Alcohol, Other Drugs, and Health: Current Evidence

JULY–AUGUST 2012

INTERVENTIONS & ASSESSMENTS

Prevalence of Alcohol Use Disorder Symptoms Increased after Bariatric Surgery

Bariatric surgery can alter alcohol pharmacokinetics, and there have been anecdotal reports that patients are at higher risk for alcohol use disorders (AUDs) after such surgery. In a prospective cohort of 2458 adults undergoing bariatric surgery, 1945 completed the Alcohol Use Disorders Identification Test (AUDIT) preoperatively ("pre-op"') and again 1 and 2 years later ("post-op"'). An AUD was defined as scoring ≥8 on the AUDIT.

- Frequency of drinking, though not number of drinks on a typical drinking day, increased 2 years post-op.
- Although hazardous consumption (>2 drinks on a typical drinking day or >5 on a single occasion) decreased from 20% to 13% in the first post-op year, it rose to 17% in the second post-op year.
- The prevalence of AUD increased from 3% pre-op to 6% 2 years later.
- Of 1283 patients with no pre-op AUD, 8% had an AUD post-op.
- Of 167 patients with post-op AUD, 61% did not have an AUD pre-op.

Comments: Alcohol use disorders increased after bariatric surgery in this cohort, and most of those affected had no prior (recent) AUD. If anything, the bias from loss to follow-up and selection might strengthen the conclusion (with heavier drinkers not being included in analyses). Interestingly, consumption amounts did not increase even as AUD symptoms doubled, a counterintuitive finding since consumption and AUD are usually correlated, and since people who experience alcohol effects at lower amounts are less likely to develop problems. It may be that more frequent use with more rapid absorption leads to harmful consequences. In any case, results suggest that informing patients of the potential risk pre-op and assessing drinking and consequences post-op is a good idea.

Richard Saitz MD, MPH

Reference: King WC, Chen JY, Mitchell JE, et al. Prevalence of alcohol use disorders before and after bariatric surgery. *JAMA.* 2012;307(23):2516–2525.

Interim Methadone with Limited Counseling for 4 Months Yields Similar 12-Month Outcomes as Methadone with Standard Counseling

Interim methadone (IM) provides 4 months of methadone and emergency-only counseling to opioid-dependent patients. This article reports 12-month results from a randomized clinical trial that previously found counseling intensity had no effect on outcomes at 4 months (see *Alcohol, Other Drugs, and Health: Current Evidence,* May–June 2011). Newly admitted participants (N=230) in 2 methadone programs in Baltimore, MD, were randomized to 1 of 3 conditions: IM for 4 months then transfer to standard methadone (SM), including routine counseling, for 8 months; 12 months of SM; or 12 months of restored methadone (RM), including routine counseling delivered by counselors with smaller caseloads.

- Treatment retention was similar between the IM (61%), SM (55%), and RM (37%) groups at 12 months in an intent-to-treat analysis.
- Positive urine-toxicology screens for opioids or cocaine declined from base-

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Counseling and Methadone Treatment Outcomes (continued from page 1)

line for the entire sample, with no differences found between groups.

Comments: At a minimum, this study suggests that, instead of being placed on a waitlist, opioid-dependent persons seeking methadone treatment should undergo methadone induction while waiting for a counseling opening. A more radical view, perhaps taken by administrators and policymakers seeking to introduce efficiencies into methadone treatment, is that standard counseling during the first few months does not appear to offer much over and above medication. That is not to say counseling is not useful; indeed, all patients in this study received standard counseling after the first 4 months. However, people whose opioid use is in early remission often have other pressing life concerns—housing, work, etc.—that loom larger on Maslow's hierarchy of needs. Given some stability in their drug habit and a few months to address these concerns, it is possible they might become more ready to hear what counselors have to say.

Peter D. Friedmann, MD, MPH

Reference: Schwartz RP, Kelly SM, O'Grady KE, et al. Randomized trial of standard methadone treatment compared to initiating methadone without counseling: 12-month findings. *Addiction.* 2012;107(5):943–952.

A Retrospective Study of High-Dose Baclofen for High-Risk Drinking Supports the Need for a Randomized Controlled Trial

Baclofen, a GABA agonist, is being tested as a potential candidate to treat alcohol dependence. Randomized trials of low-dose baclofen (30 mg per day) have had mixed results. The use of high-dose baclofen has not been studied in randomized trials, but positive results were found in a few case reports. In this study, 2 physicians examined 12-month outcomes in 181 patients with high-risk alcohol use (81% with dependence) to whom they had prescribed high-dose baclofen (mean maximum dose, 145 mg per day). One hundred thirty-two patients were available for follow-up. At 1 year,

- 43% of the original 181 patients reported abstinence, and 15% reported low-risk* drinking.
- among those available for follow-up (73%),
  - 83% were still taking high-dose baclofen.
  - 86% reported adverse effects (somnolence, insomnia, vertigo, digestive disorders, and/or confusion).
  - the proportion of psychiatric disorders was significantly lower among those with abstinence and low-risk drinking compared with those consuming higher amounts (15% versus 88%, respectively).

*Defined as ≤20 g ethanol per day for women and ≤40 g per day for men in this study.

Comments: Although results of this retrospective case series are promising, it is not possible to separate effects of the drug from effects of other things that happened during treatment (medical management, regular appointments, life events). Also, bias may have influenced the results (selection of patients and/or doctors who believe in the treatment, for example). The possible benefits identified in this case series and other case reports justify conducting a randomized controlled trial to investigate the efficacy and safety of high-dose baclofen.

Nicolas Bertholet, MD, MSc

Reference: Rigal L, Alexandre Dubroeucq C, de Beaurepaire R, et al. Abstinence and 'low-risk' consumption 1 year after the initiation of high-dose baclofen: a retrospective study among 'high-risk' drinkers. *Alcohol Alcohol.* 2012;47(4):439–442.

Does Alcohol Screening, Brief Intervention, and Referral to Treatment Work for Adolescents Presenting to Emergency Departments?

Many adolescents who present to the emergency department (ED) for injury and other problems have unhealthy alcohol use. To assess the efficacy of alcohol screening, brief intervention, and referral to treatment (SBIRT) in this population, researchers conducted a systematic review of randomized controlled trials (RCTs) of SBIRT for adolescents (age range, 11–21 years) presenting to US EDs.

- Seven RCTs met inclusion criteria, with the number of participants ranging from 94 to 853.
- Four of the 7 trials found the intervention significantly reduced alcohol use or adverse consequences (but not both) in follow-ups ranging from 3 to 12 months after the ED visit, while 3 found no significant intervention effect on either alcohol use or adverse consequences.
- Five of the 7 trials found a decrease in alcohol use and/or adverse consequences in all study arms, including the control arm.
- The largest intervention effects were seen in the 2 trials that did not include participants younger than 18 years.

Comments: This systematic review shows the efficacy of alcohol SBIRT for adolescents in the ED is still uncertain, especially for younger adolescents. Further research should assess whether different interventions are needed for different age and risk groups, evaluate different delivery models (including use of follow-up intervention sessions), and test web-based or mobile technology for follow-up assessment and intervention.

Kevin L. Kraemer, MD, MSc

Reference: Yuma-Guerrero PJ, Lawson KA, Velasquez MM, et al. Screening, brief intervention, and referral for alcohol use in adolescents: a systematic review. *Pediatrics.* 2012;130 (1):115–122.

HEALTH OUTCOMES

Do Patients with Alcoholic Cirrhosis Require Surveillance for Hepatocellular Carcinoma?

Although surveillance for hepatocellular carcinoma (HCC) in patients with alcoholic cirrhosis is recommended by some guidelines, the benefit of this practice is uncertain. To address this, researchers used a nationwide Danish registry to identify individuals with an index diagnosis of alcoholic cirrhosis between 1995 and 2005. They measured incidence of HCC and mortality from 1 year after the diagnosis until the end of 2009.

- A total of 8482 patients were diagnosed with alcohol cirrhosis, 169 of whom (2%) developed HCC, for a 5-year HCC risk of 1%.
- Hepatocellular carcinoma incidence was much higher in men (5.8 per 1000 person-years) than in women (0.7 per 1000 person-years).
- Five-year cumulative all-cause mortality was 44%, and the 5-year risk for death from HCC was 0.8% (i.e., 1.8% of deaths were due to HCC).
- Sensitivity analyses indicated an upper bound 5-year HCC risk of 1.9%, but this had no appreciable impact on cumulative mortality.

Comments: Results of this large registry-based cohort study indicate that, although patients with alcoholic cirrhosis do have increased risk for HCC and high overall mortality, their risk of dying from HCC is very low. This finding suggests that regular surveillance for HCC should not be done in patients with alcoholic cirrhosis. Since this was a single-nation analysis, it would be helpful for the study to be replicated in other countries.

Kevin L. Kraemer, MD, MSc

Reference: Jepsen P, Ott P, Andersen PK, et al. Risk for hepatocellular carcinoma in patients with alcoholic cirrhosis: a Danish nationwide cohort study. *Ann Intern Med.* 2012;156(12):841–847.

Even Occasional Cocaine, Opioid, or Amphetamine Use Persisting into Middle Age Increases Mortality

This secondary analysis of a prospective cohort study examined the impact of drug use on mortality over 18 years in a randomly selected sample of 4301 healthy adults aged 18–30 years from 4 US cities. Eligible persons completed questionnaires regarding cocaine, amphetamine, and recreational opioid use in 1987/1988 and again during at least 1 subsequent in-person examination through 2006. Trajectory analysis classed participants into 4 groups based on their pattern of drug use: 85.8% reported no use at any examination (nonusers); 7.9% matured out of early infrequent use (early occasional users); 3.7% started with infrequent

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Drug Use Persisting into Middle Age Increases Mortality (continued from page 3)

use that persisted or increased over time (persistent occasional users); and 2.6% started with frequent use that diminished over time (early frequent/later occasional users).

- All-cause mortality was 4.6% over 18 years of follow-up.
- Unadjusted mortality was higher among persistent occasional users (8.1%) and early frequent/later occasional users (6.4%) compared with early occasional users (5%) and nonusers (3.1% [p=0.003]).
- In proportional hazard models adjusted for multiple demographic, behavioral, and health-related factors, risk of death was higher for early frequent/later occasional users (hazard ratio [HR], 4.9) and was borderline significantly higher for persistent occasional users (HR, 3.3; p=0.06) compared with nonusers.

Comments: Results from this rigorous long-term cohort study confirm what has long been suspected: even after controlling for multiple important confounding factors, any use of cocaine, illicit opioids, and/or amphetamines persisting past young adulthood confers an increased risk of premature mortality. Clinicians can reasonably use this information to educate young adults who use these drugs and help motivate them to stop. Nonetheless, we await large long-term clinical trials to demonstrate whether such counseling will effectively reduce drug-related mortality.

Peter D. Friedmann, MD, MPH

Reference: Kertesz SG, Khodneva Y, Richman J, et al. Trajectories of drug use and mortality outcomes among adults followed over 18 years. *J Gen Intern Med.* 2012;27(7):808–816.

Higher Quality of Life Seen among Regular Moderate Drinkers than among Abstainers in Canada

Data from a nationally representative sample of 5404 community-dwelling Canadians aged ≥50 years were used to estimate the effects of alcohol drinking patterns* on indices of health-related quality of life (HRQL) at baseline and at 6-year follow-up. Health-related quality of life was assessed using the Health Utilities Index Mark 3. Results were as follows:

- Most participants showed stable alcohol-consumption patterns over 6 years.
- Regular moderate drinkers had the highest indices of HRQL at baseline. Subsequent changes in scores were similar in all groups except those reporting decreased alcohol consumption, who reported decreased HRQL.

*Consumption categories included lifelong abstainers, former drinkers (no alcoholic beverages in the past 12 months), infrequent drinkers (<1 drink per week), moderate drinkers (1–14 drinks per week with no more than 3 in a day for women or 4 in a day for men), and heavy drinkers (>14 drinks per week or >3 in a day for women or >4 in a day for men). One standard drink = 13.6 g ethanol in this study.

Comments: In this study, persistent moderate drinkers had higher initial levels of HRQL than abstainers and those in other consumption groups. One statistical and epidemiologic concern is that the reasons some people decreased or stopped drinking are not known. Many may have decreased their intake due to serious disease, which would also result in poorer HRQL. Further, baseline HQRL measures in this study were obtained when subjects were aged ≥50 years. Environmental effects on HRQL begin early in life, and if one adjusts for the midlife value, as was done and referred to as "baseline" in the present study, you may end up disregarding much of the effect of subsequent alcohol intake, both beneficial and harmful. Thus, the effects of continued or decreasing alcohol consumption on HRQL as one ages remain unclear.

R. Curtis Ellison, MD

Reference: Kaplan MS, Huguet N, Feeny D, et al. Alcohol use patterns and trajectories of health-related quality of life in middle-aged and older adults: a 14-year population-based study. *J Stud Alcohol Drugs.* 2012;73(4):581–590.

HIV AND HCV

Association between HIV Treatment Status and Alcohol Metabolism

Alcohol and drug use are intimately associated with HIV transmission, and alcohol is known to increase HIV disease progression. This randomized double-blind placebo-controlled study of alcohol versus placebo administration in patients with untreated HIV disease investigated the role of HIV treatment status on alcohol pharmacokinetics. Fifteen patients with untreated HIV underwent 2 sets of alcohol or alcohol-placebo administration before and after initiation of antiretroviral therapy (ART). Pharmacokinetics were measured over 8 hours following administration.

Choice of ART was at the discretion of the treating physician. Alcohol is metabolized through cytochrome P450 3A4; therefore, the authors studied HIV treatment regimens that included ritonavir (a CYP 3A4 inhibitor) or efavirenz (a CYP 3A4 inducer).

- Mean peak blood alcohol concentration (BAC) before ART initiation was 131 mg/dL (standard error [SE], 6.0). After 2–3 weeks of ART, mean peak BAC was

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HIV Treatment Status and Alcohol Metabolism (continued from page 4)

116 mg/dL (SE, 6.2), representing a 10–15% decrease.
- Alcohol area-under-the-curve was higher pre-ART initiation, with higher C_{max} and C_{min}; however, no difference was seen in alcohol elimination rates pre-initiation versus post-initiation.
- No differences in BAC were noted among patients receiving the ritonavir versus efavirenz regimen.

Comments: Although limited by small sample size, this study suggests untreated HIV is associated with higher BAC, and delayed alcohol pharmacokinetics may improve with ART. Larger studies powered to detect differences in alcohol metabolism should be performed to determine if patients with untreated HIV who ingest alcohol are at higher risk for alcohol-related adverse consequences.

Jeanette M. Tetrault, MD

Reference: McCance-Katz EF, Lum PJ, Beatty G, et al. Untreated HIV infection is associated with higher blood alcohol levels. *J Acquir Immune Defic Syndr.* 2012;60(3):282–288.

Injection-Drug and Heavy Alcohol Use Did Not Affect Hepatitis-C Treatment Outcomes in an Australian Study

Clinical trials have demonstrated the efficacy of interferon-based therapies for treatment of chronic hepatitis C virus (HCV) infection, but such studies often exclude patients with alcohol- and drug-related problems. This prospective observational cohort study recruited HCV-infected patients from 24 HCV clinics in a variety of settings, including drug-treatment and correctional centers, throughout Australia. Analyses focused on 550 treatment-naïve patients recruited between 2008–2009 who subsequently underwent treatment for HCV with pegylated-interferon and ribavirin. The median age was 46; the majority were male (63%) and had a history of prior injection drug use (68%), though few (5%) had current injection drug use. Thirty-five patients (6.4%) had current heavy alcohol use.* The primary viral genotypes were 1 and 3 (50% and 42%, respectively). The median duration of infection was 19 years (interquartile range, 10–27 years).

- Among all patients who received at least 1 dose of interferon, sustained viral response (SVR) was achieved in 60% of patients overall (50% for genotype 1 and 70% for genotypes 2 and 3). Ten percent of patients discontinued early due to nonresponse, and 10% discontinued due to adverse events or side effects.
- In the multivariable analysis, there was no significant association between SVR and past injection drug use (OR=1.67), current injection drug use (OR=0.72), or current heavy alcohol use (OR=1.10).

*Defined as >20 g per day in this study.

Comments: This study demonstrated the effectiveness of antiviral therapy when delivered in a "real-world" setting, with SVR rates nearly comparable to results observed in clinical trials. It is encouraging that the investigators did not find significant associations between injection-drug and heavy alcohol use and treatment outcomes. However, the study may suffer from selection bias, as patients with more severe drug or alcohol problems are often excluded from treatment in clinical practice. Furthermore, the systems of delivery of HCV care in Australia may be unique, making it difficult to generalize findings. Finally, this study predates the introduction of directly acting antiviral therapies for HCV; additional studies are needed to assess effectiveness of newer treatment regimens.

Judith Tsui, MD, MPH

Reference: Gidding HF, Law MG, Amin J, et al. Hepatitis C treatment outcomes in Australian clinics. *Med J Aust.* 2012;196(10):633–637.

Providing Rapid HIV Testing in Drug Treatment Centers Increased Testing Rates, but Adding Counseling Did Not Reduce Sex-Risk Behaviors

Increasing HIV testing rates is a priority, and drug treatment centers are a potential location to provide testing since they serve people at high-risk for HIV infection. In this study, adults entering drug treatment at 12 US sites who were either HIV negative or HIV status unknown (N=1281) were randomized to 1 of 3 arms: off-site HIV testing, on-site rapid testing with risk counseling, or on-site rapid testing with information only (no counseling). The main outcome measures were self-reported receipt of HIV test results at 1 month and sexual risk behaviors* at 6 months. A secondary outcome measure was self-reported needle sharing at 6 months.

- Those assigned to off-site testing were much less likely than those assigned to on-site testing to receive HIV test results (18% versus 80% in the on-site-with-counseling group and 85% in the on-site-with-no-counseling group, respectively).
- Frequency of unprotected sex over time was similar in the 3 arms.
- Among those who reported needle sharing at baseline, there was a significant reduction only among those who received counseling.

*Number of unprotected anal or vaginal intercourse episodes.

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HIV Testing with Counseling in Drug Treatment: No Effect on Sex-Risk Behaviors (continued from page 5)

Comments: This study shows that providing on-site rapid HIV testing dramatically increases testing rates. It is disappointing that counseling had no effect on sexual risk behaviors, although this cohort reported relatively low rates of sexual risk behavior at baseline. It may be better to target counseling efforts toward those reporting high levels of sexual risk behavior and needle sharing.

Darius A. Rastegar, MD

Reference: Metsch LR, Feaster DJ, Gooden L, et al. Implementing rapid HIV testing with or without risk-reduction counseling in drug treatment centers: results of a randomized trial. *Am J Pub Health.* 2012;102(6):1160–1167.

Entering Methadone Maintenance Treatment Has Little Impact on HIV Sex-Risk Behaviors in Heroin-Addicted Adults

Entry into methadone maintenance treatment (MMT) has been shown to reduce drug-related HIV risk behaviors, but the impact on HIV sex-risk behaviors is less clear. In this observational study in Baltimore, MD, 351 subjects with heroin dependence newly admitted to MMT were compared with 164 out-of-treatment subjects recruited from the street. The main outcome measures were the 10 sex-risk items on the AIDS Risk Assessment administered at baseline and at 6 and 12 months.

- The demographic characteristics of the 2 groups were similar, and there were no significant differences in age, gender, or race.
- The out-of-treatment group reported having a higher number of sexual partners than those entering MMT at baseline and at 6 and 12 months, and higher frequency of sex at baseline (but not at 6 and 12 months). Results on the other measures were not significantly different.
- Those entering MMT reported a significant reduction in 1 measured risk behavior after 6 months (but not at 12 months): frequency of unprotected sex while high or with someone who was high. Results on the other measures were not significantly different.

Comments: It is not surprising that heroin-dependent individuals who are not in treatment engage in more risky sexual behaviors, but it is disappointing that those entering treatment showed only modest changes in sexual-risk behavior. Results suggest that entry into drug treatment alone is not sufficient to change these behaviors, and that we need to pay more attention to heroin-dependent people who are not in treatment and to develop effective interventions to reduce HIV risk behaviors.

Darius A. Rastegar, MD

Reference: Mitchell SG, Kelly SM, Brown BS, et al. HIV sex-risk behaviors among in- versus out-of-treatment heroin-addicted adults. *Am J Drug Alcohol Abuse.* 2012;38(4):328–333.

Screening Tool to Identify Candidates for Pre-exposure HIV Prophylaxis in Men Who Have Sex with Men Includes Amphetamine and Alkyl Nitrite Use

Due to evidence that daily pre-exposure prophylaxis (PrEP) reduces the risk of HIV acquisition in men who have sex with men (MSM), the Food and Drug Administration approved an oral tenofovir/emtricitabine drug combination for daily use to prevent sexually acquired HIV infection. Researchers used data from 2 prospective randomized intervention trials (VaxGen's VAX004 clinical trial and the HIV Prevention Trials Network's EXPLORE study) to create a 7-item screening tool to identify MSM at highest risk for incident HIV infection who, thus, would be good candidates for PrEP. Data from each study were re-analyzed using multivariable logistic regression to determine risk factors associated with incident HIV infection. Data from the VAX004 were used to develop the risk index, and data from the EXPLORE study were used to validate the analysis.

- The screening tool (the HIV Incidence Risk Index for MSM (HIRI-MSM]) included 7 factors that contributed the following number of points:
  - age (up to 8 points)
  - number of partners in the prior 6 months (up to 7 points)
  - number of HIV-positive partners in the prior 6 months (up to 8 points)
  - 1 or more events of unprotected receptive anal intercourse (10 points)
  - 5 or more unprotected insertive anal intercourse events (6 points)
  - use of amphetamines (5 points)
  - use of alkyl nitrite (3 points)
- In the validation analysis, a score of >10 points identified individuals at high risk for HIV seroconversion with a sensitivity of 81%, a specificity of 38%, a positive predictive value of 1.2%, and a negative predictive value of 99.5%.

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Screening Tool to Assess HIV Risk Includes Amphetamine and Alkyl Nitrite Use (continued from page 6)

Comments: This HIV seroconversion prediction tool has the potential to screen MSM at increased risk of incident HIV infection who should be considered for PrEP. The tool does not identify candidates most likely to adhere to PrEP, which is a crucial factor in its implementation. Future research should include further validation of the HIRI-MSM in a prospective clinical sample that is more representative of MSM in the US (the study population was 5.6% African American, whereas African American patients account for 37% of incident HIV infection).

James Daley, MPH*
Alexander Y. Walley, MD, MSc

Reference: Smith DK, Pals SL, Herbst JH, et al. Development of a clinical screening index predictive of incident HIV infection among men who have sex with men in the United States. *J Acquir Immune Defic Syndr.* 2012;60 (4):421–427.

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The major journals regularly reviewed for the newsletter include:

Addiction
Addiction Science & Clinical Practice
Addictive Behaviors
AIDS
Alcohol
Alcohol & Alcoholism
Alcoologie et Addictologie
Alcoholism: Clinical & Experimental Research
American Journal of Drug & Alcohol Abuse
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Journal of Substance Abuse Treatment
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Psychiatric Services
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Many others periodically reviewed (see www.aodhealth.org).

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Target Audience

The target audience is generalist clinicians, many of whom have received limited training on detecting and treating substance abuse.

Educational Needs Addressed

Primary-care clinicians often miss the diagnosis of alcohol or drug problems and cannot stay abreast of the current substance-abuse literature in the context of a busy practice. Because of the effects of alcohol and drugs on adherence to care plans and physician-patient relationships, patients with alcohol or drug problems may receive suboptimal treatment for other conditions. Further, physicians sometimes perceive alcohol or drug dependence as less treatable than other medical conditions, and thus delegate responsibilities for screening and intervention to others. At the root of the screening and treatment gap is the inadequate provision of substance-abuse education in medical schools and mental-health fields. The newsletter addresses this not only by research dissemination but by providing free downloadable teaching tools for use by educators.

Educational Objectives

At the conclusion of this program, participants will be able to state the latest research findings on alcohol, illicit drugs, and health; incorporate the latest research findings on alcohol, illicit drugs, and health into their clinical practices, when appropriate; and recognize the importance of addressing alcohol and drug problems in primary care settings. In sum, the purpose of the newsletter is to raise the status of alcohol and drug problems in both academic and clinical culture to promote evidence-based screening and treatment and ultimately improve patient care.

Disclosure Statement

Boston University School of Medicine asks all individuals involved in the development and presentation of Continuing Medical Education/Continuing Education (CME/CE) activities to disclose all relationships with commercial interests. This information is disclosed to activity participants. Boston University School of Medicine has procedures to resolve apparent conflicts of interest. In addition, faculty members are asked to disclose when any unapproved use of pharmaceuticals and devices is being discussed.

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