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A Review of Pharmacological and Educational Approaches for Tobacco Cessation

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Abstract

Assisting patients to quit smoking continues to be critical for all health care providers as the Surgeon General's report in 2004 reported a significant increase in the number of diseases caused by smoking. Awareness of the extreme addictiveness of nicotine may help health care providers increase empathy for patients attempting to quit. Health care providers can identify the patient's stage of change, according to the Transtheoretical Model, and incorporate appropriate pharmacological and educational methods to aid in the quit attempt.

Introduction

One of the most pervasive and destructive drugs known to humankind is tobacco, and it is legal. It is entrenched in the culture, having played an integral role in the history of the U.S., especially in financing the War of Independence. Efforts to regulate tobacco in the U.S. started in the latter part of the 1800's. Anti-tobacco legislation was characterized by two themes: (a) fire hazards created by smoking, and (b) the morality of smoking. By the beginning of the 1900s, these issues had become less important because of the economic benefits associated with the tobacco industry and states viewing cigarette taxes as an important source of revenue. Today tobacco is an over \$50 billion industry and continues to be a significant source of revenue to state and federal governments.¹

As early as the 1950s the tobacco industry was aware that tobacco use was linked to illness. Cigarette smoking is one of the leading preventable causes of disability and death in the U.S., and it is believed that tobacco manufacturers have the technology to produce cigarettes containing fewer toxic chemicals. However, if the tobacco companies produce and advertise a safer cigarette, this implies that cigarettes already on the market are unsafe, leaving them open to further investigation.² More Americans have died from smoking than from WWII and the Vietnam conflict combined. According to the 2004 Surgeon General's Report on smoking, the list of diseases caused by smoking has been expanded to include abdominal aortic aneurysm, acute myeloid leukemia, cataract, cervical cancer, kidney cancer, pancreatic cancer, pneumonia, periodontitis, and stomach cancer.³ These are in addition to diseases previously known to be caused by smoking, including bladder, esophageal, laryngeal, lung, oral, and throat cancers, chronic lung diseases, coronary heart and cardiovascular diseases, as well as reproductive effects and sudden infant death syndrome.³ Cigarette smoking is responsible for 440, 000 deaths each year.³

The use of tobacco products represents one of the most serious public health problems today. If over 400,000 people in the U.S. were to die from influenza, tuberculosis, small pox, measles, or any other preventable disease, the situation would be deemed catastrophic. Health care professionals would mobilize forces. Either directly or indirectly, society bears the cost of tobacco-related problems, and smokers pay the price of impaired health. Smokers, on average, miss 2 more days from work than

nonsmokers and make six more visits per year to health care facilities.^{3,4} Moreover, family members of smokers make four more visits to health care facilities than families of nonsmokers. Nonsmokers pay for the health care costs of smokers through higher taxes and insurance premiums.⁵

Smoking and Health

According to Goldberg, “most people who continue to use tobacco products do so because nicotine is addictive.”⁶ The effects of smoking are very reinforcing and many people smoke while being aware of the hazards of doing so. Nicotine reaches the brain in seconds and many simply light up another when the nicotine level in the system lowers. For some, smoking has become a ritual that has been ingrained into their lives. Some experience a sense of comfort from smoking. Also, withdrawal may be uncomfortable and may include lowered heart rate, tremors, aggressiveness, hunger, heart palpitations, headaches, anxiety, lowered blood pressure, shorter attention span, increased circulation, insomnia, fatigue, drowsiness, and nicotine craving.

Nicotine is as addictive as heroin.⁷ It is 1000 times more potent than alcohol, 10 to 100 times more potent than barbiturates and 5 to 10 times more potent than cocaine or morphine. Over 4,000 chemicals are found in tobacco smoke and a cigarette contains 69 known carcinogens.^{8,9,10} Nicotine acts on the brain to alter people’s moods, appetites and alertness. Users say it helps them to maintain concentration, reduce anxiety, relieve pain and dampen their appetites. In high doses, nicotine is used in everything from insecticides to darts designed to bring down elephants.

Substances cross the placenta and reach the fetus causing (1) decreased placental blood flow, (2) increased incidence of miscarriage, unexplained vaginal bleeding, hemorrhaging and premature labor, (3) increased risk of ectopic pregnancy, (4) increased risk of low birth weight and fetal growth retardation, (5) increased risk of still birth, and (6) decreased fetal heart rate after smoking.¹¹ Smoking while pregnant results in fetal tobacco syndrome, hyperactivity and short attention span.

Carbon monoxide in tobacco smoke interferes with the fetus. Babies born to women who smoke during pregnancy weigh less than and are more likely to be delivered prematurely than babies born to women who do not smoke while pregnant.¹² Pregnant smokers have a higher incidence of spontaneous abortions (miscarriages) than nonsmokers, as well as higher rates of stillbirths.¹³ Smoking also significantly reduces fertility in women. Sudden infant death syndrome (SIDS), in which babies suddenly stop breathing, occurs at a higher rate in women who smoked during pregnancy.¹⁴ Smoking during pregnancy is also a minor risk factor for cleft lip and cleft palate in the newborn.¹⁵

Attempting to Quit

To become an ex-smoker is a process rather than an act – a process in which choices and changes must be made that will affect one’s lifestyle. These changes lead to the goal of a smoke-free life. Stages of change consist of (1) precontemplation, (2) contemplation, (3) preparation, (4) action, (5) maintenance, (6) relapse, and (7) termination.¹⁶ With motivational interviewing, one expresses empathy, avoids argumentation, rolls with resistance, supports self-efficacy, provides choice, and provides feedback. Pharmacological interventions consist of bupropion (Zyban, Wellbutrin), nicotine patch, gum, nasal spray, lozenge and inhaler. Coping skills address preparing to quit by purchasing a single pack (not the carton), switching brands, delaying each cigarette, keeping cigarettes in one place, eliminating places to smoke, and smoking only half of each cigarette. Coping skills include the 4 D’s: (1) delay, (2) deep breathing, (3) doing something, and (4) drinking water. Coping skills are involved with removing temptations, enlisting support, changing one’s usual routine, changing the way one thinks, and developing healthy eating habits. Benefits of quitting do include time, freedom, relationships, improved health, and financial reward.

The younger a person is when attempting to quit smoking, the greater is the benefit due to the body’s regenerative ability. Five to fifteen years after quitting, the risk of stroke in an ex-smoker is similar to that of a non-smoker.¹⁷ The risks of multiple types of cancers decrease significantly after quitting for ten years.¹⁷ Amazingly, the risk of death for ex-smokers of fifteen years is about the same of that of a non-smoker.¹⁷ Stopping the use of smokeless tobacco is more difficult than quitting cigarettes. A number of smokeless tobacco users switch to cigarettes although few cigarette users switch to smokeless tobacco. One reason that people have trouble overcoming tobacco dependency is that many activities trigger smoking. People are cued into smoking when waking up, having a cup of coffee, finishing a meal, talking on the phone, driving a car, or drinking alcohol. Smokers who are active alcoholics are less likely to stop smoking than smokers with no history of alcoholism, suggesting that discontinuing alcoholism might increase the potential for successful smoking cessation.¹⁸

Pomerleau, Zucker and Stewart found that 40 percent of women smokers are concerned about gaining weight once they stop.¹⁹ The average weight gain for women ranges from 8 to 10 pounds, depending on multiple factors including age and race.¹⁹ It is important to note that not all women gain weight when quitting smoking, while others may gain up to 30 pounds.¹⁹ Health care providers may be able to motivate women concerned about weight gain by focusing on how quitting smoking favorably impacts

other areas of body image including fresh breath, fewer wrinkles, whiter teeth and increased appearance of fitness.¹⁹ Being paired up with a buddy doubles one's chances of stopping smoking, regardless of the type of treatment.²⁰ Confidence, not overconfidence, in one's ability to stop smoking is a crucial variable in how long one remains abstinent.

Smoking Cessation: Pharmacological Agents

The FDA has classified nicotine as a "pregnancy category D," meaning there is evidence of risk to the human fetus. Therefore, none of the nicotine replacement formulations have received FDA approval for use in pregnancy. Although pharmacological agents may pose a risk to a developing fetus, it is arguably less than the risks of continued smoking. However, due to potential fetal harm when administering pharmacological agents during pregnancy, they should be reserved for women unable to quit using non-pharmacologic methods. Prescribing at the low end of the effective dose range and using formulations that yield intermittent, rather than continuous drug exposure, e.g., the gum, nasal spray, or inhaler, may help reduce the risk of harm.²¹

1. Nicotine gum, Nicotine Polacrilex gum (Nicorette) is available without a prescription. Nicotine gum is the only pharmacological agent that the FDA has classified as Category C.²² This agent may be an appropriate option for patients who desire oral stimulation during cessation, identify boredom as a trigger for smoking, or are concerned about weight gain after quitting.²¹ Nicotine gum (i.e. Nicorette) and other nicotine replacement systems provide a safer source of nicotine than cigarettes, since they do not contain other chemicals and carcinogens in addition to nicotine. Nicotine gum reduces withdrawal symptoms associated with cigarettes, but it does not provide the same satisfaction as cigarettes because nicotine gum is absorbed more slowly. Nicotine is absorbed irregularly and unpredictably, limiting its success. In one study, nicotine gum alone was successful in getting 11% of smokers to stop. The number increased to 27% by combining nicotine gum with attendance at a smoking cessation clinic.
2. According to Windsor, et al., patient-controlled doses in two formats (2 or 4 mg) is an advantage to nicotine gum.²² Additionally, nicotine gum has been studied with pregnancy and has shown to be an effective intervention. Disadvantages include nausea, stomach upset and heartburn.

Nicotine Patches: As of 1996, the nicotine patch, containing 30 mg of nicotine, became available as an over-the-counter drug. The patch eases withdrawal symptoms that accompany tobacco cessation. Early studies with the nicotine patch demonstrated that it was effective for helping smokers quit, but long-term effectiveness has not been established. Abstinence rates for those using nicotine patches ranged from 5.3% to 12.5%. Some users report skin rashes.²³ The biggest drawback, however, is for people to continue to smoke while wearing the patch, because they receive dangerously high levels of nicotine. In an out-of-court settlement, the Ciba-Geigy Corporation, which sells the nicotine patch Habitrol, changed its advertisements because consumers believed that the patch was more effective than it actually is. Ciba-Geigy was required to include information that pregnant women, nursing mothers, and people with cardiovascular disease should check with their physicians before using the patch. The nicotine patch is available over-the-counter and in prescription strength. The dose should directly relate to the amount of cigarettes smoked per day. This once-a-day application can also be used in conjunction with gum or the inhaler for heavy smokers. With overdose of nicotine a valid threat, combination therapy should only be used if monotherapy is unsuccessful. A recent study concludes that nicotine patch therapy in later pregnancy has potential benefit for pregnant smokers who continue to smoke despite physician advice to stop.²⁴

Advantages of the nicotine patch include different dosage levels and good compliance.²² The nicotine patch has been studied in pregnancy and "consistently doubles success rates in clinical trials."²² Unfortunately, if patch use is not monitored carefully, or if cigarettes are smoked in addition to the patch, total nicotine exposure may be more than when just smoking. Additionally, wearing the patch while sleeping may exceed the normal smoking levels. Therefore, it is recommended to remove the patch while sleeping.

3. Nicotine Inhalers: The FDA approved the nicotine inhaler in 1996 as a Category D drug.²² Similar to nasal inhalers, the nicotine nasal spray pumps small amounts of nicotine from small tubes into the nose. A common side effect is nasal and sinus irritation. Therefore, it is not recommended for people with nasal or sinus conditions, allergies, or asthma. Also, it is not recommended for use exceeding six months. In a double-blind study, smokers who tried nicotine inhalers were more likely to abstain than smokers in a placebo inhaler group. In a review of numerous studies, nicotine replacement therapy was found to double the smoking cessation rates when compared to a placebo.²

Nicotinic Inhaler is available with a prescription. The inhaler, a relatively new delivery system, has the best effects with frequent puffing. Patients who have nervous energy and need something in their hands may prefer the inhaler to gum.

The nicotine nasal spray provides similar delivery and is typically cheaper than the inhaler by approximately 50 percent.²⁵

Windsor et al. list the advantages of the nicotine inhaler as a relatively low, intermittent exposure to nicotine.²² Unfortunately, there are no studies to determine the safety of nicotine inhalers in pregnant women.

4. **Drug Therapy:** New methods of nicotine delivery are being researched. Bilayer nicotine mucoadhesive tablets would provide the patient with an initial burst of nicotine, with sustained nicotine release over the next four hours.²⁶ In addition, researchers concluded that an oral nicotine solution or nicotine lozenges might prove useful for smoking cessation with patients who cannot tolerate chewing gum.^{27,28}

In 1997 the Food and Drug Administration approved the drug Zyban for smoking cessation. Originally, as an antidepressant, how Zyban works is unclear but it does seem to reduce the desire for nicotine. Side effects associated with Zyban are dry mouth, difficulty sleeping, and skin rash. Convulsions and loss of consciousness occur in 1 in every 1,000 people who take the drug. It is contraindicated for people with epilepsy, eating disorders, and women who are pregnant or breast-feeding.²⁹

Bupropion is a monocyclic antidepressant structurally related to amphetamine. Bupropion sustained-release (SR) is the first non-nicotine-based therapy that is effective for achieving abstinence from smoking. Bupropion SR appears to reduce reported cravings, which may contribute to the overall reduction in the rate of relapse observed with this pharmacotherapy, particularly for women.

Another drug used for nicotine addiction is clonidine. Also used to treat hypertension, clonidine inhibits the craving for drugs during narcotic withdrawal. Antianxiety drugs have been given to smokers trying to quit. These drugs reduce irritability of smokers while they try to quit. In a pilot study, Prozac was found to help some individuals maintain their abstinence from cigarettes when it was combined with either group therapy or the nicotine patch. Prozac reduces appetite, and this feature might appeal to people who are concerned about weight gain when they quit smoking.

Smoking Cessation: Educational Approaches

Although nicotine replacement and other pharmacological treatments head the list of popular interventions for smoking cessation, approaches based on psychology can also assist smokers. Hypnosis, suggestion, and behavior therapies have been offered to patients and studied experimentally for several decades. Although no single psychological approach has been found to be superior to others, psychological interventions contribute significantly to successful treatment outcome in smoking cessation.³⁰

Committed Quitters Program (CQP) is a computer-tailored set of printed behavioral support materials offered free to purchasers of NicoDerm® CQ® patches, as a supplement to the nicotine patch and the standard brief User's Guide (UG) and audiotape. Among those who reported they had used their assigned materials, the CQP increased quit rates significantly at both 6 and 12 weeks over the nicotine patch, User's Guide, and audiotape alone. The combination of easily-accessible nicotine replacement therapies and effective written materials represents a useful model for efficient delivery of effective smoking interventions on a mass scale.²⁸

Chewing dextrose tablets results in a rapid increase in blood glucose levels that would be expected to yield a small reduction in these sensations that might then translate into a reduction in craving. An intervention that reduced craving might help smokers to maintain abstinence.³¹

Aversive Techniques: One aversive technique is to have smokers engage in rapid smoking until they exceed their tolerance levels and become ill. The point is to make smoking an unpleasant experience. This technique is similar to negative reinforcement. An obvious drawback is that it may seriously endanger health, especially of a person with a cardiovascular problem. Another aversive technique is to give the drug taker an electric shock when engaging in drug use. This technique has been applied to alcohol treatment, and its benefits are short-term at best.

Behavior Modification: The premise of many programs is to change behaviors linked to smoking. Basically, the smoker learns new or alternative behaviors to use in place of smoking. For example, if a person typically smokes after dinner, he or she could take a walk instead. If someone is accustomed to smoking while talking on the telephone, he or she could use paper and pencils placed next to the telephone to doodle in lieu of smoking. People can be taught to avoid or deal with situations in which the temptation to smoke might be a problem. Many behavior modification programs include support groups or a buddy system in which the buddy is called when the urge to smoke strikes.

Hypnosis: Hypnosis is successful with some people. It seems to work best with people who want it to work; it is most effective with motivated individuals. By the same token, if a person is motivated, the specific program undertaken might not matter. Hypnosis might provide the excuse to motivate people to stop smoking, although hypnosis was not found to be particularly effective for getting pregnant women to stop smoking.³²

Acupuncture: Approximately one-fourth of smokers who undergo acupuncture remain cigarette-free for at least a year. The mechanism by which acupuncture stops the desire to smoke is unclear. Nevertheless, advocates of acupuncture claim that it reduces the physical symptoms of withdrawal. Acupuncture sessions typically are 30 minutes long, and smokers receive treatment from 2 days to 3 months.

Smoking Cessation for Pregnant Women

Smoking cessation during pregnancy significantly reduces the risks of fetal death, low birth weight, and maternal complications during pregnancy, childhood asthma, lung cancer and cardiovascular disease.^{33,34} A recent study has found that maternal smoking more than doubles the estimated risk of Sudden Infant Death Syndrome.³³ The physical costs of smoking are clear. Financially, smoking-attributable neonatal costs in the U.S. represent almost \$367 million in 1996 dollars.³⁵ Unfortunately, many people addicted to nicotine, including pregnant women, are unable to quit. In addition, approximately 60% of women who quit smoking during pregnancy will return to smoking within the first six months postpartum, with 80% to 90% experiencing a relapse by twelve months postpartum.³⁴

From 5% to 15% of women who smoke quit as soon as they discover they are pregnant, but a 5- to 15-minute counseling session by a trained health care provider combined with appropriate patient educational materials would increase cessation rates to 15%-20%. Follow-up counseling could improve these rates even more. Unfortunately, counseling does not usually help heavy smokers. For those who cannot quit otherwise, the clinical practice guidelines recommend pharmacotherapy, despite a lack of evidence about the safety and efficacy of nicotine replacement therapy and bupropion use among pregnant women.³⁶ Health care providers need to question patients about possible pregnancy-related pros of smoking. Researchers have found pregnant smokers in the precontemplation, contemplation and preparation-for-action stages identify more with avoiding the difficulty of quitting while pregnant and use smoking as a form of relaxation.³⁷

Pregnant women in the preparation-for-action stage were found to be the most influenced by potential disapproval of others.³⁷ Women who receive postpartum assistance via phone calls were significantly less likely to be smoking at 8 weeks and 6 months after delivery than those who received only prepartum assistance.³⁴

Helping Patients to Quit: Recognizing the Stages of Change

Stage I. Precontemplation

Within the precontemplation stage, smokers deny having a problem. Approximately 40 percent of users are in this stage.³⁸ When questioned about tobacco use, patients may respond with a "get out of my face" reaction. Another typical reaction may be "Yes, I smoke, and I like it." When using interviewing skills, the health care provider should look for body language such as rolling of the eyes and turning away from the provider. The patient's tone may be negative, aggressive, or sarcastic.

What should the health care provider do or say when interacting with patients in the precontemplation stage? First and very important, the health care provider should stay low key and be very brief. It is important to let the user know the office would be happy to help them if they are interested in quitting. The health care provider should not allow the user to intimidate. Users expect questions about tobacco use from health care providers.

Stage II. Contemplation

When users have first identified they have a problem, they move from the precontemplation stage to the contemplation stage. Approximately 40 percent of users are in this stage.³⁸ Although the problem has been identified, the user has made no commitment to take action. Users may remain in this stage for years. When using interviewing skills, the health care provider should look for body language that is not as defensive or aggressive as users in the precontemplation stage. Users may respond to questions about smoking with "Yes, I know smoking is bad, but there's no way I can quit."

What should the health care provider do or say when interacting with patients in the contemplation stage? Health care providers should politely give as much information as possible. At the same time, it is essential to elicit much information from the user. Asking the user why he/she wants to smoke and comparing that list to why he/she wants to quit can help the user evaluate the pros and cons of smoking. The health care provider should examine the list the user has made, and tailor the education according to those pros and cons. Health care providers have the greatest potential to influence the user in this stage of change.

Stage III. Preparation-for-Action

When users have identified they are ready to quit within the next six months, they move from the contemplation stage to the preparation-for-action stage. Approximately 20 percent of users are in this stage.³⁸ Although users have agreed to try to quit, they may be hesitant. Previous unsuccessful attempts and lack of knowledge about cessation may act as barriers to quitting. What should the health care provider do or say when interacting with patients in the preparation-for-action stage? First and foremost, the health care provider should congratulate and reassure the user about the value of the decision to quit. Next, the provider should ask the user what questions they have about cessation and what can be done to help the user quit. Discussion of previous attempts can provide insight into why the user may have been unsuccessful previously. Withdrawal symptoms, coping tips and nicotine replacement therapy should all be considered for part of the user's plan to quit. The ultimate goal of working with a user in the preparation stage is to have the user set a quit date, optimally within the next two weeks.

Stage IV. Action

When users have started the process of quitting, they move from the preparation-for-action stage to the action stage. The action stage normally lasts from three to six months. Users may actually enjoy discussing smoking with their health care provider for the first time in their lives.

What should the health care provider do or say when interacting with patients in the action stage? Providing follow-up for users within the action stage is very important. Follow-up includes sending a postcard reminding the user about the quit date set may encourage the user to follow through with the quit plan. In addition, phone calls can be made to provide support and answer any questions the user may have. Ultimately, the health care provider should "brag" up the patient's efforts to quit.

Stage V. Maintenance

After the ex-user has abstained from smoking for six months, he/she moves from the action stage to the maintenance stage. The ex-user will remain in this stage for life unless relapse occurs.

What should the health care provider do or say when interacting with patients in the maintenance stage? No matter how long ago ex-users quit, it is important for the health care provider to congratulate them. Asking how quitting has benefited their lives may remind users why they quit in the first place. Asking how ex-users were successful may remind them about their ability to control their own lives. Inquiring about any perceived future obstacles provides the health care providers an opportunity to discuss ways to avoid relapse.

Relapse Prevention

Users that relapse generally start over at the contemplation stage, not precontemplation. Possible reasons for relapse include a lack of support, negative mood or depression, strong or prolonged withdrawal symptoms, weight gain, flagging motivation and feeling deprived.

Health care providers can suggest several alternatives to combat relapse. Health care providers should schedule follow up visits or telephone calls to the user to provide adequate support. In addition the provider can help the user identify internal sources of support such as family and friends. Referring the user to an organization with counseling or support can also help. Counseling is also beneficial for users who are depressed after quitting. Medications, such as Zyban, act as antidepressants and aid in smoking cessation. Several other nicotine replacement products are available to deter strong or prolonged withdrawal symptoms. Multiple attempts are often needed before a user will quite for good. It is important for health care providers to not get discouraged and give up when users relapse.

Not all patients experience withdrawal symptoms and very few experience all of them. Potential withdrawal symptoms may include: irritability, anger, hostility, anxiety, nervousness, panic, poor concentration, disorientation, lightheadedness, sleep disturbances, constipation, mouth ulcers, dry mouth, sore throat, gums, or tongue, pain in limbs, sweating, depression, fatigue, fearfulness, sense of loss, hunger and coughing. As previously discussed, the health care provider can serve as partner with the patient and work together as a team to help reduce the adverse consequences caused from tobacco products.

Conclusion

This article recognizes the potential benefits of using pharmacological agents combined with educational approaches to help combat the apparent health problems associated with the by-products of tobacco. Smoking cessation interventions can be more successful when the health care professional understands that a combined approach making use of available pharmacological agents along with existing alternatives that include behavioral and education approaches may be the most effective.

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