Smoking Cessation Clinical Practice Guidelines

The following guideline addresses the assessment and treatment of tobacco abuse and nicotine addiction. The major recommendations for physicians and other health care providers are to use office wide systems to identify smokers, treat every smoker with a cessation or motivational intervention, offer nicotine replacement except in special circumstances, and schedule follow-up contact to occur after cessation. Major recommendations are to have a structured process in place for identifying all current and former patients who smoke, to use motivational interviewing to facilitate behavior change, to offer nicotine replacement or other appropriate medications, and provide problem-solving and social support counseling.

Tobacco addiction presents a rare confluence of circumstances that mandates clinical intervention:

(1) it is a highly significant health threat,
(2) there is a disinclination among clinicians to intervene consistently, and
(3) effective preventive interventions are now available.

Smoking cessation treatment is preventive because if it is provided in a timely and effective manner, it greatly reduces the smokers risk of suffering from smoking related disease. Indeed, it is difficult to identify a condition that presents such a mix of lethality, prevalence, and neglect, and for which effective interventions are so readily available.

VPHP determined the need for clinical practice guidelines based on several factors including prevalence, related morbidity and mortality, the economic burden imposed by the condition and variations in clinical practice related to the condition. Tobacco abuse meets all of these requirements which proves the need for guidelines for the treatment of nicotine addiction.

This guideline is specifically intended to help all health care providers improve their treatment of patients with nicotine dependency.

The guideline offers a simple and flexible set of strategies designed to ensure that all patients who use tobacco are offered motivational interventions and effective treatments to overcome this powerful addiction. The guideline is intended to identify empirically based and validated assessments and treatments for tobacco dependence.

GUIDELINE RECOMMENDATIONS

Primary Care Clinicians

Though all clinicians should possess the knowledge and skills to assist patients with smoking cessation, primary care clinicians are uniquely poised to assist patients who smoke, as they have extraordinary access to this population. At least 70% of smokers see a physician each year. Moreover, 70% of smokers report that they want to quit and have made at least one serious attempt to quit. Finally, smokers cite a physician's advice to quit as an important motivator for attempting to stop.

Unfortunately, clinicians are not capitalizing fully on this unique opportunity. Only about half of current smoker's report having been asked about their smoking status or urged to quit. Fewer still have received specific advice on how to quit smoking successfully. Why don't clinicians consistently address tobacco use among their patients? Some clinicians' reluctance to

intervene may be attributed, in part, to time constraints, a perceived lack of skills to be effective in this role, frustration due to low success rates, or even a belief that smoking cessation is not an important professional responsibility. Several changes have been proposed to increase clinicians' intervention with smokers:

(1) Health care delivery practices must change so that smoking cessation interventions are institutionalized;
(2) clinicians and their patients must be reimbursed by insurers for smoking cessation counseling and pharmacotherapy;
(3) clinicians must adjust their goals so that motivational interventions are offered to smokers who are not yet committed to quitting, and
(4) standards of health care delivery must reflect the health care systems' obligation to intervene in a timely and appropriate manner with patients who smoke.

These recommendations are designed to be brief and to be consistent with those produced by the National Cancer Institute in *How To Help Your Patients Stop Smoking* and by the *American Medical Association Guidelines for the Diagnosis and Treatment of Nicotine Dependence: How to Help Your Patients Stop Smoking*, as well as others. The goals of these recommendations are clear – to change clinical culture and practice patterns to ensure that every patient who smokes is offered treatment. The recommendations revolve around a central theme: *It is essential to provide effective cessation intervention for all tobacco users at each clinical visit.*

First, institutional changes in clinical practice are necessary to ensure that all patients who smoke are identified. Second, although more intensive interventions produce greater success, the compelling time limitations on primary care clinicians demand brief interventions. Third, because many smokers are reluctant to enter into intensive cessation programs, they must receive treatment every time they visit a primary care clinician.

The Agency for Health Care Policy and Resources (AHCPR) *Guideline* recommendations for primary care clinicians emphasize the importance of systematically identifying all smokers, strongly advising all smokers to quit and determining patients' willingness to make a quit attempt. Those patients not willing to commit themselves to quitting should receive a motivational intervention to promote subsequent quit attempts. When patients are willing to make a quit attempt, primary care clinicians should assist the patients in their efforts by helping the patient set a quit date, preparing the patient for the quit date, recommending appropriate pharmacotherapy, providing self-help materials, and providing key advice including problem solving and social support. If the patient prefers a more intensive treatment or if the clinician believes more intensive treatment is appropriate, the patient should also be referred to an intensive program. All patients attempting to quit should have follow-up contact scheduled.

As of June 2022, Varenicline remains the recommended first-line pharmacotherapy. It supersedes former recommendations to use nicotine replacement therapy [NRT] as first-line. It is recommended as first-line therapy in tobacco-dependent users who are ready to initiate a smoking cessation program as well as those who wish to continue smoking. It is preferred over bupropion, even in those individuals who have co-morbid psychiatric conditions. It is also considered superior to e-cigarettes. In individuals who are ready to initiate smoking cessation, varenicline should be used in combination with a nicotine patch to increase effectiveness. For patients in whom varenicline use may be contraindicated, other traditional treatments are appropriate

Multiple forms of nicotine replacement therapy (patch, nasal spray, lozenge, gum, inhaler) are still effective, but current recommendations are that they be used for at least 12 weeks, instead

of former shorter courses.. Sustained-release bupropion hydrochloride continues to be effective.. Formerly, clonidine and nortriptyline were found to be efficacious and so were considered as second-line therapy. However, according to more current research as reported in a very comprehensive April 2022 assessment published in UpToDate, while nortriptyline does continue to hold promise as a second line drug – Clonidine seems to be fading. Some recent studies have found that combination therapy can be of benefit in smokers who are unsuccessful quitting. The use of support systems such as quit lines (1-800-QUIT-NOW) and the web (www.smokefree.gov) may increase the chances of success.

If varenicline is contraindicated,, it is still appropriate for heavy smokers to use higher dosages of an NRT or try a "patch plus" method, using the nicotine patch to provide a base level of slowly delivered nicotine and adding a more rapidly acting NRT to control breakthrough cravings. This regimen is safe because smokers typically obtain less nicotine than through smoking, and it is more effective than using a single NRT.

Cravings are a major roadblock to success in any smokers' efforts to kick the habit, and a helpful guide for advice on this issue from the CDC can be shared with patients through the following link:

> https://www.cdc.gov/tobacco/campaign/tips/quit-smoking/guide/cravings.html?s_cid=OSH_tips_D9401

Electronic cigarettes (e-cigarettes), which deliver vaporized nicotine in a tobacco free device, are gaining popularity as a "harm reduction" strategy to quit smoking. However, their safety ~~has~~ still remains to be established. In March of 2020, a press release from the American College of Cardiology released the findings on a study conducted by Mark Eisenberg et al indicating that, on a short-term basis, E-cigarettes containing nicotine were more effective than counseling alone, in smoking cessation. The conclusion of the AMA Council on Science and Public Health is still valid, namely:

"E-cigarettes might present an effective alternative to leaf tobacco use for some smokers, but clinical testing, larger population studies, and full analyses of their ingredients and manufacturing processes need to be conducted before their safety, viability, and impacts can be determined as either clinical tools or as widely available, effective alternatives to tobacco use.

Evidence is emerging that e-cigarettes may be associated with the development of pulmonary disease. The liquid in an e-cigarette may contain nicotine, tetrahydrocannabinol (THC), cannabinoid (CBD) oils, and other substances and additives. No specific e-cigarette brand or type has been incriminated as of the announcement. However, until further facts emerge, the CDC has issued interim recommendations with regards to the use of e-cigarettes- effective as of February 25,2020. These are that "e-cigarettes have the potential to benefit adults who smoke and are not pregnant, if used as a complete substitute for regular cigarettes and other tobacco products. While e-cigarettes have the potential to benefit some people and harm others, scientists still have a lot to learn about whether e-cigarettes are effective in helping adults quit smoking. Additional research can help understand the long-term health effects".

GUIDELINE RECOMMENDATIONS OF GENERAL INTEREST

1. **Promoting the motivation to quit**
   It is important for a clinician to implement the 5 A's with all patients. A*sk* all patients if he or she uses tobacco, *advise* him or her to quit, and *assess* willingness to make a quit attempt. These interventions need to be delivered to each tobacco user, regardless of his or her willingness to quit. If the patient is willing to quit, the clinician should *assist* him or her in making a quit attempt by offering medication and providing or referring for counseling or additional treatment, and *arrange* for follow-up.

   Despite receiving a clinician's advice to quit smoking, many patients are not willing to make a commitment to quit at the time of a health care visit. These patients may be uninformed, concerned about the effects of quitting, or demoralized due to previous failure. Such patients may respond to a motivational intervention. Motivational interventions that may help clinicians promote smoking cessation are characterized by the 5 R's: *relevance, risks*, *rewards, roadblocks, and repetitions*.

   Recommendation: For patients not willing to initiate a quit attempt at the time of their health care visit, clinicians should engage in a brief intervention designed to promote motivation to quit (strength of evidence = C).

2. **Relapse Prevention**
   Because of the high rates of relapse after initial abstinence, clinicians must employ strategies to assist their patients in maintaining abstinence. While relapse prevention interventions may be used with any ex-smoker when judged appropriate by the clinician, it is vital that such interventions be delivered to any smoker who has stopped within the past 3 months. This is a period of high risk for relapse. Relapse prevention interventions can be delivered via either prearranged telephone calls, televisits, clinic visits or anytime the clinician encounters an ex-smoker. It is vital that a systematic, institutionalized mechanism be in place to identify ex-smokers, because that is a necessary first step in delivering relapse prevention messages. Relapse prevention interventions can be divided into 2 categories:

   - **Minimal Practice** – These relapse prevention interventions should be part of every primary care encounter with a patient who has recently quit. Because most relapses occur within the first 3 months after quitting, relapse prevention is especially appropriate during this period.
   - **Prescriptive interventions** – These individualized relapse prevention components are based upon information obtained regarding problems the patient has encountered in maintaining abstinence. More intensive relapse prevention interventions may be delivered via primary care or through a specialist or smoking cessation program.

   Recommendation: - When clinicians encounter a recent quitter, they should reinforce their patient's decision to quit, review the benefits of quitting, and assist the patient in resolving any residual problems arising from quitting (strength of evidence = C).

3. **Smoking Cessation during Pregnancy**
   Smoking during pregnancy presents risks to both the woman and the fetus. Many women are motivated to quit during pregnancy, and health care professionals can take advantage of this motivation by reinforcing the fact that cessation will be best for the fetus, with postpartum benefits for both mother and child. A pregnant woman who still smokes should continue to be encouraged and helped to quit. Among women who stop smoking during pregnancy, there is a high rate of relapse in the postpartum period, even among women who have maintained total abstinence from tobacco for 6 or more months during pregnancy. Postpartum relapse may be decreased by continued emphasis on the relationship between maternal smoking and poor health outcomes (sudden infant death syndrome, respiratory infection, asthma, and middle ear disease) in infants and children.

   Recommendation: For every woman who is either pregnant or post-partum, the following steps should be taken: (1) Ask each at their initial pregnancy visit and at their post-partum visit if she smokes and document the patient's smoking status; (2) assist all smokers once identified, with using non-pharmacologic interventions for all patients, and nicotine replacement therapy or other medications if determined by the provider and patient to be appropriate based on the patient's specific circumstances; and (3) provide advice and assistance on how to remain abstinent. According to the latest guideline from USPSTF, the evidence for the success of behavioral interventions in pregnant women is very strong – however this cannot be said for pharmacotherapy or use of e-cigarettes.

   ***S*moking Cessation among Hospitalized Patients**
   Hospitalization can be an ideal opportunity for a patient to stop smoking, and smoking cessation may promote the patient's medical recovery. Smoking negatively affects bone and wound healing. Clinicians should use hospitalization as an opportunity to promote smoking cessation. Smokers may experience nicotine withdrawal symptoms during hospitalization. Clinicians should consider providing temporary nicotine replacement therapy during a hospitalization to reduce such symptoms and should encourage the continued use of this therapy for patients desiring prolonged abstinence. It has been documented that patients who use NRT in the hospital are more likely to continue on the NRT after discharge and have greater success at quitting long term[8]. Varenicline and bupropion are not suitable for treating acute withdrawal symptoms.

   Recommendation: For every hospitalized patient, the following steps should be taken: (1) Ask each patient on admission if he or she smokes and document the patient's smoking status; (2) for current smokers, list smoking status on the admissions problem list and as a discharge diagnosis; (3) assist all smokers with quitting during the hospitalization, using nicotine replacement therapy if appropriate; and (4) provide advice and assistance on how to remain abstinent after discharge (strength of evidence = C).

SPECIFIC RECOMMENDATIONS

1. Tobacco dependence is a chronic disease that often requires repeated interventions and multiple attempts to quit. Effective treatment exists, however, that can significantly increase rates of long-term abstinence. Clinicians should assess the smoking status of every patient and should offer each smoker an effective smoking cessation treatment. This should occur at every encounter.

2. Longer-duration, intense treatments are more effective than brief treatments. However, even brief treatments such as a physician's advice to stop smoking, can be efficacious in increasing long-term smoking cessation and physicians should offer every patient who uses tobacco at least the brief treatments shown to be effective.

3. Clinicians should (a) motivate all smokers to make a quit attempt and screen for barriers to cessation such as anxiety, other smokers in the household, fear of weight gain; (b) deliver relapse prevention interventions to all smokers who have recently quit; (c) encourage pregnant smokers to receive intensive smoking cessation counseling and possibly nicotine replacement therapy; (d) assist all hospitalized smokers to remain abstinent from tobacco during and after the period of hospitalization; (e) discuss with smokers the weight gain they may experience after quitting and recommend nicotine gum as a method to limit the weight gain; (f) offer smokeless tobacco users the same cessation counseling that is used with smokers; and (g) offer effective treatments listed in this *guideline* to all smokers regardless of ethnicity, or socioeconomic status.

4. Smokers with respiratory symptoms may be offered pulmonary function testing or chest x-ray. This practice could detect pulmonary disease at an earlier stage, and it may also help to motivate the patient to quit smoking.

5. Individual, group, and telephone counseling are effective, and their effectiveness increases with treatment intensity. Two components of counseling are especially effective, and clinicians should use these when counseling patients making a quit attempt:

    - Practical counseling (problem solving/skills training)
    - Social support delivered as part of treatment

6. While counseling and medication are effective when used by themselves for treating tobacco dependence, the combination of counseling and medication are more effective than either alone. Thus, clinicians should encourage all individuals making a quit attempt to use both counseling and medication.

7. Treatment of tobacco abuse may include the use of appropriate pharmacotherapy. First-line treatment is now considered to be varenicline unless specifically contraindicated. According to the most recent update from the American Thoracic Society, Varenicicline is more effective than nicotine patches or bupropion and, in general, has similar or fewer side effects. Furthermore, extending treatment beyond 12 weeks increases abstinence. In addition, prescribing Varenicicline to smokers who are not ready to quit also increases 6-month abstinence as opposed to waiting to initiate therapy when the individual is ready to stop smoking. Other therapies include bupropion sustained-release, and various forms of nicotine replacement therapy. Combining nicotine replacement therapy with one of the other medications may be more effective than either used alone. Patients should be screened carefully for contraindications when prescribing these medications. Contraindications for the use of bupropion include seizure disorder and history of eating disorder. Varenicline is no longer contraindicated in patients with history of psychiatric illness. Nortriptyline may be considered for use as second-line therapy.

8. Clinicians should recommend various types of support available to patients working on smoking cessation. Many hospitals, churches, community centers, etc offer support groups for smokers trying to quit. There are also numerous on-line resources for patients including smokefree.gov and quitandstayquit.com

9. If a tobacco user currently is unwilling to make a quit attempt, clinicians should use the motivational treatments shown to be effective in increasing future quit attempts.

10. For a more in depth analysis of the treatment modalities currently available and some guidance on managing relapses, you are directed to the following UpToDate, comprehensive review, published in April of 2022:

    https://www.uptodate.com/contents/pharmacotherapy-for-smoking-cessation-in-adults/

11. For the sake of completeness, it is of value to mention the work being done on the development of a vaccine for smoking cessation. In the United States, the vaccine being considered is NicVax - produced by Nabi Pharmaceuticals. It is still currently in phase III trials. The mechanism of action is prevention of nicotine binding to dopamine receptors in the central nervous system – thus inhibiting the pleasure response. The basic premise is that the vaccine will elicit an immune reaction to the nicotine molecule leading to production of antibodies to nicotine. These antibodies will then attach to any nicotine molecules in the blood stream – creating a nicotine-antibody complex that will be too large to penetrate the blood–brain barrier thus preventing nicotine from binding to dopamine receptors in the brain.Its potential uses are for both treatment of nicotine addiction as well as relapses.

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