

Press Release

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SAFE Glen Cove Coalition: Addiction Treatment Research Seeks to Reduce Drug Use

According to Dr. Nora Volkow, Director of the National Institute on Drug abuse (NIDA), for many people trying to recover from a substance use disorder, abstinence may be the most appropriate treatment objective. But complete abstinence is sometimes not achievable, even in the long-term, and there is a need for new treatment approaches that recognize the clinical value of reduced use.

According to the 2022 National Survey on Drug Use and Health, two thirds (65.2 percent) of adults in self-identified recovery used alcohol or other drugs in the past month. There is increasing scientific evidence to support the clinical benefits of reduced substance use and its viability as a path to recovery for some patients. Reducing drug use has clear public health benefits, including reducing overdoses, reducing infectious disease transmission, and reducing automobile accidents and emergency department visits, not to mention potentially reducing adverse health effects such as cancer and other diseases associated with tobacco or alcohol.

The FDA has historically favored abstinence as the endpoint in trials to develop medications for substance use disorders. Abstinence has been evaluated using absence of positive urine drug tests, absence of self-reported drug use, and regularly attending sessions where drug use is assessed. But abstinence is a high bar comparable to requiring that an antidepressant produces complete remission of depression or that an analgesic completely eliminate pain. Recognizing this limitation, the FDA encourages developers of opioid and stimulant use disorder medications to discuss with FDA alternative approaches to measure changes in drug use patterns.

A model for reduced use as an endpoint exists with treatments for alcohol use disorder. Reduction in alcohol use is relatively easy to measure since alcoholic beverages tend to be purchased and consumed in standard quantities, and substantial evidence supports the clinical benefit of reduction in heavy drinking days (defined as 5 or more drinks/day for men and 4 or more drinks/day for women). Consequently, the percentage of participants with no heavy drinking days is accepted by the FDA as a valid outcome measure in trials of medications for alcohol use disorder. The FDA recently announced a new tool through which investigators can determine if proposed treatments for alcohol use disorder (AUD) work based on whether they reduce "risk

drinking” levels. The new tool can be used as an acceptable primary endpoint in studies of medications to treat adults with moderate to severe AUD.

Use reduction could readily be used as an endpoint in the development of treatments for tobacco use disorder as well, since the number of cigarettes smoked per day is easily measured and there is evidence that 50 percent reduction in cigarette use produces meaningful reduction in cancer risk. Thus, the NIH and FDA have recently called for consideration of meaningful study endpoints in addition to abstinence in research on new smoking-cessation products; though abstinence is still required as the main outcome for medication approval.

Objective assessment of use reduction for illicit substances presents a greater difficulty given variability and uncertainty of the composition and purity of illicit drugs purchased. This challenge may account for part of the reluctance of the pharmaceutical industry to invest in developing new medications aimed at reducing drug use. Also, anecdotally, the expectation that medications that can produce complete cessation are the only treatments that will advance to market has discouraged addiction neuroscientists and some in the pharmaceutical industry from advancing new medication targets or compounds relevant to reduced use or other endpoints besides abstinence. Nevertheless, there is increasing research demonstrating the relative strength of quantitative measures of drug use frequency in assessing the efficacy of drug use disorder treatments.

Little research has been conducted on alternative endpoints in opioid use disorder treatment, but it will be needed to advance medication development in this area. Among the important research questions that still need answering is whether treatment aimed at reducing opioid use could produce better overdose-related outcomes than treatment aimed at cessation of use, since many fatalities arise from a return to use after tolerance to the drug is lost following periods of abstinence. Even in the absence of clinical trial evidence, however, any reduction in illicit substance use can reasonably be argued as beneficial, entailing less risk of overdose or of infectious disease transmission, less frequent need to obtain an illegal substance with the attendant dangers. Decreased substance use also makes it more likely that the individual can hold a job, be a supportive family member, and so on.

Volkow maintains broadening the goals of treatment to include reduced use or other clinically meaningful outcomes as a main outcome for medication approval could potentially expand therapeutic interventions and help increase the number of people in treatment. It could also reduce the stigma that is typically associated with return to use. Setting abstinence as the goal of treatment can be obstacle to treatment engagement for those who are unready or unwilling to make that commitment. And when attempts at abstinence falter, these expectations can compound the sense of failure the patient experiences.

There is little scientific evidence to support the stereotype that people who return to use after a period of abstinence inevitably do so at the same intensity. People in recovery sometimes draw a distinction between resumption of a heavy and compulsive use pattern and isolated, one-time

returns to substance use, recognizing that brief “slips” or “lapses” don’t need to be catastrophic to recovery efforts and may even strengthen the person’s resolve to recover.

When returns to use are catastrophic, the sense of failure at living up to the abstinence expectation could play a role in exacerbating further substance use. So could the rules of treatment programs or recovery communities that require abstinence.

Recognizing that recovery is often nonlinear, a more nuanced view of treatment is needed, one that acknowledges that there are multiple paths to recovery. Expecting complete abstinence may be unrealistic in some cases and can even be harmful. It can pose a barrier to seeking and entering treatment and perpetuate stigma and shame at treatment setbacks. By the same token, reduction of substance use has important public health benefits as well as clinical benefits for patients, and recognition of this could greatly advance medication development for treatment of addiction and its symptoms.

The National Institute on Drug Abuse (NIDA) is a component of the National Institutes of Health, U.S. Department of Health and Human Services. NIDA supports most of the world’s research on the health aspects of drug use and addiction. The Institute carries out a large variety of programs to inform policy, improve practice, and advance addiction science. For more information about NIDA and its programs, visit www.nida.nih.gov.

SAFE, Inc. is the only alcohol and substance abuse prevention, intervention and education agency in the City of Glen Cove. Its Coalition is conducting prevention awareness campaigns entitled, "Keeping Glen Cove SAFE," to educate and update the community regarding alcohol, tobacco and other drug use and its consequences. To learn more about the SAFE Glen Cove Coalition please follow us on www.facebook.com/safeglencovecoalition or visit SAFE’s website to learn more at www.safeglencove.org.