Creating a New Standard for Addiction Treatment Outcomes

A Report from the Institute for Behavior and Health, Inc.

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Preface

On March 24, 2014, the Institute for Behavior and Health, Inc. (IBH) hosted a one-day symposium in Washington, DC of thought leaders with expertise in addiction treatment, research, health care, public policy, and government to discuss current outcome measures of treatment for substance use disorders and to recommend ways these measures could be improved. These individuals comprise the IBH Addiction Treatment Outcomes Working Group.

The symposium established a framework with a long-range perspective for the evaluation of addiction treatment. This framework recognized that addiction was a commonly chronic relapsing disorder and that follow-up monitoring and support after treatment was almost always absent, making relapse the expected outcome of addiction treatment. The new outcome evaluation framework aimed to make recovery the expected outcome of addiction treatment. Assessment of the success of addiction treatment would not be measured only, or even primarily, by what happens during treatment, as is common today, but rather by what would happen after treatment: “Then what?” would be the fundamental new question for treatment evaluation.
IBH Addiction Treatment Outcomes Working Group

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Introduction
The United States has had a century of experience with independent clinicians and programs that deliver services to treat persons suffering from substance use disorders. For the most part these addiction treatment programs and clinicians operate in a specialized segment of medical care that lack standards of effectiveness and measures of long-term outcomes. Though substance use disorders are chronic illnesses, unlike the routine treatment for other chronic conditions such as diabetes or heart disease, there is no long-term or lifelong model of addiction treatment and few replicable standard measures of long-term treatment outcomes.

Presently, the typical measure of the effectiveness of substance use disorder treatment is reduction in the quantity or frequency of substance use during the course of a treatment intervention or, in rare instances, up to 12 months post-intervention. Such a short follow-up interval fails to reveal whether there are long-term benefits derived from a particular episode of treatment. A shift to long-term outcome measures of sustained recovery as opposed to short-term periods of reducing the use of one or more drugs has the potential to change the way in which treatment is evaluated. The data from such a long-term outcome evaluation has the potential to guide changes in treatment to improve long-term outcomes.

This report from the Institute for Behavior and Health, Inc. proposes a standard measure of five-year recovery for the treatment of substance use disorders. This long process of change begins by redefining the initial primary goal of addiction treatment as being both long-term abstinence from the use of alcohol and other drugs and improved quality of life. It also begins with identifying practical strategies for how long-term patient outcomes can be assessed. How can addiction treatment programs and clinicians that provide episodes of treatment for substance use disorders, insurance companies that cover the costs of this care, and others including employers and the criminal justice system assess long-term outcomes? Using sustained five-year abstinence and recovery as the primary measure of treatment outcomes can reshape both research and clinical practice. It can increase the quality of treatment, spawn a new generation of monitoring and care management and deliver more consistently the outcome widely sought but seldom achieved: a sustained addiction- and substance-free, healthy lifestyle.

The adoption of five-year abstinence and recovery as a treatment outcome measure would not replace other measures of effectiveness, including in-treatment assessments, but it would add to those measures. It would ensure that the standard measure of treatment effectiveness is long-term recovery and it would encourage addiction treatment programs and clinicians to make recovery the expected outcome of treatment. This report suggests a way forward to a standard of five years for assessing the outcomes of addiction treatment. It encourages providers and payers in addiction treatment to develop a variety of ways to assess five-year outcomes with the goal of improving treatment outcomes.

The report briefly reviews the definition of “recovery”, reviews the evidence that supports the proposition that long-term recovery can be the expected outcome of substance use disorder treatment, and discusses alternate methods that could be used to collect five-year abstinence and recovery
outcome data. An Appendix reviews the current measures of effectiveness and evidence-based treatment for substance use disorders.

**Making Recovery the Expected Goal of Addiction Treatment**

Sustained recovery and an improved quality of life should be the expected goal of treatment for substance use disorders. A broadly representative group of experts convened by the Betty Ford Institute in 2007 defined recovery as “a voluntarily maintained lifestyle characterized by sobriety, personal health, and citizenship.”[^1] The American Society of Addiction Medicine (ASAM) defined recovery as “a process of sustained action that addresses the biological, psychological, social, and spiritual disturbances inherent in addiction. This effort is in the direction of a consistent pursuit of abstinence, addressing impairment in behavioral control, dealing with cravings, recognizing problems in one’s behaviors and interpersonal relationships, and dealing more effectively with emotional responses. Recovery actions lead to reversal of negative, self-defeating internal processes and behaviors, allowing healing of relationships with self and others. The concepts of humility, acceptance, and surrender are useful in this process.”[^2] The Substance Abuse and Mental Health Services Administration (SAMHSA) defines recovery from mental disorders and substance use disorders as, “a process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential.”[^3]

Recovery implies long-term abstinence from the use of alcohol and other drugs. This report considers abstinence to be an immediate goal of treatment both during episodes of treatment and following discharge from treatment. The use of prescribed medicines, including buprenorphine, methadone and naltrexone, as intended by prescribing physicians is fully compatible with abstinence, but the nonmedical use of other drugs, including alcohol, is not. The gold standard for this model of abstinence used by programs featured in this report is also the standard of the 12-step fellowships of Alcoholics Anonymous and Narcotic Anonymous. Abstinence is not necessarily a primary objective of all addiction treatment programs. Some set a treatment goal, of cutting down on alcohol or other drug use or so called “responsible” or “safe” use of alcohol or other drugs. While there is evidence that a significant reduction in alcohol drinking is beneficial to health, total abstinence is the preferred and most stable outcome goal for treatment programs.

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Recovery also includes healthy living, wellness, and productive engagement.\textsuperscript{4} Common measures of addiction treatment assess outcomes only during treatment and measure only the reduction in the use of a specific drug. This discrepancy is especially egregious because all episodes of addiction treatment are brief, while substance use disorders are life long, with a continuing threat of relapse. There is a popular perception that treatment ‘fixes’ those with substance use disorders. This perception fails to recognize the lifelong nature of the disorder. It has important public health policy implications because it limits the way that outcomes of treatment and other interventions are defined and measured, and encourages acceptance of limited outcomes.

\section*{Perspective: Measuring Abstinence to Show Long-Term Recovery}

Because abstinence is a realistic objective in addiction treatment and is a primary foundation for establishing recovery, this report places emphasis on measuring abstinence. The programs featured in this report measure abstinence with results from frequent, random drug and alcohol testing. Such results demonstrate that five-year abstinence is being achieved by individuals with substance use disorders.

As noted, in this report there is much more to recovery than abstinence. Only after an extended period of abstinence, improved state of personal health and engaged citizenship, can an individual be considered to be in recovery.

\section*{The New Paradigm for Recovery}

New systems of active, long-term care management – which may include episodes of relapse followed by return to addiction treatment – demonstrate that long-term abstinence and recovery can be the expected outcome of addiction treatment. Long-term abstinence is best exemplified by the system of care management used for the past four decades to treat addicted physicians, commercial pilots and lawyers. This model of long-term, active care management for substance use disorders, termed the New Paradigm, is comparable to the way treatments for other chronic conditions today are managed in medicine.\textsuperscript{5}

\textbf{Physician health programs}. Physician health program (PHP) care management requires abstinence conditions (for alcohol and all non-prescribed drugs), intensive and sustained monitoring and deterrence through swift, certain, and meaningful consequences for non-compliance. The length of the PHP model of care management separates this model from other treatment interventions. Participating physicians


\textsuperscript{5} Ibid.
are required to sign a five-year monitoring contract. The PHP program typically begins with a formal episode of treatment, either residential or intensive outpatient day treatment, lasting between 30 to 90 days (with an average of 72 days). Following successful completion, participants are subject to intensive random substance testing throughout the duration of the program, although the frequency of testing tapers over time and as a result of sustained compliance. With random testing at any frequency, testing can occur on any day, even the day immediately following a test. This random testing is crucial to the effectiveness of the PHP care management and the New Paradigm. The long-term outcomes of the PHPs are consistent across primary substances of abuse (e.g. alcohol and intravenous use of opiates), and among physicians from different specialties (e.g. surgeons and anesthesiologists).

The long-term recovery rates for physicians in PHPs are between 70-96 percent which is the highest in all of the treatment outcome literature. A longitudinal cohort study of 904 physicians admitted to 16 PHPs used outcome measures of program completion, continued abstinence of alcohol and other drug use, and continued occupation after five years. Of the original sample, there were known outcomes for 802 physicians. Only 155 (19.3 percent) failed to complete their contract of treatment and supervision; over half of these individuals voluntarily stopping their medical licenses, another 30 percent had their medical licenses revoked, and others died either during monitoring or before five-year follow-up. Of the 647 (80.7 percent) physicians that completed treatment and resumed practice under supervision and monitoring, alcohol or drug use was detected by urine testing in only 126 (19 percent) over the five-year period with only 33 (26 percent) of these participants who had a test positive for alcohol or drug use having repeat positive test results. Approximately 81 percent of participants never failed a test for alcohol or any other drug during their five-year participation in the PHP. At the five-year follow-up, 78.7 percent of the participants were licensed to practice and still working. The remainder of participants were retired (3.5 percent), died (3.7 percent), or had an unknown status (3.2 percent). Only 10.8 percent had their licenses revoked.

The concern has been raised that the PHP results are atypical because they apply to a specific population that is well-educated and highly motivated to comply with program requirements and remain abstinent. Physicians in PHPs are faced with the loss of their medical license (i.e., their

livelihood) and, as such, might be less resistant to behavior change; however, evidence from two criminal justice programs that have similar intensive monitoring procedures suggest that similar rates of long-term abstinence and improved quality of life can be achieved in criminal offender populations with substance use problems.

**Criminal justice programs.** Participants in Hawaii’s Opportunity Probation with Enforcement (HOPE) have significant documented substance use problems and are at high risk for violating probation. In HOPE, offenders are subject to frequent random drug and alcohol testing for up to five years. A missed test or a positive drug test is met with an immediate short-term jail stay. Formal addiction treatment is available to offenders who request it and to those who demonstrate the need for treatment by repeated non-compliance and relapse to drug use. A randomized controlled evaluation found that after one year in the program, compared to offenders on standard probation, HOPE participants were 72 percent less likely to use drugs and 55 percent less likely to be arrested for a new crime.11

South Dakota’s 24/7 Sobriety Project is a similar program that specifically focuses on repeat driving under the influence (DUI) offenders. Participants are subject to twice-daily alcohol breath tests or to wearing continuous alcohol monitoring ankle bracelets, and subject to random drug urinalysis or wearing drug patches to detect the use of illegal drugs. Any positive test results in an immediate short-term jail stay. Formal addiction treatment is available but optional. Over the course of an average 120 days in the program, 55 percent of participants never fail an alcohol test, 16.7 percent fail once, 12.5 percent fail only twice and 16.9 percent fail three or more.12 DUI recidivism is substantially lower among 24/7 Sobriety participants at one, two and three years following program completion and repeat offenses have dropped 12 percent at the county level.13

Drug Courts serve high-risk, high-need criminal offenders with diagnosed substance use disorders who are eligible for community supervision such as probation.14 Participants are supervised by multidisciplinary teams that develop individualized treatment plans. Participants attend regular judicial status hearings and are subject to frequent random drug testing and gradually escalating sanctions, including short jail stays, for infractions of supervision such as drug use or missed appointments. Because Drug Court participants are mandated to participate in formal addiction treatment offenders are retained in addiction treatment longer than in other correctional programs. The impact of Drug Courts is impressive, significantly reducing re-arrest rates and promoting abstinence from alcohol and

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drug use. With cessation of drug use, there comes the potential for the improved quality of life in true recovery.

**Implications for five-year abstinence and recovery outcomes.** The findings from the PHPs and from criminal justice system programs using similar long-term monitoring with consequences for any use of alcohol or other drugs are in stark contrast to typical outcomes for other programs. The latter programs show that a substantial percentage of participants (40-60 percent) relapse within six months of completing an episode of formal addiction treatment. The promising evidence from the New Paradigm programs provides a benchmark against which other programs can measure attainment of long-term abstinence and recovery as a realistic standard for treatment outcome.

A hallmark of the New Paradigm of care management pioneered by the PHPs and other innovative programs is prolonged and intense monitoring through frequent random drug and alcohol testing to discourage and to identify substance use. A similar treatment parallel now occurs in medical practice. Recognizing that many chronic illnesses have significant behavioral elements and that compliance with good medical care is essential to manage chronic diseases, there is a new commitment to use of routine, sustained and long-term monitoring of patient behavior and compliance to improve outcomes. The commitment to patient-centered medical care with long-term monitoring and frequent assessment holds great promise for the management of substance use disorders. With such a model, health care clinicians could be encouraged to monitor patients with these disorders routinely regarding the status of their recovery. The successful management of substance use disorders includes conducting frequent random tests for the use of alcohol and other drugs as a routine monitoring of compliance, similar to the sustained monitoring for diabetes and hypertension. This model of integrated long-term monitoring and care management now being widely adopted throughout medicine holds the promise of incorporating many elements of the PHP model into routine health care for every patient suffering from a substance use disorder. In this context it is essential that health care clinicians not only recognize their important role in medically managing substance use disorders but that they also understand that long-term recovery is the objective. That means articulating this objective to patients and monitoring for its achievement. It also means that among health care there is must be a general recognition that the goal for patients with significant substance use disorders is complete abstinence from the use of alcohol and other drugs, and accompanying steps towards an improved quality of life.

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Developing a New Framework for Long-Term Addiction Treatment Patient Outcomes

The Appendix at the end of this document provides a broad overview of some of the current standards for determining the effectiveness of substance use disorder treatment interventions. These current standards mainly focus on substance-specific outcomes of patients while in treatment, and in the short-term following discharge. It is not useful to eliminate the current welter of methods to assess the efficacy of specific substance use disorder treatment interventions. Instead, there is an opportunity to raise the relevance of assessment standards by adding the long-term perspective with a focus on sustained recovery.

As of 2014, with the implementation of the Affordable Care Act (ACA), services for substance use disorders must be included in all health insurance sold on Health Insurance Exchanges or provided by Medicaid. This will greatly increase access to addiction treatment for individuals who had previously been unable to afford these services. The Department of Health and Human Services (DHHS) is charged with the responsibility of identifying which evidence-based services will be insured. More specifically, DHHS “will take into account evidence on what services allow individuals to get the treatment they need and help them with recovery”.16 Ideally, patients would have access to those services that have the strongest evidence-base as well as the best long-term outcomes for sustained recovery.

In addition to the impending increase in the number of individuals eligible for coverage of addiction treatment, in the current fiscal climate there is an intense focus on potential cost-saving strategies. With addiction treatment fewer instances of relapse and improved long-term outcomes in sustained recovery will lead to reductions in the costs associated with substance-related hospitalizations, impaired driving crashes, and incarceration. Research has shown that for every dollar spent on substance use disorder treatment, there is a return of $4-7 in reduced theft, drug-related crime, and criminal justice costs; with healthcare in this equation, the savings are a ratio of 12:1.17 It is important that insurance providers support treatment and care monitoring that improves their members’ health, reduces their future health care costs and most notably, reduces readmission for treatment of substance use disorders.

Cost-savings aside, when individuals with substance use disorders enter addiction treatment programs there is an expectation on the part of their families, employers, insurers and others that once patients complete the episode of care and are discharged, they will be securely on the road to long-term recovery. The new focus of treatment evaluation fits with this common expectation for the outcome of treatment even though it contrasts strikingly with the current performance of addiction treatment.

Presently, there is a lack of long-term outcomes data on patients who are discharged from addiction treatment programs. We challenge treatment programs and payers to measure the long-term outcomes of patients treated for substance use disorders following discharge, including abstinence. The data collected from these studies will significantly improve the outcomes of treatment programs and will help payers, patients, and patients’ families identify programs that best achieve abstinence that moves them towards sustained long-term recovery.

This report describes strategies to measure long-term successful patient outcomes from addiction treatment. We explore three sources for outcome data collection: 1) addiction treatment programs, 2) outside evaluators including research organizations and consumer satisfaction organizations, and 3) addiction treatment payers, including insurance providers. There are many useful data elements that can be collected to determine long-term recovery outcomes. We focus on a few fundamental and practical ways to enhance and extend the present limited approach to evaluating treatment outcomes.

**Approach #1: Standard Treatment Patient Outcome Assessment**

The first approach to evaluating patient outcomes is for addiction treatment programs to follow-up with patients and/or their families for an extended period of time after discharge, for both patients that complete treatment and for patients who leave against medical/program advice.

In preparation for this follow-up, at patient intake treatment programs should collect contact information for patients and designated family members to facilitate follow-up contacts. Patients and their families should understand at the outset of admission that the program will follow-up with them after the episode of treatment. Suggested follow-up outcome measurement intervals include one-year, three-years, and five-years post-discharge. The following sample data would be collected, ideally from patients directly, but possibly from family members, if appropriate. For this reason consent should be obtained from patients at intake for these data to be collected.

» Following discharge from treatment was the patient monitored by the program for alcohol and other drug use (i.e. biological testing)?

» Periods of abstinence (that are not substance-specific): through self-report, biological monitoring (if conducted) and treatment readmissions
  > Less than 30 days / 30-90 days / 3-6 months / 6-12 months /12-18 months, etc.

» Periods of relapse: through self-report, biological monitoring (if conducted) and treatment readmissions
  > Self-report alcohol use since discharge from treatment: None / Occasionally / Monthly / Weekly / Daily
    ▪ If yes, indicate: with problems/ without problems
  > Number of heavy drinking days per month
  > Self-report drug use since discharge from treatment: None / Occasionally / Monthly / Weekly / Daily
    ▪ If yes, indicate: with problems/without problems
    ▪ List of drugs used

* The questions listed in this report are examples of useful data points to be collected. This report should not be used as a survey instrument but rather inform the development of survey instruments.
Circumstances that led to relapse(s)
Changes in substances used and changes in frequency/quantity of use
Involvement in community-based recovery support (e.g. 12-steps): None / Occasionally / Monthly / Weekly / Daily
Recovery self-status evaluation: Do you consider yourself to be in recovery? Yes/No
Desire for recovery: Do you want to be in recovery? Yes/No
Employment/education status and recent history
Substance-related emergency department visits
Substance-related hospital admissions
Substance-use related illness/disease
Substance-related accidents (e.g. workplace, motor vehicle crashes)
Substance-related arrests/incarceration
Global functioning/quality of life
Psychological / subjective outcomes: cravings, mental health (anxiety/depression), overall health
Overall, how helpful was the treatment experience?
  1 Extremely unhelpful / 2 Moderately unhelpful / 3 Somewhat unhelpful / 4 Neither helpful or unhelpful / 5 Somewhat helpful / 6 Moderately helpful / 7 Extremely helpful
What elements of the treatment experience were most and least helpful?
What activities following treatment were most and least helpful in maintaining recovery?

This is an extensive list that can be amended or shortened with the understanding that the focus needs to be on the extent to which the former patients are in sustained recovery, including being abstinent from alcohol and other drug use. It is unlikely that every addiction treatment program will be able to follow-up consistently with every patient over prolonged periods of time. Therefore, it is suggested that while every patient be contacted by programs as part of routine follow-up (e.g. 3 months), treatment programs conduct extensive follow-up with an admission cohort of patients through each follow-up interval at one-year, three-years and five-years post-discharge.

There are practical concerns and considerations associated with treatment programs conducting these internal evaluations of patient program outcomes. For example, treatment programs may have incentive to alter their data for marketing purposes showing inflated rates of success. Similarly, patients may not accurately report their own outcomes or alternately, only those who are doing well may be inclined to provide information about their outcomes following discharge. Additionally, because this approach to measuring patient outcomes wholly relies on practitioners to collect data and input the information on a consistent basis, this could become onerous and resource-intensive and it may be necessary to create incentives or requirements for treatment programs to collect these outcome data.

There are many differences between state and private treatment agencies and an absence of standardized reporting and central repositories may cause discrepancies between reporting. In all such programs, a modest level of oversight would ensure the integrity of data and findings. A potential solution to ease the data collection process for both state and private treatment programs, and to increase consistency across treatment programs, is the development of electronic options for assessments. Every addiction treatment program would use the same application and the data would...
remain in a consistent format to be stored in a single location for that specific program. This would also permit aggregation and analysis of data from multiple treatment programs.

An important concern is confidentiality and ensuring privacy of patient information. It is presumed that private treatment programs own their data but would have the option of sharing their data to be pooled with data collected by state treatment agencies. Important questions to be addressed include to which national agency would the state treatment outcomes be reported, who is responsible for analyzing the data, and how would the data be publicized?

Thus, standard epidemiologically-driven questions that can be understood by every patient/family member need to be crafted to allow for analyses of the characteristics of persons who succeed and those who do not without information and selection bias.

**Approach #2: Independent Outcome Assessment Focused on Patient Satisfaction**

A second approach to evaluating treatment outcomes is to use a framework similar to customer satisfaction research. In this model, a research entity outside the treatment program would follow-up with a representative sample of patients after discharge to report short- and long-term outcomes. In this model patients (and when possible, their family members) report their level of satisfaction with the treatment process and determine whether the specific episode of treatment met their desired outcomes. It could also identify the extent to which patients achieved sustained recovery and used recovery support services after treatment discharge. This model could stand alone or be complementary to Approach #1 in providing an *additional and confirming* system to evaluate treatment outcomes.

The independent research entity would contact all patients or an admission cohort following discharge from a treatment program. In anticipation of making these contacts, consent would need to be obtained at intake.

Ideally, the *same data items* in the previous Approach #1 would be collected from patients and the families, following discharge from treatment. These data relate to, among other items, periods of abstinence, periods of relapse, involvement in community-based recovery support, self-report recovery status and desire for recovery. Like Approach #1, the suggested follow-up intervals to collect this data include one-year, three-years and five-years post-discharge.

In addition to collecting the data items in Approach #1, in Approach #2, the independent research entity would collect data about the opinions of the treatment experience from both patients and their families. The following data would be collected from patients directly at one-year, three-years and five-years post-discharge:

» On a scale from 1 to 7, how helpful was this episode of treatment?
  > 1 Extremely unhelpful / 2 Moderately unhelpful / 3 Somewhat unhelpful / 4 Neither helpful or unhelpful / 5 Somewhat helpful / 6 Moderately helpful / 7 Extremely helpful

» For patients receiving medication-assisted treatment, while in treatment, were you compliant with medication (i.e. buprenorphine or methadone) for your opiate use disorder?
  > Not at all / Somewhat / Mostly / Completely
» On a scale from 1 to 7, how helpful was treatment for a co-morbid psychological and/or psychiatric condition? (0 Did not participate)
> Were you compliant with medication and/or therapy for your co-morbid disorder?
> > Not at all / Somewhat / Mostly / Completely
> On a scale from 1 to 7, how helpful was attending 12-Step meetings while in treatment? (0 Did not participate)
> On a scale from 1 to 7, how helpful were group counseling sessions in treatment? (0 Did not participate)
> On a scale from 1 to 7, how helpful were individual counseling sessions in treatment? (0 Did not participate)
> On a sale from 1 to 7, how helpful were scheduled substance use screens in treatment? (0 Did not participate)
> On a scale from 1 to 7, how helpful were random substance use screens in treatment? (0 Did not participate)
> What was the approximate out-of-pocket cost to you personally?
> > Lost earnings?
> > Cost of treatment?
> > Other costs?
> Do you consider the costs of this treatment episode money well spent?
> > Not at all / Somewhat / Mostly / Completely
> > Why or why not?
> Did this treatment program meet your expectations?
> > Why or why not?
> Would you recommend this treatment program to others with substance use disorders?
> > No / Yes with reservations / Yes without reservations
> > Why or why not?

In collecting patient outcome data using the self- and family-report model of Approach #1 and the customer satisfaction model of Approach #2, it must be understood that patients may be hostile to a treatment program due to the circumstances that led them to treatment admission and/or discharge in the first place. This approach could be particularly challenging for offender populations mandated to treatment, especially if relapse has the potential to result in sanctions. It would be important for the entity conducting this research (including the treatment program in Approach #1) to follow an admission cohort at the same interval for all patients and determine if the sample could be biased (e.g. only those who are doing well, or alternatively, those who had bad treatment experiences are likely to want to participate).

The independent entity collecting these outcome data should follow up with family members to determine the veracity of patient claims and to ascertain family opinions in relation to the treatment experience and patient progress post-discharge. This additional information would be particularly useful as some patients may not be able to fully assess their progress or could be in denial about relapse.

The following treatment program outcome measures could be collected by the independent entity through follow-up with designated family members of patients at the three intervals post-discharge:
» On a scale from 1 to 7, how helpful was this episode of treatment to the patient?
  > 1 Extremely unhelpful / 2 Moderately unhelpful / 3 Somewhat unhelpful / 4 Neither helpful or unhelpful / 5 Somewhat helpful / 6 Moderately helpful / 7 Extremely helpful

» For patients receiving medication-assisted treatment, while in treatment, was the patient compliant with medication (i.e. buprenorphine or methadone)?
  > Don’t know / Not at all / Somewhat / Mostly / Completely

» Was the patient treated for a co-morbid psychological and/or psychiatric condition as part of the substance use disorder treatment?
  > Don’t know / Yes / No
    ▪ If yes, on a scale of 1 to 7, how helpful was this treatment?
  > Was the patient compliant with medication and/or therapy for the co-morbid disorder?
    ▪ Don’t know / Not at all / Somewhat / Mostly / Completely

» What was the approximate out-of-pocket cost to the patient (if known)?
  > Lost earnings?
  > Cost of treatment?
  > Other costs?

» Do you consider the costs of this treatment episode money well spent?
  > Not at all / Somewhat / Mostly / Completely
  > Why or why not?

» Did this treatment program meet your expectations?
  > Why or why not?

» Would you recommend this treatment program to others with substance use disorders?
  > No / Yes with reservations / Yes without reservations
  > Why or why not?

» Do you think the patient is in recovery? Yes / No

This broader data set collected by an independent entity would provide treatment programs with insight about how discharged patients perceive their treatment experiences as well as the perceptions of the value and impact of the treatment episode by family members. This information would inform addiction treatment programs to help them improve the quality of the services they provide to patients and their families.

**Approach #3: Recovery-Oriented System Model and Health Care Payers as Consumers**

In this approach, healthcare payers (i.e. insurance companies, Medicaid, Medicare) track their patients’ admissions to addiction treatment programs to identify the programs that yield the best outcomes, specifically measured by low re-admission rates. This approach is particularly useful in the current shift in health care delivery from fee-for-service to fee-for-performance. This form of evaluation encourages addiction treatment programs to focus on long-term care of patients. In this model, it is in the interest of all addiction treatment programs to ensure that re-admission rates after discharge, whether to their own programs or others following discharge, remain low. This approach will help payers identify programs that will result in costs-savings for the treatment of substance use disorders.

In order to produce low readmission rates, addiction treatment programs could be influenced to orient their care toward long-term recovery.
Figures A and B depict a system of care for substance use disorders. They demonstrate the shift from the starting point of problem drug use (i.e. substance use disorder) through possible stages and then to the achievement of recovery. Patients enter the system of care – either voluntarily or by mandate – to an episode of treatment. In an idealized seamless transition from addiction to recovery, patients would enter a formal addiction treatment program and be discharged after the episode of treatment is complete (at the medical recommendation of the program). Leading up to and after discharge, the individual would be closely connected to recovery support services with the goal of preventing relapse to substance use. After an extended period of abstinence – and improved state of personal health and engaged citizenship – the individual would reach the condition of recovery which would be maintained for a lifetime.

**Figure A.**

![Substance Abuse System of Care](image1)

**Figure B.**

![Substance Abuse System of Care](image2)
When relapse occurs, there is a need to immediately intervene with the individual, through recovery support services and possible readmission to treatment. Figures A and B show that it is not just a treatment system supported by recovery support services, but the close interaction of episodes of treatment and relapse prevention services that create increasing periods of abstinence until recovery is ultimately achieved.

For addiction treatment programs to be recognized by healthcare payers as high-achieving in terms of long-term patient outcomes, the following information would be collected and analyzed:

- Average wait times for program admission
- Attrition rate / rate of successful patient treatment completion (discharge not against medical/program advice)
- Rate of patient readmission to treatment
- Periods of patient abstinence determined through:
  - Biological monitoring in treatment and following treatment
  - Treatment readmissions
- Periods of patient relapse determined through:
  - Biological monitoring in treatment and following treatment
  - Treatment readmissions
- Use of recovery support services (e.g. linkage to 12-step programs)
- Connection to/coordination with primary care clinicians prior to discharge
- Follow-up with the patients, families and primary care physicians
- Substance-related emergency department visits
- Substance-related hospital admissions
- Substance-use related illness/disease
- Substance-related accidents (e.g. workplace, motor vehicle crashes)
- Substance-related arrests / incarceration

Like Approaches #1 and #2, there are limitations to Approach #3. One such limitation of Approach #3 is the risk of programs seeking to achieve “good” outcomes by limiting readmission in cases when treatment is needed. For this reason, in Approach #3, it would be useful to follow-up with a random sample of patients, independent from the insurance company, to ensure patients are getting the help they need and that the insurance companies are not simply avoiding readmission but that patients are abstinent and doing well. Denying readmission when treatment is needed is not a good outcome; when treatment is needed, it must be provided.

Summary

Each of the three approaches to evaluate addiction treatment outcomes is distinct in its purpose, but all assume the objective of the desired outcome is complete and long-term abstinence from nonmedical use of addictive substances. Approach #1 requires treatment programs to evaluate their patient outcomes based on self-report (and biological monitoring, if available) through follow-up with patients one-year, three-years and five-years post-discharge.

Approach #2 builds on the data collected in Approach #1 by having an entity separate from the treatment programs follow up at one-year, three-years and five-years post-discharge with patients and
their families to capture their opinions about the quality and impact of the treatment provided. In each of these intervals, both patients and designated family members are contacted to determine specifically whether or not the treatment episode met their expectations.

Finally, Approach #3 focuses on the healthcare industry as a consumer interested in identifying the treatment programs that produce the best long-term results, including specifically low rates of readmission, and thus, produce the greatest cost-savings. This approach, while practical, comes with it the potential for short-changing the path to final recovery in the name of cost savings.

Over the course of the suggested follow-up intervals, some patients will be readmitted to the same or other addiction treatment programs. Likewise, the event that may have set an individual on the path to recovery may not be captured in these evaluations. There is no obvious way to ensure that treatment programs receive “credit” for helping individuals achieve recovery. It is most important now to develop new frameworks for addiction treatment programs to monitor long-term patient outcomes, for the benefit of patients and their families, to contain short- and long-term costs, and to ensure that referral is to the programs that produce the best long-term outcomes. This report is written to define the ultimate goal of treatment as well as to encourage this development of effective strategies to assess long-term outcomes of treatment.

**Conclusions and General Recommendations for Improving Long-Term Patient Outcomes**

This report advocates for the creation of five-years of abstinence on a path to full recovery as the standard outcome measure of the treatment of individuals with substance use disorders. Although substance use disorders are serious chronic illnesses that require long-term care, the vast majority of addiction treatment programs provide only brief episodes of care. Use of the five-year standard requires the identification of what happens to patients after they are discharged from treatment.

The question of how patients with substance use disorders can best reach the desired outcome of five-year abstinence and full recovery is, for now, largely answered by the evidence provided by the systems of care management termed the New Paradigm for Recovery. These programs demonstrate that long-term abstinence and achieving a higher quality of life can be the outcome for a majority of patients regardless of the drugs they have used. In fact, recovery can be the expected outcome of treating and managing substance use disorders. Such programs require long-term active care management to extend and support relatively brief episodes of addiction treatment. This long-term monitoring of substance use disorders fits into the standard medical model of the care of many chronic diseases and can be managed in a variety of settings including primary care.

Achieving the proposed outcome of five-year abstinence and recovery requires long-term engagement of patients. This includes linking patients and their families prior to and following treatment discharge to primary care physicians for long-term care. It also includes long-term monitoring of substance use with random drug and alcohol tests either by the primary care physicians and/or by external monitoring services. Higher rates of achieving sustained recovery mean lower health care costs and improved health.
The three approaches to outcomes measurement proposed in this report suggest methods of documenting the long-term outcomes of patients treated for substance use disorders and have the potential to be implemented widely. Documenting the long-term outcomes of individuals with substance use disorders discharged from addiction treatment programs should lead to improved care and better delivery of services. Moreover, monitoring the long-term outcomes of patients should assist payers (and families) to assess which programs result in the best outcomes and the most cost-savings.

Making five-year abstinence and recovery a standard outcome measure of treatment evaluation and making these evaluations public could challenge treatment programs and clinicians to focus their efforts to achieve better long-term patient outcomes. Hopefully coupled with innovations in treatment, the demonstrated results of patient monitoring and management following addiction treatment will bring significant improvement in the nation’s public health.
Appendix: Current Substance Use Disorder Treatment Efficacy Standards

There are many varying models of addiction treatment. Some treatment models treat all types (and co-occurring) substance use disorders, while others prioritize the treatment of specific substance use disorders. Additionally, some forms of addiction treatment include the use of medication (e.g. buprenorphine, methadone).

Before reviewing the current treatment efficacy measures for treating addiction and specific substance use disorders, we first review terminology and how practices are evaluated as ‘evidence-based.’

A. Defining ‘Efficacy’ and Evidence-Based Treatment Practices (EBPs)

The term evidence-based treatment refers to interventions, practices, and techniques that have proven to have positive or preferred outcomes through consistent scientific study.\(^a\)\(^b\) Because these interventions are validated by research to ‘work’ their wide implementation is encouraged. Efficacy and effectiveness are terms often used interchangeably; however, in the context of treatment outcomes, they have slightly different meanings. Treatment efficacy is the “clinical benefit produced by the intervention in the context of controlled research”, whereas effectiveness refers to the “clinical benefit produced in a clinical setting under naturalistic conditions” (p.95).\(^c\)

The classification of interventions as evidence-based or effective requires high quality research designs. Randomized controlled trials (RCTs) or rigorous quasi-experimental designs are most commonly used for the purpose of demonstrating efficacy.\(^d\) The accepted standard is a minimum of two rigorous studies with similar findings on key outcomes that demonstrated positive outcomes (see the Food and Drug Administration Model).

To critically evaluate a substance use disorder treatment study, the design is not the only element to consider. Different levels of evidentiary strength create a hierarchy by which researchers can draw conclusions about research findings.\(^e\) These standards are as follows:

- **Gold standard** – multiple replications of RCTs in different sites. There must be significant and sustained reductions in risk behaviors and controls for sample attrition. A preponderance of evidence supporting effectiveness across multiple sites is needed to meet this evidentiary standard. Research designs that adhere to the gold standard have high internal and external validity.


Silver standard – quasi-experimental design with strong statistical controls but includes the same outcome and replication requirements as the more stringent gold standard.

Bronze standard – matched comparison groups without adequate statistical controls.

To determine whether an intervention is effective over time, it is recommended that a longitudinal design be employed in which data is collected at multiple intervals. In the context of the current discussion, extended longitudinal study is needed to assess long-term outcomes of specific interventions and treatments.

The implementation of an intervention is an additional consideration as factors related to delivery and practice can potentially influence treatment outcomes. For example, fidelity to the treatment model, practitioner buy-in and training, delivery setting, and can alter the way in which a patient experiences an intervention which could, subsequently, yield different effects – positive or negative.¹

B. Current EBP Classification Models and Approaches

A multitude of models and approaches are currently utilized by government agencies and the addiction field to determine whether treatment interventions are effective. Some models demand high levels of scientific rigor through RCTs whereas others rely upon synthesis of evidence and practitioner consensus as the basis for evidence-based designations. Table 1 at the end of the Appendix provides an overview of several such models.

Regardless of the approach taken, the longer the study, the more information can be gathered about the effectiveness of the intervention. Longitudinal studies can identify optimal dosages, individual effective components of interventions, and the effectiveness of the intervention among different populations. It is this type of long-term follow-up (e.g., Phase IV in the NIH Guidelines) that elicits valuable information from a practice and performance measurement perspective as it sheds light on what is working well over time.

C. Current Addiction Treatment Efficacy Measures

The following is a review of current efficacy measures used in clinical trials leading to labeled and off-label use for addiction treatment.

Behavioral Therapy

Many studies include a psychotherapy component, commonly as an adjuvant to pharmacotherapy.²¹

Specific methodologies include:

- Motivational enhancement therapy
- Cognitive behavioral therapy
- Contingency management

Pharmacological Therapy
While short-term therapeutic endpoints may be adequate for some targets of addiction treatment, such as overdose and withdrawal, treatment for prevention of relapse and craving management require endpoints that focus on long-term efficacy. Although one may consider these as separate modalities of addiction therapy, it would be inappropriate to say that one approach can be used to obtain successful long-term outcomes, particularly since one cannot begin to consider prevention of relapse without initial adequate detoxification. In addition, treatment of substance dependence to prevent relapse may also serve to manage or prevent withdrawal symptoms; such as with nicotine replacement therapy and opioids for opioid maintenance, among others.

While specific pharmaceuticals used in treatment of underlying addiction vary by substance, efficacy endpoints utilized in clinical trials often focus on relapse prevention, psychological and subjective progress, or social recovery.

Relapse prevention is the primary goal of addiction treatment, allowing for full rehabilitation of patients to lives without substance dependence. Reason would imply that relapse prevention would exclusively refer to abstinence from the substance of use for the full course of a study, but in reality, some clinical trials focus on short-term abstinence of one to three weeks. In defense of this method, some studies have suggested that continuous cocaine and alcohol abstinence of three weeks is predictive of long-term cocaine abstinence. More lenient endpoints may not always be justified, but may be used due to a shorter study duration, high attrition, or perhaps high variability of time to response among patients. Study durations range from 1 week to 2 years, varying widely between treatments of various substances. For example, studies of alcohol dependence range from 4 weeks to 2 years, while duration of studies for treating cocaine dependence have a much shorter range of 5 to 25 weeks. Many studies only recorded outcomes for a mere 12 weeks. Although study duration varies, even in the case

of substantial duration of a year or more, primary endpoints for efficacy may be assessed at much sooner time points, rather than the full length of the study. Another point of interest is that many studies choose retention in treatment as a surrogate for relapse prevention. Although retention in adequate treatment programs is vital to success of a recovering addict, it does not confer that a treatment is efficacious or that a subject does not relapse to some extent. Lastly, a quantification of substance use may be used to demonstrate a change in overall use. While this has the ability to demonstrate treatment efficacy, one cannot use these endpoints to assess whether a patient can attain complete abstinence from a substance with a particular treatment.

Psychological evaluations and subjective progress can be used to characterize a patient’s recovery, their addiction severity (i.e. Addiction Severity Index, Clinical Global Impression score for dependence), cravings (i.e. Visual Analog Scale, Craving Analogue Scale, Voris Cocaine Craving Questionnaire, Obsessive Compulsive Drinking Scale), and/or withdrawal symptoms. Often, additional assessments for depression or anxiety are also included and evaluated. Finally, some studies also examine aspects of social recovery, such as avoidance of criminal activity or re-incarceration, and consistent employment. These endpoints might be considered somewhat secondary to preventing further substance use, but are significant when assessing the effects of treatment on all aspects of recovery.

Table 2 at the end of the Appendix examines these endpoint categories in the context of various treatments for each substance-specific substance use disorder. The agents listed have been studied for their efficacy. Inclusion in this table does not imply that their efficacy has been established.

D. Limitations of Current Efficacy Standards/Models
Current research of treatment interventions suffer from a variety of methodological weaknesses. These include poor research design, unclear or varying definitions of research concepts, low internal and/or external validity, small sample sizes, and insufficient statistical calculations. The way in which the success or efficacy of treatment is measured also varies widely across studies.

Critical analysis of current substance use disorder treatment evidence standards revealed four major limitations:

1. **Follow-up intervals.** Findings of treatment intervention efficacy in the absence of any follow-up post-discharge or exit, fails to make a case for any long-term effects. Most interventions are relatively short in duration and while there may be positive effects in substance use during treatment, there is no way to determine whether those effects are sustained post-treatment. In order to determine whether there is lasting change in substance use behavior, follow-up is necessary. Moreover, a single follow-up interval within a few months of treatment cessation is not enough to establish a finding of prolonged recovery. To determine the duration or decay of effects, and to identify the conditions under which long-term sobriety may be achieved, a longitudinal or cohort study design spanning several years should be selected. This means the funding agencies

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must be willing to “pay it forward” and allow some grants to be extended years, rather than limiting them to just five years. The research team may not be able to discover how successful the treatment was if they are only allowed to follow the participants for one or two years. Reviewers need to understand the importance of longitudinal research. Too often major studies have been shut down when reviewers write on the summary statements that the study lacked innovation, that no new information would come from a longitudinal study, or that not enough publications had been written yet, when the final endpoint had not even been reached. Moreover, grant reviewers could benefit from training on the importance of these study designs.

2. Outcome measure definitions. The absence of standardization or uniform definitions for outcome measures can make comparisons among interventions challenging. For instance, measures such as sobriety, relapse, recovery, and alcohol and other drug use can each be defined very differently according to individual agencies or study methods. A similar problem exists in the criminal justice system with the outcome measure of recidivism. The lack of a uniform definition limits the ability to make accurate comparisons from one agency to another let alone from one jurisdiction to another. Moving forward, the development of standard, agreed-upon treatment outcome measures with universal definitions could be useful.

3. Evidence threshold. There is a lack of agreement among experts on a specific minimum threshold of evidence or cut-off point below which evidence should be considered insufficient for a finding of effectiveness. Similarly, there is debate as to whether a small amount of evidence constitutes no evidence. There is great disparity in outcome effects for alcohol and other drug interventions. As the analysis demonstrated, some ‘evidence-based’ interventions have small or incremental positive results that are present only during the course of the intervention whereas other interventions have pronounced positive results that are sustained over time a much longer timeframe. Yet both may be deemed evidence-based.

4. Treatment success. The limitation of current substance use disorder treatment evidence is the lack of consensus regarding successful outcomes. It is this lack of consensus that motivates the development of the new standard proposed in this report. What treatment outcomes are deemed a success? Long-term recovery, decrease in alcohol and other drug use, or a certain amount of time between discharge and relapse? The answers to these questions are largely dependent on what standard the field wants to hold itself to and whether the perception of treatment success is long-term sobriety or if relapse is considered to be inevitable in most cases.

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Tables

*Table 1 was developed by Erin Holmes, MA. Table 2 was developed by Amelia N. Deitchman, PharmD (PhD Candidate).*

**Table 1. Substance Use Disorder Treatment Models and Requirements to Determine Effectiveness**

<table>
<thead>
<tr>
<th>Model</th>
<th>Purpose and approach</th>
<th>Requirements</th>
</tr>
</thead>
</table>
| Food and Drug Administration (FDA) Guidelines | The FDA is responsible for the review of scientific evidence to determine whether pharmaceutical treatments are safe for public consumption. In order for a medication to be approved by the FDA, there must be a substantial body of evidence that demonstrates that the drug is both safe and effective.                                                                                       | Rigorous standards  
Multiple, replicated RCTs  
High methodological quality of evidence  
Findings of a positive treatment effect relevant to target groups  
Findings replicated in a minimum of two different studies  
Overall consistency of evidence in the direction of effect  
Significant scientific agreement (Taxman and Belenko, 2011)                                                                                                                                                                                                                           |
| National Institutes of Health (NIH) Guidelines | The NIH guidelines translate and expand the FDA model applying it to behavioral health interventions. This model consists of four different phases of clinical trials to evaluate the effectiveness of treatment interventions.                                                                                      | Phase I trials involve a small test group of 20 to 80 subjects. It is at this stage that early indications and evidence of efficacy emerge. These initial trials also identify potential side effects, determine dosages, and evaluate the safety of the intervention (NIH, 2013).  
Phase II trials are larger and involve 100 to 300 subjects. The focus of this phase is to determine the efficacy of the treatment within a controlled setting and a focused target population.  
Phase III trials are conducted in multiple locations and settings where the researchers have less control over a larger number of subjects (1,000-3,000). The multisite nature and extended length of these trials allows researchers to collect longitudinal data and determine effectiveness over time, monitor potential side effects, and make comparisons to other interventions (NIH, 2013).  
Phase IV involves the continued collection of data after the interventions has been marketed.                                                                                                                                                                                               |
| Center for Substance Abuse Prevention (CSAP) Guidelines | The CSAP guidelines are used to classify treatment interventions as evidence-based.                                                                                                                                                                                                                                                                       | Interventions must meet one or more of the following to be considered evidence-based:                                                                                                                                                                                                                                                                                                                  |
The approach utilized by CSAP is advantageous in that there are multiple criteria to determine whether evidence exists to establish effectiveness.

- Inclusion in Federal registries of evidence-based interventions (such as the National Registry of Evidence-Based Programs and Practices (NREPP));
- Reported in peer-reviewed journals with positive effects on the primary targeted outcome; and,
- Documented evidence of effectiveness based on guidelines developed by the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Center for Substance Abuse Prevention (CSAP, 2009). These guidelines require that the intervention be:
  - Based on a theory of change that is documented in a conceptual model;
  - Similar in content and structure to other interventions that are found in Federal registries or academic literature.
  - There should be documentation of instances of past implementation where there was attention to scientific standards of evidence with results that show a pattern of positive effects.
  - The intervention should be “reviewed and deemed appropriate” by a panel of experts comprised of prevention researchers and practitioners (CSAP, 2009).

National Institute on Drug Abuse (NIDA) Principles

NIDA uses a consensus approach in formulating its *Principles of Drug Addiction Treatment* (Taxman and Belenko, 2011). The majority of the Principles are, in fact, considered to be best practices in the field as opposed to empirically validated EBPs. The use of a consensus approach can complement rigorous scientific study. The experiences of practitioners should not be undervalued as they have insight into the barriers and challenges associated with the translation of treatment research into practice in a real-world setting.

Qualitative methods such as focus groups and key informant interviews are used to obtain the professional opinion of practitioners about which practices and interventions they deem effective.
Table 1 References


Table 2. Endpoints in the Treatment of Substance Use Disorders, by Substance

<table>
<thead>
<tr>
<th>Drug</th>
<th>Study Duration</th>
<th>Study Agents</th>
<th>Endpoints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicotine</td>
<td>24 to 52 weeks</td>
<td>varenicline&lt;sup&gt;10–29&lt;/sup&gt;, bupropion sustained release&lt;sup&gt;13,14,17&lt;/sup&gt;, and nicotine replacement&lt;sup&gt;10,11,27&lt;/sup&gt;</td>
<td>Relapse Prevention: Dropouts or treatment retention</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Abstinence</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• 7-day point-prevalence abstinence</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Carbon monoxide-confirmed continuous abstinence at 9, 12, 24, and 52 weeks</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Self-reported at 4 weeks, 6 months, and 2 years</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Smoking less than 5 cigarettes during the previous 6 months, and none in the week prior to visit</td>
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<td></td>
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<td></td>
<td>Cravings</td>
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<td></td>
<td></td>
<td>Psychological and subjective progress</td>
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<td></td>
<td></td>
<td></td>
<td>Social Recovery</td>
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<tr>
<td>Alcohol</td>
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<tr>
<td>Disulfiram</td>
<td>8 to 52 weeks</td>
<td></td>
<td>Abstinence</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Time to first heavy drinking day</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Number of abstinent days</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Consecutive abstinence for 3 or 4 weeks</td>
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<td></td>
<td></td>
<td></td>
<td>• Continuous</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Relapse</td>
</tr>
</tbody>
</table>

Notes: In one study, the consumption of five or more drinks for men and four or more drinks for women was termed a “heavy drinking day”, while other studies used this definition to describe the “relapse” endpoint. Although other studies defined “relapse” slightly differently, as the consumption of more than five drinks in 24 hours (i.e. 40 g of alcohol).
<table>
<thead>
<tr>
<th>Drug</th>
<th>Study Duration</th>
<th>Study Agents</th>
<th>Relapse Prevention</th>
<th>Psychological and subjective progress</th>
<th>Social Recovery</th>
</tr>
</thead>
</table>
| **Opioid antagonists** | 4 to 54 weeks (mode 12 weeks) | naltrexone<sup>34,37-78</sup>, nalmefene<sup>79-81</sup> | Time to relapse, heavy drinking  
  - Variations in definitions range from ≥ 4 SDU to ≥ 9 SDU, with different cut-offs for men versus women in most cases. **Most common**: ≥ 5 SDU for men or 4 for women  
  - Drinking ≥ 5 days per week  
  Degree of drinking  
  - Light, moderate, risky drinking with varying definitions  
  - Drinks per drinking day  
  - “Good clinical outcome” based on amount of drinking  
  Abstinence  
  - Number of days  
  - Cumulative abstinence | Cravings | |
| **Acamprosate** | 8 weeks to 24 months | | Time to relapse, heavy drinking; similar variations as described above  
  - Relapse duration  
  - Relapse severity  
  Degree of drinking  
  - Percent heavy drinking days  
  - Drinks per drinking day  
  - “Good clinical outcome”  
  Abstinence  
  - Days abstinent  
  - Continuous abstinence  
  - Between visit abstinence  
  - Time to first drink | Craving (Clinical Global Impression Scale) | |
<table>
<thead>
<tr>
<th>Drug</th>
<th>Study Duration</th>
<th>Study Agents</th>
<th>Relapse Prevention</th>
<th>Psychological and subjective progress</th>
<th>Social Recovery</th>
</tr>
</thead>
</table>
| Anticonvulsants     | 4 to 52 weeks  | topiramate<sup>24,42,103–110</sup>, gabapentin<sup>111–115</sup>, valproate<sup>111,116,117</sup>, levetiracetam<sup>118,119</sup>, carbamazepine<sup>120–122</sup>, tiagabine<sup>123</sup> | Time to relapse, heavy drinking: similar variations as described above  
- Heavy drinking with or without problems  
- Dropouts  
- Minor, major, severe relapse  

Degree of drinking  
- Moderate drinking  
- Sustained heavy drinking days: 3 consecutive heavy drinking days  
- Duration of heavy drinking  
- Drinks per drinking day, week  

Abstinence  
- Days abstinent  
- Complete abstinence  
- Continuous abstinence  

Cravings (OCDS and Craving Analogue Scale)                                                                                                                                                                                                                     |                                        |                                |
| Opiates             |                |                                                                              |                                                                                                                                                                                                                                                                                                                                                       |                                        |                                |
| Methadone           | 1 month to 2 years |                                                                              | Relapse  
- Heroin use: hair analysis and self-report  
- Illicit drug use: urine drug screen and self-report for heroin, amphetamines, cocaine, barbiturates and alcohol; Frequency ranged from monthly to daily collection  
- Program retention, compliance, continued treatment post-study  

Risk behavior  
- HIV, HCV seroprevalence  
- Syringe sharing  

Health  
Mortality  
Employment  
Education  
Reincarceration |                                        |                                |
<table>
<thead>
<tr>
<th>Drug</th>
<th>Study Duration</th>
<th>Study Agents</th>
<th>Relapse Prevention</th>
<th>Psychological and subjective progress</th>
<th>Social Recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Naltrexone</td>
<td>1 to 12 months (avg 6 months)</td>
<td></td>
<td>Relapse</td>
<td>Cravings</td>
<td>Reincarceration</td>
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<td></td>
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<td></td>
<td>• Retention in treatment</td>
<td>• Cravings</td>
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<td>• Retention without relapse</td>
<td>• Opioid withdrawal ratings</td>
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<td>• Days to drug use: urine drug screen</td>
<td>• Dependence severity rating by patient</td>
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<td>Abstinence</td>
<td>• Psychosocial adjustment and psychopathology</td>
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<td></td>
<td>• Monthly abstinence</td>
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<td></td>
<td>• Complete abstinence</td>
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<tr>
<td>Buprenorphine +/- naloxone</td>
<td>2 to 52 weeks</td>
<td></td>
<td>Relapse</td>
<td>Cravings</td>
<td>Incarceration, criminal behavior</td>
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<td></td>
<td></td>
<td></td>
<td>• Retention in treatment, compliance (attendance)</td>
<td>• Opioid withdrawal ratings</td>
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<td></td>
<td>• Drug use: self-report and urine drug screen for opioids, cocaine, amphetamines, cannabis, and benzodiazepines, breath alcohol</td>
<td>• Dependence severity rating by patient</td>
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<td>Treatment dosage</td>
<td>• Psychosocial adjustment and psychopathology</td>
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<td></td>
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<td>• % taking original dose</td>
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<td>• % requesting dose change</td>
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<td>• Dose adequacy</td>
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<td>continuous abstinence</td>
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<td>Psychosocial Combined with Maintenance Therapy</td>
<td>6 to 48 weeks</td>
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<td>Relapse</td>
<td>Severity of dependence as addiction severity index (ASI) and risk assessment battery</td>
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<td>• Retention in treatment</td>
<td>• Average maintenance treatment dose</td>
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<td>• Compliance to counseling; adherence</td>
<td>• Psychiatric symptoms/psychological distress</td>
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<td>Degree of use by urine drug screen</td>
<td>• Internal-External Locus of Control</td>
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<td>Abstinence</td>
<td>• Interpersonal Trust</td>
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<td>• 3 consecutive weeks</td>
<td>• State-Trait Anxiety</td>
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<td>• Social Desirability</td>
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<td>Criminal activity</td>
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<td>Drug</td>
<td>Study Duration</td>
<td>Study Agents</td>
<td>Relapse Prevention</td>
<td>Psychological and subjective progress</td>
<td>Social Recovery</td>
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<td>Cocaine/Stimulants</td>
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<tr>
<td>Psychostimulants</td>
<td>6 to 24 weeks</td>
<td>modafinil(^{216}), selegiline(^{217}), methylphenidate IR and SR(^{218-220}), dextroamphetamine IR and SR(^{221-224}), mazindol IR(^{225-228}), bupropion IR and SR(^{229-231})</td>
<td>Relapse: • Retention in treatment • Self-reported use 1-3 times weekly urine drug screen Continuous abstinence for 2 or 3 weeks</td>
<td>Cravings (VAS, brief substance craving scale (BSCS), cocaine craving questionnaire (CCQ), or Tiffany Cocaine Craving Scale)</td>
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<tr>
<td>Disulfiram</td>
<td>11 to 12 weeks</td>
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<td>Relapse: • Retention in treatment • Abstinence duration with and without alcohol Degree of use • Frequency and intensity of use: days per week, grams per week • Urine drug screen 3 times per week • Dollar value of daily cocaine use Abstinence: days to continuous abstinence for 3 weeks</td>
<td>Cravings (VAS) Addiction severity index</td>
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<td>Anticonvulsants</td>
<td>1 to 24 weeks</td>
<td>lamotrigine(^{229}), gabapentin(^{239-241}), carbamazepine(^{242-247}), phenytoin(^{248,249}), tiagabine(^{241,250,251}), topiramate(^{252})</td>
<td>Relapse: Study dropout Degree of use • Self-reported • Thrice weekly urine drug screen Weekly abstinence</td>
<td>Cravings</td>
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<td>Drug</td>
<td>Study Duration</td>
<td>Study Agents</td>
<td>Relapse Prevention</td>
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<tr>
<td>Antidepressants</td>
<td>2 to 25 weeks</td>
<td>imipramine, desipramine, fluoxetine, nefazodone, paroxetine, venlafaxine, ritanserin, selegiline, buspirone, gepirone, L-tryptophan, citalopram, sertraline</td>
<td>Relapse: Retention to treatment, attendance, Study dropouts, Abstinence</td>
<td>Cravings (cocaine craving scale, VAS)</td>
<td>Addiction severity index</td>
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<td>Severity of use: Self-reported use, 13-items Quantitative Cocaine Inventory (QCI)</td>
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<td>Abstinence: Longest period of continuous abstinence, Continuous abstinence for 3 weeks</td>
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<td>Dopamine agonists</td>
<td>1.5 to 16 weeks</td>
<td>carbidopa/levodopa, amantadine, pramipexole</td>
<td>Relapse: Retention in treatment, Degree of use by urine drug screen</td>
<td>Cravings: VAS, Voris Cocaine Craving Questionnaire</td>
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<td>Degree of use by urine drug screen</td>
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<td>Severity of dependence: CGIS, ASI</td>
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<td>Antipsychotics</td>
<td>5-168 days</td>
<td>haloperidol, risperidone, olanzapine</td>
<td>Relapse: Retention in treatment</td>
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<td>Cannabis</td>
<td>11-13 weeks</td>
<td>dronabinol, lofexidine, divalproex, nefazodone, bupropion SR, lithium, entacapone</td>
<td>Relapse: Treatment retention, Time to dropout, Degree of use</td>
<td></td>
<td>Craving (Marijuana Craving Questionnaire)</td>
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<td></td>
<td>Degree of use: Self-reported use – strong</td>
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<td>Severity of dependence: CGIS</td>
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<tr>
<td>Drug</td>
<td>Study Duration</td>
<td>Study Agents</td>
<td>Relapse Prevention</td>
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</table>
|      |                | atomoxetine\(^{304,305}\), buspirone\(^{306}\), fluoxetine | correspondence to urine drug screen\(^{300}\)  
- Days of use per week  
- Hits per day\(^{307}\)  
- Urine drug screens (except when treated with dronabinol) for cannabinoids, opiates, methadone, barbiturates, amphetamine and cocaine  
- Dollar amount spent on cannabis since last visit  
Abstinence  
- Number consecutive days of abstinence  
- Abstinence during the final 2 weeks of treatment  
- 3 consecutive weeks of abstinence | | |

Notes: Interestingly, one study\(^{308}\) followed a group of ten adolescents treated with 12 weeks of fluoxetine for major depression with comorbid alcohol and cannabis abuse. After one, three, and five years, dependence was determined based on DSM-IV criteria. This is the only study found with such extensive follow-up that used diagnostic criteria to evaluate absence of dependence.
Table 2. References


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