



Treating Tobacco Use Disorder in Behavioral Health Populations:

Innovative Approaches and
Uses of Approved Medications

A Project of  **CAI**

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Executive Summary

Tobacco use, especially cigarette smoking, is the leading preventable cause of chronic disease and death in the United States. Individuals with serious mental illness smoke at much higher rates than the general population and, as a result, suffer more smoking-related morbidity and mortality.

Treating tobacco use disorder (TUD) in behavioral health populations, including individuals with serious mental illness and substance use, should be part of an overall recovery process, as central to care as treating the underlying mental illness and substance use disorder.

The focus of this report is on innovative uses of approved medications that improve treatment outcomes of TUD. It draws from the Public Health Service Clinical Practice Guidelines on *Treating Tobacco Use and Dependence*, the *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.)^{1,2} and other primary source materials. It provides an overview of the seven FDA-approved medications for treating tobacco use, recommended use of those medications associated with improved outcomes, and key messages for treating TUD in behavioral health populations.

It is intended for [behavioral health providers](#) (BHPs) practicing in all treatment settings and highlights the important role that BHPs have in addressing tobacco use. Below is an overview of key messages.



Key Messages



Key Message 1

Tobacco use disorder (TUD) is an addiction and should be treated as a chronic relapsing condition



Key Message 2

FDA-approved medications for treating TUD are effective



Key Message 3

FDA-approved medications for treating TUD are safe



Key Message 4

Medication-Assisted Treatment (MAT) is the gold standard for treating TUD



Key Message 5

Varenicline, when used as monotherapy **OR** combination nicotine replacement therapy are the two most effective medication treatment options for TUD



Key Message 6

Consider using higher dosages of NRT and increase duration of medication treatment



Key Message 7

MAT should be considered for behavioral health clients who may not yet be ready to treat their TUD

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Introduction

Although overall smoking rates in the United States have declined significantly, tobacco use is still the leading preventable cause of disease, disability, and death. Nicotine is the addictive component in all tobacco products, and [tobacco use disorder](#) (TUD) should be treated as a chronic relapsing condition.^{3,4,5,6}

Disparities in tobacco use and resulting chronic conditions are evident in behavioral health populations, defined here as those with serious mental illness and substance use disorders, who are most negatively affected.

Tobacco use itself impacts multiple behavioral health outcomes because it is:

- ✓ **Associated with a greatly increased risk of substance use disorder relapse.⁷**
- ✓ **May interact with or compromise the efficacy of antipsychotic medication treatment.**

Compared to the general population, individuals with serious mental illness or substance use disorder are disproportionately affected by tobacco use disorder with rates at least double that of the general population, and in the case of serious mental illness, it can be much higher.⁸

BHPs play an important role in providing enhanced services to treat TUD and are well positioned to provide their patients with effective TUD treatment.

The recent popularity of electronic cigarettes has added complexity to the treatment of TUD as the e-cigarette industry has promoted their products as smoking devices with harm reduction potential. However, research surrounding the efficacy of e-cigarettes to actually reduce harm remains unclear.⁹

The U.S. Food and Drug Administration (FDA) defines electronic cigarettes or Electronic Nicotine Delivery Systems (ENDS) as non-combustible tobacco products. The FDA does not, regulate, closely monitor, or test ENDS ingredients as it does with other medications so chemicals in ENDS, including nicotine content, can vary greatly.

Other countries, including the UK and in the EU, have a cap on nicotine content of 20mg/mL. Most ENDS products sold in the US have 2-3 times this content.¹⁰ There is insufficient data to suggest that using ENDS increases cessation or reduces cigarette smoking. Thus, the use of ENDS should be treated as a form of TUD requiring evidence-based treatment services.

The purpose of this report is to provide BHPs practicing in outpatient, hospital, residential, integrated and stand-alone settings, updated information on innovative medication-based tobacco use treatment approaches. BHPs can use these approaches to dramatically improve health outcomes in behavioral health populations.¹¹

Notes for this Report

In this report, we highlight evidenced-based approaches to treating TUD in behavioral health patients. Several medication treatment options are discussed that research shows are effective for behavioral health patients who use tobacco products. This report also provides important considerations for addressing and improving treatment outcomes of TUD within behavioral health settings.

Throughout this report we will be using the term tobacco use disorder (TUD) rather than tobacco dependence or nicotine addiction. This is due to recent changes to the substance use disorder section of the Diagnostic and Statistical Manual of Mental Disorders, the fifth edition (DSM-V). The term dependence and addiction in previous versions of the DSM had dual meanings. In order to avoid confusion between the terms, the fifth edition (DSM-V) now uses the over-arching term substance use disorder.¹²

Additionally, we define behavioral health providers (BHPs) as a provider who has been trained to provide mental health and substance use services. Typically, BHPs are psychologists, social workers, licensed professional counselors, and psychiatrists. For more of our established definitions of terms please see the [Definitions section](#).



Disclaimer: *The key messages presented in this report are recommendations and considerations for treating TUD, not mandates, and cannot account for all potential clinical circumstances. Behavioral health providers are encouraged to apply the recommendations in the clinical context of each individual patient.*

Key Messages for Treating Tobacco Use Disorder in Behavioral Health Populations

Key Message 1

Tobacco use disorder is an addiction and should be treated as a chronic relapsing condition.

The National Institute of Drug Abuse (NIDA) defines addiction as a chronic disease similar to other chronic diseases such as diabetes and cardiovascular disease. As a definitive source of information on TUD, NIDA provides a wealth of evidence-based information for health care providers. NIDA has historically framed TUD by outcome measures in terms of quitting, cessation, and abstinence. This, however, is changing.

In a NIDA-sponsored study known as, “Ask about smoking, not quitting: a chronic disease approach to assessing and treating tobacco use,”¹³ the authors noted that treatment—both counseling and pharmacotherapy—may be needed at various intervals for extended periods of time, perhaps over an individual’s lifetime.

In many ways, this would mirror the treatment of other chronic conditions, such as diabetes, hypertension, hyperlipidemia, opioid use disorder, or alcohol use disorder. Unfortunately, clinical trials of TUD treatment still generally model outcome measures in terms of cessation, abstinence, or quitting, measured at discrete time points.

In making a shift away from these terms, BHPs can reinforce to their patients that tobacco use is a recurring and remitting behavior

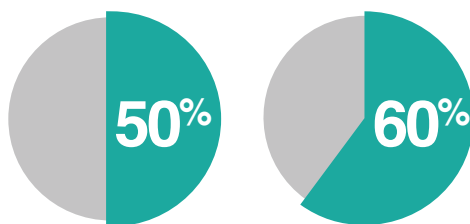
— one that is not simply “cured.”



**Key
Message 2**

FDA-approved medications for treating tobacco use disorder include five nicotine replacement therapies (patch, gum, lozenge, nasal spray and inhaler), and two medications (varenicline and bupropion). All are effective evidence-based pharmacotherapies.

All seven FDA-approved medications for treating TUD are deemed effective. Overall effectiveness will vary depending upon how these medications are prescribed. Of the seven FDA-approved medications, five contain nicotine and are referred to as nicotine replacement therapies (NRT). Two medications do not contain nicotine.¹³ All forms of NRT use improve the odds of a positive TUD treatment outcomes.



One study, for instance, demonstrated that the chances of successfully treating TUD were increased by 50% to 60% as a result of NRT use.¹⁴

NRTs alleviate the physiological and psychomotor withdrawal symptoms that otherwise occur in the absence of “usual levels” of nicotine, thus decreasing motivation to use tobacco. They deliver nicotine in safer and less addictive formats than cigarettes and other tobacco products. The two tobacco use treatment medications that do not contain nicotine are varenicline (varenicline tartrate, sold as Chantix® in the United States, Champix® in Europe) and bupropion (bupropion, sold as Zyban® or Wellbutrin®). Both come in tablet form and are only available by prescription.

Nicotine Replacement Therapies (NRT):

Nicotine Transdermal Patches.



The nicotine patch is a long-acting product that can deliver nicotine continuously for up to 24 hours; whereas the oral/nasal products are shorter-acting (i.e., up to 2 hours per dose). Patches are applied to the skin and deliver nicotine at a relatively steady rate. They are available in a range of dosages, which permits variation, as a function of the degree of nicotine addiction.

Nicotine Gum.



This was the first NRT made available to consumers. It is absorbed through the oral mucosa and importantly, is not chewed like ordinary confectionary gum. Nicotine gum is intermittently chewed until a flavored taste and tingling sensation is experienced by the user. User should then hold or park the nicotine gum between the cheek and their gums for up to 30 minutes or until the taste dissolves. Nicotine is absorbed through the oral mucosa during this phase.

Nicotine Lozenge.



Like nicotine gum, the lozenge is not chewed. Instead, it dissolves in the mouth over approximately 30 minutes, with some variation across individuals. As with nicotine gum, nicotine from the lozenge is absorbed slowly through the oral mucosa and delivered into systemic circulation. The lozenge provides an alternative to the gum for persons who need intermittent and controllable nicotine dosing, but who do not find gum chewing acceptable. The amount of nicotine absorbed per lozenge is somewhat higher than that delivered by gum.





Nicotine Oral Inhaler.

This NRT is only available by prescription. The inhaler consists of a mouthpiece and a plastic cartridge containing nicotine. It was designed to satisfy behavioral aspects of smoking, namely, the hand-to-mouth ritual, while delivering nicotine to reduce physiological withdrawal symptoms produced by tobacco withdrawal.

It is important to note that although termed an “inhaler” the majority of nicotine is delivered into the oral cavity (36%) and in the esophagus/stomach (36%). Very little nicotine is delivered to the lung (4%). The rate of absorption is similar to that of nicotine gum and nicotine lozenges.



Nicotine Nasal Spray.

This NRT is available only by prescription. The option of nasal spray was designed to deliver doses of nicotine more rapidly. The device available to consumers is a multi-dose bottle with a pump mechanism fitted to a nozzle that delivers 0.5 mg of nicotine per 50-uL squirt. Each dose consists of two squirts, one to each nostril. Nicotine nasal spray is absorbed into the blood more rapidly than all other NRT forms.

Non-Nicotine Therapies or Tobacco Use Treatment Medications:



Varenicline.

Available only by prescription, varenicline is a partial agonist of the alpha4/beta2 subtype of the nicotinic acetylcholine receptor and works by reducing the urge and craving for nicotine, and by decreasing its pleasurable effects on the brain.



Bupropion.

Also available only by prescription, bupropion exerts its effect primarily through the inhibition of dopamine reuptake into neuronal synaptic vesicles. It is also a weak noradrenalin reuptake inhibitor and has no effect on the serotonin system. In the form of Zyban®, it is packaged for treating tobacco use. As Wellbutrin®, it is prescribed as an anti-depressant medication.

**For More Information on Each Medication
Including Contraindications Please
See the Appendices**



Key Message 3

FDA-approved medications for tobacco use disorder are safe and there are no significant increases in neuropsychiatric adverse events associated with prescribing them to behavioral health populations.

The cumulative evidence indicates that the entire spectrum of NRT medications is safe, and effective. Used in standard doses, NRT does not deliver nicotine as rapidly as a cigarette and other tobacco products (i.e., hookahs, smokeless tobacco, or cigars). Indeed, smoking produces higher peaks of nicotine in contrast to NRT.¹⁵

In essence, NRT is a low-dose nicotine product producing a stable minimal level of blood nicotine – enough to avert craving, but not enough to have high addictive liability.

One of the most common misconceptions regarding the safety of NRT use involves concern about cardiovascular disease. The misconception usually involves nicotine patches and the belief that they increase the risk of heart attacks, especially for people who smoke and use nicotine patches simultaneously. However, studies have shown that there is no increased likelihood of cardiovascular events from NRT, when compared with people who continue to smoke.^{16,17} The benefit of NRT to enhance efforts to quit smoking successfully is clear and convincing. Additionally, NRT is even more effective when it is used in conjunction with other treatment approaches, such as counseling.

Overall, the accumulating evidence strongly suggests that the benefits of nicotine pharmacotherapy use to treat TUD greatly outweigh any risks, even among smokers with stable heart disease. Also, the concomitant use of tobacco and NRT does not result in increased risk to a person's health.¹⁸ Further, from a behavioral perspective it has been shown that smokers tend to titrate their nicotine intake to achieve a relative constant dose, which could lead to a reduced intake of combustion products and a favorable risk–benefit profile.¹⁹ Thus, concomitant use may lead to lower exposure to the harmful combustion products of tobacco smoke. The side effects from using NRT are minimal. When they do occur, they are usually related to skin irritation from patches and irritation to the inside of the mouth from gum and lozenges. Given the large amount of research and cumulative evidence on the efficacy of NRT, it is common for clinical guidelines to recommend its use as a first line treatment for people seeking pharmacological help to treat their addiction to tobacco.^{20,21}

Pfizer --the manufacturer of varenicline-- was commissioned by the FDA to undertake a large randomized, double blind trial to study the comparative safety and efficacy of varenicline, bupropion, nicotine patch, and placebo.



Referred to as the EAGLE study (*Evaluating Adverse Events in a Global Smoking Cessation Study*)²² 8,144 participants were enrolled from clinical trial centers, academic centers, and outpatient clinics, across 16 countries, between Nov, 2011, and Jan, 2015.

This trial allowed for comparisons of TUD treatments among smokers with and without co-occurring psychiatric disorders. Results of this study showed positive effects of both medications in terms of achieving abstinence. Varenicline was significantly more effective than the nicotine patch or placebo. Bupropion was significantly more effective than placebo, but not more effective than the nicotine patch. Importantly, there was no significant increase in neuropsychiatric adverse events attributable to any of the three treatment conditions in comparison with the placebo condition.

Safety of these medications is also addressed by a number of other studies. A review published in *Nicotine & Tobacco Research*, titled *Varenicline as a Cause of Suicidal Outcomes*, reviewed post-marketing analyses, case reports, clinical trials, uncontrolled observational studies, controlled observational studies, and studies of smokers with psychiatric problems that have associated varenicline use with suicidal behaviors.²³

The study concluded that among the more rigorous study designs (pooled analyses of placebo-controlled trials or large controlled observational studies):

Evidence consistently showed that varenicline either does not cause increased suicidal outcomes or if an association does exist, the effect is minor.

Further, a study published in the British Medical Journal, entitled *Risk of neuropsychiatric adverse events associated with varenicline: systematic review and meta-analysis*, found no evidence of an increased risk of suicide or attempted suicide, suicidal ideation, depression, or death linked to varenicline.²⁴ Other studies have found similar null associations.



A study in Current Medical Research and Opinion, entitled *A double-blind study evaluating the long-term safety of varenicline for smoking cessation*, demonstrated that 1 mg of varenicline taken twice daily can be safely used for up to one year.²⁵

Additionally, a Cochrane review of Antidepressants for smoking cessation examined 65 trials of bupropion and found that serious adverse events were rare and did not lead to stopping use of the medication.²⁶ Although bupropion-SR has been associated with adverse effects on patients with bipolar disorder and/or a history of eating disorders, it has largely proven to be a safe medication for the vast majority of people with TUD.²⁷ With the caveat that this medication should not be provided to those with bipolar or eating disorders, it is a valuable treatment for TUD. Overall, this body of reviewed evidence from these and other studies prompted the U.S. FDA to remove the black box label warnings from both varenicline and bupropion. The black box warnings alerted patients about the risk for serious neuropsychiatric events seen in patients quitting smoking.

Prescribing Considerations.

When prescribing medications to treat TUD, treatment should be individualized based on a patient's psychiatric disorder, current medications, how the medications interact with tobacco use, and costs. Decisions also need to reflect the patient's preference, smoking habits, and tolerance of adverse effects, including nicotine withdrawal symptoms.²⁸

During the treatment process, the dosage of medications designed to treat TUD, may need to be adapted to the specific needs of the patient. Tar in tobacco smoke may change the metabolism of many antipsychotics, antidepressants, and anxiolytic medications,²⁹ thus when smokers initially quit, blood levels of psychotropic medications may rapidly rise, increasing the risk of side effects if dosages are not reduced.³⁰



Key Message 4

Medication-Assisted Treatment (MAT) is the gold standard for treating tobacco use disorder.

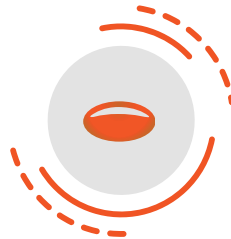
Medication-assisted treatment (MAT) is the use of medications in combination with behavioral support to treat substance use disorders.³¹ Evidence from a Cochrane review strongly supports the idea that combining pharmacotherapy and behavioral interventions is, in fact, the ideal treatment for TUD. The Cochrane group reviewed fifty-three studies, with more than 25,000 participants, and results indicated that using a combination of behavioral support and medication significantly increased the chances of successfully treating TUD by 70 to 100 percent for at least six months compared with only brief advice or support.

MAT interventions for smokers with serious mental illnesses.

There is evidence that supports the use of medication assisted treatment for TUD as effective and safe for those with serious mental illness including schizophrenia, bipolar disorder, and major depression. These severe mental illnesses are not worsened by using MAT to treat TUD. **MAT is recommended with two important caveats:**

- ✓ **behavioral health providers must monitor and adjust psychotropic medication levels to ensure that side effects don't emerge as nicotine use declines**
- ✓ **bupropion should not be prescribed when there is a history of eating disorder or bipolar disorder**

Moreover, people with one or more of these mental health issues do not experience an increase in their psychiatric symptoms when they are in the process of treating their TUD. Specifically, for schizophrenia a review of clinical trials sheds some valuable light on this point. Among stable but symptomatic persons being treated for schizophrenia (on an outpatient basis), MAT was associated with a significant increase in abstinence rates in contrast to placebo-control groups. MAT included bupropion, varenicline, and various forms of NRT.³³



Another study provided evidence supporting the effectiveness and safety of Varenicline, in combination with behavioral support and counseling, among persons dealing with bipolar disorder and major depressive disorder.³⁴

Although more research is needed regarding specific treatment guidelines for treating TUD among people dealing with bipolar disorder and major depressive disorder, controlled clinical trials have yet to produce negative findings relative to the use of MAT exacerbating psychiatric conditions or symptoms.³⁵ However, it has been suggested that persons dealing with bipolar disorder and/or major depressive disorder – who are also attempting to treat TUD—may require additional periods of maintenance on MAT.³⁶ BHPs can further support this protracted maintenance period through the use of behavioral counseling and support.

Treating TUD with MAT is associated with long-term improvement in both psychiatric symptoms and cognitive functioning among people with Serious Mental Illness.^{37,38}



Key Message 5

Varenicline, when used as a monotherapy OR a combination of a long-acting plus a short-acting nicotine replacement therapy, are the two most effective pharmacotherapy options for tobacco use disorder.

Varenicline as a monotherapy.

A substantial amount of research now provides robust evidence regarding the efficacy of varenicline. Summarized in a Cochrane review, results of 39 studies comparing varenicline to placebo, bupropion, or the nicotine patch found the following:³⁹

27
trials

with 12,625 people showed that varenicline at standard dose (1mg twice a day) more than doubled the chances of quitting compared with placebo

5
trials

with 5,877 people showed that the number of people stopping smoking with varenicline was higher than with bupropion

8
trials

with 6,264 people showed the number of people stopping smoking with varenicline was higher than NRT

Combination NRT.

Alternatively, research shows that using combination NRT is as effective as prescribing varenicline. Combination NRT involves the use of a long acting NRT (patch) in combination with a short acting NRT (gum, lozenge, inhaler, or nasal spray). A Cochrane Review covering 267 studies, involving 101,804 participants found that combining two types of NRT ⁴⁰ was as effective as using varenicline, and helped more people to quit than single types of NRT.

The patch provides long lasting and consistent levels of nicotine while the short acting NRT delivers nicotine at a high rate for a short period of time. This combination provides the advantages of a steady dose of nicotine from the patch augmented with increased nicotine for short periods in response to cravings and other withdrawal symptoms. According to the Clinical Practice Guidelines for Treating Tobacco Use and Addiction: 2008 Update, there is evidence that using combination NRT may be particularly effective in suppressing tobacco withdrawal symptoms, which may be especially helpful to highly dependent smokers or those with a history of severe withdrawal.

A Cochrane Review of 63 trials covering 41,509 participants showed that combination NRT works better than prescribing a single form of NRT alone.⁴¹ Using the patch along with another type of NRT such as gum or lozenge together made it 15% to 36% more likely that an individual would successfully stop smoking than if they had used a single NRT.

Meta-analyses also have found that combining 2 different nicotine replacement products (such as the nicotine patch and lozenge) was associated with quit rates similar to varenicline alone.^{42,43} The use of varenicline or combination nicotine replacement plus behavioral support should be used as first-line treatment.⁴⁴ (*Refer to Key Message 4 for more background and details.*)

The odds of successful treatment are three to four times higher with varenicline OR combination long-acting plus short-acting NRT compared with placebo.



Key Message 6

Behavioral health providers should consider using higher dosages of NRT medication as well as increasing the duration of medication treatment for behavioral health patients to improve outcomes of tobacco use disorder treatment.

Dosing considerations are key when treating patients with behavioral health conditions for TUD. Evidence shows that those with these conditions are likely to smoke at higher levels consuming more cigarettes per day and be more highly addicted to nicotine.⁴⁵ Higher doses of NRT and longer durations of treatment may be necessary to account for the severity of addiction.

One study determined that higher dose nicotine patches are more efficacious than lower dose patches among heavy smokers.^{46,47} Another study among smokeless tobacco users found that high-dose nicotine patch therapy resulted in a greater reduction of tobacco withdrawal symptoms among smokeless tobacco users using at least three cans of smokeless tobacco per week. The study concluded that high-dose nicotine patch therapy is safe and well tolerated in this population of tobacco users.⁴⁸

Regarding the duration of therapy for behavioral health patients, evidence suggests that it may be beneficial to continue medication treatment for longer periods, even indefinitely, to prevent relapse to smoking. This strategy is similar to what is used in methadone maintenance programs for heroin-dependent patients, where patients may be maintained on daily doses of methadone for years.⁴⁹ Although nicotine is not entirely without risk, nicotine maintenance with approved treatments is clearly safer than tobacco-delivered nicotine (with its hundreds of accompanying toxins and carcinogens).

Therefore, indefinite use of medication to prevent relapse may be considered for some patients. A Cochrane review of relapse prevention interventions for smoking cessation found that the most promising treatments involved extending treatment with tobacco use treatment medication, in particular, varenicline.⁵⁰

Additionally, a study on “maintenance therapy” with varenicline demonstrated that smokers who achieved abstinence for at least 7 days at the end of 12 weeks of treatment and were then given an additional 12 weeks of varenicline treatment showed significantly greater continuous abstinence in the next period of 12 weeks compared with persons not receiving this added 12-week regimen. This difference was maintained for one year.⁵¹ Following an initial 7-day period of abstinence from nicotine, extending varenicline treatment for an additional 12 weeks appears to be an efficacious strategy for treating TUD.



Key Message 7

Medication assisted treatment should be considered for behavioral health patients who may not yet be ready to treat their tobacco use disorder (precontemplation stage) but would benefit from reduced smoking.

For behavioral health patients who are not ready to stop using tobacco, TUD treatment medications and NRT can be started prior to abstinence and can substantially improve chances of successfully treating TUD.⁵² Multiple systematic reviews of randomized, controlled trials indicated that NRT is an effective intervention in achieving sustained abstinence for smokers who have no intention to quit immediately or are simply unable to attempt an abrupt end to their addiction.



In these studies, the effectiveness of NRT was usually augmented with regular behavioral support and monitoring.^{53,54}

Another review examined whether a reduction in smoking among those not currently interested in quitting (i.e., persons who were less than fully committed) may undermine future cessation efforts. It also investigated whether a reduction in smoking among those not currently interested in quitting decreases the risks of developing smoking-related diseases.

The review found that reduction in smoking among those not currently interested in quitting did not undermine future cessation efforts, and evidence suggested that reduction was associated with greater efforts at future cessation.⁵⁵ In a related meta-analysis of smokers entering cessation programs but not being fully committed to quitting, it was reported that varenicline was associated with higher rates of abstinence from tobacco when compared with other cessation medications, with cessation rates at 6 months of 33.2% compared with 23.4% for the nicotine patch and 24.2% for bupropion.⁵⁶

Varenicline has an accepted dosing regimen where patients can gradually reduce smoking while using the medication. The dosing regimen recommends that a patient start varenicline and reduce smoking 50% by week 4, reduce an additional 50% by week 8, and continue reducing smoking with a goal of complete abstinence by week 12. It also recommends that patients who achieve abstinence by 12 weeks continue to take varenicline for another 12 weeks as it increases their chances of maintaining abstinence.⁵⁷ Another study found that using NRT prior to quitting may improve quit rates versus using it beginning on the quit date only.⁵⁸

There is also evidence that NRT sampling can meaningfully impact motivation and self-efficacy surrounding cessation, even for those with low or no motivation to quit. NRT sampling involves engaging smokers in the process of quitting without any expectation for them to quit immediately or abruptly by providing starter packs of NRT.^{59,60,61}

All medication options are safe to use prior to actual quitting, though bupropion does have more contraindications to consider prior to starting than NRT or varenicline.

Considerations for Behavioral Health Treatment Settings

In addition to the key messages above, there are other important considerations related to improving tobacco use treatment within behavioral health settings. A primary consideration involves ensuring that comprehensive treatment of TUD and addiction be prioritized in behavioral health treatment settings, when practical. Behavioral health treatment settings should have strong tobacco-free policies that address both indoor and outdoor spaces. These and other considerations are addressed below.

Psychiatric hospitalizations provide a unique opportunity to treat tobacco use:



Although hospital-based settings, specifically psychiatric hospitals, have not traditionally been viewed as a “golden opportunity” to help patients treat their addiction to tobacco, the infrastructure of psychiatric hospitals is indeed conducive to BHPs achieving great success with behavioral health patients housed in these settings. For instance, from the moment of intake until the moment of discharge, persons housed in these highly structured settings are likely to pass through several cycles of periodic success and failure in their efforts to treat TUD. Given the constant availability of BHP-guided programming to treat TUD, the periods of failure can become times to engage and/or re-engage these patients in treating their TUD.

The result of this ongoing presence of a program to treat TUD is an integrated care model that can be streamlined by delivery through either a single BHP, or through a team approach.

Promoting the use of NRT to support social inclusion:

Social inclusion offers opportunities for patients to re-engage with the community and form positive relationships which may lead to a higher quality of life. NRT serves not only to treat TUD but may be a means to improve social inclusion for behavioral health patients. Since individuals impacted by behavioral health problems are disproportionately affected by TUD, use of tobacco products may prevent patients from being able to participate in everyday activities within the community.

Over the last 10 years, social norms around smoking have become much more restrictive. Smoking is not allowed in many public and private spaces including places of employment, parks and playgrounds, religious worship centers, restaurants and spaces for social gatherings, public transportation etc.

Additionally, as of July 31, 2018 all Public Housing Agencies (PHAs) across the United States adopted and implemented a policy that requires all PHA properties funded by Department of Housing and Urban Development to be 100% smoke free indoors, and within 25 feet of buildings.

Other housing authorities are following suit. It is also harder for smokers to gain employment. A study comparing employment in smokers and nonsmokers showed that by 12 months, smokers were less likely to have found a job than nonsmokers.⁶⁷ Providers should explore encouraging patients (no matter what stages of change they are in) to use NRT to not only treat their tobacco use but to improve their quality of life in other key areas.

Leverage peer support to enhance treatment of tobacco use:

Behavioral health programs should consider leveraging peers to enhance treatment of tobacco use. Research has shown that generally partnering with a trained peer who has ‘lived experience’ can improve quit rates for people with mental illnesses and addiction.⁶⁸

Additionally, results from the evaluation of CHOICES, a Peer-to-Peer Tobacco Education and Advocacy consumer driven program for addressing tobacco in people with mental illness, is promising.⁶⁹

Outpatient smokers who received a CHOICES peer-to-peer session at 1-month follow up, reported smoking an average of 13 cigarettes per day which was significantly lower than the baseline of 19. Also, 29% of participants tried to quit smoking in the month after the peer session and another 55% reduced their smoking. Feedback from smokers about the program was positive, as 71% said it was a lot easier to talk with another tobacco user about smoking compared to their psychiatrist or other staff. Peer-to-peer communication about tobacco use can be an effective approach to increase awareness and change smoking behavior for people with mental illnesses and addiction.





Addressing employee smoking:

Employee smoking can be a barrier to effective TUD treatment in behavioral health settings. Staff who use tobacco are less likely to encourage TUD treatment among patients than those who do not use tobacco; and they are more likely to perceive obstacles, rather than opportunities, to providing treatment.⁷⁰

Additionally, staff who smoke while at work can unintentionally trigger patients who may be struggling to avoid the sight or smell of tobacco. Staff that use tobacco can unintentionally convey a mixed message about the importance of treating tobacco use if the patient knows the staff member is also an active tobacco user. Senior leadership, human resources and other motivated staff should develop and launch tobacco-free initiatives, and create opportunities for staff to increase skills related to tobacco interventions and to explore how their own tobacco use might impact the quality of service delivery.

By addressing employee smoking behavioral health programs can promote staff health and wellness and improve health outcomes for patients.

Adopt system improvements that integrate TUD treatment into routine clinical care:

Given that behavioral health programs are well-positioned to deliver counseling and evidence-based programs to treat TUD, it is important that treatment is integrated into behavioral health services. Some important principles are:

- ✓ Behavioral health programs should work to institutionalize TUD treatment interventions into routine clinical care to ensure that every patient is properly screened for tobacco use, that tobacco use status is documented in the medical record, and that patients who are diagnosed with TUD are provided with options for evidence-based treatments.
- ✓ Systems improvements should be tailored to the specific behavioral health facility's culture, its financial resources, workflow, and staffing arrangements, referral resources, patient populations, electronic health records functionality, and internal and external quality improvement requirements.
- ✓ Provide TUD services in harmony with services related to substance use disorder.
- ✓ Recognize that a strong association exists between mental health issues and TUD⁷¹— this means that “dual treatment” is necessary.
- ✓ Use the established patient-counselor relationship to maximize treatment outcomes for all three issues (TUD, mental health issues, and substance use disorder).

Conclusion

Tobacco Use Disorder (TUD) is the single most devastating addiction in the United States, and the leading cause of preventable morbidity and mortality. Patients with behavioral health conditions, compared with the general population, suffer inordinately from TUD and subsequent chronic disease. Behavioral Health Providers (BHPs) can play a critical role in treating this addiction in their patients by employing FDA-approved medications in innovative ways.

The most effective pharmacotherapy methods are varenicline and combination long-acting and short-acting nicotine replacement therapy. Both methods are safe for behavioral health populations and have similar side effect profiles as placebo. For patients in precontemplation mode, starting TUD treatment with medication is effective, leads to better treatment outcomes, and may improve quality of life. The use of these medications combined with provider counseling and behavioral support (MAT) effectively increase the odds of patients reducing tobacco consumption and enhance treatment outcomes overall, thus reducing the negative health effects of tobacco products on behavioral health patients. BHPs can optimally assist their patients by treating TUD using MAT and behavioral health support.

An added skill for BHPs is to foster a community norm within behavioral health settings of prioritizing TUD treatment as well as accepting and praising people who boldly commit to treating their TUD. Developing leadership from within the BHP community (e.g., finding a popular opinion leader who can be a “champion” of treating TUD) may be one of the best methods available for developing this norm.

BHPs and other professionals must advocate for improved policy supports for treating TUD. For example, it is entirely reasonable (and consistent with the idea of changing community norms) that all out-patient mental health treatment programs should exist within smoke-free physical environments. Within these environments, the installation and support of programs to treat TUD should include mandated access to, and assistance from, health systems improvement programs. Finally, it is vital to advocate for strong benefits for pharmacotherapy which have no prior authorization or course limits and broad insurance coverage of TUD treatment programs when they are integrated into a larger model of care.



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Center for Health Systems Improvement for a Tobacco-Free New York:

Launched in July 2014 by CAI and funded by the NYS Department of Health's Bureau of Tobacco Control, the Center for Health Systems Improvement for a Tobacco-Free New York C-HSI supports health systems improvement grantees across New York State by developing resources and tools to integrate TUD treatment into primary care, behavioral health, and substance use treatment settings. These resources include webinars, training resources, and tobacco treatment financing resources that support the universal provision of evidence-based tobacco use treatment services.

The New York State Tobacco Control Program (NYS TCP):

The New York State Department of Health envisions a tobacco-free and vape-free society for all New Yorkers. The Bureau of Tobacco Control administers the state's Tobacco Control Program (TCP) to reduce illness, disability and death related to tobacco use and secondhand smoke exposure, and to alleviate the social and economic burdens caused by tobacco use. TCP uses an evidence-based, policy-driven and cost-effective approach to decrease tobacco initiation by youth, motivate adult smokers to quit, and eliminate exposure to secondhand smoke.

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Definitions

Behavioral Health.

Behavioral health care includes mental health care, substance use disorder treatment and care, health behavior change, and attention to family and other psychosocial factors.⁷²

Behavioral Health Provider (BHP).

A behavioral health provider offers care to people who experience mental health and substance use challenges by offering services such as assessment, diagnosis, treatment, medication, counseling and support. Providers may include psychiatrists, psychologists, licensed clinical social workers, licensed mental health counselors, psychiatric mental health nurses, psychiatric nurse practitioners, advance practice registered nurses, registered professional nurses and peer support workers as well as other titles.

Tobacco Use Disorder (TUD).

It is a DSM-5 (Diagnostic and Statistical Manual of Mental Disorders, fifth edition), diagnosis assigned to individuals who are dependent on the drug nicotine due to use of tobacco products, including Electronic Nicotine Delivery System (ENDS).⁷³

Boxed Warning or Black Box Label Warning.

A black box warning appears on the label of a prescription medication to alert consumers and healthcare providers about safety concerns, such as serious adverse effects or life-threatening risks. This is based on reasonable evidence of a causal association between the drug and the adverse event. The warning is intended to describe a discrete set of adverse reactions and other potential safety hazards that are serious or are otherwise clinically significant, because they have implications for prescribing decisions or for patient management.^{74,75,76}

Substance Use Disorder/Addiction.

Substance use disorder (SUD) is a complex condition in which there is uncontrolled use of a substance despite harmful consequences. People with SUD have an intense focus on using a certain substance(s) such as alcohol, tobacco, or illicit drugs, to the point where the person's ability to function in day-to-day life becomes impaired. People keep using the substance even when they know it is causing or will cause problems. The most severe SUDs are sometimes called addictions.^{77,78}

Nicotine.

Nicotine is the ingredient in tobacco products (including ENDS) that causes TUD. A powerful stimulant, even in very small amounts, nicotine is the main alkaloid of tobacco smoke and the principal modulator of the psychopharmacological effects associated with addiction.

Monotherapy.

Although multiple evidence-based approaches to helping behavioral health patients end their addiction on tobacco exist, is not unusual for a BHP to use just one approach. This is known as monotherapy.

Combination Therapy.

When multiple evidence-based approaches to helping behavioral health patients treat their addiction on tobacco are used, this is known as combination therapy.

Combination NRT.

Involves the use of a long acting NRT (patch) in combination with a short acting NRT (gum, lozenge, inhaler, or nasal spray). It offers constant levels of nicotine replacement provided by the patch and prevents the onset of severe withdrawal symptoms while the short acting nicotine replacement delivers nicotine at a faster rate and is used as needed to control cravings and withdrawal symptoms that may occur.

Combustible Tobacco.

This term is used to represent tobacco products that are smoked but do not come packaged as typical products such as cigarettes, cigars, etc.

Vaping and Electronic Nicotine Delivery Systems (ENDS).

The use of propylene glycol and other potentially carcinogenic chemicals in e-cigarettes creates a vapor that simulates tobacco smoke. Known as vaping, this system of delivering nicotine to the central nervous system constitutes an epidemic in the United States. Vaping is thus a behavior that is based on the use of the product known as the Electronic Nicotine Delivery System (ENDS).

Serious Mental Illness.

According to the National Institute of Mental Health, serious mental illness is, “a mental, behavioral, or emotional disorder resulting in serious functional impairment, which substantially interferes with or limits one or more major life activities.”⁷⁹

Medication-Assisted Treatment (MAT).

Medication-assisted treatment is the use of medications, in combination with counseling and behavioral therapies to treat substance use disorders.⁸⁰ Medications used in MAT are approved by the Food and Drug Administration.

Harm Reduction.

Stemming from the discipline of public health, this term represents a compromise between complete abstinence from a given health risk behavior and being fully engaged in that risk behavior. For example, smoking cigarettes with greatly reduced levels of nicotine would be considered a form of harm reduction.

Social Inclusion.

It is the process of improving the terms on which individuals and groups take part in society and occurs when the design and administration of any health-related program is based on a philosophy of pluralism in race, ethnicity, sex, gender, sexual orientation, gender expression, age, socioeconomic status, and religious preference.

Stages of Change Model (Transtheoretical Model).

The Stages of Change Model, also called the Transtheoretical Model, explains an individual’s readiness to change their behavior. It describes the process of behavior change as occurring in stages. These stages include Pre-contemplation, Contemplation, Preparation, Action, Maintenance, and Termination.⁸¹

Health Systems Improvement (Tobacco Control).

Involves institutionalizing tobacco use treatment interventions into routine clinical care in health care systems (e.g., clinics, hospitals etc.). The goals of health systems improvement activities with regards to treatment of tobacco are to ensure that (1) every patient is screened for tobacco use and tobacco use status is documented, and (2) patients who use tobacco are provided with evidence-based treatments.

Appendices

RESOURCES

APPENDIX A: CLINICAL PRACTICE GUIDELINE TREATING TOBACCO USE AND ADDICTION: 2008 UPDATE

[Clinical Practice Guideline Treating Tobacco Use and Addiction: 2008 Update](#)

The 2008 update to Treating Tobacco Use and Addiction, a Public Health Service-sponsored Clinical Practice Guideline, is an updated version of the 2000 Treating Tobacco Use and Addiction Guideline. It is the product of a private-sector panel of experts (“the Panel”), consortium representatives, and staff. The update was written to include new, effective clinical treatments for TUD that have become available since the 2000 Guideline was published.

APPENDIX B: NICOTINE REPLACEMENT THERAPY AND PHARMACOTHERAPY

[Pharmacologic Product Guide: FDA-Approved Medications for Smoking Cessation](#)

This chart was developed by the American Academy of Family Physicians, RX for Change, and the University of California San Francisco Smoking Cessation Leadership Center. It outlines the FDA Approved Medications for Smoking Cessation. It provides product Information, dosages, advantages, disadvantages, adverse effects, precautions, and costs per pill for each medication.

[Coping with Nicotine Withdrawal- Be Free with Nicotine Replacement Therapy \(NRT\) Toolkit](#)

This toolkit provides resources for people and providers to support using NRT including a video discussing NRT as a way to prevent withdrawal symptoms and cravings and introduces the idea that NRT can be used in situations where a person can’t smoke, or where smoking isn’t allowed.

APPENDIX C: DRUG INTERACTIONS WITH TOBACCO SMOKE AND SMOKING CESSATION MEDICATION

[Drug Interactions with Smoking Cessation Medication and Tobacco Smoke](#)

Developed by The University of Ottawa Heart Institute Model. This chart outlines interactions with tobacco smoke and smoking cessation medication.

[Drug Interactions with Tobacco Smoke](#)

Developed by The Regents of the University of California this chart outlines the many interactions between smoke and medications that have been identified

[Graylands Hospital Drug Bulletin Psychotropic Drugs– the Effect of Smoking and Caffeine](#)

This bulletin reviews the impact of smoking and caffeine on psychiatric medication and includes practical strategies on how to manage patients who change their smoking status or caffeine consumption.

APPENDIX D: PROGRAMS THAT ADDRESS TOBACCO USE

[Health Systems for Tobacco Free New York](#)

Health Systems for Tobacco Free New York is a network of grantees, covering all New York State counties, who provide practice facilitation services to health care systems to improve the reach and delivery of evidence-based tobacco use disorder treatment to all New Yorkers who smoke or use other tobacco products. The grantees work with hospitals, community health centers, federally qualified health centers, mental health, and behavioral health service agencies, with a focus on agencies and organizations that serve people with low education, low income or mental illness.

[The New York State Smokers' Quitline \(NYSSQL\)](#)

The New York State Smokers' Quitline (NYSSQL) is a service of the New York State Department of Health Tobacco Control Program and based at Roswell Park Comprehensive Cancer Center in Buffalo, N.Y. It is a free and confidential program providing evidence-based services to New York State residents who want to stop smoking or using other forms of tobacco. The Quitline also provides free starter kits of nicotine replacement therapy (NRT) to eligible New Yorkers. Providers or patients can contact the New York State Smokers' Quitline at 1-866-NY-QUITS (1-866-697-8487) or visit www.nysmokefree.com.

[Consumers Helping Others Improve Their Condition by Treating Smoking \(CHOICES\)](#)

A New Jersey based Peer-to-Peer Tobacco Education and Advocacy consumer driven program for addressing tobacco in people with mental illness.

APPENDIX E: TOOLKITS AND MANUALS:

[Tobacco-Free Workplace Toolkit: Healthier & More Productive](#)

Toolkit provides information on how to design, implement, and evaluate comprehensive tobacco-free policies and related activities including smoking-cessation support for their employees and covered dependents.

[Manual for Developing a Worksite Wellness Plan](#)

This guide can serve as a basic start for developing an employee wellness plan. It is accompanied by an outline to comprehensively assess, plan, and implement programs, policies, and supportive changes within the work setting.

[A Practical Guide to Working with Health-Care Systems on Tobacco-Use Treatment](#)

This guide reviews what is known about implementing comprehensive tobacco-control and treatment strategies within health-care systems. Provided within are examples of effective partnerships between public health agencies, health-care systems, and the business community. Also included is a primer designed to promote a better understanding of health care for those not familiar with systems operations.

[Center for Health Systems Improvement- TUD Regulation Crosswalk](#)

This document helps to examine and compare regulations and standards of care that partnering behavioral health sites must adhere to. The tool compares areas of compliance for:

- The Office of Alcoholism and Substance Abuse Services
- The Office of Mental Health Clinic Sites
- The Office of Mental Health Personalized Recovery Oriented Services Sites

APPENDIX F: TRAINING RESOURCES

[Center for Health Systems Improvement-TUD Screening and Treatment in Behavioral Settings: \(E-Learning Toolkit\)](#)

This e-Learning course was developed to build the capacity of behavioral health providers to deliver evidence-based TUD screening and treatment to their patients, ultimately supporting the integration of this best practice into standard delivery of care. This course consists of five modules and two additional modules that house tools and resources. It is available for you to navigate and move through at your own pace and offers CASAC credits for those who are eligible.

[Center for Practice Innovations: Focus on Integrated Treatment \(FIT\)-Tobacco Dependence Treatment Module](#)

The FIT tobacco dependence treatment module provides a review of the health effects of smoking. Trainees will learn how to describe the rates of tobacco dependence in the general population and among those with mental disorders. This module also describes pharmacologic and psychosocial treatment approaches.

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