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Alcohol, Other Drugs, and Health: Current Evidence

NOVEMBER - DECEMBER 2019

PRESCRIPTION DRUGS & PAIN

Discontinuation of Opioids for Chronic Pain in Primary Care Associated With Subsequent Overdose Mortality

Opioid registries and other monitoring strategies seek to reduce opioid-related harms among patients who receive long-term opioid therapy (LTOT) for pain. Enhanced monitoring may result in LTOT discontinuation based on safety concerns, but what happens to patients after LTOT discontinuation is unknown. This retrospective cohort study examined the opioid registry of an urban primary care clinic, including 572 patients who received LTOT between 2010 and 2015. Mortality, prescription opioid use, and primary care visits were compared between patients who discontinued LTOT versus those who maintained it.

- Three-quarters of patients had mental health conditions, one-third had substance use disorders, and chronic medical conditions were common.
- Sixty percent of patients had LTOT discontinued over the study period.
- LTOT discontinuation was mostly initiated by providers (80%), not patients.
- Overall mortality in the cohort was 20% (4.7 per 100 person-years) with 4% dying of a definite or possible overdose.
- LTOT discontinuation was significantly associated with overdose death (hazard ratio, 2.9).
- Of patients who had LTOT discontinued, three-quarters subsequently received opioids from other prescribers and only half maintained primary care at the clinic.

Comments: In this cohort, overdose risk remained high after LTOT discontinuation. The study's methodology cannot establish a causal relationship between LTOT discontinuation and future overdose death, but there is good reason for concern. The best strategy for responding to "red flag" behaviors uncovered by monitoring is still unclear; however, clinicians need tools, including options for opioid use disorder treatment and comprehensive pain management, to enhance patient safety.

Aaron D. Fox, MD

Reference: James JR, Scott JM, Klein JW, et al. Mortality after discontinuation of primary care-based chronic opioid therapy for pain: a retrospective cohort study. *J Gen Intern Med.* 2019;34(12):2749–2755.

Updated HHS Guidelines: Avoid Rapid Tapering or Sudden Discontinuation of Prescription Opioids

A substantial number of Americans are receiving opioid medications for chronic pain. In 2016, increasing concerns about the risks of these medications led the Centers for Disease Control to develop guidelines that included a recommendation to avoid prescribing dosages above 90 morphine milligram equivalents (MME) per day. Some interpreted this

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Updated HHS Guidelines: Avoid Rapid Tapering or Sudden Discontinuation of Prescription Opioids (continued from page 1)

recommendation to mean that individuals who were already prescribed higher dosages should have the dosage reduced, leading to forced precipitous tapers and reports of harm associated with this practice. In response to this, the US Department of Health and Human Services has issued a guide on “appropriate dosage reduction or discontinuation of long-term opioid analgesics” that includes the following recommendations:

- “Avoid insisting on opioid tapering or discontinuation when opioid use may be warranted.”
- “Avoid misinterpreting cautionary dosage thresholds as mandates for dose reduction.”
- “If a patient exhibits misuse behavior or other signs of opioid use disorder” and “criteria for opioid use disorder are met (especially if moderate-severe), offer or arrange for medication-assisted [sic]* treatment.”
- “If patients on high opioid dosages are unable to taper despite worsening pain and/or function with opioids, whether or not opioid use disorder criteria are met, consider transitioning to buprenorphine.”

* AOD Health (and the National Institute on Drug Abuse) recommend use of accurate, non-stigmatizing terminology, such as “medication for opioid use disorder,” “medication for addiction treatment (MAT),” or simply “medication,” in lieu of “medication-assisted treatment.”

Comments: This guide is a much-needed clarification that emphasizes a patient-centered approach to helping individuals who have been prescribed opioids for chronic pain. It also advocates for expanded use of buprenorphine to include individuals at high risk who do not necessarily meet criteria for opioid use disorder. Although prescribing opioids—particularly at high doses—should be avoided, we should not punish patients who are in this situation.

Darius A. Rastegar, MD

Reference: The U.S. Department of Health and Human Services Working Group on Patient-Centered Reduction or Discontinuation of Long-term Opioid Analgesics. *HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*. U.S. Department of Health and Human Services. October, 2019. <https://www.hhs.gov/opioids/treatment/clinicians-guide-opioid-dosage-reduction/index.html>.

Trends and Rapidity of Dose Tapering Among Patients Prescribed Long-term Opioid Therapy, 2008–2017

Long-term opioid therapy (LTOT) for chronic pain is associated with a dose-dependent increased risk of opioid-related harms. Numerous policy and practice initiatives have promoted LTOT tapering despite a lack of evidence to guide tapering practices. Recently, emerging reports of harms associated with involuntary and/or rapid LTOT tapers led authors of the 2016 Centers for Disease Control and Prevention guideline for prescribing opioids for chronic pain, the Food and Drug Administration (FDA), and the US Department of Health and Human Services to publish cautionary guidance on LTOT tapering practices. While the population-level prescription opioid supply has fallen in the US in recent years, LTOT tapering trends are unknown. This study examined trends in the rate and rapidity of tapering among more than 100,000 individuals receiving stable LTOT in a large US claims database from 2008 through 2017.

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Trends and Rapidity of Dose Tapering Among Patients Prescribed Long-term Opioid Therapy, 2008–2017

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- The percentage of LTOT recipients experiencing tapers increased gradually from 11% in 2008 to 14% in 2015, and then more sharply to 16% in 2016 and 22% in 2017.
- 19% of LTOT tapers were classified as rapid with a rate exceeding 40% dosage reduction per month (10% per week).
- Rapid LTOT tapering was more common in 2016–2017 compared with earlier years.

Comments: The rate and rapidity of LTOT tapering increased substantially in 2016 and 2017, corresponding

with contemporaneous initiatives targeting LTOT, including the publishing of the CDC guideline. Nearly 1 in 5 tapers proceeded at a rate exceeding expert opinion maximum rates of 10% per week. In the absence of evidence-based LTOT tapering protocols, policies and practices should be instituted to support and incentivize providers to avoid involuntary, rapid LTOT tapers.

Marc R. Larochelle, MD, MPH

Reference: Fenton JJ, Agnoli AL, Xing G, et al. Trends and rapidity of dose tapering among patients prescribed long-term opioid therapy, 2008–2017. *JAMA Netw Open.* 2019;2(11):e1916271.

Withdrawal Symptoms Associated With Opioid Use Disorder Among Patients Prescribed Opioids for Chronic Pain

Individuals who are prescribed opioids are expected to develop tolerance and experience withdrawal symptoms if they stop taking them. For this reason, the *DSM-5* states that tolerance and withdrawal should not be counted as criteria when considering whether patients who are prescribed opioids have an opioid use disorder (OUD). This study looked at 207 individuals with chronic pain who were prescribed opioids to determine whether withdrawal symptoms (as measured by the Adjective Rating Scale for Withdrawal) were associated with OUD.

- Of the 207 patients, 55 (27%) had symptoms of moderate OUD and 35 (17%) had severe symptoms in *DSM-5* assessments that excluded tolerance and withdrawal criteria.
- Of those who reported mild withdrawal symptoms, 11% had moderate-to-severe OUD, compared with 27% who had moderate withdrawal and 62% who

had severe withdrawal. Those who reported more severe withdrawal tended to be receiving higher doses of opioids, but the difference was not significant.

- On multivariable analysis, severe withdrawal symptoms were associated with a diagnosis of OUD (adjusted odds ratio, 7.1); the only other factors that were significant were lower age and receiving anxiolytics. Opioid dose was not included in this model.

Comments: This study suggests that patients who are prescribed opioids for chronic pain and who report moderate-to-severe withdrawal symptoms should be assessed for OUD, and that these symptoms should not be dismissed as an expected consequence of receiving opioid medication.

Darius A. Rastegar, MD

Reference: Coloma-Carmona A, Carballo JL, Rodríguez-Marín J, Pérez-Carbonell A. Withdrawal symptoms predict prescription opioid dependence in chronic pain patients. *Drug Alcohol Depend.* 2019;195:27-32.

INTERVENTIONS & ASSESSMENTS

Cannabinoid Agonist Oral Spray Nabiximols Modestly Reduces Cannabis Use

Cannabis use and use disorder are common and increasing. There is no effective pharmacologic treatment for cannabis use disorder and a previous trial of dronabinol, an oral synthetic tetrahydrocannabinol (THC) product, failed to show a significant impact on cannabis use. Nabiximols is a combination of THC and cannabidiol (CBD) delivered as an oral spray. In this 12-week study conducted in Australia, 128 volunteers with ICD-10 cannabis dependence were randomized to receive either placebo spray or nabiximols; dosing was flexible—up to 32 sprays/day, which in the nabiximols group would deliver 86 mg of THC.

- Treatment retention was similar in both arms: 49% of those assigned to nabiximols and 47% assigned to placebo.
- The nabiximols group reported fewer days of cannabis use over the 84-day trial: a mean of 35 days versus 53 days in the placebo group.
- Measures of cannabis-related problems, withdrawal, and craving improved in both groups, without significant differences between the two. Nabiximols had few side effects and 75% of those who received placebo and 82% of those who received nabiximols said they would recommend the medication to a friend seeking treatment.

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Cannabinoid Agonist Oral Spray Nabiximols Modestly Reduces Cannabis Use (continued from page 3)

Comments: This study shows that this THC/CBD spray leads to a modest reduction in self-reported days of cannabis use among treatment-seeking individuals with ICD-10 cannabis dependence. The possible reasons why this medication was modestly effective while dronabinol was not include the delivery system, flexible dosing, and the combination of

CBD with THC. It remains to be seen whether this treatment improves clinical or functional outcomes.

Darius A. Rastegar, MD

Reference: Lintzeris N, Bhardwaj A, Mills L, et al. Nabiximols for the treatment of cannabis dependence: a randomized clinical trial. *JAMA Intern Med.* 2019 [Epub ahead of print]. doi: 10.1001/jamainternmed.2019.1993.

HEALTH OUTCOMES

Prenatal Cannabis Use is Associated with Pre-Term Birth and Other Adverse Outcomes

Cannabis use among women of childbearing age is common, and many continue use while pregnant. With recent legalization in Canada and parts of the US, cannabis use during pregnancy will likely become more common. Researchers investigated whether self-reported prenatal cannabis use was associated with pre-term birth (<37 weeks) and 10 other maternal, perinatal, and neonatal outcomes among pregnant women in the BORN Ontario database between 2012 and 2017. To address confounding in this retrospective cohort study, they matched pregnant women who used cannabis with pregnant women who did not. Participants and controls were matched on age, parity, income, smoking status, alcohol use, opioid use, selective serotonin reuptake inhibitor use, other drug use, maternal mental health conditions, antenatal care, and year of birth.

- Overall, 661,617 of 759,281 (87%) pregnant women had sufficient data to be included. The mean age was 30 years, and 9427 (1.4%) reported cannabis use.
- In the matched cohort, self-reported cannabis use was associated with increased risk of preterm birth at <37

weeks (relative risk (RR), 1.41), small for gestational age (RR, 1.53), placental abruption (RR, 1.72), stillbirth (RR, 1.25), transfer to the neonatal intensive care unit (RR, 1.40), and Apgar score <4 (RR, 1.28).

- Cannabis use was associated with a reduced risk of pre-eclampsia (RR, 0.90) and gestational diabetes (RR, 0.91).

Comments: Despite the matched analysis, residual confounding may have biased these results. Furthermore, the study does not explore the importance of the timing or amount of prenatal cannabis use. Regardless, women should be advised that cannabis use during pregnancy may be associated with adverse peri- and neonatal outcomes.

Miriam Harris, MD† and Alexander Y. Walley, MD, MSc

† Contributing editorial intern and Addiction Medicine Fellow, Boston Medical Center/Boston University School of Medicine

Reference: Corsi DJ, Walsh L, Weiss D, et al. Association between self-reported prenatal cannabis use and maternal, perinatal, and neonatal outcomes. *JAMA.* 2019;322(2):145–152.

Synthetic Cannabinoids Associated With Specific Severe Neuropsychiatric Outcomes in Adolescents

Toxicity from synthetic cannabinoid use can lead to severe illness requiring intensive care. This report analyzed multi-center toxicology data on adolescents aged 13–19 (N=348) who presented to an emergency department between January 2010 and October 2018 for treatment of symptoms related to either cannabis or synthetic cannabinoid use.

- Teens who had used only synthetic cannabinoids had greater odds of coma and/or central nervous system depression (odds ratio [OR], 3.42) and seizures (OR,

3.89), compared with those who had used only cannabis.

- Teens who had used only synthetic cannabinoids had significantly lower odds of agitation compared with those who had used only cannabis (OR, 0.18).
- Polydrug exposure was more common and involved more substances among individuals who used cannabis compared with those who used synthetic cannabinoids.

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Synthetic Cannabinoids Associated With Specific Severe Neuropsychiatric Outcomes in Adolescents (continued from page 4)

Comments: While both synthetic cannabinoids and cannabis bind to cannabinoid receptors 1 and 2, their physiological effects differ. These findings are an important reminder that different compounds in a psychoactive class can lead to vastly differing physiological effects and toxicities. This general principle underscores the need

for a regulatory framework for addictive substances to protect public health.

Sharon Levy, MD, MPH

Reference: Anderson SAR, Oprescu AM, Calello DP, et al. Neuro-psychiatric sequelae in adolescents with acute synthetic cannabinoid toxicity. *Pediatrics*. 2019;144(2).

Are Drinking Goals Associated with Outcomes Among People with Alcohol Use Disorder?

This study aimed to assess treatment outcomes among patients with alcohol use disorder who reported drinking goals at the beginning of treatment, categorized as: abstinence, “low-risk” drinking,* or no decided goal. Data came from a longitudinal study in which patients were recruited 2004-2012 from 3 treatment settings: a 12-step-oriented outpatient treatment center, a 12-step-oriented inpatient center, and a community outpatient center offering psychosocial treatment. Patients (N=349) were followed up 2.5 and 5 years after entering treatment. Overall, 25% were women, the mean age was 48 years, and 93% met criteria for *DSM-IV* alcohol dependence.

- Most patients reported abstinence as their drinking goal (64%); 19% reported a goal of low-risk drinking and 17% were undecided.
- The group with abstinence as a goal and those undecided had more years with unhealthy alcohol use compared with those aiming for low-risk drinking (13 years, 12 years, and 7 years, respectively). At treatment entry, those with abstinence as a goal drank more than those undecided or aiming for low-risk drinking (880g/week, 480g/week, and 427g/week, respectively).
- There was a significant reduction in drinking over time for all groups and at 5 years 65% of partici-

pants achieved either abstinence or low-risk drinking.

- There were no significant differences between the 3 groups in alcohol consumption at follow-up, but there was a significant interaction effect between group and time, indicating that those with abstinence as a goal had a sharper decrease in alcohol use than the two other groups.

* Defined as average weekly consumption of <110 g alcohol for women and <170 g alcohol for men.

Comments: In this observational study, it is difficult to ascertain whether these outcomes were due to abstinence as a treatment goal, or to characteristics associated with the treatment goals (e.g., severity of alcohol use disorder), or to treatment that matched the goal (i.e., 12-step, abstinence-oriented). It is a stretch from these data to conclude that abstinence is a better treatment goal overall, but it appears that the patients with more severe disorders tended to choose abstinence as a goal and possibly had better outcomes than those who did not. Regardless of their treatment goals, all patients improved; this should encourage clinicians to offer treatment to all patients, regardless of their drinking goals.

Nicolas Bertholet, MD, MSc

Reference: Berglund KJ, Rauwolf KK, Berggren U, et al. Outcome in relation to drinking goals in alcohol-dependent individuals: a follow-up study 2.5 and 5 years after treatment entry. *Alcohol Alcohol*. 2019; 54(4):439–445.

The Association of Alcohol Consumption with the Risk of Dementia

While previous research has related alcohol intake to the risk of dementia, this study importantly focuses on elderly people participating in a randomized trial of Ginkgo biloba that had a null result (N=3021, median age 78 years, 46% female), evaluating the association of alcohol consumption with mild cognitive impairment (MCI) and dementia. There were 512 new cases of dementia diagnosed over a 6-year follow up; diagnoses were validated by cognitive evaluations, MRI, and an expert panel of clinicians. At least some alcohol con-

sumption was self-reported at baseline by 58% of participants. Researchers adjusted results for potential confounders, including body weight, smoking, diabetes, cardiovascular and other diseases, depression, race, ethnicity, clinic site, educational level, social activity, medication use, and genotype for APOE e4, which is associated with Alzheimer’s disease.

- Among participants without MCI at baseline (n=2548), alcohol consumption was not significantly associated with lower risk of dementia (compared with <1 drink per

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The Association of Alcohol Consumption with the Risk of Dementia

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week); the hazard ratio (HR) for dementia with abstinence was consistent with a slightly higher but non-significant risk (HR 1.17 [95% Confidence Interval [CI], 0.84-1.62]).

- Participants with MCI at baseline (n=473) consuming >14 drinks/week had a non-significantly increased risk for dementia (HR, 1.72 [95% CI, 0.87-3.40]).
- Daily consumption of 1 drink was associated with a lower dementia risk than less-than-daily consumption of ≥2 drinks (HR, 0.45 [95% CI, 0.23-0.89]).

Comments: An important strength of this study was the extensive evaluation for cognitive impairment and dementia in these older adults. Overall, these data are not inconsistent with most previous studies that show a J-shaped association for the relation of alcohol consumption to the risk of dementia, with abstinence associated with higher risk, and regular but not excessive drinking associated with higher risk (though not statistically significant in this study; e.g., <https://www.bu.edu/aodhealth/2018/12/11/dementia-risk-with-low-amounts-of-alcohol/>).

R. Curtis Ellison, MD

Reference: Koch M, Fitzpatrick AL, Rapp SR, et al. Alcohol consumption and risk of dementia and cognitive decline among older adults with or without mild cognitive impairment. *JAMA Netw Open.* 2019;2(9):e1910319.

HIV & HCV

Cannabis Does Not Affect Nonmedical Opioid Use, Opioid Medication Dose, or Pain Outcomes Among People Living With HIV

Chronic pain is common among people living with HIV (PLWH). Both HIV and chronic pain are approved conditions for receipt of medical cannabis in many of the 29 states and District of Columbia that allow it. In a cohort of PLWH receiving opioid treatment of chronic pain, researchers investigated the prevalence of any cannabis use and assessed nonmedical opioid use using the Current Opioid Misuse Measure, and opioid dose using the morphine equivalent daily dose (MEDD). They also assessed HIV viral suppression and pain outcomes using the Brief Pain Inventory, which measures the severity of pain and its interference with daily functions on a scale of 0–10.

- Of 166 participants, 65% were male, 72% were black, and the median age was 55 years. The median MEDD was 15 mg; pain severity and interference was a mean of 6/10 (SD 2); and 89% of participants had an undetectable viral load at baseline.
- 85% of participants reported ever having used cannabis and 43% reported cannabis use in the past 12 months; 15% of the cohort reported daily use and 8% met criteria for a cannabis use disorder. Of the patients with cannabis use in the last 12 months, 66% used it for pain.
- There was no association between past-year cannabis use and current non-medical opioid use, MEDD, or pain severity and interference. In sensitivity analyses adjusting for depressive symptoms and substance use disorder (other than cannabis use disorder), past-year cannabis use was associated with 3-times increased odds of having a detectable viral load.

Comments: Among a cohort of PLWH prescribed opioid therapy, cannabis use was common and did not have an impact on nonmedical opioid use, opioid dose, or pain severity and interference, but it did have a negative impact on viral suppression. This study adds to the growing evidence that providers can draw from when

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Cannabis Does Not Affect Nonmedical Opioid Use, Opioid Medication Dose, or Pain Outcomes Among People Living With HIV (continued from page 6)

counseling patients about the potential benefits and harms of cannabis use. Given that it did not improve pain and was associated with worse HIV outcomes, these results suggest that states should consider evidence when making decisions about medical cannabis laws.

Jeanette M. Tetrault, MD

Reference: Merlin JS, Samet JH, Cheng DM, et al. Marijuana use and its associations with pain, opioid dose, and HIV viral suppression among persons living with HIV on chronic opioid therapy. *J Acquir Immune Defic Syndr*. 2019;82(2):195–201.

Substance Use Stigma Has a Negative Effect on Antiretroviral Adherence Among People Living With HIV

People living with HIV (PLWH) who use drugs face intersectional (e.g., multiple sources of) stigma that may negatively affect antiretroviral adherence. Researchers explored the impact of substance use (SU) stigma on antiretroviral adherence behaviors among 172 PLWH. Study participants completed surveys on SU, SU stigma, ART adherence, and HIV-related stigma. Multivariable logistic regression models were adjusted for sociodemographic characteristics, severity of alcohol and other drug use, HIV-related stigma, and social support.

- 66% of participants had moderate/high risk scores for cocaine, 65% for cannabis, and 66% for hazardous alcohol consumption.*
- 60% of patients reported less than optimal antiretroviral adherence.
- The adjusted odds ratios for optimal antiretroviral adherence among participants experiencing moderate levels of anticipated SU stigma (adjusted odds ratio [aOR], 0.36), and very high levels of anticipated SU stigma (aOR, 0.25) were significantly lower than among participants experi-

encing low levels of anticipated SU stigma (reference). No association was found for participants experiencing high anticipated SU stigma.

* Based on the Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) for drugs, and the Alcohol Use Disorders Identification Test-Consumption (AUDIT-C) for alcohol.

Comments: In this study of self-reported antiretroviral adherence among PLWH who also use drugs, substance use stigma was associated with less than optimal adherence, even when controlling for HIV-related stigma. The impact of intersectional stigma on health outcomes remains an open question, and could be addressed in research that includes robust measures of adherence among PLWH who also use drugs.

Jeanette M. Tetrault, MD

Reference: Stringer KL, Marotta P, Baker E, et al. Substance use stigma and antiretroviral adherence among a drug-using population living with HIV. *AIDS Patient Care STDS*. 2019;33(6):282–293.



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Where: Wylie Inn and Conference Center, Beverly, MA

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Sponsors: National Institute on Drug Abuse (NIDA) and Boston University School of Medicine.

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When: April 26-29, 2020

Where: Wylie Inn and Conference Center, Beverly, MA

Cost: There is no tuition for fellows. Accommodations and travel for fellows are funded.

Sponsors: National Institute on Drug Abuse (NIDA) and Boston University School of Medicine.

For more information or to apply: Visit www.bumc.bu.edu/fit, or contact Caroline Dames (caroline.dames@bmc.org, 617-414-6603).