

**Ongoing Monitoring of Alcohol Use Tied to Clear Consequences: An
Evidence-Based Strategy for Enhancing the Likelihood of Sustained Sobriety**

By

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The financial cost of Americans' addiction to alcohol and other drugs is over \$600 billion dollars per year¹ and our failure to effectively treat it are a primary driver for increased healthcare utilization, disability claims, and criminal justice costs.² The toll in human suffering for the addict, their family, and others impacted by their addiction-related behaviors are incalculable. Alcohol addiction and episodic 'problem drinking' alone account for more than 100,000 deaths per year³ and America's criminal justice system is overwhelmed with nearly 70% of those incarcerated have underlying alcohol or drug use disorders.⁴ While over 23 million Americans suffer from addiction to alcohol and drugs with an additional 40 million others meeting the criteria for the less severe 'medically harmful use of alcohol or other drugs' diagnosis, only about 2.5 million (4%) of these people enter treatment for their disorder each year.^{1,5,6} For those who do enter treatment, relapse often following discharge is now widely acknowledged by those in the substance use disorder treatment community. Follow-up studies of alcoholics have found that 65 to 70% relapse within a year of completing treatment with a majority relapsing within less than three months.^{7,8} Relapse rates are similar or even worse for those addicted to alcohol along with other drugs.^{7,9}

The frequency of relapse is so common, that it has become a defining characteristic of substance use disorders. In a recent white paper for the American Society of Addiction Medicine, drug and alcohol addiction is defined as "a chronic, ***relapsing brain disease*** that is characterized by compulsive drug-seeking behavior and drug use that continues despite harmful consequences. ***It is a brain disease, because drugs and alcohol change the way the brain is structured and works.*** Although the initial decision to take drugs is voluntary, physical changes in the brain following successive bouts of use can reduce a person's ability to exert self-control over their drug use. ***These alterations in the brain's structures and its motivational, cognitive and inhibitory functions result in behavioral changes that persist long after drug use has ceased. This helps to explain why drug (and alcohol) abusers are at risk for relapse even after long periods of abstinence and despite the potentially devastating consequences***" (emphases added).¹⁰ Despite a growing number of treatment innovations, few have been validated as substantially reducing relapse rates and ensuring a high probability of sustained recovery.

Long-term ongoing monitoring of alcohol/substance use tied to clear consequences for any instance of continued use is the most promising evidence-based intervention for dramatically enhancing the likelihood of sustained abstinence. Table 1 summarizes the findings from four outcome studies comprising almost 10,000 participants with substance use disorders that incorporated this strategy as a central component into their intervention program. Such programs for physicians and pilots were first developed in the 1980s and evaluations of them have found long-term success rates of 75 to 90%.^{11,12} The high level of success from these programs has resulted in them being extended to lawyers¹³ and many other professions with State licensing boards.¹⁴ Similar levels of success for ongoing monitoring of alcohol/substance use tied to clear consequences have been found in the criminal justice system^{15,16} with 67 to 78% of DUI offenders fully abstaining from alcohol use despite the fact that almost half had three or more prior DUI arrests.¹⁶

DuPont and Skipper¹⁴ have highlighted key components for these programs' success. They include 1) long-term frequent testing for alcohol use; 2) zero-tolerance for any use of alcohol; and 3) clear consequences for any alcohol/substance use or noncompliance with other features of the treatment program thereby setting a high standard of expectation for "total abstinence and treatment compliance." As Skipper and Dupont emphasize,¹⁷ while each of these intervention programs use leverage to enforce the abstinence standard be it the loss of license to practice one's profession or immediate brief incarceration; they note that "leverage also can be exercised in families, workplaces and schools. Contingency management studies suggest that even minor forms of leverage, such as the weekly allowance or use of the family car for teenagers, can be extremely effective."¹⁸



Breath testing for alcohol began being used widely in the health and criminal justice sectors in the 1960s. FDA approval of a variety of breath testing technologies surged in the early 2000s both for alcohol and for use in such areas as infectious disease and cancer risk. A level 1 CPT code, 82075, has been in use for many years. While breath testing has not been widely used in clinical practice, new wireless technologies greatly expands the capacity to use alcohol breath testing across patient cohorts, populations, and platforms.¹⁹

Due to the length of time addictive drugs remain in the body following use, urine testing is the most common form of monitoring though this lacks the certainty of detection unless tested for one or more times per week. The value of urine testing for alcohol use though is more limited since it metabolizes quickly in the body and alcohol itself remains detectable for only hours following use. For this reason ethyl glucuronide (EtG), a metabolite of alcohol, is typically assessed for in urine since trace levels of EtG are detectable for up to a week following an episode of heavy drinking. While being widely used, a key limitation though of urine testing for EtG is the likelihood of false positive and false negative findings. As Skipper et al note, positive test results can result from "extraneous exposure to alcohol from any of a myriad of products such as food, mouthwash, hand-sanitizing gels, or over-the-counter medications. Also, in vitro formation of EtG from bacterial action in urine in some settings or from consuming sugar and yeast has been reported."²⁰ Furthermore, there is not an agreed to cutoff score for distinguishing between drinking and such extraneous exposures.

Due to the problems with urine testing for alcohol use, continuously worn transdermal alcohol sensors on the ankle have been used to ensure certainty of detection.^{16,21} While highly accurate in detecting any alcohol use, the key drawbacks of long-term monitoring using transdermal sensors include 1) the intrusiveness of continuously wearing a cumbersome and often noisy device around one's ankle; 2) discomfort to many wearers especially when exercising and sleeping; 3) stigmatizing wearers when others discover they are shackled to it; and 4) the devices cannot be submerged in water.¹⁷ These drawbacks significantly limit the implementation of transdermal sensors beyond offenders in the criminal justice system. Twice-daily alcohol breath tests have also been used with success¹⁶ but this is impractical for long-term monitoring since it requires the alcoholic to twice-daily meet with the person monitoring their abstinence.

Recently, a new breath analyzer device manufactured by Soberlink has become available that ensures the certainty of detection without the drawbacks of transdermal sensors or the requirement of meeting face-to-face with the person monitoring the alcoholic's abstinence. The Soberlink device combines a breath analyzer with cellular, GPS, digital photo, and facial recognition technologies working in conjunction with a smartphone. In their own privacy, the person being monitored blows into a small pocket-sized breath analyzer while a photo of their face is taken mid-exhalation. The device then time/date stamps the test results, GPS location, and facial image, and immediately transmits this

information over a secure wireless network to Soberlink's HIPAA-compliant monitoring website where facial recognition technology compares the incoming photo to the one on file to confirm identity. Instant text &/or email alerts are sent to report any positive test results or if a test is missed to the case manager monitoring the person's recovery. If a test is positive, the person is prompted automatically by his/her smartphone to retake the test 15 minutes later to confirm that it was not a false positive finding due to extraneous exposure to alcohol vapor in the air (e.g., mouthwash or hand sanitizer). The Soberlink website allows the case manager to setup a unique testing schedule for each person they are monitoring and the person is prompted by their smartphone prior to each scheduled test. Due to the ease and confidentiality of testing which preserves the monitored person's dignity, it is common for people to be tested 3 to 4 times a day and thereby create a comprehensive record of their sobriety.

The Soberlink device was recently evaluated in a naturalistic research trial of social drinkers comparing its accuracy in detecting drinking episodes to randomly-administered weekly urine testing.²⁰ This study used the most common cutoff score for EtG (500 ng/ml) to distinguish between positive and negative urine test findings. The study found a very high compliance rate with Soberlink testing (96%) and the technology accurately identified 98.8% of the 84 drinking episodes that occurred among subjects during their 5 weeks of monitoring. Randomly-administered urine testing also had a high compliance rate (92%). In contrast though to Soberlink testing, of the 55 urine tests that were submitted, only 1 was positive for EtG indicating a true positive rate of only 1.2% (1 of 84) and this single positive finding was obtained the morning after a subject had consumed 5 drinks the night before. The high level of false negative findings (54 of 55) in this sample of social drinkers using the most common UtG cutoff suggests that many drinking episodes are not detected by randomly-administered weekly urine testing. Despite urine testing's widespread usage in assessing for EtG with over 5 million tests conducted each year, its high false negative rate in randomized weekly testing as documented in this study enables alcoholics monitored by this method to drink without certainty of detection. This fact presents significant issues to case managers relying on weekly urine testing as the sole means of detecting drinking episodes and applying contractual consequences when total abstinence is not sustained.

The Soberlink device and monitoring system has successfully been used in the Texas criminal justice system and for the long-term monitoring of alcoholics following intensive treatment since 2011. In the recent clinical trial, subjects overwhelmingly preferred the privacy and convenience of Soberlink testing to randomly-administered weekly urine testing. The Soberlink system represents a significant advance for treatment programs implementing the ongoing monitoring of alcohol use tied to clear consequences for every instance of continued use. Soberlink provides a powerful deterrent to the alcoholic to not drink due to the near 100% certainty of detection which is then confirmed as a true positive by retesting within 15 minutes. Soberlink users commonly report that this certainty of prompt detection provides the added motivation they often need to not drink when they are most vulnerable to relapse.

Substance use disorders occur in approximately 8 to 12% of American adults and alcohol is the most common addiction²² with exceedingly high costs to the individual, their family, and society-at-large. Alcoholism is a chronic, relapsing brain disease that is highly resistant to even the best treatment efforts. Long-term continuous monitoring of alcohol consumption tied to clear consequences for any drinking episode is one of the few evidence-based interventions for dramatically enhancing the likelihood of sustained abstinence. Given alcoholism's exceptionally high relapse rate following treatment-as-usual, it is a waste of treatment resources and a severe disservice to the alcoholic and his or her loved ones to not incorporate this intervention into their long-term treatment.

Table 1
Outcome Studies Using Ongoing Monitoring of Substance
Use Tied to Clear Consequences

Study	Subjects/Design	Key Findings
McLellan et al ¹¹	904 physicians enrolled in one of 16 state physician health programs (PHP) due to a substance use disorder. Physicians in PHP programs sign long-term contracts stipulating they will adhere to the PHP's care management plan and submit to frequent random testing to ensure they remain abstinent from any addictive drug or alcohol use. If a physician relapses, he/she is removed from practice and referred to additional evaluation/treatment and more intensive monitoring.	<ul style="list-style-type: none"> • 155 of 802 (19.3%) with known outcomes failed the program, usually early during treatment • 521 of the 647 (80.5%) who completed treatment and resumed practice were found to have not engaged in alcohol or drug misuse based on frequent and randomly administered urine testing over 5 years • While 19.5% tested positive for alcohol or drug use in at least one urine test, only 33 (26%) of these physicians had a repeat positive test • At five year follow-up, 631 (78.7%) were licensed and working, 87 (10.8%) had their licenses revoked, 28 (3.5%) had retired, 30 (3.7%) had died, and 26 (3.2%) had unknown status.
ALPA ¹²	Over 5,000 substance abusing pilots enrolled in the ALPA program with features similar to PHPs.	<ul style="list-style-type: none"> • Long-term recovery rate of 90% • As of July 2008, over 4,200 pilots had been successfully treated and returned to work under ongoing monitoring.
Hawken & Kleiman ¹⁵	493 probationers randomly assigned between probation-as-usual (PAU) and the HOPE program. The HOPE program included random drug testing. Detected probation violations including any drug use, missed tests, or missed appointments, resulted in brief incarceration.	<p>Compared to PAU, in a one-year period HOPE probationers were:</p> <ul style="list-style-type: none"> • 55% less likely to be arrested for a new crime • 72% less likely to use drugs • 61% less likely to miss appointments and • 53% less likely to have their probation revoked.
Loudenburg et al ¹⁶	4,009 offenders (primarily DUI, with 48% having 3 or more DUI arrests) for whom substance use was a contributing factor to their illegal behavior enrolled in the South Dakota's 24/7 Sobriety program. The program included 1) twice-daily alcohol breath tests or wearing transdermal sensors, 2) random urine testing for selected offenders, and 3) positive tests for alcohol/drugs or missed meetings resulted in brief incarceration.	<ul style="list-style-type: none"> • Of over 800,000 twice-daily alcohol tests, 99.4% passed and only 0.6% of tests were failed or unexcused • 66.6% of offenders assigned to twice-daily alcohol breath tests never failed a test while 17.1% failed only one test and 9.7% failed twice • 78% of offenders assigned to transdermal alcohol bracelet monitoring fully abstained from drinking.

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