

Nicotine/Tobacco Addiction Treatment

Case related questions.

Scenario: Mrs. Terry is a 34-year-old woman with a history of mild intermittent asthma, opioid use disorder, and depression who comes to your outpatient pulmonology office for an initial visit. She was diagnosed with asthma as a teenager with mild reversible obstruction noted on spirometry (FEV1 Z-score -1.68), reporting one exacerbation over the last year requiring outpatient prednisone. She takes albuterol as needed and was previously on inhaled fluticasone several years ago.

Question 1: You want to gather information regarding Mrs. Terry's nicotine/tobacco use. What information is important to collect and why?

Scenario cont.: Ms. Terry states that she smokes cigarettes every day. She started smoking at age 15 and smokes about 1 pack per day (i.e., 19 pack-years). She feels compelled to smoke within 15 minutes of awakening with her morning coffee and has noticed smoking much more during emotional stress. Ms. Terry acknowledges that it may not be the healthiest habit for her, but she feels that it has now become a significant part of her life. She has been contemplating cutting back and asking you what you think about e-cigarettes, as she has heard they are mostly water vapor and, therefore, healthier than regular cigarettes.

Question 2: How do you approach her question regarding using e-cigarettes for nicotine/tobacco use treatment?

Scenario cont.: Mrs. Terry decides against vaping and asks you what options exist to help her cut back on her cigarette smoking.

Question 3: What are currently available treatment options for nicotine/use treatment?

Scenario cont.:

After discussing some of the initial treatment options with Ms. Terry, she informs you that she is hoping to have another child and wonders how a pregnancy might impact the approach to smoking cessation pharmacotherapy. She also asks about any implications of her history of depression, as she has heard that some of the available medications might affect mood.

Question 4: Are there special considerations for pharmacotherapy for patients of child-bearing age or those that are breastfeeding?

Question 5: Is varenicline safe to prescribe to those with neuropsychiatric history?

Nicotine/Tobacco Addiction Treatment

Authors Janaki Deepak MBBS, FACP
Jason Stankiewicz, MD
Frank Leone, MD, MS

Editor Amik Sodhi, MBBS, MPH

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Educational Objectives:

1. Review key features in obtaining a medical history pertinent to nicotine/tobacco use
2. Review relevant discussion points regarding e-cigarette use in pulmonology practice
3. Review concepts to apply when counseling treatments for patients with nicotine/tobacco use disorders
4. Review the relevance of psychiatric comorbidities in nicotine/tobacco use

Scenario: Mrs. Terry is a 34-year-old woman with a history of mild intermittent asthma, opioid use disorder, and depression who comes to your outpatient pulmonology office for an initial visit. She was diagnosed with asthma as a teenager with mild reversible obstruction noted on spirometry (FEV1 Z-score -1.68), reporting one exacerbation over the last year requiring outpatient prednisone. She takes albuterol as needed and was previously on inhaled fluticasone several years ago.

Question 1: You want to gather information regarding Mrs. Terry's nicotine/tobacco use. What information is important to collect and why?

Nicotine/tobacco dependence is the leading cause of preventable death in the United States.¹ Over 70% of individuals who smoke will access healthcare throughout the year and will have an opportunity to receive any of several evidence-based treatment methods, including counseling, nicotine replacement therapy (NRT), and other pharmacotherapies. Pulmonologists are uniquely positioned to engage with patients who may use nicotine/tobacco given the close relationship between these substances and their impact on a patient's pulmonary disease(s), comorbid disease(s), quality of life, and other considerations, including implications for oxygen therapy and lung cancer screening.

The “5 As” framework outlines an approach to incorporate brief office-based interventions to counsel patients on nicotine/tobacco use (Table 1). The first step in the 5As includes asking about nicotine/tobacco use systematically in order to identify every patient who presents with nicotine/tobacco use. It is also important to collect a patient’s pack-year history (pack year history = cigarettes/day x duration of years smoked) to identify the relative exposure of nicotine/tobacco use to approximate the risk of certain diseases (*i.e.*, chronic obstructive pulmonary disease (COPD), lung cancer) and the intensity of nicotine addiction.²

Additionally, anyone who smokes should be evaluated for eligibility for lung cancer screening with annual low-dose CT scans. This should be considered in patients that are a) age 50-80 who have at least a 20-pack year history and b) either currently smoke or have quit smoking within the last 15 years³ – although the recommendation to stop screening after 15 years of abstinence was recently omitted from American Cancer Society guidelines.⁴

Table 1. The “5 As” Model for Treating Tobacco Use and Dependence

Ask	Systematically identify all tobacco users at every visit
Advise	Strongly urge all tobacco users to quit
Assess	Determine willingness to make a quit attempt
Assist	Aid the person in quitting (provide counseling and medication)
Arrange	Ensure follow-up contact

Adapted from A Clinical Practice Guideline for Treating Tobacco Use and Dependence: 2008 Update.

Several questionnaires have been developed to better understand the severity of nicotine addiction. This information collected can potentially inform the prescribed intensity and duration of treatment for nicotine/tobacco dependence. Table 2 outlines the scoring scheme for the Fagerström Test for Nicotine Dependence⁵ (FTND). A more simplified approach has been described by simply using the patient’s time to the first cigarette of the day to stratify as the intensity of addiction⁶: time ≤30 minutes is associated with higher intensity addiction, and thereby may require higher intensity therapy compared to the time to first cigarette >30 minutes from awakening.

Table 2. The Fagerström Test for Nicotine Dependence

Question	Answers	Score
How many cigarettes do you smoke per day?	≤10 11-20 20-30 >30	0 1 2 3
How soon after waking do you smoke?	≤5 min 6-30 min 31-60 min >60 min	3 2 1 0
Which cigarette would be the most difficult to give up?	First in AM Any other	1 0
Is it hard to refrain from smoking where it is forbidden?	Yes No	1 0
Do you smoke even though you are sick in bed all day?	Yes No	1 0
Do you smoke more often in the first few hours of the day, compared to the rest of the day?	Yes No	1 0

Scores correlating to 8+ (highly dependent), 5-7 (moderately dependent), 3-4 (low-moderately dependent), 1-2 (minimally dependent).

Adapted from Heatherton et al.

For those patients who are not ready to quit smoking, it is useful to inquire further about their motivations and thoughts. The 5 R's⁷ (Relevance to the patient's individual situation, Risks of continuing tobacco use, Rewards of tobacco cessation, Roadblocks to quitting and how to overcome them, Repetition of the conversation at each visit) is a motivational interview model that can be useful in navigating this conversation.

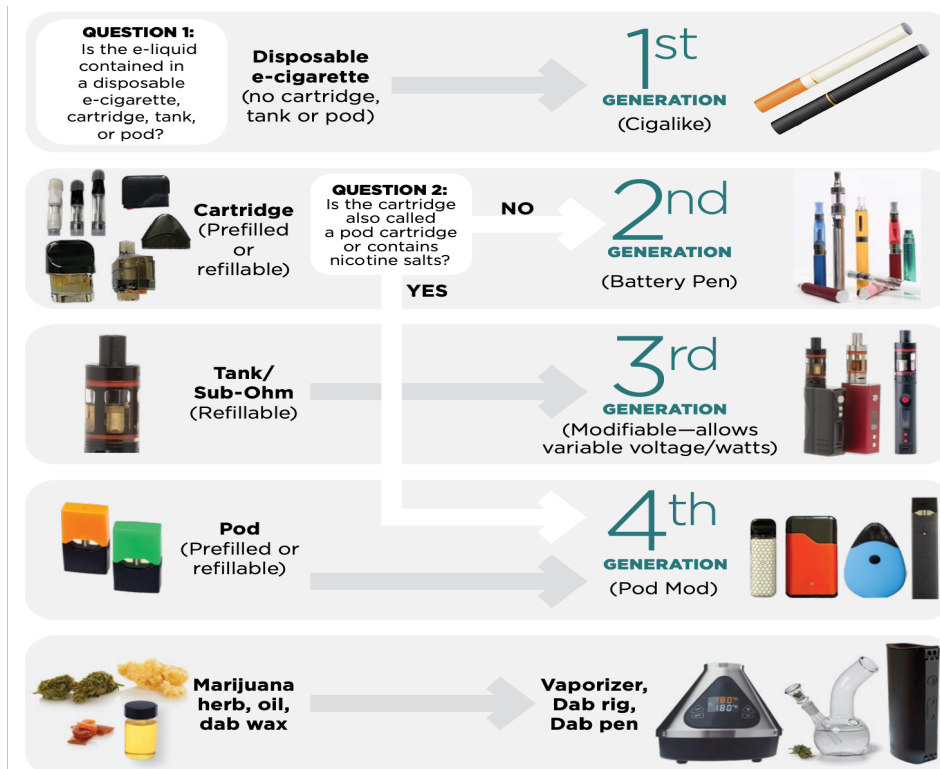
Scenario cont.: Ms. Terry states that she smokes cigarettes every day. She started smoking at age 15 and smokes about 1 pack per day (i.e., 19 pack-years). She feels compelled to smoke within 15 minutes of awakening with her morning coffee and has noticed smoking much more during emotional stress. Ms. Terry acknowledges that it may not be the healthiest habit for her, but she feels that it has now become a significant part of her life. She has been contemplating cutting back and asking you what you think about e-cigarettes, as she has heard they are mostly water vapor and, therefore, healthier than regular cigarettes.

Question 2: How do you approach her question regarding using e-cigarettes for nicotine/tobacco use treatment?

The basic anatomy of an electronic cigarette (i.e., e-cigarettes, e-cigs, vapes, vape pens, dab pens, dab rigs, tanks, mods, pod-mods, electronic nicotine delivery systems (ENDS), JUUL) consists of a power source utilized to heat a coil that aerosolizes an e-liquid to be delivered to the user⁸ (Figure 1). Heat-not-burn devices are similar, but rather than vaporizing liquid they heat tobacco to a high temperature below its combustion point to produce a nicotine containing vapor without producing smoke or ash.⁹ Various generations of products are commonly used today. While e-cigarette liquid contains water, other

compounds are included in varying concentrations, including nicotine, flavors (menthol, sweeteners), bases (propylene glycol, vegetable glycerin), with changes in composition resulting after combustion.¹⁰ Additionally, devices can be modified or “hacked” to allow varied product and potential toxin administration, including volatile organic compounds, heavy metals, and other particles.

Figure 1. Overview of Electronic Cigarette Products



Adapted from E-cigarette, or vaping, products visual dictionary.¹¹

E-cigarettes have been associated with pulmonary diseases. In July 2019, the United States experienced an outbreak of E-cigarette or vaping product use-associated acute lung injury (EVALI), responsible for at least 2,600 cases and 68 deaths.¹² Tetrahydrocannabinol (THC)-containing products accounted for most cases, strongly associated with the constituent vitamin E acetate. Before this outbreak, several other reports documented various lung injury patterns associated with e-cigarette use. Given the potential for lung disease and nicotine addiction, history taking should include e-cigarette habits: frequency, device(s) used, e-liquid(s) used, and specific modifications made to the device.

Although some have proposed e-cigarettes for nicotine/tobacco use treatment, e-cigarette products have only recently been introduced to the market, and there is limited information regarding their safety and efficacy. Additionally, there is no strong supporting evidence for e-cigarette use over currently approved safe and effective pharmacotherapies. In this context, it is wise to share this uncertainty regarding e-cigarettes with patients and encourage using established and approved methods for nicotine/tobacco use treatment (*i.e.*, counseling, NRT, and other pharmacotherapies). Table 3 identifies the estimated nicotine content in various nicotine-containing products.

Table 3. Approximate Nicotine Content in Various Nicotine Products

Product	Nicotine content in mainstream smoke
Cigarette	0.5-1.6 mg per cigarette
Roll-your-own cigarette	1.5-1.8 mg per cigarette
Cigar	
Little cigar	1.5 mg per cigar
Large cigar	1.4 mg per cigar
Premium cigar	3.4 mg per cigar
Bidis (hand-rolled Indian cigarettes)	2.7 mg per bidi
Chutta (hand-made Indian cigars)	6.98 mg per chutta
Clove cigarettes	2 mg per cigarette
Waterpipe tobacco (i.e., hookah)	2.25-2.94 mg per smoking session (i.e., 10 g, 100 puffs, 1 puff/second, 30 seconds between puffs)
E-cigarette	
Disposable	0.74 mg per 15 puffs in standard machine conditions
Prefilled	1.06 mg per 15 puffs in standard machine conditions
Tank	1.39 mg per 15 puffs in standard machine conditions
example: JUUL	5.0% JUULpod contains 40 mg (59 mg/mL) 3.0% JUULpod contains 23 mg (35 mg/mL)

Note that smoke machine conditions may not estimate actual nicotine exposure, as many individuals may significantly vary their behavior including puffing patterns, intervals, blocking filter holes, and smoking to a certain butt length.

Adapted from Djordjevic et al.¹³

Scenario cont.: Mrs. Terry decides against vaping and asks you what options exist to help her cut back on her cigarette smoking.

Question 3: What are currently available treatment options for nicotine/use treatment?

The backbone of established treatment methods for nicotine/tobacco use includes counseling and pharmacotherapy.^{14,15} Counseling in the forms of individual counseling, group counseling, and telephone counseling has been described as successful. Additionally, supplemental therapy can include internet, mobile phone texting, and app-based services. The 1-800-QUIT-NOW Quitline is a patient resource that often includes free telephone-based counseling and support in obtaining pharmacotherapy. Other potential resources for behavioral intervention include phone-based apps, such as QuitGuide, quitSTART, and Stay Quit Coach.

The 2020 American Thoracic Society (ATS) Clinical Practice Guidelines¹⁶ recommend the following approach to pharmacologic therapy:

1. Varenicline as a first line agent over nicotine replacement therapy or bupropion alone
2. Varenicline plus nicotine replacement therapy as a preferred agent over varenicline alone, and therapy should be continued for at least 12 weeks
3. In patients who continue to use tobacco, it is recommended to start varenicline rather than wait until patients are ready to stop smoking

The combination of counseling and pharmacotherapy modalities has the best-associated outcomes.¹⁷ A Cochrane Review in 2013¹⁸ compared major pharmacotherapies compared to placebo on smoking abstinence and revealed efficacy for NRT (odds ratio (OR) 1.84; 95% confidence interval (CI) 1.71-1.99), bupropion (OR 1.82; 95% CI 1.60-2.06), and varenicline (OR 2.88; 95% CI 2.40-3.47). Overall, varenicline was superior to single NRT and bupropion. Notably, there was no difference between combined NRT and varenicline. Table 4 reviews practical information regarding prescribing select pharmacotherapies, and Figure 2 reviews an example of a scheme for prescribing combined NRT.

Table 4. FDA-approved Medications for Smoking Cessation

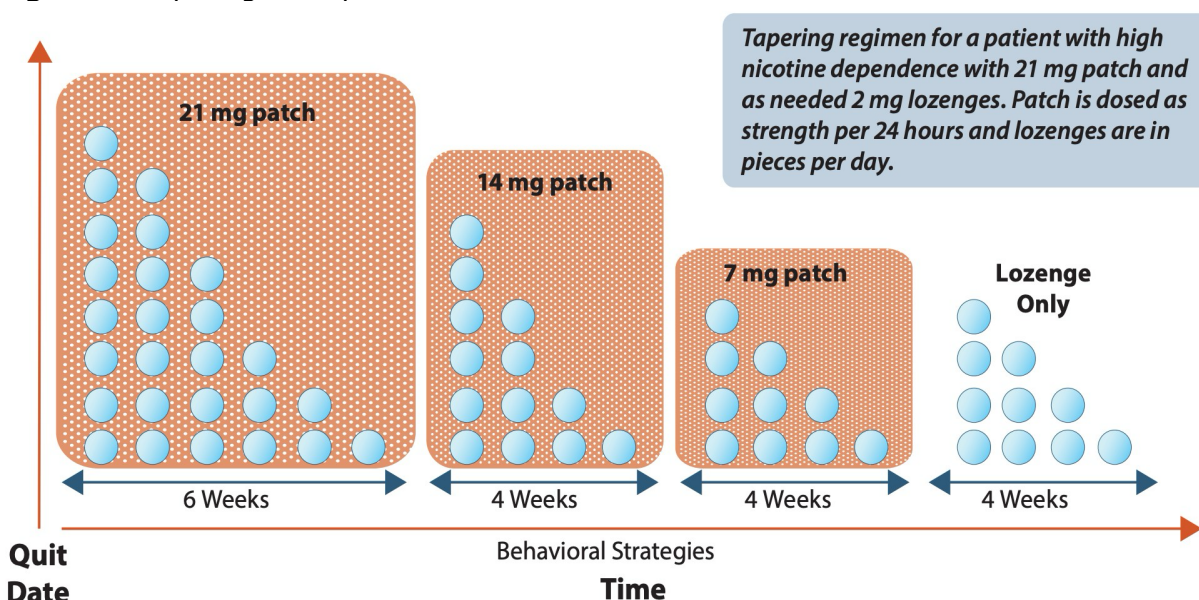
Nicotine replacement	Formulations*	Dosing	Adverse effects
Gum	2 mg 4 mg	Week 1-6: 1 piece q 1-2 hours Week 7-9: 1 piece q 2-4 hours Week 10-12: 1 piece q 4-8 hours Duration: ≤12 weeks Maximum: 24 pieces/day	Mouth/jaw soreness Hiccups Dyspepsia Hypersalivation Lightheadedness Nausea/vomiting Throat and mouth irritation
Lozenge	2 mg 4 mg	Week 1-6: 1 piece q 1-2 hours Week 7-9: 1 piece q 2-4 hours Week 10-12: 1 piece q 4-8 hours Duration: ≤12 weeks Maximum: 24 pieces/day	Nausea Hiccups Cough Heartburn Headache Flatulence Insomnia
Transdermal patch	7 mg 14 mg 21 mg	>10 cigarettes/day: 4-6 weeks: 21 mg/day 2 weeks: 14 mg/day 2 weeks: 7 mg/day Duration: 8-10 weeks ≤10 cigarettes/day: 6 weeks: 14 mg/day 2 weeks: 7 mg/day	Local skin reactions Headache Sleep disturbances
Nasal spray	10mg/mL solution	1-2 doses/hour (1 dose=2 sprays) Duration: 3-6 months Maximum: 5 doses/hour or 40 doses/day	Nasal and/or throat irritation Rhinitis Tearing Sneezing Cough Headache
Oral inhaler	10 mg cartridge delivers 4-mg inhaled vapor	6-16 cartridges/day 1 cartridge q1-2 hours Duration: 3-6 months	Mouth and/or throat irritation Cough Headache Rhinitis Dyspepsia Hiccups

Bupropion SR	150 mg tablet	150 mg p.o. every morning 3 days 150 mg p.o. b.i.d. Duration: 7-12 weeks, up to 6 months Maximum: 300 mg qd	Insomnia Dry mouth Nervousness/ difficulty concentrating Nausea Dizziness Constipation Rash Seizures (risk is 0.1%, but exercise caution in patients with prior history of seizures) Neuropsychiatric symptoms (rare)
Varenicline	0.5 mg 1 mg	Day 1-3: 0.5 mg Day 4-7: 0.5 mg b.i.d. Week 2-12: 1 mg b.i.d. Duration: 12 weeks; consider an additional 12 weeks in selected patients	Nausea Sleep disturbances Constipation Flatulence Vomiting Neuropsychiatric symptoms (rare) **There was a recall of varenicline from 2021-2022 due to concern for higher than allowed levels of nitrosamine as a potential carcinogen. As of May 2022, it is now available to be prescribed again.

**4 mg for 1st cigarette ≤30 minutes after waking, 2 mg for 1st cigarette >30 minutes after waking, 21 mg/day for >10 cigarettes per day, 14 mg/day for ≤10 cigarettes per day.*

Adapted from Smoking Cessation: A Report of The Surgeon General.¹⁹

Figure 2. Tapering Example for Combination NRT



Note that the decision and specific plan of tapering should be tailored to the individual needs of the patient.

Adapted from Tobacco Use Disorder A Provider's Guide to Counseling and Medication Treatment to Help Veterans with Tobacco Cessation.²⁰

Even though the patch recommendations are to decrease the dosing, in reality the number of cigarettes smoked does not fully inform the actual nicotine dose. The nicotine dose delivered by smoking can vary significantly due to factors such as the depth and frequency of inhalation, the type of cigarette, and individual metabolic differences.

The American College of Cardiology (ACC), in their 2018 Expert Consensus Decision Pathway on Tobacco Cessation Treatment, acknowledges that nicotine replacement therapy (NRT) dosing should be individualized and that the standard dosing recommendations may not be sufficient for all smokers, particularly heavy smokers.²¹ The ACC guidelines suggest starting with a 21 mg patch for those smoking ≥ 10 cigarettes per day, but they also note that higher doses may be necessary for some individuals to achieve adequate nicotine replacement and reduce withdrawal symptoms.

Studies have shown that higher doses of transdermal nicotine can be safe and effective for heavy smokers. For instance, Fredrickson et al. demonstrated that a 44 mg/day nicotine patch was well-tolerated and provided higher nicotine replacement levels compared to standard doses.²² Similarly, Hatsukami et al. found that higher doses of nicotine patches (up to 45 mg/day) were generally well-tolerated and led to significant reductions in smoking and biomarkers of exposure.²³

While most of the high-quality evidence centers around pharmacologic options or behavioral interventions for smoking cessation, other interventions can be considered in some patients. There is some evidence that acupuncture or hypnotherapy could help selected patients, though the results of numerous studies have mixed conclusions.

Scenario cont.:

After discussing some of the initial treatment options with Ms. Terry, she informs you that she is hoping to have another child and wonders how a pregnancy might impact the approach to smoking cessation pharmacotherapy. She also asks about any implications of her history of depression, as she has heard that some of the available medications might affect mood.

Question 4: Are there special considerations for pharmacotherapy for patients of child-bearing age or those that are breastfeeding?

For many reasons, pregnant patients should receive special attention with regard to provider-initiated interventions. Potential perinatal implications of continuing to smoke include a higher risk of orofacial clefts, fetal growth restriction, placenta previa, abruptio placentae, preterm labor and rupture of membranes, low birth weight, increased perinatal mortality, ectopic pregnancy, decreased maternal thyroid function.²⁴ Additionally, a 2017 meta-analysis²⁵ showed that smoking cessation had been associated with decreased incidence of low fetal birth weight (odds ratio 0.65, 95% CI 0.42-0.88).

The general approach to counseling and non-pharmacologic treatment remains the same for pregnant patients. Counseling should be started early on in a patient's pregnancy. Regarding pharmacotherapy in pregnant patients, the USPSTF²⁶ concluded there was insufficient data on the risks versus benefits of pharmacotherapy in pregnant women (I statement) as recently as 2021. While the efficacy of NRT in pregnant patients has not been well studied, the Smoking, Nicotine and Pregnancy (SNAP) trial in 2014²⁷ did show less infant impairment at the 2-year mark when mothers used NRT vs. placebo (OR 1.40, 95% CI 1.05-1.86, $p=0.023$).

Bupropion has been shown in small observational studies²⁸ to improve smoking cessation compared to control, and there is no evidence of increased risk of overall fetal anomalies or adverse pregnancy events with its use. Bupropion does cross the placenta, and there has been inconsistent data on cardiovascular malformations. Bupropion also accumulates in breast milk at doses of 300 mg or higher, but this is unlikely to correlate with clinically significant drug levels in breast milk.²⁹ At the same time, infant seizure events have been potentially linked with bupropion exposure through breast milk.³⁰

Varenicline also has limited data in pregnant patients. Survey data from a 2016 study²⁵ showed no increase in congenital malformations. However, this study limited varenicline use to the first trimester, and several participants had early discontinuation of the medication.

It is important to carefully discuss the potential risks and benefits of using these medications in pregnant or breastfeeding patients.

Question 5: Is varenicline safe to prescribe to those with neuropsychiatric history?

Individuals with mental health illnesses often have an elevated risk of comorbid conditions and benefit from introducing nicotine/tobacco use pharmacotherapy. However, varenicline previously had an FDA black box warning on its label initially in 2009, alerting patients to the risk of serious neuropsychiatric adverse events including suicide and depression. Concerns were also raised about neuropsychiatric adverse events in patients prescribed bupropion SR. However, the Evaluating Adverse Events in a Global Smoking Cessation Study (EAGLES)³¹ was published in 2016 which randomized 8,144 patients with and without psychiatric disease who were active smokers to interventions including varenicline, bupropion, NRT, and placebo. The study demonstrated an overall low rate of serious adverse events, and there was no statistically significant difference in overall or serious neuropsychiatric events between treatments in all patients, in patients with psychiatric disorders, or in patients without psychiatric disorders.

Subsequently, the FDA black box warning was removed in 2016. The 2020 ATS Clinical Practice Guideline on initiating pharmacologic treatment in tobacco-dependent adults recommends that "for tobacco-dependent adults with comorbid psychiatric conditions, including substance use disorder, depression, anxiety, schizophrenia, and/or bipolar disorder, for whom treatment is being initiated, we recommend varenicline over a nicotine patch (strong recommendation, moderate certainty in the estimated effects)." Regarding patients with concurrent substance use disorder, a 2017 prospective study³² showed continued smoking was associated with substance use (OR=1.56, 95% CI=1.10-2.20) and substance use disorder relapse (OR=2.02, 95% CI=1.65-2.47).

Scenario cont.:

After an informed discussion, Ms. Terry wishes to start varenicline. You provide her with instructions, potential side effects, and a scheduled follow-up phone call in about 4 weeks. You congratulate her on her motivation and effort to improve her health.

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Nicotine/Tobacco Addiction Treatment

Post-Test Case Related Questions

1. Which of the following is true regarding smoking cessation outcomes:
 - a. Combination of counseling and pharmacotherapy has shown to have the best outcomes.
 - b. The use of E-cigarettes is recommended to help patients quit smoking
 - c. Use of nicotine-replacement therapy has higher smoking cessation rates compared to use of varenicline.
 - d. Bupropion is an ineffective therapy for smoking cessation
2. Which pharmacotherapy regimen would be the preferred option, based on the 2020 ATS Clinical Practice Guideline on smoking cessation, for 65-year-old patient with a 35-pack-year history of smoking as well as underlying epilepsy:
 - a. Bupropion combined with nicotine transdermal patch
 - b. Varenicline combined with nicotine transdermal patch
 - c. Varenicline combined with bupropion
 - d. Nicotine transdermal patch combined with nicotine nasal spray

Nicotine/Tobacco Addiction Treatment

Post-Test Case Related Questions with Answer Key

1. Which of the following is true regarding smoking cessation outcomes:
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