

Comment on CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016

Docket No. CDC-2015-0112

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This comment is focused specifically on urine drug tests (UDT) and Recommendation #10 which requires patients to submit to drug screens in order to obtain pain medication. The paper is divided into four sections and these are “evidence review,” “critique of individual statements within the guideline and contextual evidence review,” “historical perspective,” and “discussion and conclusion.”

This author is the leading opposition to random drug testing in pain management in the literature.(1-13) Aside from the fact there is no proof of efficacy,(14-16) UDT is likely unconstitutional in a number of pain management settings (2, 8, 17) and evidence suggests it was driven by profits.(5) Moreover, drug testing in pain management costs an estimated \$2 billion per year (18) and may harm the patient and the patient-provider relationship.(4, 12) The CDC made an error in judgment by including UDT as part of their recommendation and it should be corrected.

In the first two sections there are statements and questions in bold face that should be addressed by the CDC.

Evidence Review

Three systematic reviews found insufficient proof of efficacy for UDT.(14-16) The efficacy of an intervention means that benefit outweighs harm, but patient harm or harm to the patient-provider relationship has never been evaluated with UDT. In other words, not a single study has ever evaluated the efficacy of urine drug testing in pain management.

The CDC overlooked the fact that urine drug testing may be unconstitutional in a number of settings.(2, 8, 17) The ACLU of Indiana challenged drug testing in pain management and won.(17) This author informed the CDC’s report author Roger Chou (via email on 2/9/2015) and CDC’s expert Joana Starrels (via email on 1/14/2014) that there was a Fourth Amendment, Federal Constitutional issue surrounding UDT in pain management.

Why didn’t the CDC address the constitutional issue?

There is evidence that drug testing in pain management was driven by profits (5) and Joanna Starrels was notified of this via email on 2/17/12.

Why did your experts ignore the profit motive behind UDT?

For any report to be objective, the opposition’s evidence must be taken into consideration.

Why did the CDC ignore the opposition’s arguments and evidence?

Critique of Individual Statements within the Guideline and Contextual Evidence Review

Both the CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016 (G) and Online Appendix 2: Contextual Evidence Review (C) contain incorrect assumptions and internal inconsistencies regarding UDT.

On page 3G it is written, *“Existing guidelines share some common elements, including dosing thresholds, cautious titration, and risk mitigation strategies such as using risk assessment tools, treatment agreements, and urine drug testing.”*

Relying on existing guidelines which ignore science and the law is also not evidence. Moreover, industry influences pain associations and they write guidelines.(19-21)

Jeanne Lenzer and colleagues write, *“However, widespread financial conflicts of interest among the authors and sponsors of clinical practice guidelines have turned many guidelines into marketing tools of industry.”*(20)

On page 31G it is written, *“10. When prescribing opioids for chronic pain, providers should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs (recommendation category: B, evidence type: 4).”*

On page 16G it is written, *“Category B recommendations were made when there was broad agreement that the advantages and disadvantages of a clinical action were more balanced, but advantages were significant enough to warrant a recommendation.”*

What advantages were significant enough to warrant a UDT recommendation?

On page 13C it is written, *“Unfortunately, it is challenging to determine whether the benefits of urine drug testing outweigh the costs, given the limited rigorous evidence of the effectiveness of urine drug testing as a risk mitigation strategy [122].”*

On page 13C it is written, *“Resource allocation (cost) is an important consideration in understanding the feasibility of clinical recommendations. This includes cost of recommended practices, costs of alternatives, and costs averted if effective practices are implemented. Practices that have high costs relative to their anticipated benefits are less likely to be recommended.”*

UDT in pain management costs an estimated \$2 billion per year (18) with no proof of efficacy.(14-16) How can the CDC recommend it in good conscience?

On page 56G it is written, *“Because pain management in patients with substance use disorder can be complex, providers should consider consulting substance use disorder specialists and pain specialists regarding pain management for persons with active or recent past history of substance abuse.”*

This author is neutral on UDT for individuals in recovery and on opioid therapy.

On page 31G it is written, *“Urine drug tests can provide information about drug use that is not reported by the patient.”*

In general, patient compliance to medication is poor (22-24) and studies suggest this is also true for people with chronic pain using opioids.(25) In addition, illicit drugs have been found in the urine of people using pain medication, mostly cannabis.(25, 26)

Yet, after billions of dollars spent on UDT, there is no solid evidence that a positive UDT for cannabis or other drugs influences or changes a provider’s prescribing habits or benefits the patient.

On page 31G it is written, *“In addition, urine drug tests can assist providers in identifying when patients are not taking opioids prescribed for them, which might in some cases indicate diversion or other clinically important issues such as difficulties with adverse effects.”*

Where is the evidence for this statement? In the Guideline it states (below) that there is no proof of efficacy, there are false negatives/positives, and results can be misinterpreted.

On page 10G it is written, *“No study evaluated the effectiveness of risk mitigation strategies (use of risk assessment instruments, opioid management plans, patient education, urine drug testing, use of PDMP data, use of monitoring instruments, more frequent monitoring intervals, pill counts, or use of abuse-deterrent formulations) for improving outcomes related to overdose, addiction, abuse, or misuse.”*

On page 10C it is written, *“For example, there are many reasons a patient prescribed opioids might not test positive for prescribed opioids on urine drug testing. In addition to diversion, these might include patients not taking opioids because of lack of efficacy or actual or feared adverse drug effects, as well as tests that are falsely negative because of analytical limitations [114]. Urine drug tests can also be falsely positive because of issues such as the presence of metabolites from prescribed opioids that appear to represent non-prescribed opioids [115]. Providers frequently misinterpret findings from urine drug tests.”*

On page 31G it is written, *“Urine drug testing results can be subject to misinterpretation and might sometimes be associated with practices that might harm patients (e.g., stigmatization, inappropriate termination from care).”*

Why didn’t the CDC address the harm done to the patient-provider relationship?

Drug testing can create an adversarial treatment environment as a person with pain may interpret a required random drug test to mean the physician does not trust the patient’s word.(4, 12) Adversarial treatment environments, like workers’ compensation, have a tendency to be more expensive than those without conflict and outcomes are generally worse.(27-29)

On page 35G it is written, “..best available evidence that was interpreted and informed by expert opinion. The clinical scientific evidence informing the recommendations is low in quality. ”

On page 1C it is written, “CDC conducted ‘rapid reviews’ of the contextual evidence to supplement the clinical evidence review.”

The CDC has low quality evidence and it conducted a “rapid review” of the contextual evidence. The opioid epidemic has been going on for many years and a thoughtful review is required for informed recommendations.

Historical Perspective

There are a number of conflating factors which have led to the CDC’s recommendation for UDT in pain management—none of which have to do with quality patient care. These include the Federal Government’s complicity in the overprescribing of drugs, the unethical marketing of OxyContin by Purdue Pharma, the profit motive which drove drug testing patients in pain, and physicians’ fears and inability to effectively treat pain.

We live in a drug addled society with Americans consuming record amounts of prescription drugs, including opioids.(30, 31) In other words, American healthcare providers are exceptional at writing prescriptions. Someone needs to tell them to, “Just say ‘no.’” The pharmaceutical industry’s direct-to-consumer advertising (DTCA) has driven demand for drugs and has contributed to the escalating cost of prescription medications.(32, 33) Both Congress and the FDA are largely responsible for this overprescribing public health issue since they have allowed DTCA to exist and spread.(34-36)

What has not been investigated is the influence the incessant drug ads have had on the American culture and more importantly, the American psyche in terms of one’s views on drug use, prescription or otherwise. Almasi and colleagues writes, “DTCA pushes a ‘Brave New World’ where if ‘anything unpleasant should somehow happen, why, there’s always [the sedative] soma to give you a holiday from the facts.’”(37) DTCA may influence the abuse of opioids and other drugs.

The pharmaceutical company Purdue Pharma was responsible for one of the most deceptive marketing campaigns in history with their medication OxyContin, a timed-release oxycodone.(4) Art Van Zee writes, “A consistent feature in the promotion and marketing of OxyContin was a systematic effort to minimize the risk of addiction in the use of opioids for the treatment of chronic non–cancer-related pain.”(38) As a result, OxyContin became the poster boy for prescription drug abuse (39, 40) and Purdue was fined \$600 million to settle criminal complaints.(41) That has had little impact on the Sackler family, Purdue’s owners, with Forbes estimating their worth at \$14 billion.(42) Although Purdue is not completely responsible for the current opioid abuse epidemic, they certainly have played a meaningful role.(38, 43) In addition, a congressional investigation suggested that the pharmaceutical industry has promoted opioid sales through a number of organizations including the American Pain Society and the American Academy of Pain Medicine (21), both of which write treatment guidelines.(19)

As opioid abuse and overdose deaths began to rise,(44) so did the drug testing industry within pain management .(5) Drug testing labs used a similar strategy as the pharmaceutical industry in promoting their wares and money was used as an incentive to drug test. A 2012 article entitled,

“Profit-Driven Drug Testing,” presented Medicare data which showed a meteoric rise in drug testing and the paper reads, “A deeper examination finds that between 2000 and 2009, the total number of CLIA-waived drug tests (CPT Code 80101QW) paid for by Medicare and conducted at physicians’ offices increased approximately 3,172,910%; with 101 tests conducted in 2000 and 3,204,740 in 2009.[19] Furthermore, during that same time period and within the specialty of anesthesiology, CLIA-waived drug tests increased 63,687,900%.”(5)

The annual cost of drug testing in pain management is estimated at \$2 billion per year.(18) Unfortunately, that may be a gross underestimate since no study has ever evaluated the indirect costs of patient harm or harming the therapeutic patient-provider relationship—likely the most important aspect of pain management.(4) A November, 2014 article in the Wall Street Journal reported that some physicians are making more money from drug testing patients than treating them.(45)

Not unlike big pharma, there appears to be a dearth of integrity in the drug testing industry.(46-48) Millennium Health, the largest drug tester in pain management, was recently fined \$256 million by the US Department of Justice and then filed for bankruptcy.(47) This led to the discovery that the founders took \$1.3 billion out of the business in 2014.(49) Ameritox, the second largest drug tester, actually paid physicians to drug test their patients, and as a result was fined \$16.3 million by the Justice Department.(46) Calloway Laboratories is yet another drug testing lab that was prosecuted and it is going out of business.(48)

This author asked Debra Maul, whistleblower in the laboratory industry, for her comment on UDT in pain management for this paper. Debra wrote, “Personally, I believe it’s all about the money. When I entered the laboratory business in 2003, it was very difficult to get physicians to test their patients. In 2007, when Millennium entered the industry with the POCT business model, pain doctors significantly increased their patient testing, I believe, because they could make money on in-office testing. New labs were popping up everywhere promoting this business model.”

She continued, “If you look at the information the WSJ obtained from CMS regarding Medicare reimbursements for UDT, reimbursements for simple UDTs grew significantly from 2007 until reimbursements were cut in 2010. Then in 2011 and 2012, high tech drug testing took a big jump, I believe, due to laboratories promoting in-office analyzers and other high-tech testing equipment to doctors, so they could continue billing for UDTs. It will be interesting to see what happens with in-office testing and the entire UDT market, with the significantly reduced reimbursements this year.”(50)

What follows is a list of drug testing labs and the amount they were reimbursed by Medicare for urine drug testing in 2012. These numbers come from Medicare’s website and were provided by Debra Maul.

Millennium: \$109,031,768.90

Ameritox: \$99,553,258.87

Aegis: \$36,140,368.03

Alere: \$16,937,116.27

AIT: \$13,845,880.55

Dominion: \$12,551,313.22

Calloway: \$6,918,972.76

To complicate matters, healthcare providers do a poor job at treating chronic pain (51, 52) and opioids may not be the best choice for the long-term treatment of chronic, non-acute, non-malignant pain.(53) Moreover, insurers have been known to reimburse for pain medication and not physical therapy.(54) It is likely that a number of clinicians prescribe opioids because they don't know what else to do, and then perform random drug tests in hopes of mitigating any damage they may cause, but it does not work. There is a great need to develop and test cost effective, alternative interventions to pharmacotherapy for the treatment of chronic pain and illness in the primary care setting.

The overriding factor in this historical perspective is the consistent and negative impact industry has on medicine and in this case, pain medicine. A good example of how close the drug testing industry gets to individuals who write guidelines, please go to this link and note the presenter is the lead author of the Guideline and a conference sponsor is a drug testing lab:

<http://nationalrxdrugabusesummit.org/biographies/dr-deborah-dowell-2/>. (Accessed January 5, 2016.)

Discussion and Conclusion

There is no question that industry has a negative influence on medicine. Stamatakis and colleagues write, "The industry has created means to intervene in all steps of the processes that influence healthcare research, strategy, expenditure and practice. These include evidence base production, evidence synthesis, understanding of harms issues, cost-effectiveness evaluation, clinical guidelines formation, healthcare professional education and direct influences on healthcare professional decisions."(55) Urine drug testing in pain management costs an estimated \$2 billion per year (18) and there is no proof of efficacy.(14-16) Moreover, it may cause patient harm and harm to the patient-provider relationship (4, 12) and thus increase healthcare costs even further.

The desire for profits likely started and maintains UDT in pain management (5, 45, 46) along with fear. Fear of prosecution has been attributed to the proliferation of drug testing by doctors treating chronic pain (56, 57) and Goldberg and Rich write, "This singular focus strongly suggests purposes beyond ensuring quality patient care, such as fear of regulatory scrutiny and potential legal liability."(57)

The CDC has turned a blind eye to a number of important issues regarding UDT in pain management including its constitutionality and the fact that it was likely driven by profits. Groupthink can negatively influence treatment guidelines (58) and that is likely to blame for the CDC urine drug test recommendation. Giving a person with pain a "choice" to either submit to a drug test or not receive pain medication is really the option to either submit to a search or suffer, and that is coercion.(12) It exemplifies patriarchal medicine at its worst and is the antithesis of patient-centered care. James L. Madara, MD, CEO of the American Medical Association, was quoted as saying about the CDC Guideline, "The guidelines and supporting discussion are devoid of a patient-centered view and any real acknowledgment or empathy of the problems chronic pain patients may face."(59)

The CDC should not recommend UDT as part of the current Guideline since there is no proof of efficacy, it may be unconstitutional, and was likely driven by profits and nurtured through fear. Furthermore, it is very expensive and may cause harm to the patient and patient-provider

relationship. The CDC should only be recommending proven interventions which don't squander scarce healthcare resources. Prasad and colleague write, "Divesting from ineffective and harmful medical practices has the potential to improve outcomes for patients, and mitigate the unsustainable rise in healthcare costs."(60)

Declaration of Conflicts of Interest

The author declares no conflicts of interest.

About the Author

Mark Collen is an independent scholar and patient advocate. He serves on the editorial board of the *Journal of Pain & Palliative Care Pharmacotherapy* and has peer reviewed manuscripts for journals including *The Patient: Patient-Centered Outcomes Research*, *The American Journal of Pharmacy Benefits*, and *The Clinical Journal of Pain*. In addition, Collen is founder of PainExhibit.org, an online art exhibit from artists with chronic pain. The mission is to educate healthcare providers and the public about chronic pain through art and to give a voice to the many who suffer in silence.

This paper is available in its entirety at:

http://www.researchgate.net/profile/Mark_Collen/publications

<http://independent.academia.edu/MarkCollen>

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