OMA Position Paper

Rethinking Stop-Smoking Medications: Treatment Myths and Medical Realities

(January 2008)

As with other drug dependencies, tobacco dependence is a progressive, chronic, relapsing disorder.[1] Unlike other drug dependencies, however, tobacco dependence is still normalized in society.

Recent survey data indicate that almost five million Canadians aged 15+ smoke, and that the vast majority of them smoke on a daily basis.[2]

Tobacco addiction can be treated successfully,[3] and sustained tobacco abstinence has numerous and significant health benefits.[4] Physicians, especially primary care providers, are in the best position to assist smokers in making these health gains, and counseling smokers to quit is recommended during periodic health examinations.[5]

Clinicians can choose from a number of strategies to help patients achieve tobacco abstinence. Broadly, these involve creating smoke-free environments at home, work and social situations, including vehicles, behavioural strategies to manage cravings, prevent relapse and stay smoke free, and the use of stop-smoking medicines.

A discussion of the environmental and behavioural strategies is beyond the scope of this paper. Rather, the reader is encouraged to consult published clinical U.S.[6,7] and U.K.[8] guidelines for helping patients quit smoking. These are based on thorough reviews of the literature and expert opinions of advisory panels. (See also the Cochrane Database of Systematic Reviews.[9])

This paper will address one important and frequently misunderstood component of treating tobacco dependence: the use of stop-smoking medications.

Nicotine replacement therapies, bupropion and varenicline are three effective stop-smoking medications which have been approved by Health Canada. Ideally, use of these medications should be accompanied by counseling.

In Ontario, the OMA collaborates in the development and delivery of continuing education programs about cessation counseling through the Clinical Tobacco Intervention Program.[10] There are also a number of toll-free counseling and quit lines, and free web-based behavioural support programs that are funded by governments and pharmaceutical companies.

Nicotine replacement therapy (NRT) is considered a cornerstone in clinical guidelines for smoking cessation in the U.S.[6,7] and the U.K.[8]

NRT makes it easier to avoid smoking by replacing some (but not all) of the nicotine that smokers obtain from tobacco.[11] Thus, it reduces withdrawal symptoms (e.g., irritability, headaches, cravings) from tobacco abstinence by supplying nicotine in a safe manner, without the harmful constituents contained in tobacco smoke.

NRT is available in Canada in the form of nicotine gum, lozenge, inhaler and nicotine patches. These are available as general sales products in Ontario, which means they can be sold in grocery and convenience stores, increasing their availability as options for smokers.

Bupropion hydrochloride is one of two non-nicotine-based medications used to help quit smoking. Bupropion's efficacy does not appear to be due to its antidepressant effects.[12] Recent data suggest that it works by being metabolized to hydroxybupropion and acting as a competitive antagonist of nicotine at the nicotine receptors in the brain.

Bupropion should not be used for patients with seizure disorders, or those with a current or prior diagnosis of bulimia or anorexia nervosa.[13] Furthermore, it should not be used in patients treated with other medications that contain bupropion, or in individuals concurrently receiving monoamine oxidase inhibitors. The risk of seizures associated with bupropion use, although low (1 in 1,000, which is similar or

SUMMARY OF RECOMMENDATIONS

1. Stop-Smoking Medications should be made available to patients with cardiovascular disease who have not been able to quit using non-pharmacologic methods.

2. As with other drugs, nicotine replacement therapy (NRT) dosage should be modified to suit the smoker's needs. Use of the appropriate combination of products is also necessary.

3. NRT should be made available to pregnant women who are unable to quit using non-pharmacologic methods. As with other drugs, NRT dosage should be matched to suit the smoker's needs.

4. Partners who smoke should not smoke around pregnant women; they should be encouraged to quit, and should also consider using stop-smoking medications.

5. Cessation medications should be made available for smokers under 18 who want to quit.

6. Smokers should be encouraged to consider use of the various NRT products concurrently, and/or in combination with bupropion as needed, to control their withdrawal symptoms.

7. Smokers should be encouraged to individualize their NRT dosage to meet their nicotine needs.

8. Hospitals should include cessation medications in their drug formularies, and should offer a cessation program based on the Ottawa model to all smokers admitted to their facility. Standard orders should be available to relieve withdrawal and enhance the likelihood of cessation.

9. The attending physician should routinely offer cessation medications to hospitalized patients who smoke, including patients in psychiatric wards.

10. When smokers know of their hospitalization in advance, these patients should be offered assistance in gaining skills to abstain from tobacco, including the offer of cessation medications. Ideally this should be done six weeks prior to their admission.

11. Smokers should be encouraged to use NRT for as long as needed to maintain or prolong tobacco abstinence. Periodic assessments to evaluate the continued use of nicotine should be offered to the patient.

12. Physicians should consider prolonging varenicline therapy for patients for at least 24 weeks if they are not smoking 12 weeks after they have started the medication.

13. Smokers who cannot imagine being without their cigarettes should try using NRT to take a "cigarette holiday." Over time, these smokers should attempt to gradually extend the duration of these cigarette-free periods.

14. Highly dependent smokers who are unable or unwilling to quit completely should use NRT to help them substantially reduce their cigarette consumption. Over time, these smokers should, ideally, replace more and more of the tobacco they use with NRT.

15. The recent approval by Health Canada of nicotine gum for the purpose of reducing consumption in those who continue to smoke should be extended to all forms of NRT.

16. The manufacturers of NRT products should make these products available at every retail outlet where tobacco products are sold and retailers should display them prominently.

17. The federal government should remove the GST on NRT products.

18. The pharmaceutical industry should work to closely match the package quantity of NRT to tobacco products and ensure that the cost of nicotine replacement therapies not exceed the cost of tobacco products.

19. Cessation medications should be covered under both public and private health insurance plans without penalizing the most dependent smokers who might need long-term treatment to quit successfully.

20. Free NRT programs should be offered annually to help large number of smokers making a quit attempt to be successful.

less than selective serotonin reuptake inhibitors), increases with higher doses of bupropion.[13]

Varenicline is the newest non-nicotine-based medication available. It acts on the alpha4 beta2 nicotinic acetylcholine receptor in the brain, which is also responsive to nicotine. Varenicline acts as a partial agonist stimulating the sufficient release of dopamine to reduce craving and withdrawal, while simultaneously acting as a partial antagonist to block the effect of nicotine.[14]

There are second-line medications (clonidine and nortriptyline) for the treatment of tobacco dependence that should be considered in certain circumstances.

Medications are likely to play a more central role in the future treatment of tobacco dependence as the shrinking residual population of smokers represent those who may be more highly addicted and therefore have been unable to quit.

Across Canada, almost 22 per cent of daily smokers aged 15+ said they smoke their first cigarette within five minutes of waking[15] (part of a measure indicating very high nicotine dependence[16]) and 33 per cent within 30 minutes of waking.[15] When asked, without prompting, what would make them quit, 17 per cent of smokers in Canada said that nothing, or only their own death, would make them quit.[17]

The OMA would like to reduce the burden from continued smoking by promoting evidence-based strategies that meet the needs of smokers. We recognize that increasing the use of cessation medications will assist in achieving this goal. This paper will address common misconceptions regarding stop-smoking medications, as there is a great need for clarification in this area.

Recommendations in this paper broaden the therapeutic potential of cessation medications. They also call for regulatory and policy changes to increase recognition of, and access to, stop-smoking medications.

This position paper is based on up-to-date scientific and clinical evidence and experience. Its development is consistent with the OMA's role in contributing to community programs and policies aimed at the prevention of tobacco use and treatment of tobacco dependence over the past 40 years.

Safety

Myth #1

Nicotine is the harmful substance in cigarettes.

Medical Reality

It is not nicotine, but the thousands of toxins present in tobacco and its combustion products, that are responsible for the vast majority of tobacco-caused disease.

Cigarettes are a well-known cause of cancer, chronic respiratory illnesses, and heart disease.[18] There are more than 4,000 compounds in tobacco and tobacco smoke, and over 40 of these substances, including benzopyrene, nitrosamines, vinyl chloride, arsenic, chromium, and nickel, are known to cause cancer.[18]

Nicotine has long been believed to be one of the major toxins that contributes to tobacco-caused disease. However, it is the myriad other toxins in cigarette smoke that is responsible for the majority of these harmful effects.[19]

Nicotine has not been shown to cause cancer.[19] It is not implicated in the development of chronic respiratory disorders due to smoking. Heart disease caused by smoking is largely due to tobacco combustion products, not nicotine.[19]

It is the delivery system through tobacco smoke, not nicotine, which is responsible for the vast majority of tobacco-caused disease.

Myth #2

Nicotine's addictive potential is the same regardless of whether nicotine is obtained through NRT or cigarettes.

Medical Reality

Cigarettes are far more addictive than nicotine replacement products primarily because of the way in which they deliver nicotine.

Nicotine can be a highly addictive drug, as addictive as heroin or cocaine.[3] Its addictive potential differs primarily by the rate and route of nicotine dosing.[20] Inhalation of nicotine through cigarettes is the most addictive method of nicotine delivery.[20] Because nicotine from cigarettes is absorbed through the lungs, nicotine levels in the blood reach a peak within seconds then decline rapidly, and this pattern is repeated and reinforced with every inhalation. The quick delivery of nicotine to the brain results in a faster and more intense response, which leads to addiction.[21]

Currently available nicotine replacement products, although so-named, do not actually "replace" all of the nicotine that is obtained from cigarettes.[11] These products do not produce the high nicotine levels in the blood obtained from cigarette smoking.

The patch delivers nicotine through the skin much more slowly, in lower doses, and more evenly than cigarettes.[21] With the patch, nicotine levels in the blood rise over hours, which results in a very slow onset of effects.[22] Because of the rate and route of drug delivery, the nicotine patch has no addictive potential.[22]

Gum releases nicotine with chewing, and it is absorbed through the mucous membranes into the bloodstream over 20 to 30 minutes.[21] Lozenges work in a similar manner, releasing nicotine on contact. Nicotine is absorbed more rapidly from the gum and lozenge than from the patch, but much more slowly than from cigarettes. Because of the rate and route of drug delivery, nicotine gum and lozenge have little addictive potential.[22]

The inhaler produces a spray that delivers the nicotine, which is also absorbed through the mucous membranes. Once again, this is slow compared to smoking.

The behavioural aspect of drug administration is also an important factor associated with addiction. With cigarette smoking, it is very easy for a user to reinforce his or her tobacco addiction. Assuming 10 puffs per cig-

arette, a pack-a-day smoker can repeat the regular "hand- to-mouth" motion 250 times a day, or over 90,000 times a year.[23] The smoker is also able to self-titrate the nicotine dose on a puff-by-puff basis to meet his or her needs. By inhaling more deeply or at a faster rate, or by blocking filter holes in so-called "mild" or "light" cigarettes (that are present to dilute the inhaled substances with air), the smoker is able to increase the amount of nicotine that is obtained through the cigarette.[20]

The "immediate release" replacement products like the inhaler, gum or lozenge are usually taken in response to a craving. Therefore, these behaviours are reinforcing, although less so than cigarettes due to the amount of nicotine and less social desirability of these products compared to cigarettes.

The nicotine inhaler does replicate some of the hand-to-mouth behavioural and titration aspects of smoking. However, the nicotine does not enter the lungs and is absorbed through the mucous membrane lining the oral cavity. Use of nicotine gum, on the other hand, has some behavioural reinforcing effects (chewing is required to release the nicotine), but far fewer than those of cigarette smoking.[21] Use of the nicotine patch involves little or no behavioural component, as it need only be applied and left on the skin.[21] Therefore, the use of the patch is least likely to be behaviourally reinforcing.

The cigarette has become a highly engineered and carefully designed nicotine delivery system. It is far more addictive than nicotine gum and the patch. Essentially, the cigarette does for nicotine what crack does for cocaine: it makes a highly addictive form of the drug more readily available and convenient to repeatedly self-administer, resulting in higher rates of morbidity and mortality.[1] This is because the total harm that can be caused by a product is a function of its inherent danger, frequency of use and prevalence of use. Therefore, cigarettes are by far the most dangerous and lethal consumer product on the market today, and are estimated to kill about 500 million people globally in the next 50 years.

Myth #3

Nicotine replacement therapy is hazardous for smokers.

Medical Reality

Nicotine replacement therapy is safe for smokers.

NRT provides nicotine to the smoker without the dangerous toxins that are present in cigarettes and cigarette smoke. These toxins, not nicotine, are responsible for the vast majority of smoking-caused disease. NRT is considered a "clean" nicotine delivery system and is safe for smokers.

Major adverse effects from using nicotine gum or the nicotine patch are very rare.[24] In addition, the nicotine gum and patch have little or no addictive potential, whereas cigarettes are the most addictive and toxic form of nicotine delivery. As a general rule, nicotine administered as a medication is far safer than nicotine obtained by cigarette smoking.[25]

Myth #4

Smoking while using NRT causes heart attacks.

Medical Reality

Use of NRT while smoking does not increase cardiovascular risk.

Smokers are already at high risk for cardiovascular events. Smoking causes serious cardiovascular effects, such as atherosclerosis, acute myocardial infarction, stroke, and sudden death.[18] These health hazards are caused primarily by cigarette combustion components, not nicotine.[19]

Nicotine affects the cardiovascular system by acting as a stimulant, e.g., by increasing heart rate and heart contractility.[26] These effects do not increase with higher nicotine intake, which may occur when nicotine is obtained from two sources at once, such as smoking while using NRT.[27]

A widespread misconception exists among physicians and the public that smoking while using the nicotine patch poses additional dangers to a smoker's cardiovascular system. This myth likely originated from six highly publicized case reports in the media in 1992 about individuals who had suffered heart attacks while smoking and using the patch.[28] A subsequent investigation found no evidence of increased toxicity among smokers using the patch.[29]

The Lung Health Study, the largest study on the safety of NRT, and the only study to date investigating long-term NRT use (up to five years), found no statistical increase of cardiovascular risk among those who used tobacco and NRT together.[30]

In another study, smokers on high-dose patch therapy (up to 63 mg/24 hr nicotine patches) did not experience any short-term adverse effects on their cardiovascular system.[31]

Myth #5

Patients with heart disease should not use nicotine replacement products.

Medical Reality

It is more dangerous for patients with heart disease to continue to smoke than to use NRT. Given the seriousness of their medical condition, cardiac patients who cannot quit using non-pharmacologic methods should be among those first considered for NRT and other cessation medications.

It is extremely dangerous for patients with heart disease to continue to smoke. Smoking causes the activation of coagulation pathways and the promotion of thrombosis, which can cause heart attacks.[32] A cardiac patient who smokes also exposes himself or herself to significant heart toxins, such as carbon monoxide and oxidant gases, which reduce oxygen delivery to the heart.[32]

As mentioned, tobacco-caused heart disease is caused primarily by toxins other than nicotine. However, nicotine may aggravate cardiovascular disease through its stimulant effects.[32]

Nonetheless, studies consistently

show that the nicotine patch is safe among patients with cardiovascular disease.[29,33] Cardiac patients who used the nicotine patch were not found to have greater rates of death, heart attacks, or cardiac-related hospitalizations compared to those who did not use NRT.[34] NRT should be considered for cardiac patients who cannot quit using non-pharmacologic methods.

The use of nicotine replacement is a pragmatic strategy to help smokers admitted to the coronary care unit to manage withdrawal. In the absence of NRT, some smokers sign themselves out of the hospital to have a cigarette. Treating the withdrawal is often the first step in engaging such smokers in cessation programs in follow-up.

Bupropion is not prohibited for patients with heart disease.[13] About five per cent of patients with stable congestive heart failure (CHF) who are treated with NRT may develop elevation of systolic pressure.[13]

Varenicline usage in patients with cardiovascular disease is the subject of ongoing research.[35] Studies to date on such usage in cardiac patients have shown no cardiovascular adverse events.[35,36]

Underlying the approach should be the utmost need to help the patient to stop smoking as a life-saving measure.

Recommendation #1: Stop-smoking medications should be made available to patients with cardiovascular disease who have not been able to quit using non-pharmacologic methods.

Recommendation #2: As with other drugs, NRT dosage should be modified to suit the smoker's needs. Use of the appropriate combination of products is also necessary.

Myth #6

Pregnant women should never use NRT.

Medical Reality

NRT is safer than smoking for the pregnant woman and her fetus if she is unable to quit smoking with a behavioural intervention. Pregnant women who cannot quit using non-pharmacologic means should be considered for NRT.

The risks of cigarette smoking during pregnancy are well-known: cigarettes substantially increase the risk of spontaneous abortion, prematurity, low birthweight, and perinatal mortality, and these hazards increase with higher cigarette consumption.[37] The mechanisms behind these effects are not clear, however, nicotine is suspected to cause some of these effects through its reduction in uterine blood flow.[38]

There is no safe dose of nicotine during pregnancy,[38] and ideally, pregnant women should be both tobacco-free and nicotine-free. This is especially important during the third trimester, when the fetus responds most adversely to nicotine administration.[38]

Many smokers continue to smoke during pregnancy, although they may reduce their daily cigarette consumption. Among women who quit upon learning of their pregnancy, an estimated 21 per cent to 35 per cent relapse before their date of delivery.[39]

Physicians face a serious ethical dilemma when treating pregnant women who smoke. NRT, although potentially harmful to the fetus, is far safer than cigarette smoking, which exposes the woman and her fetus to a myriad of dangerous toxins and more dangerous levels of nicotine. Most importantly, NRT may help pregnant women stop smoking altogether and reap the substantial health benefits of tobacco abstinence that arise from quitting any time during pregnancy.[4]

The OMA recommends that NRT should be considered for pregnant women who are unable to quit using non-pharmacologic means. Continued smoking during pregnancy guarantees fetal exposure to nicotine in its most addictive and toxic form.

Physicians must inform pregnant women of the risks and benefits of NRT in relation to cigarette smoking. Moreover, smoking is also harmful in the post-partum period, being associated with a decreased likelihood and duration of breast feeding. There is also the increased and continuing risk of sudden infant death syndrome (SIDS) in the newborn due to second-hand smoke in the home.

Bupropion is not prohibited in pregnant women.[13] There is no evidence of fetal or reproductive harm due to bupropion.[13] The use of bupropion among pregnant women should be based upon an assessment of the potential risks and benefits of treatment during consultation between an individual patient and her physician. This medication might have good effect, especially if the woman suffers from depression, which is often comorbid with smoking.

Varenicline has not been studied in pregnancy. It is still a new drug and should not be used in pregnant women until animal and human data is collected.

It is also important to note that exposure of the pregnant mother to second-hand smoke causes low birth weight and sudden infant death syndrome, and may cause spontaneous abortion, as well as have an adverse impact on cognition and behaviour in the offspring.[40]

Partners who smoke should not smoke around pregnant women; they should be encouraged to quit, and consider stop-smoking medications. Moreover, since male smokers have abnormal sperm due to the carcinogens in smoke, it is ideal that both partners quit smoking for at least three to four months before attempting to conceive.

Recommendation #3: NRT should be made available to pregnant women who are unable to quit using non-pharmacologic methods. As with other drugs, NRT dosage should be matched to suit the smoker's needs.

Recommendation #4: Partners who smoke should not smoke around pregnant women; they should be encouraged to quit, and should also consider using stop-smoking medications.

Myth #7

Smokers under 18 should not use cessation medications.

Medical Reality

Most daily smokers begin smoking before age 18, and are therefore already getting nicotine. The nicotine patch and gum are far safer than smoking. Cessation medications should be considered for all smokers, including those under 18.

Cigarette smoking is an addiction that is most likely to become established during adolescence.[41] Studies of youth have shown that the first symptoms of dependence can appear in a matter of days or weeks of intermittent tobacco use.[42]

In Ontario, almost two-thirds of daily smokers report smoking daily before age 18, eight per cent before age 13.[43] It is not surprising, then, that many adolescent smokers are already addicted to nicotine and report suffering withdrawal symptoms similar to those reported by adult smokers.[41,44]

In one study, over half of youth smokers in Ontario had attempted to quit smoking in the past year.[45] Over 40 per cent of these youths were not able to remain abstinent for longer than a week, and almost 60 per cent of the youths who had attempted to quit reported that quitting was very difficult or fairly difficult for them.[45] Unless evidence shows contravening risk, it would be unjustified to deny treatment to these youth and expose them to the potential for injury or death.

There is no evidence that nicotine replacement is harmful to children and adolescents.[6] Children and adolescents who need NRT to quit should not be denied this treatment. NRT provides them with a safer delivery form of nicotine than cigarette smoking, helps them control their withdrawal symptoms, and most importantly, may help them quit.

Clinical guidelines on smoking cessation in the U.S.[6] and the U.K.[8] indicate that youths are a legitimate population in which to consider NRT. A recent trial concluded that the nicotine patch is a safe component to a smoking cessation program for youths.[46]

Bupropion is not prohibited in individuals under age 18.[13] The use of bupropion among smokers under 18 should be based upon an assessment of the potential risks and benefits of treatment. It should be noted that bupropion is used to treat attention deficit disorder and/or depression in youths under the age of 18.

Varenicline is not prohibited for youths. Its use should be based on demonstrable needs of the patient.

Recommendation #5: Cessation medications should be made available for smokers under 18 who want to quit.

Effectiveness

Myth #8

Stop-smoking medications are not effective in helping people quit.

Medical Reality

Cessation medications are effective with or without counseling. NRT and bupropion have each been found to approximately double quit rates compared to placebo, and varenicline triples quit rates.

All three classes of cessation-medications are effective at treating tobacco addiction and alleviating withdrawal symptoms.[35,36,47]

NRT has been studied the most extensively, and doubles the long-term quit rate when compared to unmedicated attempts.[35,36,47]

Bupropion now has over 10 years of study and also achieves a doubling of the quit rate.[35,36,47]

Varenicline is the newest stop-smoking medication but the studies done,[14,48,49,50,51] which meet the standard of rigorous review,[35,47] show a three-fold increase of quit rates.

Myth #9

The various nicotine replacements should not be used at the same time and/or in combination with bupropion.

Medical Reality

The nicotine patch and gum/lozenge/inhaler may be used at the same time and/or in combination with bupropion.

Combining nicotine gum with patch therapy has been found to provide superior quit rates than the gum or patch alone, without an increase in adverse effects.[7,52] For some people, this dual therapy is better than nicotine gum or the patch alone at reducing nicotine withdrawal symptoms.[53]

The combined use provides a quick release replacement, and the patch is a convenient therapeutic option as it gives the user a steady intake of nicotine that can be supplemented with other NRT to respond to momentary smoking urges.[11]

Use of the gum with the patch has been recommended in clinical guidelines on smoking cessation in the U.S.,[7] and in a 1999 update of the pharmacotherapy of smoking by a group of prominent U.S. smoking cessation experts.[52]

NRT can also be used in combination with bupropion.[13] For some people, combined use of bupropion with NRT may be an effective strategy,[54] particularly if single therapy is inadequate. About five per cent of patients taking combined therapy may develop emergent hypertension.[13]

Varenicline is a fairly new treatment and its place in combination therapy is still evolving. Initially, it was thought that it could not be used in combination with NRT because it is a partial nicotine antagonist. It is now being used with NRT in some U.S. and European settings, particularly in hospitals. NRT is being used to relieve acute withdrawal and varenicline given simultaneously, the NRT being tapered as varenicline levels rise.

As yet, there are no published papers, but physicians should be watchful in the next year since guidance is likely to be forthcoming. However, if a smoker is still smoking while taking maximum doses of varenicline, the addition of NRT may be justified to eliminate smoking altogether.

Recommendation #6: Smokers should be encouraged to consider use of the various NRT products concurrently, and/or in combination with bupropion as needed, to control their withdrawal symptoms.

Use

Myth #10

NRT should only be taken in doses recommended by the manufacturer.

Medical Reality

Smokers should be in control of how they use NRT, and should vary the dose according to their own needs. Like smoking, it takes time to learn how best to use NRT in a manner that maximizes its benefits.

Smokers develop a pattern of behaviour that provides them a combination of pleasurable effects and relief from withdrawal symptoms. Cigarette smoking is a very easy and effective means of achieving both of these, and the smoker has learned over time to do this with finesse and flexibility. This accounts for the automaticity of smoking behaviour that can be triggered by countless cues or triggers both within the smoker and the environment.

Without cigarettes, a smoker may suffer withdrawal symptoms, such as depressed mood, irritability, difficulty concentrating, and anxiety.[55] For many smokers, these withdrawal symptoms can be quite severe and extremely difficult to manage. Thus, the treatment should be flexible enough to put more control in the hands of the smoker in order for the medications to suit his or her needs. NRT dosage, as outlined in the labeling, are only guidelines, and should be individualized. Like smoking, it takes time to learn to use NRT in a manner that maximizes its benefits.

Recommendation #7: Smokers should be encouraged to individualize their NRT dosage to meet their nicotine needs.

Myth #11

Enforced smoking abstinence during hospitalization often results in patients quitting.

Medical Reality

Enforced smoking abstinence during hospitalization is unlikely to result in a patient quitting. Smokers should be routinely offered stop-smoking medications prior to and during their hospital stay.

For smokers, abstinence from smoking is stressful in its own right. Hospitalization, regardless of the reason, induces a high level of anxiety and stress in both smokers and nonsmokers alike. The combination of the two factors compounds stress on the hospitalized smoker. This may lead the smoker to reach for cigarettes at the first available opportunity. Smoke-free ordinances in hospitals are necessary as they work in the best interests of all patients. However, enforced smoking abstinence without the provision of additional assistance does not appropriately serve the health-care needs of tobacco-dependent patients.

For smokers who know of their hospitalization in advance, the physician should offer assistance in gaining the skills to abstain from tobacco. This may include preadmission initiation of cessation medications. There is strong evidence to support preoperative smoking cessation at least six weeks prior to surgery to reduce respiratory complications and produce other health benefits.

Hospitalization presents a unique opportunity for smokers to learn how to alleviate their withdrawal symptoms during their stay and beyond discharge. It is a time when smokers have increased contact with health professionals who can provide detailed and personalized advice on abstaining from tobacco.[56]

The University of Ottawa Heart Institute began an in-hospital smoking cessation program based on these and other principles of best practice.[57,58] The results were an amazing abstinence rate of 46 per cent at six months. The program has since been expanded to all hospitals of the Champlain Region, 10 other hospitals in Ontario, and hospitals in British Columbia and New Brunswick.[59] It should ultimately be extended to all Ontario hospitals.

Recommendation #8: Hospitals should include cessation medications in their drug formularies, and should offer a cessation program based on the Ottawa model to all smokers admitted to their facility. Standard orders should be available to relieve withdrawal and enhance the likelihood of cessation.

Recommendation #9: The attending physician should routinely offer cessation medications to hospitalized patients who smoke, including patients in psychiatric wards.

Recommendation #10: When smokers know of their hospitalization in advance, these patients should be offered assistance in gaining skills to abstain from tobacco, including the offer of cessation medications. Ideally this should be done six weeks prior to their admission.

Myth #12

Cessation medications are only appropriate for short-term use.

Medical Reality

NRT should be used for as long as needed to maintain or prolong tobacco abstinence. Some people may need this support for years. Varenicline's effectiveness is enhanced over a second course of treatment.

Long-term use of NRT has been reported in studies and in clinical observations.[60] This appears to be a strategy to maintain or prolong tobacco abstinence, not a sign of dependence.[60]

The safety of long-term use of nicotine gum has been demonstrated in the Lung Health Study.[30] This investigation found no evidence of adverse effects with extended nicotine gum use, based on the experience of over 3,000 users over a period of up to five years. Long-term use of these nicotine medications is far preferable to long-term tobacco use. Use of these safer alternative nicotine delivery systems can be part of a long-term harm-reduction strategy.[61]

One long-term trial of bupropion failed to detect an effect on reduction or cessation.[62]

Varenicline has been shown in one study to be even more effective if the initial 12-week course is continued for a second 12 weeks. This resulted in a 35 per cent increase of the already excellent quit rate at one year.[48] The safety of varenicline at one year has been established.

Recommendation #11: Smokers should be encouraged to use NRT for as long as needed to maintain or prolong tobacco abstinence. Periodic assessments to evaluate the continued use of nicotine should be offered to the patient.

Recommendation #12: Physicians should consider prolonging varenicline therapy for patients for at least 24 weeks if they are not smoking 12 weeks after they have started the medication.

Myth #13

Nicotine gum, inhaler, lozenge or the patch should only be used by those who are ready to quit smoking and should not be used by those who just want to reduce their tobacco use.

Medical Reality

NRT can be used by people who are not yet ready or able to quit as, for some individuals, being tobacco-free is not a foreseeable goal. NRT may help these smokers take a "cigarette holiday," or, in some cases, substantially reduce their smoking as an interim, achievable step toward tobacco abstinence.

For some smokers, total abstinence from tobacco is not a foreseeable goal.[63] These smokers may not be able to imagine being without cigarettes for a day, or even a few hours. NRT may be useful for these individuals who are not yet ready, or able, to quit by helping them abstain from cigarettes for a short period of time, even during a day at work or during a long plane trip. This "cigarette holiday" may introduce the option of eventually becoming tobacco-free. Individuals who use this strategy should attempt to gradually extend the duration of these cigarette-free periods.

There is no safe level of smoking. The risks of smoking-caused diseases such as cancers, chronic respiratory diseases, and cardiovascular disease increase with higher cigarette consumption.[64] Therefore, theoretically, smokers can reduce their tobacco-related health risks by substantially reducing their cigarette consumption. But this may not always lead to a reduction in exposure to tobacco toxins since smokers can change their smoking behaviour (e.g., take deeper or longer puffs) in order to proportionately obtain more nicotine from each cigarette.[65] Since this compensatory response to reduced smoking appears to be driven by nicotine needs, NRT can help smokers reduce their tobacco consumption while minimizing compensation behaviour.[66]

Studies have shown that NRT can help reduce smoking consumption among smokers not deliberately trying to cut down.[67,68] In one study, smokers using NRT were able to reduce their smoking by over 50 per cent while still maintaining a perceived comfortable level of smoking.[68]

Evidence from the Lung Health Study shows that the use of long-term NRT while smoking is not more harmful than smoking alone.[30] Gradually decreasing cigarette use has been shown to increase motivation and confidence to quit, and to promote overall quitting.[69] Individuals who employ this strategy should, ideally, replace more and more of the tobacco they use with NRT.

Recommendation #13: Smokers who cannot imagine being without their cigarettes should try using NRT to take a "cigarette holiday." Over time, these smokers should attempt to gradually extend the duration of these cigarette-free periods.

Recommendation #14: Highly dependent smokers who are unable or unwilling to quit completely should use NRT to help them substantially reduce their cigarette consumption. Over time, these smokers should, ideally, replace more and more of the tobacco they use with NRT.

Recommendation #15: The recent approval by Health Canada of nicotine gum for the purpose of reducing consumption in those who continue to smoke should be extended to all forms of NRT.

Access

The nicotine-dependent individual currently has two options for obtaining nicotine: NRT, manufactured by the pharmaceutical industry, or tobacco products, manufactured by the tobacco industry. These nicotine delivery systems, however, are fundamentally different in their effects on tobacco dependence and in their ability to cause harm.[61]

Cigarettes are manufactured and marketed with the intention of sustaining tobacco dependence. The aim of NRT, on the other hand, is to end tobacco dependence.

Cigarettes deliver nicotine in a manner that maximizes its addictive potential. Cigarettes are a "dirty" drug delivery system that delivers not only nicotine, but also a myriad of toxins that are responsible for the greatest burden of tobacco-caused disease.

NRT delivers nicotine in its pure form in a manner that has low addictive potential. Whereas cigarettes have an established record of death and disease, NRT has an established record of safety and effectiveness. In summary, tobacco promotes its own consumption and thereby the continued harm to the smoker, whereas medicinal nicotine can interrupt the continued use of tobacco while reducing harm to the smoker.

From a regulatory perspective, NRT products are far more restricted than cigarettes — the most hazardous nicotine delivery system available to consumers. Differences in the regulatory status of nicotine in tobacco

products, compared to nicotine in non-tobacco products, lie at the root of this paradox.[70]

Tobacco products are governed by the Tobacco Act[71] and the Smoke-Free Ontario Act[72] at the federal and Ontario levels, respectively. These are regulatory frameworks which presume the products to be legal unless specifically restricted by law.[73] NRT products, on the other hand, are governed by the Food and Drugs Act[74] and the Drug and Pharmacies Regulation Act[75] at the federal and Ontario levels, respectively. These are regulatory frameworks which assume products to be illegal unless specifically permitted by law.[73]

The legislation that governs tobacco sets fewer restrictions on access to, and development of, tobacco products than does the legislation that governs NRT products. For example, tobacco manufacturers are relatively free to manipulate taste and other sensory characteristics to enhance the appeal and continued use of their products. In contrast, making minor changes to such aspects of NRT products (e.g., to increase their palatability and acceptance among smokers) may require years of testing and regulatory review in order to get approval by Health Canada.

People who are addicted by smoking tobacco find the lack of accessibility of NRT to be a barrier to their efforts to stop smoking. Tobacco is an attractive source of nicotine available at outlets in every shopping corner in the country. The smokers who find themselves short at 10:00 p.m. have no difficulty in buying tobacco from a local quick market or gas station. However, it may be some distance to a pharmacy where NRT is sold, and those outlets may be closed. Helpful products should be made equally available to help support people in need.

In Ontario, as of May 31, 2008, all tobacco products will be required by law to be hidden from view until requested by a customer. There will be no displays of tobacco products on store shelves or walls.

Recommendation #16: The manufacturers of NRT products should make these products available at every retail outlet where tobacco products are sold and retailers should display them prominently.

Cost is another barrier to the access of NRT. Although the unit costs of NRT and cigarettes can be similar, a one-time purchase cost of NRT (about $30 for a week's supply) is much higher than a one-time purchase cost of cigarettes (up to $10 for a pack). This larger single expenditure is especially problematic for low-income individuals, who tend to have higher smoking rates and lower quitting rates.[76] The cost at the consumer level can be reduced in a variety of ways. In 2007, the Ontario Government removed the provincial tax on NRT products.[77] This laudable action will benefit all those in need and help level the financial playing field between cigarettes and NRT.

Recommendation #17: The federal government should remove the GST on NRT products.

Recommendation #18: The pharmaceutical industry should work to closely match the package quantity of NRT to tobacco products, and ensure that the cost of nicotine replacement therapies not exceed the cost of tobacco products.

Myth #14

It is not cost-effective to cover stop-smoking medications under health insurance plans.

Medical Reality

The use of stop-smoking medications is a cost-effective strategy. All stop-smoking medications should be covered under health insurance plans.

The costs associated with smoking to the health-care system and to employers are staggering. In 1991, in Canada, health-care costs associated with smoking were estimated to be $2.5 billion, and smoking-related costs due to worker absenteeism were estimated to be $2 billion.[78] On the other hand, strategies to help smokers quit, including the use of stop-smoking medications, have been found to be extremely cost-effective.[79] Greater spending on such interventions produces greater net benefits.[79]

Currently, cessation medications are not covered by the Ontario Drug Benefit Plan (ODB). Coverage of these medications under the provincial health insurance plan is a tremendous opportunity for the government to implement a strategy that makes sense from a fiscal, social, and health point of view. The ODB covers people on welfare, who are the least able to afford the weekly cost of NRT compared to cigarettes.

Cessation medications should also be covered under private health insurance plans. Current coverage of smoking cessation products under such plans varies, as these arrangements are made between the employer and the insurer. For instance, these plans may provide some coverage for prescription products, but not necessarily for over-the-counter products. In addition, reimbursement under these plans may be without restrictions, or limited to a maximum expenditure over a lifetime, or a specific number or duration of courses of therapy. Ideally, reimbursement should be based on the treatment that is needed by the smoker.

Recommendation #19: Cessation medications should be covered under both public and private health insurance plans without penalizing the most dependent smokers who might need long-term treatment to quit successfully.

Myth #15

It is not effective to mail NRT to smokers who call quit lines.

Medical Reality

It has been demonstrated in both Ontario and New York State that motivated smokers will call quit lines, have NRT products mailed to them, and experience higher quit rates than those who attempt to quit without medication.

The programs are able to get three per cent to five per cent of eligible smokers to make quit attempts within a very short period of time. For example, the Smoking Treatment for Ontario Patients (STOP) study in Ontario was able to enroll 13,000 smokers in one month to receive free NRT after a 10-minute phone call. The quit rates in these smokers is between 11 per cent to 22 per cent at one year, with as little as five weeks of NRT.

Given the reach of these interventions to smokers who live in communities without access to stop-smoking services, this population based model has tremendous impact in a very short period of time.[80]

Recommendation #20: Free NRT programs should be offered regularly to help large number of smokers making a quit attempt to be successful.

Conclusion

This paper is based on the most recent expert opinions, medical experience, and scientific evidence.

Currently, access to safe medications is restricted, myths regarding the dangers of these medications are perpetuated, and drug plans do not always cover stop-smoking medications. Regrettably, the smoker is often left with the option that is the cheapest, most readily-available, and most harmful source of nicotine that exists: cigarettes.

Clinicians and policy-makers should use this document to help make sound, evidence-based decisions that work in the best interests of smokers and society-at-large. It is time to provide smokers with access to the assistance they need.

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