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# Reduction in heavy drinking as a treatment outcome in alcohol dependence

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**Abstract**

In the field of clinical alcohol disorders treatment in North America, abstinence continues to be largely viewed as the optimal treatment goal; however, there is a growing awareness of limitations when abstinence is considered the only successful outcome. Although this issue has been discussed in research settings, new studies on the public health significance of heavy drinking (defined as five or more standard drinks per drinking day in men, and four or more standard drinks per drinking day in women) in the past 10 years suggest that clinical providers should consider the value of alternative outcomes besides abstinence. A focus on abstinence as the primary outcome fails to capture the impact of treatment on reduction in the pattern and in the frequency of alcohol consumption. In addition, evaluating reduction in drinking as "positive" has value for patients as an indicator of clinical progress. Measurement of continuous variables, such as the quantity and the frequency of alcohol consumption, has provided a clearer understanding of the scope of alcohol-related morbidity and mortality at the societal level, and of the relationship between individual patient characteristics and the naturalistic course of alcohol use, abuse, and dependence. A review of these characteristics suggests that there are clinical benefits associated with reducing heavy drinking in alcohol-dependent patients. Given the significant public health consequences associated with heavy drinking and the benefits associated with its reduction, it is proposed that researchers, public health professionals, and clinicians consider using reduction in heavy drinking as a meaningful clinical indicator of treatment response, and that outcomes be individualized to patients' goals and readiness to change.


*Keywords:* Substance abuse; Outcomes; Evaluation; Treatment response; Health effects

## 1. Introduction

The burden of disease in alcohol disorders is enormous. The estimated economic cost of alcohol problems in the United States was US$184.6 billion for 1998 alone (Department of Health and Human Services, 2000). Alcohol dependence is a major public health problem; worldwide, alcohol is the fourth leading cause of disability (Murray & Lopez, 1996). Alcohol dependence is present in approximately 4% of the adult population in the United States in a 12-month period (Grant et al., 2004), is common among primary care patients (O'Connor & Schottenfeld, 1998; Fleming, Barry, Manwell, Johnson, & London, 1997), and may contribute to > 100,000 preventable deaths per year (McGinnis & Foege, 1999).

The negative health consequences of alcohol drinking have especially been linked to patterns of chronic heavy drinking (Murray & Lopez, 1996; Rehm, Gmel, Sempos, & Trevisan, 2003). Heavy drinking is typically defined in the research literature as five or more standard drinks per drinking day in men, and four or more standard drinks per drinking day in women (Anton et al., 1999; Kranzler,

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Modesto-Lowe, & Van, 2000; National Institute on Alcohol Abuse and Alcoholism, 2005; O'Malley et al., 1992; Volpicelli, Alterman, Hayashida, & O'Brien, 1992). Reduction in such heavy drinking has been increasingly studied in clinical treatment studies. For example, in the recently published large-scale multicenter COMBINE study (Anton et al., 1999), "time to first heavy drinking day" was one of the primary efficacy measures. In this study, naltrexone, in combination with medical management, was found to reduce the risk of a heavy drinking day over time compared to placebo.

Early epidemiological research highlighted the importance of assessing various patterns of drinking, rather than focusing only on abstinence (Cahalan & Cisin, 1968). The development of the widely used Timeline Follow-Back method (Sobell & Sobell, 1992) to measure changes in the quantity and in the frequency of drinking made reduction in drinking levels a standard outcome measure in many clinical trials. In addition, a National Institute of Alcohol Abuse and Alcoholism expert panel specifically recommended that "percent days of heavy drinking" be used as the optimal measure of alcohol treatment outcome in efficacy studies (Sobell, Sobell, Connors, & Agrawal, 2003).

Despite this long-standing use of reduction in drinking levels as an outcome measure in alcohol treatment research, and the more recent attention on some investigations specifically focused on reduction in heavy drinking, the alcohol treatment service delivery sector in North America maintains a predominant focus on abstinence as the measure of optimal treatment effectiveness. The somewhat different issue of "controlled drinking" (Sobell & Sobell, 1978, 1995) generated a long-standing controversy that has partially clouded the larger issue of measuring drinking reduction in clinical care. Thus, to date, measures of reduced drinking developed in research settings have not translated well to the clinical treatment of alcohol dependence.

In this article, we present the case for a reconsideration of alternatives to abstinence as measures of treatment effectiveness to be used in clinical settings for patients with a diagnosis of alcohol dependence. In particular, evidence is presented for the role and for the utility of reduction in heavy drinking as a clinical measure of treatment effectiveness. The primary justifications for this reconsideration are as follows: (1) extensive data that have accumulated on the personal and societal costs of heavy drinking, and (2) the broader range of psychosocial treatment options and new pharmacotherapies, including extended-release formulations, that are now available for the treatment of alcohol dependence. This broader range of treatment options allows for extending the treatment of alcohol dependence into a variety of service sectors that include patients who may not be ready for abstinence as a treatment goal.

To understand the potential role of reduction in heavy drinking as a measure of treatment effectiveness in clinical settings, it is useful to clarify the distinction between goals of treatment and measures of effectiveness. "Goals of treatment" can be defined as proximal behavioral health objectives regarding alcohol use. Such goals may differ between patients and providers, but it is important to establish a shared goal at the start of treatment for successful collaboration. In clinical practice, goals may require reconsideration and renegotiation during the course of treatment. A clinical "measure" is a tool for evaluating how the patient is progressing toward the goal. The ability to set achievable goals and to utilize high-resolution measures aids the individualization of treatment. Some patients, for example, may not be ready for a goal of abstinence. For these patients, reduction in heavy drinking may be the appropriate short-term goal, and effectiveness can be gauged relative to this goal. In addition to patient treatment goals and provider treatment goals, there are goals defined by societies or cultures with regard to alcohol use that can influence individual goals.

In this article, we first discuss the strengths and weaknesses of various measures of treatment effectiveness used in alcohol dependence treatment and research. We then review selected current literature on the impact of heavy drinking on public health, and we conclude by providing a vision of alcohol treatment that targets treatment goals and their corresponding measures to each individual patient.

## 2. Outcome measures in alcohol dependence treatment and research

### *2.1. Abstinence as an outcome measure*

Abstinence is an all-or-nothing outcome that has long been regarded as the primary objective of alcohol treatment. Duration of abstinence is the sine qua non of effective treatment and research (Finney, Moyer, & Swearingen, 2003; Jellinek, 1960; National Institute on Alcohol Abuse and Alcoholism, 2005). However, there is a growing awareness of the limitations of abstinence as a primary end point (Miller, Walters, & Bennett, 2001; Wang, Winchell, McCormick, Nevius, & O'Neill, 2002). A number of factors underlie this concern.

Abstinence is a categorical and definitive measure that represents the safest outcome for patients in the views of both clinicians and researchers. In the real world, however, it is often difficult for alcohol-dependent patients to initiate abstinence; many are either not interested in abstinence at the time of entering treatment or unable to commit to abstinence at the time of entering treatment. As a consequence, most clinical trials have included a limited subpopulation of motivated participants who are willing and able to successfully initiate a short period of abstinence prior to treatment. Such trials have limited generalizability to the broader population of alcohol-dependent individuals.

Studies that examine the duration of abstinence usually measure "time to first drink." This approach, however, fails to incorporate into the analysis patients' subsequent drink-