (ecstasy).

Also, in forensic contexts, confirmatory testing (performed with laboratory-based chromatography paired with mass spectrometry) is performed only if the screening test yields a presumptive positive result. Test results are usually examined by a trained medical review officer (MRO) and there is zero tolerance for confirmed positive findings — possibly including harsh penalties (eg, job loss or incarceration) [Federal Register 2004; Laffer et al. 2011; SAMHSA 2012; Schonwald 2012].

In pain care settings, patients are typically expected both to *test positive* for prescribed medications that otherwise might be considered substances of abuse, such as opioids or benzodiazepines, and to *test negative* for non-prescribed controlled medications and illicit drugs. As in forensic testing, medication monitoring and drug detection in pain treatment patients often begins with in-office urine screens to provide general information on the drugs or drug classes that are present.

However, a problem here is that many of these point-of-care (POC) screening devices contain panels for a limited number of drugs or drug classes. Thus, a given device may not be designed to detect some of the most commonly prescribed medications, including synthetic (eg, methadone) and some semisynthetic (eg, oxycodone) opioids, some benzodiazepines (eg, clonazepam), muscle relaxants (eg, carisoprodol), and other pain-care-relevant and illicit drugs [SAMHSA 2012].

Furthermore, preliminary POC screening test cutoff concentrations may not be low enough in some instances to detect therapeutic doses of medications or small amounts of illicit substances (eg, cannabinoids, methamphetamine) [SAMHSA 2012]. The *cutoff* is an administratively determined concentration of a drug or metabolite, at or above which the result is reported as positive (drug present), and below which the result is reported as negative (drug absent) [Leavitt 2005].

So, basic in-office screening tests can, within minutes, provide a preliminary indication of whether or not a patient is likely to be taking the drug or class of drug of interest

[Peppin et al. 2012]. However, this alone is often insufficient to address the questions that must be asked and answered in patients being treated for pain [SAMHSA 2012; Webster and Dove 2007].

Therefore, a portion of the patient's urine specimen is sometimes sent to a laboratory for highly accurate quantitation and identification of specific drugs and/or their metabolites, using lower cutoff levels and an extended test menu. If a broad enough approach is used, it will inform the clinician of a wide variety of pharmacologic substances in the patient's urine — whether prescribed, nonprescribed, or illicit — within a turnaround of a few days or less (depending on laboratory capabilities), allowing for timely patient care decisions [Peppin et al. 2012].

It is important to emphasize that, while there has been a great deal of concern about opioid analgesic prescribing, these are not the only medications used in pain management and worthy of monitoring. It can be of vital importance to know, as part of the treatment plan and for safety reasons, whether or not patients are taking their antidepressants, anticonvulsants, anxiolytics, muscle relaxants, or other agents as prescribed. UDT, using advanced laboratory-based assays, can help to provide the answers.

Directives for Adopting UDT

U.S. state legislatures as well as federal agencies — including the Drug Enforcement Agency (DEA), Food and Drug Administration (FDA), Substance Abuse and Mental Health Services Administration (SAMHSA), and the White House's Office of National Drug Control Policy (ONDCP) — are all grappling with meeting the challenges associated with opioid analgesics. In this regard, the importance of adopting UDT in clinical pain treatment practice has been emphasized in a number of guidance documents and legislative or other actions:

- In May 2012, SAMHSA published their first-ever guide to clinical drug testing in primary care [SAMHSA 2012]. This manual describes and recommends how practitioners can use drug testing to help monitor patients' use of prescribed medications as part of a pharmacovigilance approach and to identify patients who may need interventions for substance use disorders. There are important implications in this government-approved guidance for compliance by clinicians who treat beneficiaries of public assistance programs, such as Medicaid, Medicare, and others.

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Stewart B. Leavitt, MA, PhD
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- In July 2012, as a component of its Risk Evaluation and Mitigation Strategy (REMS) for extended-release (ER) and long-acting (LA) opioid analgesics, the U.S. FDA specified the following as a component of therapy management: *"Prescribers should monitor patient adherence to the treatment plan, especially with regard to misuse and abuse by …. [u]nderstanding the utility and interpretation of drug testing (eg, screening and confirmatory tests), and using it as indicated"* [FDA 2012, p 4]. Thereby, such testing may become a *de facto* standard of care when treating patients with ER/LA opioids, and noncompliant prescribers might expose themselves to regulatory scrutiny or other repercussions.

- Also in July 2012, the Kentucky legislature implemented House Bill 1, and the Board of Medical Licensure invoked newly instituted policies for controlled substance prescribing, requiring baseline UDT to determine whether medications being prescribed are in the patient's system, and whether nonprescribed and illicit drugs are absent. Furthermore, during long-term opioid therapy, UDT is required in a "random manner at appropriate times" to determine whether the patient is taking prescribed medications and/or nonprescribed or illegal substances. Confirmatory testing is required for unexpected "red flag" screening test results, and patients may be discharged from pain treatment and/or referred to specialists (eg, addiction treatment), as deemed appropriate [Kentucky 2012].

  It should be noted that, plagued by "pill mills" and reckless distribution of opioid analgesics, very similar rules had earlier been proposed by the Florida State Board of Medicine. Mandatory UDT would be required when initiating therapy and randomly at least twice throughout the year; patients with abnormal test results could be discharged from treatment with controlled substances [Miller 2011, Peppin et al. 2012].

  These Florida rules were not implemented due to concerns about economic impact. However, at the time, they were among the most aggressive proposed in any state and there was discussion that they might become a model of standard patient care adopted by other states (as subsequently occurred in Kentucky).

- In other state actions being closely watched,

information noted and, when relevant and available, URL links must be provided. URL links open in a new window, and access was checked prior to posting; however, some may change and not function in the future, which is beyond our control.

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aggressive new rules implemented in early 2012 by Washington state for the management of chronic noncancer pain — intended to curb rising opioid overdose deaths — include a provision that patients must conform to a treatment agreement and consent "to provide biological samples for urine/serum medical level screening when requested by the physician." No specifics regarding the type and frequency of testing are indicated in the Washington legislation [Washington 2012].

- On a municipal level, the New York City Department of Health and Mental Hygiene published guidance on monitoring prescription drug adherence and nonprescribed drug use, recommending initial UDT and behavioral assessment followed by random UDT yearly for low-risk patients and up to every three months in those at high-risk [Paone et al. 2011].

Additionally, of the numerous peer-reviewed articles discussing the importance of UDT in pain-treatment practice, the following might be noted as being of particular prominence:

- All major clinical guidelines addressing opioid analgesic prescribing for chronic pain also stress the need for medication monitoring and drug detection via UDT [refs in Peppin et al. 2012]. The most recently updated guidelines, in July 2012 [Manchikanti et al. 2012], which also are informed by earlier guidance documents, concluded that there is good evidence to strongly recommend UDT at treatment initiation and for subsequent adherence monitoring to decrease prescription drug abuse or illicit drug use when patients are receiving chronic pain management therapy. However, while such testing is strongly recommended, it generally is not mandated *per se* in current guidelines documents.

- In a first of its kind document on urine drug monitoring in pain care, an expert panel published consensus recommendations in July 2012 specifically addressing questions of which patients to test, which substances to test for, how often to test, and how to act on test results [Peppin et al. 2012]. While much of the guidance is based on limited evidence, this document helps to establish a framework for standardized UDT practices in the treatment of chronic pain with opioids.

- In a newly updated version of the text, *Responsible*

Opioid Prescribing, from the Federation of State Medical Boards, author Scott Fishman, MD, recommends laboratory urine toxicology testing as an essential ingredient of assessing adherence to prescribed treatment regimens involving controlled substances [Fishman 2012].

- Clinical guidance specifically for family practitioners has strongly recommended UDT at the initiation of opioid therapy for chronic pain and randomly thereafter, and for both patients at high- and low-risk of abusing those medications [McBane and Weigle 2010].

- In seminal guidance papers on the subject, Douglas L. Gourlay, MD, Howard A. Heit, MD, and colleagues advocate for a "Universal Precautions" approach to patient-centered UDT [Gourlay et al. 2005, 2010, 2012]. This recognizes that all patients have some degree of risk for problematic medication and other substance use, and all of them can benefit from appropriate, ongoing monitoring as an essential component of safe and effective pain care.

Clearly, there are directives and recommendations coming from various authorities favoring the adoption of a pharmacovigilance approach, with UDT as an essential component, when it comes to prescribing controlled substances in pain care settings. However, in opposition and fair balance, there have been some arguments against the routine application of UDT in pain management settings, particularly coming from patient advocates.

One such advocate, Mark Collen, writing in peer-reviewed literature, has asserted that mandating drug testing in all patients seeking pain care might constitute a "suspicionless and warrantless search" that violates individual constitutional rights and protections in the U.S. [Collen 2011]. Furthermore, he writes that treatment agreements requiring consent to random drug testing may not be enforceable since they might be considered "unconscionable adhesion contracts," may not be understood by patients, and patients in pain may not be in a state of mind to competently enter into such an agreement [Collen 2009].

Others have recognized the irrevocable harm that can be done if patients are denied adequate treatment (or any treatment at all) or are discharged due to the misinterpretation of UDT results [Gourlay et al. 2010, 2012; Schonwald 2012]. At the very least, unskillful communication regarding UDT issues, including the requirement for monitoring as a condition of opioid

pharmacotherapy and the handling of unexpected test results, can erode the patient-practitioner relationship of trust and confidence that is essential to the provision of effective healthcare.

Concerns about potential negative effects of UDT are legitimate [Schonwald 2012]; however, these pertain particularly to situations in which testing is used coercively, as a form of adversarial surveillance to detect and punish potentially aberrant behaviors, than as part of a consensual therapeutic partnership between provider and patient. Still, clinicians must balance benefits and potential pitfalls of medication monitoring and drug detection, while also taking into account associated expenditures in an era of limited financial and staff resources available for healthcare delivery [Laffer et al. 2011].

UDT is a subject that many practitioners, and their patients, would prefer to ignore; however, it demands attention. There is an implication that healthcare providers who do not comply with the various directives and recommendations may not be following best medical practices, which could be problematic if a clinician's prescribing of controlled substances comes into question for one reason or another.

As Jennifer Bolen, JD, observed during a presentation at PainWEEK 2011, medical review boards and law enforcement look at UDT as an important and legitimate part of efforts to prevent opioid abuse and diversion [Pain Live 2011]. Although federal government agencies — the DEA for example — do not currently require UDT, in court it is often held as a standard of responsible practice; so, failure to follow this standard (or at least demonstrate an understanding of UDT and explain any reasons for not testing) can have consequences.

Bolen — who is a former Assistant U.S. Attorney and is now a prominent legal consultant in the pain field — advises that all clinicians who treat patients with opioids for pain should be able to demonstrate that they have given consideration to a drug testing program in their practices and have knowledge of current guidelines and any existing regulations. She stresses that ignoring this responsibility is not an option; "the consequences of playing ostrich are severe." Practitioners who try to hide their heads in the sand regarding UDT may end up regretting it.

Conclusions & Coming Attractions

As Gourlay and colleagues [2010, 2012] stress, like any other medical test, UDT should be performed foremost with the goal of improving patient care. In the case of opioid analgesics, there are the added goals of mitigating risks of medication misuse, abuse, or diversion and associated adverse events.

Secondarily, healthcare providers are often concerned with protecting themselves from being misled by the small minority of persons who seek pain medications for nonmedical purposes. However, it has been said that any practitioner who is putting patient needs first will be duped on occasion; yet, a pattern of being repeatedly "fooled" may demonstrate lax pharmacovigilance practices.

While a well-designed and consistently applied drug testing program can be an important tool for making clinical decisions, it should not be the *only* tool [SAMHSA 2012]. And, just as with all other components of pain management, practitioners need to weight benefits versus drawbacks of UDT while taking into account cost concerns. In theory, UDT is a relatively straightforward diagnostic tool; however, there are many complexities surrounding its application in clinical pain management, and there is much to learn. Here are some of the questions to be addressed in further *Pain-Topics UPDATES* in this series on *Understanding UDT*:

- To what extent is UDT being applied in pain treatment settings and how skilled are clinicians in its use?

- What are the rationales and benefits for implementing UDT as a program of medication monitoring and drug detection in any clinical practice?

- What is the present scope of patient adherence to prescribed medication regimens and prevalence rates of substance misuse, abuse, and addiction in pain-care settings? How has UDT been used to evaluate these problems?

- What clinical research evidence is available to support UDT in benefitting pain care, helping to stem opioid-related problems, and helping practitioners to comply with best practice standards of care?

- What are the limitations of what UDT can and cannot do? How can it best be used in conjunction with other measures of patient behaviors regarding medication taking and substance use?

- In view of the advantages and limitations, how can an ongoing and consistent program of UDT in daily practice be economically justified?

- What are the potential quandaries and pitfalls faced by practitioners who do not implement a UDT program as a routine part of pain care?

- What guidance is available for who to test and when, and what drugs/substances should be tested?

- What are the different drug tests available and the advantages of each? What is the relative importance of accuracy, reliability, sensitivity, and specificity?

- What are the many factors that can influence potentially inappropriate positives and negatives when it comes to interpreting test results? How common is test subversion by patients and what can be done to prevent it?

- How can UDT results best be used to counsel patients regarding medication nonadherence and/or aberrant substance-use behaviors?

These are just some of the topics to be covered, so follow along as there is much more to come in this series.

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About the Authors:

Gary M. Reisfield, MD, is the Chief of Pain Management Services, Division of Addiction Medicine, Department of Psychiatry, at the University of Florida College of Medicine. He is board-certified in anesthesiology, pain medicine,

and addiction medicine. He is a gubernatorial appointee to the Implementation and Oversight Task Force of Florida's Prescription Drug Monitoring Program, a member of the editorial review board of the *Journal of Opioid Management*, and a certified Medical Review Officer. Dr. Reisfield has participated as a consultant to Millennium Laboratories.

Stewart B. Leavitt, MA, PhD, is Executive Director and Editor of *Pain Treatment Topics* and was formerly the founding Editor of *Addiction Treatment Forum*. He studied biomedical communications at the University of Illinois Medical School, Chicago, and served as a Commissioned Officer in the U.S. Public Health Service. His advanced degrees are from Northwestern University, Evanston, IL, focusing on health/medical research and education. Dr. Leavitt's work is supported by unrestricted medical education grants from Purdue Pharma LP, Endo Pharmaceuticals, and Millennium Laboratories.

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Posted by SB. Leavitt, MA, PhD at 8/27/2012 05:32:00 PM

7 comments:

Husband of a 14 year pain patient said...

My personal Opinion. There is no diagnostic benefit of UDT's with the legitimate and properly treated pain patient, especially "random" checks. You either trust your patient or you don't. If you don't, trust them, then don't treat them. Quite frankly, the pill counts and the UDT's are all a sign of doctor-patient distrust. One physician put it well when he said, "the

doctor patient relationship is based on trust, and when the trust is not there, the relationship can no longer exist." Lets randomly check ANY AND ALL patients, and I bet you will find more illicit drug abuse than you would ever find in the small group of legitimate PROPERLY treated pain patient. Key words being PROPERLY AND APPROPRIATELY TREATED PAIN PATIENT.

September 3, 2012 10:04 AM

SB. Leavitt, MA, PhD said...

Thank you, for the comment above. You are assuming that UDT is used primarily to detect illicit drugs in a game of "gotcha." This is not our perspective.

This will be discussed more in an upcoming article in this series; however, for safety's sake, prescribers absolutely must know of everything that the patient is taking and there are many reasons that patients are not always forthcoming with complete information. Sometimes patients do not know specifically what they have been prescribed by their healthcare providers, or they may forget to mention less frequently taken medications, or they may not think it is important to include meds not taken for pain --- none of these is due to deception or illicit drug use or abuse, but prescribers still need to know of these drugs.

Patients have died because a physician prescribing opioids did not know of medications prescribed by other healthcare providers. So, the old saying, "trust but verify," can have some lifesaving implications when it comes to properly using UDT as a tool to help insure patient safety. And, it does not automatically mean that the prescriber is accusing the patient of any wrongdoing.

September 3, 2012 10:56 AM

Anonymous said...

It's about money. Medtox lost a law suit claiming their UDT could predict how much medication the patient was taking. This was proven wrong, and it didn't cost the company any money, meanwhile it has created mistrust between some doctors and patients. Also, I have seen reports that the doctor makes $150.00 per test, per patient from Medicare. I signed a statement that plainly reads, any medication

from any doctor for any reason will be reported to the doctor or you will be terminated as a patient. I see both sides, but to be treated like you are a crook being arrested for a crime is terrible. It is bad enough being crippled for life, especially when it wasn't my choice to end up this way. In all fairness, some doctors ought to have to take a UDT also.

September 3, 2012 9:29 PM

SB. Leavitt, MA, PhD said...

Just to keep the record straight, I believe that the company named in the comment immediately above is ***incorrect***.

September 3, 2012 10:14 PM

Husband of a 14 year pain patient said...

Thank you for your insight and in all sincerity, I do not think it is a game of "gotcha", it is really all about patient-doctor trust. Going further and based on the logic presented, ALL patients for ALL doctors who are being prescribed, ANY medication, should be tested. Why limit it to Pain patients and opiods? There are many dangerous and safety related potential drug interactions with more than just opiods. And following the logic further, if it is a safety related issue, why not require testing for ALL patients? Many patients have more than one doctor and specialists for non-pain related diagnosis(after re-reading the article, that may be what you are addressing?). As anonymous said, it is the patient's responsibility to inform the doctor of any other treatment.
Pain patients, as with others, probably have routine lab work as recommended, by their physician. I know that we do. If that is to include UDT, so be it, but the government should get their hands out of making it mandatory, and the testing, if it is so valuable, should not be limited to pain patients.
Personally, I think it should be at the discretion of the treating physician, with a clear medical basis for requiring the test and a clear description of why the test is needed and what the doctor is looking for in the results. This open, informative and non-coerced method would show doctor-patient trust. Basically, and I think we all agree, the current Opiod Agreements and Mandatory pill counts and mandatory UDT's, all make the, already in pain, patient feel distrusted and looked down upon, which only adds to their already painful life, and we are

happy that you and your colleagues are addressing, this and all issues to make the treatment of pain patients what it needs to be. Thank you!

September 4, 2012 9:44 AM

SB. Leavitt, MA, PhD said...

Medication monitoring and drug detection via clinical drug testing, such as UDT, is simple in concept and very complicated when it comes to proper use and interpretation. As a pharmacovigilance approach, UDT could be useful and important in many clinical settings; not just in pain management. However, there also can be high costs associated with UDT, depending on how comprehensive the testing, so it is a clinical tool that must be used judiciously and responsibly. There are a great many facets of this to be discussed and considered, with an emphasis on patient benefits and safety, which we will be doing as other articles in this series of *UPDATES* unfolds in the months ahead.

September 4, 2012 10:45 AM

Anonymous said...

I am so very sorry, Dr. Leavitt. You are correct Sir, the company that lost the law suit is Ameritox, not Medtox. Please forgive the error, and can you make the correction? Thank you very much.

September 9, 2012 7:59 PM

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