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The Need for Point-of-Care Testing of All Illicit Substances

Channie Cretsinger

University of Tennessee, Knoxville, ccretsin@vols.utk.edu

Jeremy Kourvelas MPH

University of Tennessee Institute for Public Service, jeremy.kourvelas@tennessee.edu

Jennifer G. Tourville DNP

University of Tennessee, Institute for Public Service, jennifer.tourville@tennessee.edu

Julia van Zyl MD

University of Tennessee Medical Center, JVanzyI@utmck.edu

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The Need for Point-of-Care Testing of All Illicit Substances

KEY POINTS

- An estimated [107,477 overdose deaths](#) occurred in the United States within the last year, with about 4,000 of those deaths being Tennesseans. Over 80 percent of these deaths are attributable to opioids such as fentanyl, for which there does not exist tests approved by the Food and Drug Administration (FDA) for point-of-care testing (POCT). POCT is intended to be used near or at the site of the patient and is performed outside of a physical clinical laboratory, usually at the bedside. A classic example of this is a bedside glucose test in the hospital.
- Tests for fentanyl and other illicit substances already exist but are limited to forensic use only. Without a point-of-care approved test, providers cannot legally use them to diagnose patients with a possible overdose and must rely on inference and guesswork.
- A Clinical Laboratory Improvement Amendments (CLIA) waiver would allow these tests to be used in healthcare settings. Meeting the requirements for a CLIA waiver would be fairly easy, given the opioid crisis has already been declared a national public health emergency.
- With polysubstance overdose as the new norm, the problem extends beyond fentanyl to other substances that also lack a point-of-care test, such as xylazine. A blanket CLIA waiver for all illicit substances that have a forensic use equivalent would significantly increase the diagnostic capacity of acute care providers treating individuals suffering from possible drug overdoses.

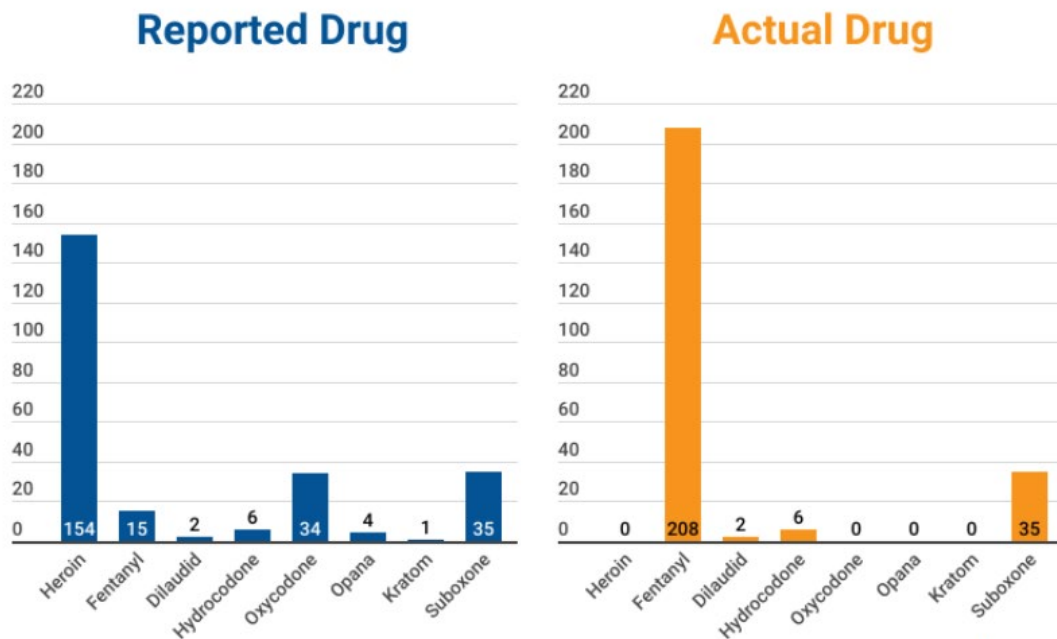
FENTANYL AND ITS CONTRIBUTION TO OVERDOSES

From August 2021 to 2022, an estimated [107,477 overdose deaths](#) occurred in the United States, with around 4,000 of those deaths being Tennesseans. In 2021, [81.9 percent](#) of overdose deaths involved at least one opioid, with the most commonly involved opioid being illicitly manufactured fentanyl.

[Fentanyl](#) is a synthetic opioid originally used in hospital settings to treat severe pain and terminal illnesses. Fentanyl is 50 to 100 times more potent than morphine but about [20 times cheaper than heroin](#) and has since become the major driver of [fatal and nonfatal overdoses](#). When speaking of fentanyl, the conversation also includes its numerous analogs,

some of which are more powerful than the traditional pharmaceutical fentanyl. The fentanyl commonly found today are not originating from pharmaceutical diversions, they are being manufactured illicitly. In the U.S., over 20 analogs have been found, with some far more toxic than others. For example, [carfentanil](#) is a fentanyl variant that is 100 times more potent than pharmaceutical-grade fentanyl and 10,000 times more potent than morphine. Carfentanil is lethal at 2 milligrams.

Even more concerning is the contamination of other illicit substances with fentanyl. Drugs like heroin and meth are increasingly becoming laced with fentanyl. [illegal pill presses](#) are used to manufacture fentanyl-laced pills resembling drugs like oxycodone or other prescription drugs, such as [counterfeit Xanax and Adderall](#). People might buy and consume prescriptions on the street which are contaminated with fentanyl, causing them to unintentionally overdose. Unintentional fentanyl consumption has already become the status quo. Data provided by the University of Tennessee Medical Center (UTMC) shows patients' reported drug of choice compared to what drug was found in their system. In these data, 154 people reported consuming heroin among reports of other substances. Ultimately, not one individual had heroin in their system in this case. The overwhelming majority of individuals had unknowingly consumed fentanyl.



Unintentional fentanyl consumption is now the status quo. In these data, 154 people reported consuming heroin, among reports of other substances. In reality, the overwhelming majority of individuals had unknowingly consumed fentanyl.



Source: Data provided by the University of Tennessee Medical Center

Synthetic opioids are continuously being created and distributed in unregulated, illicit contexts, much faster than tests to detect them are being approved for [point-of-care testing](#) (POCT). When it comes to POCT urine drug screens, these tests usually only include the federal five: (1) marijuana, (2) cocaine, (3) opiates—including opium and codeine derivatives, (3) amphetamines and methamphetamines, and (4) phencyclidine (PCP). Opiates are [naturally occurring opioids](#) such as morphine and codeine; panel urine tests do not include synthetic opioids like fentanyl. Due to its difficulty to obtain, pharmaceutical fentanyl was not considered an illicitly-used drug until recently, after illicit variants became so widespread. Now, with nearly [50 percent of all drug overdoses](#) involving multiple substances and deaths from [illicitly manufactured fentanyl](#) increasing, POCT for fentanyl is being re-evaluated. In the last five years, there have been [repeated calls](#) from [multiple stakeholders](#) for the FDA to approve point-of-care fentanyl screening tests, but as of 2023, this has still not been granted.

THE TECHNOLOGY FOR FENTANYL TESTING ALREADY EXISTS, BUT THERE ARE IMPORTANT LIMITATIONS

Some facilities are already able to test for fentanyl. The FDA has approved a number of fentanyl [reagents](#) for chemical analyzers used in laboratory testing. While it is true that these fentanyl reagents cost [less than a dollar per test](#), these machines are expensive, and even if a hospital has one, upgrading the machine to test for fentanyl comes with a steep up-front cost that many small, rural hospitals would not be able to easily afford. Additionally, these machines require trained staff and regular maintenance, which are also expensive. These are exactly the arguments the [California Hospital Association](#) (CHA) made in response to the passage of [Tyler's Law](#) in the summer of 2022.

Tyler's Law requires all acute care hospitals to test for fentanyl every time a urine drug screen is ordered. Because POCT fentanyl screening is not approved by the FDA for clinical use, this essentially mandated that all California hospitals and clinics that test for illicit drugs buy and maintain a chemical analyzer capable of screening for fentanyl, and no state funds were set aside to compensate the facilities. The CHA endorsed the concept of mandating fentanyl screening, but could not support the law unless it was amended to compensate for these funds. If those funds were not to be set aside, they recommended the state use its share of the opioid abatements to pay for these machines and upgrades. This means that in California, money that might get spent on prevention or treatment might instead get spent on helping hospitals comply with this equipment requirement.

Testing for fentanyl with chemical analyzers has another crucial limitation: instrument drug testing takes a lot of time to process the results. Even if fentanyl testing is ordered for [stat laboratory](#), the [turnaround time](#) can be up to one hour, whereas bedside urine testing has a turnaround time of [15 minutes or less](#).

POCT for fentanyl would save both time and money. For example, this [14-panel urine test](#) tests for most common illicit substances, including fentanyl, but as of now it can only be used by law enforcement, but not by providers in a clinical setting.

This technology is identical to at-home [fentanyl test strips](#) (FTS). Created for forensic use and employment drug screenings, FTS were decriminalized and made available for at-home use in [May 2022](#) with the goal to bolster harm reduction efforts. The thought was simple: if people who use drugs can test those substances with FTS, they might not use drugs that are found to be positive for fentanyl, avoiding a potential overdose. Though designed as a urine panel, FTS can still work on a substance dissolved in water. In an acute care setting, where a patient, who has already overdosed, the FTS would be used in their original urine panel context to identify the substances involved. No new technology or instruments are required.

CLIA WAIVER

There is already a legal mechanism available that would permit acute care providers to order and use urine fentanyl tests that already exist for forensic and employment use purposes: the Clinical Laboratory Improvement Amendments (CLIA) waiver. [CLIA-waived tests](#) are defined as “simple laboratory examinations and procedures that have an insignificant risk of an erroneous result.” Given that rapid fentanyl urine tests are deemed accurate enough for law enforcement, the same test should satisfy the accuracy requirement needed for a CLIA waiver.

The [Centers for Medicare and Medicaid](#) (CMS) is the only entity capable of issuing a CLIA waiver, and certain criteria must be met. The most important is the declaration of a public health emergency, which has been in effect for the opioid crisis since October 26, 2017. The CLIA waiver is intended to ensure the following:

1. Sufficient [healthcare items and services](#) are available to meet the needs of individuals enrolled in Social Security Act programs in the emergency area and time periods.
2. Providers who [give such services in good faith](#) can be reimbursed and exempted from sanctions (absent any determination of fraud or abuse).

Testing for fentanyl in emergency departments and acute care facilities certainly addresses these purposes. Allowing fentanyl testing to be CLIA waived could significantly increase the diagnostic capacity of acute care providers.

“BLANKET” WAIVERS

While a CLIA waiver for fentanyl POCT would have the most important impact on provider diagnostic ability, there are still some issues that remain. Many of the fentanyl-inclusive tests that are already available on the market also test for other substances. For example, this [14-panel T-Cup urine test](#) contains testing for numerous drugs in addition to fentanyl. However, two additional substances this test screens for—[kratom](#) and [ethyl glucuronide](#), a

metabolite of alcohol—also lack CLIA-waived POCT. This means that even with a CLIA waiver for fentanyl, this product still could not be legally used in clinical settings.

In the past, CMS has granted blanket waivers to cover public health emergencies that extend beyond a contained geographic area. The overdose crisis meets these criteria. A blanket CLIA waiver for all illicit substances that have a forensic use equivalent would allow providers to accurately treat overdoses and keep up with emerging trends in substance use. For example, the FDA recently released an [alert to providers](#) on the drug [xylazine](#), a veterinary sedative. Importantly, [98.4 percent of the deaths](#) involving xylazine also involved fentanyl . However, the medication to treat opioid overdoses, naloxone, [does not work for xylazine](#). Taken together, these two facts indicate the need to test for as many prominent illicit substances as possible. As with fentanyl, [bedside xylazine testing exists](#) but is not yet approved for clinical use. It is anticipated that a [forensic use test for xylazine](#) is imminent. Having a blanket CLIA waiver in place would make such a test immediately available to providers, helping them stay proactive in diagnosing and treating individuals suffering from possible drug overdoses.

POLICY BRIEF AUTHORS:

Channie Cretsinger, Graduate Intern, UT Institute for Public Service, SMART Initiative
Jeremy Kourvelas, MPH, Program Coordinator, UT Institute for Public Service, SMART Initiative
Jennifer Tourville, DNP, Executive Director, UT Institute for Public Service, SMART Initiative
Julia van Zyl, MD. Hospitalist at University of Tennessee Medical Center