Feds focus on naloxone and fentanyl test strips, blame COVID-19 for OD increases

Last week, the federal Centers for Disease Control and Prevention (CDC) announced that the predicted overdose death count for the 12-month period ending April 2021 is more than 100,000. That’s one death every five minutes, said Rahul Gupta, M.D., director of the Office of National Drug Control Policy (ONDCP), at a Nov. 17 press briefing with the heads of the CDC, the National Institute on Drug Abuse (NIDA), the Drug Enforcement Administration (DEA), the Department of Health and Human Services (HHS) and the Substance Abuse and Mental Health Services Administration (SAMHSA).

Gupta said people with substance use disorders (SUDs) need access to harm reduction, evidence-based treatment and recovery support services, as well as primary prevention and supply reduction. He stressed that none of this could be done without the support of Congress, which is

Researchers hope psilocybin could improve quit rates for smokers

With nicotine being one of the most addictive substances and the available treatments for nicotine addiction leading to no better than a 30% success rate, it’s no wonder that a newly announced multisite study of the psychedelic psilocybin for smoking cessation is generating excitement. While taking care not to oversell the potential of this strategy, those involved with the research hope at least that a large study with a diverse population will help identify who might eventually benefit most from the alternative approach.

“"If we could double abstinence rates, it would ultimately translate to millions of lives saved and substantial cost savings," Peter Hendricks, Ph.D., one of the study’s principal investigators based at the University of Alabama at Birmingham School of Public Health, told ADAW.

Taking that kind of long-term view of the cost-benefit equation will be important if psilocybin ever receives federal approval as a treatment for smoking cessation, as the upfront costs associated with administering psychedelics in controlled settings supervised by health professionals have already raised concerns about who would agree to pay for these treatments (see “Psilocybin: Next to treat depression, OCD and nicotine addiction,” ADAW, Sept. 27; https://onlinelibrary.wiley.com/doi/10.1002/adaw.33204).

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The 100,000 overdose deaths in the year ending in April, announced last week by the CDC, call for more naloxone and fentanyl test strips, according to federal officials.

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“why we need Congress to fully fund President Biden’s budget request.”

All of the speakers called for funding for naloxone and for fentanyl test strips as the main elements of harm reduction. Asked about injection sites, Gupta demurred, saying he would not respond because the issue is in litigation.

But he did say that as a practicing clinician, he believes an overdose is a “cry for help, and for far too many people that cry goes unanswered.”

HHS Secretary Xavier Becerra said treatment and recovery support is essential, because once someone is rescued from an overdose with naloxone, that’s not the end of the story. “We’re not going to let you go; we’re going to help you,” he said. We asked both the ONDCP and HHS to clarify exactly how this would work: getting someone from a naloxone rescue to treatment to recovery supports. Christopher Garrett, spokesman for SAMHSA, did clarify, especially in light of the fact that many people who are rescued from overdoses with naloxone need repeated rescues.

“It is important to realize that a single dose of naloxone may be effective in reversing an overdose, there still are medical risks as the naloxone wears off,” said Garrett. “If it is important that whenever possible, the patient is evaluated in the emergency room as respiratory depression may reoccur. After such interventions the initiation or continuation of treatment in the community may commence.”

But what about people who just go back to dangerous drug use after being rescued? “The scenario you describe highlights the important role of peer supports, people who can be a presence for someone in a hospital emergency department who has overdosed and could benefit from hearing from a person in recovery who has been in that situation and who can share the benefits of pursuing treatment,” said Garrett “SAMHSA certainly supports that peer role. However, the scenario of a recurring issue also speaks to the need for people to be able to access a workforce that can screen, intervene and make appropriate referrals to treatment and future prevention and harm reduction. That broader context speaks to the importance of the nation having a strong prevention, medical and behavioral health workforce in place to provide appropriate options for prevention/harm reduction, treatment and recovery support services to people who are grappling with opioid use disorders. It also speaks to the importance of interventions, inclusive of peer supports, that meet people where they are. All of these approaches, with the goal of enhancing motivation and engagement in services that will save and improve lives, are crucial.”

The harm-reduction aspects, which Becerra said at the press briefing are “novel for the federal government,” are limited to fentanyl strips and naloxone.

Evidence-based treatment includes prescribing medication for SUDs, said Becerra.

40% reduction from HEAL?
The crisis is getting worse, the officials admitted. Asked about this, especially in view of the $350 million HEAL initiative by the National Institutes of Health three years ago, which was meant to decrease overdose deaths by 40%, NIDA Director Nora Volkow, M.D., blamed the problem on COVID-19, which nobody predicted when the HEAL grants were put through
Congress. COVID-19 has caused an increase in overdose deaths because the pandemic resulted in stress that people tried to relieve by using drugs, and also caused a collapse in community supports, she said.

However, one year ago, Volkow said that the 40% reduction was still planned, despite COVID (see ‘HEALing Communities: In spite of COVID-19, 40% OD death drop still planned,’ ADAW Oct. 26, 2020; https://onlinelibrary.wiley.com/doi/10.1002/adaw.32870). NIDA responded to our question about this discrepancy by noting that the HEAL study isn’t over yet and that when it is, the reduction may have occurred.

“The epidemic is morphing and that SAMHSA policies are woefully lacking,” H. Westley Clark, M.D., J.D., dean’s executive professor at Santa Clara University, told ADAW last week. “They are repeating the problems of the early 2000s when the focus was on heroin despite the data showing that prescription opioids was a rising issue,” said Clark, former director of SAMHSA’s Center for Substance Abuse Treatment. “Methamphetamine overdose deaths and methamphetamine use are clearly altering the face of the

Drug dealers ‘a click away’

DEA Administrator Anne Milgram said illicit fentanyl, sometimes in counterfeit pills, is responsible for most of the overdoses. And it's not necessary to go to “open-air” drug markets anymore. “Drug dealers are now in our homes,” she said. “Wherever there's a smartphone or a computer, a drug dealer is one click away.”

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Trends in U.S. Drug Overdose Deaths (1999 - 2019)
The overdose crisis has evolved over time and is now largely characterized by deaths involving illicitly manufactured synthetic opioids, including fentanyl, and, increasingly, stimulants. Since 1999, the rate of overdose deaths has increased by over 250%.

This graph shows the total number of drug overdose deaths in the United States from 1999 to 2019. The data shows that overdose deaths involving synthetic opioids excluding methadone have increased 50-fold, up to over 35,000 in 2019. Overdose deaths involving psychostimulants (primarily methamphetamine) with abuse potential have increased 30-fold, up to over 15,000 in 2019. Overdose deaths involving cocaine have increased 4-fold, up to over 15,000 in 2019. And overdose deaths involving prescription opioids have increased 4-fold, but are on the decline with less than 15,000 in 2019.

Source: National Vital Statistics System Mortality File
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epidemic,” he said. “SAMHSA keeps promising a change in the SOR policy, but nothing has changed other than more people are dying from methamphetamine and cocaine.”

NIDA’s Volkow is clearly aware of the enforcement challenges, noting that both fentanyl and methamphetamine are synthetic and “much more profitable for the illicit drug market than drugs that require cultivation like heroin and cocaine.” But she is also clearly appalled by the numbers. “We have the tools, we have the knowledge of how to address this,” she said. “We understand that naloxone works.” But it’s too late for those 100,000 victims. “Whether it’s fentanyl or methamphetamine, these are among the most lethal drugs.”

CDC role

Many years ago the CDC said that prescription opioids were causing the overdose problem, and that by decreasing prescribed opioids the overdoses would go down (see “Experts on heroin overdoses: Decrease initiation, increase treatment,” AD4W May 4, 2015; https://onlinelibrary.wiley.com/doi/10.1002/adaw.30174). Prescriptions of opioids decreased, but overdoses went up. We asked the CDC to explain, and once again (see “CDC begins to backtrack on its pain guideline, saying it was ‘misapplied’,” AD4W May 6, 2019; https://onlinelibrary.wiley.com/doi/10.1002/adaw.32349) the CDC seems to acknowledge that the decrease in opioid prescriptions is responsible for the increase in illicit fentanyl overdose deaths. “The prescription opioid-involved deaths have indeed decreased since 2013, but synthetic opioids (largely illicitly manufactured fentanyl) appear to be the main driver of drug overdose death,” a CDC spokeswoman told AD4W last week, noting that “72.9% of opioid-involved overdose deaths involve synthetic opioids.” She added that the overall increase caused by illicit fentanyl “may be partly owing to an overall decline in the amount of opioids prescribed.” She did not, however, go so far as to say that the CDC’s own recommendations to cut back on prescriptions were responsible for the decline in prescriptions.

Federal funding for fentanyl test strips

The Centers for Disease Control and Prevention (CDC) and the Substance Abuse and Mental Health Services Administration (SAMHSA) announced in April that federal funding may now be used to purchase rapid fentanyl test strips (FTSs), which can be used to determine if drugs have been mixed or cut with fentanyl, providing people who use drugs and communities with important information about fentanyl in the illicit drug supply so they can take steps to reduce their risk of overdose.

“This is a major step forward in the ongoing and critical work to prevent overdose and connect people who have substance use disorders to evidence-based treatment options,” said then Acting Deputy Assistant Secretary for Mental Health and Substance Use Tom Coderre, the interim leader at SAMHSA. “This will save lives by providing tools to identify the growing presence of fentanyl in the nation’s illicit drug supply and — partnered with referrals to treatment — complement SAMHSA’s daily work to direct help to more Americans.”

“We must do all we can to save lives from drug overdoses,” said CDC Director Rochelle P. Walensky, M.D., M.P.H. “The increase in drug overdose deaths related to synthetic opioids such as illicitly made fentanyl is a public health crisis that requires immediate action and novel strategies. State and local programs now have another tool to add to their on-the-ground efforts toward reducing and preventing overdoses — in particular, fentanyl-related overdose deaths.”

This change applies to all federal grant programs as long as the purchase of FTSs is consistent with the purpose of the program.

SAMHSA’s State Opioid Response (SOR) grant aims to address the opioid crisis by increasing access to medication-assisted treatment, reducing unmet treatment need and reducing opioid overdose—related deaths through supporting prevention, treatment and recovery activities for opioid use disorder. SOR supplements current state and territory opioid-related activities and supports a comprehensive response to the opioid epidemic.
effective, evidence-based treatments to patients with OUD in primary care, psychiatric care, substance use disorder treatment, and pain management settings,” said Garrett. “The PCSS-Universities grant will expand or enhance access to medication therapies for substance use disorders and other treatment modalities at the community level by investing in the nation’s medical workforce educational system,” he said. “This grant program funds education and training in the multiple therapeutic options available for substance use disorders for students pursuing careers in the medical, physician assistant, and nurse practitioner fields.”

In addition to providing education and funding to promote a robust workforce, SAMHSA supports also Historically Black Colleges and Universities Center of Excellence in Behavioral Health, said Garrett. “The program recruits diverse students to careers in the behavioral health field to address substance use and mental health disorders.”

Contingency management

“Considering the increasing rate of individuals dying from stimulant-related ODs (with or without fentanyl) and the absence of an FDA approved medication what is being done to promote CM as a mainstream intervention for reducing OD deaths among people with stimulant use disorder?” asked Richard Rawson, Ph.D., referring specifically to SAMHSA’s limit of $75 annual for incentives for CM. He added that stimulant use disorders are over-represented among Black and AI/AN groups.

“SAMHSA is engaging with other federal partners to determine what this limit might be in order to provide effective, evidence-based interventions for stimulant use disorders and polysubstance misuse,” said SAMHSA’s Garrett. “Further to this, the Department of Health and Human Services has convened a workgroup to bring together stakeholders to review current barriers to the implementation of evidence-based contingency management programs, to create ways to overcome these, and to then promote evidence-based contingency management practices.”

“Fentanyl is a remarkably deadly drug,” said Rawson. “It needs to be in the center of the current OD death discussion.” He added, however, that many of the fentanyl OD deaths resulted from people purchasing cocaine or methamphetamine and dying from fentanyl that has been mixed into the cocaine/meth supply. “To bring these individuals into treatment and reduce their overdose risk, there needs to be effective treatment for stimulant use disorder.”

He noted that there is an increase in methamphetamine-related OD deaths with and without fentanyl as a result of the much more potent and lethal methamphetamine.

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**Telehealth faulted for missing signs of drug misuse/SUDs**

Signs of drug misuse and substance use disorders (SUDs) are missed due to telehealth, according to many physicians surveyed about telehealth during COVID-19 by Quest Diagnostics, a company that conducts drug testing and provides other laboratory services to clinicians. There are potentially far-reaching consequences for patients at risk, according to the survey report, released last week.

Almost two-thirds of physicians are worried that they have missed signs of drug misuse or SUDs in one or more of their patients during the pandemic, according to the report, *Health Trends: Drug Misuse in America, 2021*.

Most adults (60%) delayed or skipped in-person physician appointments during the pandemic. The pandemic saw steep declines in clinical drug testing (as well as testing for cancer, hepatitis and diabetes).

There are concerns that patients at high risk for drug misuse or SUDs are likely to stop seeing their doctor not only during the pandemic, but permanently. Most physicians (88%) believe clinical drug testing is critical to preventing misuse, but Quest saw a 70% decline in such tests between March 2020 and May 2020. This lack of testing, according to 80% of physicians, puts more people at risk for undetected drug misuse or SUDs.

**Telehealth flaws**

And telehealth visits are a poor replacement for in-person visits and, if necessary, drug testing, the report found. Physicians can’t determine if patients are at risk for prescription drug misuse, or already misusing them, with only telehealth visits. Most physicians (91%) are confident they can recognize the signs of prescription drug misuse based on

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