

Applying a Chronic Disease Paradigm to Safe and Effective Treatment of Tobacco Addiction

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ABSTRACT

Tobacco consumption remains the leading preventable cause of death, disease and disability. Nicotine is the chemical compound sustaining tobacco addiction, a lethal chronic disease, and the major cause of other prevalent chronic diseases. The downward trend of prevalence rates in Canada appears to have levelled with smoking rates hovering at 18%. Of those individuals who currently smoke, 70% would like to stop and half will try to quit at least once this year. But unless provided with evidence-based and multimodal treatment, only 3-5% of individuals who try will be abstinent six months later. International standards recommend treatment that includes offering combinations of counselling and pharmacotherapy for every individual wanting to quit.

But unlike other chronic diseases, most individuals with tobacco addiction are often precluded from treatment because prevailing ideologies frame their disease as a “lifestyle choice”. This profound misinterpretation of a chronic disease poses a significant barrier to effective tobacco control and a major contributor to unsustainable growth in excess health spending across Canada. Our existing tobacco control paradigm will likely not yield the desired health outcomes and costs savings until policy and clinical practice are aligned with scientific evidence. Furthermore, an urgent need is identified to incorporate an increased level of vigilance for depression and other neuropsychiatric issues has been identified.

This manuscript outlines the health professional’s legal duty to treat and introduces a single algorithmic approach to achieve such. This integrated and unified approach is aimed at defragmenting current approaches by crossing disciplines and levels of care. This guide for safe and effective treatment delivery may be particularly appropriate to resource-scarce settings.

RÉSUMÉ

La consommation du tabac demeure la principale cause évitable de décès, de maladie et d’invalidité. La nicotine constitue l’élément chimique qui entretient l’accoutumance au tabac, une maladie chronique fatale, et la principale cause d’autres maladies chroniques courantes. La tendance à la baisse que l’on constate au Canada semble s’être nivelée et les taux de consommation du tabac stagnent à 17 %. Parmi les personnes qui fument à l’heure actuelle, 70 % voudraient mettre fin à leur habitude et la moitié tenteront de le faire au moins une fois cette année. Mais à moins qu’elles ne reçoivent un traitement éprouvé et multimodal, seulement 3,5 % de ces personnes s’abstiendront encore de tabac six mois plus tard. Les normes internationales des traitements recommandés proposent une combinaison de séances de consultation et de pharmacothérapie pour les personnes qui souhaitent cesser leur consommation de tabac. Il existe six médicaments sur le marché canadien.

À l’encontre des autres maladies chroniques cependant, l’accoutumance au tabac n’est pas soignée d’emblée à cause de l’idée répandue que cette maladie est un choix de vie. Cette interprétation erronée d’une maladie chronique crée un obstacle important à une lutte efficace contre le tabac et contribue largement à la croissance incontrôlable des dépenses de soins de santé. Le paradigme en place sur la lutte contre le tabac ne donne vraisemblablement pas les résultats voulus en matière de santé et ne contribue pas non plus à des économies de coûts. Nous faisons face à un besoin urgent d’harmonisation des politiques et des pratiques cliniques, appuyée par des preuves scientifiques. Il existe des traitements sûrs et efficaces, mais leur application nécessite un grand degré de vigilance des éléments neuropsychiatriques liés au tabac. Nous proposons qu’une seule approche algorithmique, faisant appel à différentes disciplines et différents niveaux de soins, oriente la prestation d’un traitement sûr. Elle pourrait être particulièrement appropriée à un cadre de ressources limitées.

INTRODUCTION

Tobacco remains the only legal consumer product that will kill at least one out of every two of its regular users when used exactly as intended by the manufacturer. In the general population, the health dangers of smoking tobacco are well known and the pillars of comprehensive tobacco control, established and proven to remedy the tobacco epidemic, are broadly publicized and disseminated. Yet progress in reducing the rate of smoking appears to be leveling off with 18% of the Canadian population older than age 15 smoking (1). Tobacco control is at a crossroads and updated policies and paradigms, those that provide greater emphasis on cessation, are needed to stimulate further progress.

Nicotine is the chemical compound sustaining addiction to tobacco (2). Tobacco addiction (nicotine use disorder, nicotine dependence, or tobacco dependence) is widely recognized as a chronic condition, and the major cause of other prevalent chronic diseases. As cigarette smoking is the predominant nicotine delivery mechanism in persons addicted to nicotine, it also is a direct and major contributor to the three leading causes of death in Canada: circulatory system diseases, cancer, and respiratory system diseases (3). Smoking remains the single most important risk factor for respiratory disease, including chronic obstructive pulmonary disease (COPD), with mortality of COPD seven times higher in smokers than in non-smokers (4). As with other risk factors related to the metabolic syndrome, tobacco consumption has been recognized as a bona fide contributor to the development of diabetes and hypertension (5).

Chronic diseases (i.e. those conditions of an ongoing or recurrent nature) pose a vast challenge to health professionals, policy makers, and governments. The World Health Organization (WHO) estimates that 60% of all deaths worldwide result from chronic disease and, with the increasing age of the general population in Canada, so does the prevalence of chronic disease. The estimated cost, direct and indirect, related to substance use and misuse totaled almost \$40 billion CAD in 2002, and almost half of this was attributable to tobacco smoking (6). The rise in prevalence of chronic diseases, changes in clinical treatment thresholds, along with the plateau in numbers of smokers and their recalcitrance (7), may well predict even greater demands on the health care system in the years ahead.

This review aims to summarize updated treatment approaches to tobacco addiction, including pharmacotherapy and psychosocial interventions, within a broader tobacco control framework and against the backdrop of empirical cessation policy-related elements. It will introduce into Canadian literature an algorithmic approach to tobacco addiction treatment that crosses the levels of care and will also introduce the concept of health professionals' legal duty to treat tobacco addiction.

Tobacco addiction is a bona fide chronic disease:

The *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR)* categorizes

nicotine dependence as a mental condition (disorder) in the category of substance-related disorders. A positive diagnosis is made when 3 or more of the following 7 criteria are met within a 1-year time span: Tolerance, withdrawal, smoking more than usual, a persistent desire to smoke despite efforts to decrease intake, extensive time spent smoking or purchasing tobacco, postponing work, social, or recreational events in order to smoke, and continuing to smoke despite health hazards (8).

Nicotine exerts a strong behavioural influence, and this contributes to the erroneous perception that tobacco addiction is purely a choice. Individuals who smoke do not wake up every morning to make a deliberate choice to spend \$10-\$20 per day, or roughly \$4000 per year for a pack-a-day smoker, to buy cigarettes, or to continue to invest in an industry that was recently been found guilty of criminal activities in Canada and elsewhere in the world. Viewing consumption of tobacco as simply a choice, failing to take the chronic disease nature of the condition into account, has led to the misguided notion that individuals should first try to abstain from smoking in an unaided way, or first to read a brochure to quit, and only after repeated failures should they be allowed to access treatment.

Tobacco (nicotine) dependence is recognized as a chronic disease by most authorities, including Health Canada, the Canadian Medical Association, and the World Health Organization, and is classified as such in major disease classification systems (9). Following chronic exposure to nicotine, profound psychophysiological changes occur. Comparing tobacco dependence with another chronic disease outlines some of the common characteristics these two conditions may share.

Addiction is a preventable and treatable disease, as opposed to a simple "choice", a "lifestyle issue", a social problem, a lack of education, or purely of culpable behavior (in terms of own health and the damage inflicted). Scientific evidence has identified that addiction develops as a result of a complex multi-factorial interaction between repeated exposure to drugs, and biological, psychological, spiritual, environmental factors. The belief that addiction is self-afflicted and self-modifiable, often perpetuated by well-intentioned but inappropriately credentialed tobacco control advocates, has contributed to the limited access tobacco addiction treatment seen across Canada. Current policy measures and lack of pharmacotherapy coverage are symptomatic of governments' failure to take into account the neurological changes nicotine dependence has on motivation pathways in the brain.

The conventional view of addiction has been described as "impaired control over a reward-seeking behavior from which harm ensues" (10), and as "repeated failures to refrain from drug use despite prior resolutions to do so" (11). Addiction refers to a psychiatric syndrome, induced by exposure to a particular drug, which produces chronic changes in the brains "motivational system" as a consequence of which "a reward-seeking behavior has become out of control" (10). This complex brain disorder results from the chronic effects of a specific (addictive) drug on the brain's structure and function.

Table 1:

Variable	Hypertension	Tobacco Use / Dependence
Prevalence	19%	17%
Percentage of sufferers receiving treatment (pharmacotherapy)	80%	<20%
Mortality rates	1%	50%
Causes / contributes to multiple secondary diseases or conditions?	Yes	Yes
Cost-effective, safe and effective multimodal treatment available?	Yes	Yes
Psychosocial interventions should include psychoeducation and lifestyle change recommendations?	Yes	Yes
Polytherapy (medication combinations) endorsed as safe and effective?	Yes	Yes
Typical duration of treatment in practice.	Open-ended; "As long as it takes", often life-long.	Mostly no treatment, otherwise less than 3 months.
Coverage for pharmacotherapy on provincial formulary?	Universal	Exception.

Decision-making and behavior are subsequently influenced by the underlying pathophysiological changes in the brain. A variety of biological (including genetic), psychological, spiritual, and social contextual factors modulate these changes in the brain.

Tobacco addiction is perpetuated by the ability of cigarettes, by design, to rapidly introduce nicotine and a host of other chemicals to the "addiction centers" of the brain, i.e. the reward pathways. To increase the addictive nature of nicotine, smoked tobacco (by rational design of cigarettes) delivers nicotine in a partially free-based format to the brain. After nicotine's delivery through the arterial system to the brain, it binds primarily to alpha-4 beta-2 ($\alpha_4\beta_2$) nicotinic receptors. These receptors, naturally a ligand for acetylcholine, are central to the initiation and maintenance of addiction. Stimulation of these nicotinic receptors causes the generation of an action potential that stimulates other brain centers, and this results in the release of dopamine in the "pleasure center" of the brain. When chronically stimulated by nicotine, up-regulation and desensitization of these receptors follow (12). Over time, the entire reward pathway can become desensitized, and represents a second major maladaptive change in brain function in response to tobacco administration.

Unlike other chronic diseases, most persons who smoke do not receive treatment:

For the chronic disease of hypertension, 80% of Canadians receive evidence-based treatment, and 66% of persons with hypertension are *successfully* treated for their chronic condition (13). For tobacco addiction, the treatment rates are substantially lower and, unlike that for hypertension and other chronic diseases, is not universally covered for related cost nor is it readily available, accessible or affordable. Seventy per cent of persons who smoke say they regret ever starting and would like to give it up, and 50% of smokers will make at least one cessation attempt per year (14). Most

(64%) who attempt to quit will try to do so unaided (14), and reduction of consumption is the most common strategy most persons who smoke will use in their quit attempts (14). It is erroneous to suggest that because unaided cessation is the most common method employed, it is the most effective one to achieve abstinence. Fewer than 20% of smokers receive pharmacotherapy for the treatment of this condition and, without treatment (i.e. unaided) only 3-5% of persons attempting to quit will remain abstinent from tobacco at 6 months (16). The suggestion that the first-line of treatment of chronic disease should be an "unaided" one may be viewed as tantamount to negligence by clinicians.

Tobacco smoking has been singled out as the leading preventable cause of death and disease but in reality other contributors to metabolic syndrome and/or chronic diseases rarely occur in isolation of each other. Hypertension, hypercholesterolemia, obesity, diabetes, depression, tobacco smoking, respiratory complaints and a sedentary lifestyle frequently co-occur. Many Canadian treatment systems remain trapped in archaic silos of managing one disease at a time, and this presents another barrier for access to treatment. It is not uncommon to hear that treating tobacco addiction "is not my job". Whose "job" is it?

Further, the use of a short-term, acute care paradigm to 'cure' any chronic disease is obviously flawed. Following a short-term paradigm for tobacco addiction is equally illogical and compromises the chances of cessation success. It is not expected that individuals with diabetes will be able to maintain blood glucose levels within desired parameters without ongoing monitoring and managements but, when it comes to smoking, individuals are expected to quit. Such practices are themselves an unfortunate legacy of the "just be strong" perspective that guided cessation attempts in the past. This ideology maintained that a "little bit of help is all you should need" given that "moral fibre" was the ultimate determinant of cessation success.

Contemporary best practices are shifting to reflect a far more realistic understanding of the nature of tobacco addiction and the processes required to successfully manage this disease condition. The most rational approach is reflected in a dovetailing of various interventions within a broader tobacco control strategy and including treatment across the continuum of care delivery. Such strategies can be developed and implemented in a highly time-efficient manner and have demonstrated clinical effectiveness (17). A recent Cochrane review showed that full coverage of smoking cessation medications significantly improved one-year abstinence rates among all smokers (RR 2.45, 95% CI 1.17-5.12) (18), with the potential for almost 2 million life-years gained in Canada (19). The cost per life year saved is small compared to the gains, and the number of individuals needed to treat to save one life is nine (20), and this makes smoking cessation one of the most robust and clinically meaningful interventions any health professional can offer.

Tobacco addiction is “chronic disease by design” driven by a powerful vector:

This pandemic of tobacco-related diseases is transmitted by an industry which serves as its vector. The vector is maintained by the industry’s greed - unparalleled in its capacity to induce suffering and unrivalled in its amoral duplicitous conduct as it seeks to maintain profits of billions of dollars. Over the past 50 years, the tobacco industry has strenuously rejected any responsibility for the devastating health consequences of its products. It has been characteristic of the industry to consistently seek to subvert, distort and denigrate all of the evidence that has accumulated regarding the lethal nature of its products. It has frequently conspired with tobacco industry-friendly scientists and physicians with the sole aim to cast doubt on the link between tobacco use and the array of resulting disease states, the risks of second-hand smoke, and the addictive nature of nicotine. This collaboration has sabotaged public health efforts and continues to do so. The tobacco industry were recently criminally convicted for their actions in the contraband industry that plagues Canada today.

Although the tobacco epidemic is a 20th century phenomenon, the contemporary presence of tobacco on the Canadian market remains a historical anomaly. If tobacco products were introduced to the market for the first time today, they would be rejected as unfit for human consumption and would not be a legal product. Tobacco smoke contains 172 toxic substances, 33 hazardous air pollutants, 47 chemicals restricted as hazardous waste, and 67 known human or animal carcinogens in tobacco (21). It has no sustaining value to life. Yet tobacco continues to escape most of the governmental regulatory mechanisms developed to protect the Canadian public and its health from dangerous consumer products and medications.

Tobacco addiction is an “addiction by design” (22), and hence a “chronic disease by design”. This rationally designed and maintained chronic disease yields billions of dollars in profit but at the cost of the public health care system. A former Commissioner of the US Food and Drug Administration aptly noted that the tobacco industry ought to be dismantled (23).

The World Health Organization’s Framework Convention on Tobacco Control (24) urges the denormalization of the tobacco industry (25) while, at the same time, reducing the demand for tobacco through education, communication, enhanced public awareness, and the training of health professionals to facilitate the treatment of tobacco addiction on a broad scale.

Every person has the right to optimal health:

The WHO Constitution declares that “the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being” (26). Like with other chronic diseases, this right also belongs to every person who suffers from tobacco addiction. It is widely acknowledged that the single most important step in achieving optimal health is to stop using tobacco. This can only be fully realized by firstly recognizing that nicotine dependence is a chronic and treatable condition, and that it remains every health professional’s ethical and legal responsibility to help patients with this disease. The Canadian Society of Respiratory Therapists have recognized this responsibility. They collaborated with 8 other national healthcare societies and associations, including the Canadian Medical Association and the Canadian Nurses Association, to identify the role of health professionals in smoking cessation, and reinforce the need for a comprehensive, collaborative approach to treatment that is supported with resources and incentives (27).

Evidence-based treatments of tobacco addiction are considered safe, effective and remarkably cost-effective on Provincial jurisdictional level (28), and smoking cessation is considered the “gold standard” of preventive clinical interventions. Only nine smokers need to be successfully assisted with cessation in order to prevent one premature tobacco related death (20). No other preventive interventions are known to be as robust and other preventive strategies, such as the control of hypertension or the treatment of dyslipidemia, require the treatment of vastly more patients to show a similar effect (20). Yet the rate of individuals managed for the chronic disease of tobacco addiction falls far behind that for other chronic disease conditions. Several factors may contribute to this including an unresponsive health system, and the lack of preparation of health care providers to treat, amongst others. The out-of-pocket costs associated with receiving treatment which affects the mentally ill to a greater degree than others who are less disenfranchised.

Our current status may be accounted for what the authors coin as the “shadow side of advocacy”, a counterproductive phenomenon. Canadian tobacco control strategies, despite vast successes, have contributed to stigma towards those with the disease (as an unintended consequence of denormalization and smoke-free policies), have advocated for requirements that unaided efforts be exhausted before treatment is offered, and the profound misunderstanding of tobacco addiction as a disease condition has not been addressed. As a result, governments and policy makers are often continuing to classify smoking as a “lifestyle choice” and, when the disease condition is not recognized, excludes their responsibility to cover treatment.

WHAT IS A RATIONAL APPROACH TO TOBACCO ADDICTION TREATMENT?

The best results for tobacco addiction treatment are achieved with a comprehensive, multidisciplinary approach that assures the availability, affordability and accessibility to longitudinal and diversified psychosocial and pharmacological interventions. Further, effective interventions dovetail population-based interventions with individually based interventions. Empirically demonstrated successful population-based interventions include increasing the cost of tobacco through taxation, smoke-free policies, prevention of uptake, restrictions of sales, achieving parity of coverage of pharmacotherapy, and implementing comprehensive tobacco control programs. Existing tobacco control policies, by neglecting smoking cessation, have resulted in the situation whereby the most marginalized and vulnerable members of Canadian society have disproportional rates of smoking, and carry the burden of tobacco-related disease and mortality (28). The fact the most people quit smoking without any help is not a function of the effectiveness of unaided cessation but rather a reflection on the lack of access to evidence-based care. By increasing availability, accessibility, and affordability, massive gains are expected over and above the current plateau reached in reducing smoking rates in Canada.

Given the evidence of the effectiveness and safety of cessation interventions, including when provided for those with mental illness, our biggest challenge is not a lack of knowledge on how to treat this disease but rather to embrace policies that will improve the opportunities for intervention. Cessation policy development can indeed offer the greatest prospects for declines in smoking-caused death over the next 30 years, and will most likely come from increasing adult cessation (29). Cessation policies, fully integrated into the health treatment system, have been shown to create the conditions to support tobacco dependence treatment that, by following best practice treatment guidelines, include provision for nicotine detoxification by using nicotine replacement therapy, treatment goals of abstinence, relapse prevention and relapse management, and offering treatment on a longitudinal paradigm consistent with other chronic relapsing medical diseases (29).

Incorporating tobacco dependence treatment into health organizational administration, on par with the management of other chronic diseases, is required to achieve the goal of reducing the prevalence of smoking and the impact of the chronic disease of tobacco addiction. Mechanisms to facilitate health providers with managing tobacco addiction include mechanisms to identify all individuals that use tobacco products, priming / prompting treatment, facilitating linkages to resources, identify options for help, and provide feedback on their performance. The greatest gains in treatment are expected to come from tailoring interventions to align the best evidence with the treatment situation. For example, a treatment algorithm in acute hospital settings may focus on identification, management of nicotine withdrawal and referral to treatment on discharge.

Integrating comprehensive psychosocial and pharmacological treatments improve outcomes, and should be offered to every smoker interested in making a cessation attempt. For that purpose, it is the duty of every jurisdiction and every system to ensure that resources are available to offer evidence-based psychosocial and pharmacological cessation interventions, of sufficient duration. Consultation-liaison services need to be available to ensure more complex cases are managing in an appropriate fashion, and sensitivity to particular gender and socio-cultural differences need to be taken into account in offering cessation interventions. A comprehensive discussion of these elements falls outside the scope of this manuscript.

Optimal tobacco control programs require an array of integrated strategies and interventions, including all pillars of tobacco control. The goal of reducing smoking prevalence rates requires a comprehensive and integrated approach, combining policies with evidence-based cessation policies. Cessation policies should include expanded cessation treatment coverage, mandated adequate funding for evidence-based quitlines (provided they are demonstrated to have achieved outcomes are per international standards) as well as web-based interventions, support for healthcare systems' changes to prompt, guide, and incentivize tobacco treatment, support for improved individually tailored, stepped-care approaches, and long-term effectiveness of evidence-based treatments (29). Recent simulation modeling evidence (30) suggests that cessation treatment policies have the strongest effect on reducing prevalence rates, followed by cigarette tax increases, smoke-free air laws and mass media / educational policies. Appropriate levels of taxation, traditionally lauded for its impact, will continue to have a significant impact on deterring smoking (particularly among adolescents) while reinforcing commitments to cessation.

For cessation, evidence-based guidelines strongly support the so-called "5-A Approach" (31): consistent screening for, and documentation of, tobacco use (Ask & Assess); the provision of specific advice (A3) regarding the benefits of cessation; an offer of particular assistance (A4) with a cessation attempt (which entails pharmacotherapy and counselling); and arrangements (A5) for appropriate follow-up. This "5-A Approach" is considered standard: Ask, Assess, Advise, Assist, and Arrange follow-up. The consistent application of such a strategy is consistent with a longitudinal approach to the management of this chronic disease.

Clinical evidence supports the offer and provision of safe effective treatment to every person addicted to tobacco. A combination of simple, strategic behavioural counselling and pharmacotherapy should be offered to every smoker interested in quitting – and will significantly enhance the likelihood of a successful cessation attempt (32-34) Those who are not ready to make an attempt at cessation should be offered simple, sympathetic counselling designed to permit a reassessment of their reasons for continued smoking and an invitation to seek assistance with cessation at any time. Psychosocial and pharmacological interventions include:

A. Psychosocial interventions (31):

- **Counseling** (group or individual; office-based, telephone, or web-based) should be routinely offered in combination with medication in order to yield enhanced success in cessation outcomes. There is, however, the expectation for these programs to ensure that the content and mechanisms of delivery meet standards of care. This may not be occurring universally.
- **Simple strategic advice** regarding the avoidance of high risk situations for relapse, the recognition of settings or circumstances in which smoking has been particularly common, the management of acute cravings, and the development of family smoking guidelines for home and car are all important in accentuating the likelihood of cessation success.

Pharmacological interventions (31,35,36-38):

- **Nicotine replacement therapy (NRT):** Nicotine, albeit addictive, is safe and effective for the treatment of tobacco addiction, in a broad range of populations. Nicotine replacement therapy is available in Canada in four forms (transdermal patch, chewing gum, inhaler, and lozenge) and is not associated with the development of cancer. All smokers seek to maintain a certain, individualized level of nicotine; which may exceed the dose of 21mg, and which may include combinations of different NRT formulations at the same time. When nicotine levels fall, distinct and usually significant discomfort occurs (withdrawal symptoms) serving to overturn any conscious decisions to stop smoking. The provision of nicotine via the venous system, following its administration to the skin or mucous membranes of the mouth and throat, stimulates nicotine receptors and extinguishes the symptoms of withdrawal. This permits a would-be non-smoker to go about normal activities, free of the discomfort that normally occurs with cessation attempts. The concept of reduce-to-quit, i.e. cutting back while administering pharmacological nicotine, has gained popularity and enjoys on-label registration status in Canada, as a safe and effective method to help persons quit smoking.

The appropriate use of NRT (particularly when titrated to reflect a person's individual need) is efficacious and usually doubles success rates. Combinations of NRT (i.e. use of the patch and gum, or patch and the inhaler) are further associated with increased levels of success. The scientific evidence does not support the use of alternative tobacco-based nicotine delivery systems, e.g. smokeless tobacco, or 'snus' as an aid to smoking cessation. Despite claims to the contrary, these are not considered to serve as a "harm reduction" measure, and may discourage or postpone cessation efforts in smokers who would otherwise have quit, or may induce another form of tobacco dependency with associated health consequences, e.g. pancreatic cancer.

Although patients are usually discouraged from smoking while starting nicotine replacement products, pharmaceutical-grade nicotine alone does not pose an

increased cardiovascular risk, even when combined with combustible tobacco products.

- **Bupropion** is a prescription medication initially registered and used as an anti-depressant. It was subsequently, and serendipitously, found to be effective in producing smoking cessation, and was subsequently tested and registered in this regard. Although its mechanism of action for smoking cessation is largely unknown, it is now understood that bupropion maintains levels of dopamine in the reward centers of the brain by inhibiting the reuptake of this neurotransmitter. It also affects levels of norepinephrine, a chemical known to be associated with the development of the symptoms of withdrawal. Bupropion has been shown to double the success rates of quitting smoking. It should not be used in persons with seizure disorder, those addicted to alcohol and at risk of withdrawal, and persons with eating disorders. It is also not to be combined with the antidepressant formulation of the same drug.
- **Varenicline** is a third-generation smoking cessation pharmacotherapy. It directly and distinctly binds to the $\alpha_4\beta_2$ nicotinic receptor, blocking the receptor sites (in exactly the same way that a key in a lock prevents the insertion of another key) while at the same time partially stimulating those same receptors. Thus, the $\alpha_4\beta_2$ nicotinic receptor continues to transmit a neurological impulse that, while reduced in intensity, causes the release of small amounts of dopamine in the reward centers of the brain, but only at a strength of about half that of nicotine from a cigarette. As a result the smoker experiences little to no withdrawal symptoms, and if a cigarette is smoked, no pleasurable sensation is experienced (the 'key in the lock' prevents the nicotine 'key' from being inserted).

Varenicline may be superior for cessation when compared with NRT and bupropion. The odds ratio of quitting with varenicline is approximately 3:1, and current evidence suggests that it is not causally associated with a higher rate of neuropsychiatric adverse effects than placebo or bupropion, with the exception of the symptom of sleep disturbance (38). Most recently, the maintenance dose of 1mg bid po was supplemented with a lower maintenance dose of 1mg per day, or 0.5mg twice per day.

Bupropion (for depression) can be combined with varenicline, but the impact on smoking cessation remains speculative. Varenicline, cleared mainly by the kidneys and bypassing the hepatic cytochrome system, may be combined with the range of antidepressants, and no clinically meaningful pharmacokinetic or pharmacodynamic drug interactions are anticipated.

Towards Canadian Guidelines for Tobacco Addiction Treatment (31, 37):

At the 58th Annual Meeting of the Canadian Psychiatric Association, the Addiction Section of the CPA adopted the USDHHS (31) Clinical Practice Guidelines' summary as a template for the guidance of their members as they

deliver smoking cessation treatments to their patients and communities. These are the set guidelines which are also supported by the Canadian Society of Respiratory Therapy on its website, and along with the Canadian Action Network for the Advancement, Dissemination and Adoption of Practice-informed Tobacco Treatment (CAN-ADAPTT)₂ (37). It offers a comprehensive guideline set with recommendations for a broad range of populations such as those with mental illnesses. The USDHHS guideline recommendations are summarized as follows:

1. “It is essential that clinicians and health care delivery systems consistently identify and document tobacco use status and treat every tobacco user seen in a health care setting.
2. Tobacco dependence (TD) is a chronic disease that often requires repeated intervention and multiple attempts to quit. Effective treatments exist, however, that can significantly increase rates of long-term abstinence.
3. Tobacco Dependence treatment (TDRx) is effective across a broad range of populations. Clinicians should encourage every patient willing to make a quit attempt to use the counseling treatments and medications recommended in this Guideline (see #6).
4. Brief TDRx is effective. Clinicians should offer every patient who uses tobacco at least the brief treatments shown to be effective in this section.
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), and social support delivered as part of treatment.
6. Effective medications are available for TD, and clinicians should encourage their use by all patients attempting to quit smoking—except when medically contraindicated or with specific populations for which there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers, and adolescents). Six (in Canada) first-line medications reliably increase sustained abstinence.
7. Counseling and medication are effective when used by themselves for treating TD. The combination of counseling and medication, however, is more effective than either alone. Thus, clinicians should encourage all individuals making a quit attempt to use both counseling and medication.
8. Telephone quitline counseling is effective with diverse populations and has broad reach. Therefore, both clinicians and health care delivery systems should ensure patient access to quitlines and promote quitline use.
9. If a tobacco user currently is unwilling to make a quit attempt, clinicians should use motivational treatments in increasing future quit attempts.

10. TDRx is both clinically effective and highly cost-effective relative to interventions for other clinical disorders. Providing coverage for these treatments increases quit rates. Insurers and purchasers should ensure that all insurance plans include the counseling and medication identified as effective as covered benefits”.

Integrating outpatient and hospital-based algorithms:

A single safety-sensitive, medically guided treatment algorithm (Figure 1), available at www.tracii.ca, was developed to assist with navigation of safety concerns related to quitting and pharmacotherapy, and to integrate outpatient and inpatient treatment, including withdrawal management and cessation. For hospital-based involuntary abstinence (which is not the equivalent of enforced cessation), the routine offering of nicotine is recommended to avoid withdrawal from nicotine even for persons not interested in extended abstinence from tobacco (i.e. quitting smoking). This is a similar approach to the management in hospitals of withdrawal from other substances (i.e. alcohol, benzodiazepines), representing a precursor to engagement in longitudinal abstinence, and should not be confused with disease treatment. Withdrawal management is not the same as smoking cessation. Prior to discharge, in the person on a nicotine agonist (nicotine replacement therapy), a referral should be made (and documented) to existing cessation programs, and one or more of the six medication options could be discussed as a cessation option along with linking the person with psychosocial counselling. As most individuals want to stop smoking, those who have successfully achieved short-term abstinence in hospital by managing nicotine withdrawal, particularly if supported to do so by health providers by providing the adequate dose of nicotine, typically in combinations with each other, may be more likely to be interested in accessing cessation interventions (32-34). Although most smokers are interested in quitting, only few are able to do so abruptly, and providing nicotine as a withdrawal management regime (prior to quitting) may offer the opportunity for some to change the behavioural components with greater success. This approach has been demonstrated to encourage subsequent quit attempts (32).

The assumption that patients admitted to smoke-free settings are either interested or ready to quit is erroneous, and the confusion between the management of withdrawal and cessation treatment prevails. Cessation treatment, as with any chronic, relapsing disease, requires a longitudinal treatment paradigm. The focus on withdrawal management in the hospital setting is a bona fide first step, with referral for longitudinal disease management, which may include hospital-based initiation of pharmacotherapy for this purpose, is more consistent with the evidence-based management of other chronic diseases, which includes addictions.

The algorithm offers a minimal investment scenario whereby the bare essential interventions include screening for nicotine dependence with every patient and routine detoxification management. This is paired with clear

communication that abstinence is not the same as cessation, and that the goal of the smoke-free environment is occupational health-driven. Support for avoiding involuntary withdrawal symptoms is offered, not for the initial purposes of cessation, and irrespective of interest in quitting smoking. This should be repeated and documented for the duration of the hospital stay, and for patients interested in exploring the extension of a treated (with NRT) abstinence state, to thus qualify as “cessation”, a referral is made to existing telephone-based, web-based, or other available cessation resources.

The algorithm proposes serial screening assessment with every individual that uses tobacco throughout the cycle of smoking and relapse. This step is considered necessary because there is significant co-morbidity between nicotine addiction and depressive symptoms, estimated at 40% to 60%. Furthermore, neuropsychiatric adverse event association with smoking cessation may be profound (38), including depressed mood and suicidal ideation. These are related to a likely confluence of a variety of factors, and may contribute to the risk of harm for a number of individuals, with or without mental illness. These neuropsychiatric considerations, including the most salient pharmacotherapy recommendations related to suicide and depression, are summarized at: http://la-press.com/article.php?article_id=2191

A CASE FOR ACCREDITATION OF HOSPITAL-BASED SYSTEMS?

Like in the US, accreditation standards should include at least the screening for tobacco, offering of adequate withdrawal management, and a link to cessation treatment. Performance measurement of clinicians and hospital systems should be linked to screening for tobacco, detoxification management in involuntary abstinence states in smoke-free settings, and a referral to at least one cessation treatment system. Utilization of pharmacotherapy, i.e. prescriptions by physicians to smoking patients, should also be viewed as a performance indicator.

DO HEALTH PROFESSIONALS HAVE A LEGAL DUTY TO SCREEN FOR, AND TREAT TOBACCO ADDICTION IN PATIENTS UNDER THEIR CARE?

As the true disease nature of tobacco addiction becomes more recognized, and the availability of effective treatments become more known, so will the relevance to Canadian law. Health professionals are expected to exercise reasonable skill, care, and judgment in the care for their patients. In the context of the bona fide chronic medical condition of tobacco dependence, and where a duty to care exists, health professionals’ failure to exercise reasonable actions, may give rise to potential for legal challenges. The failure to diagnose, the failure to offer treatment, the failure to ensure continuity of care, or the failure to adequately advise of medical risks associated with the condition may foreseeable contribute to damages. Although this has not been tested in Canadian courts, at the time of this publication, sufficient grounds exists to suggest that health consumers may attempt to claim

FIGURE 1.



health professionals’ negligence in situations of a derelict of the duty, directly leading to damages because of the treatable condition of smoking.

Similar to the treatment of other chronic conditions, it is reasonable to assume that a health professional may have a duty-of-care tobacco dependence (TD) in his / her patient population. Failure to screen for this condition and offering of treatment options or referral options may constitute a failure to meet standards of care in some professions. This may include either primary treatment (Rx) provision, or ensuring continuity of care in the form of a referral to a safe and effective treatment service. Health professionals’ awareness of the potential risks may allow for mechanisms to ameliorate such, by incorporating evidence-based safe and effective tobacco addiction care into daily practice.

CONCLUSIONS

Tobacco addiction is not simply a lifestyle choice. It is a vector-driven chronic disease, which is prevalent, lethal and treatable - yet it is undertreated. Treatment is guided by validated guidelines, endorsing a range of safe and effective evidence-based treatment interventions. These typically include a combination of pharmacotherapy and counselling, in a longitudinal context, recognizing the true chronic disease nature of tobacco addiction. Yet, the majority of smokers remain untreated.

This chronic disease represents one of the most significant missed opportunities in health - the result of outdated concepts regarding the underlying mechanisms

that perpetuate smoking and, in part, a legacy of the tobacco industries' lavish and longstanding efforts to portray smoking as a matter purely of individual choice. Further, healthcare systems have not embraced the true nature of the condition, and compared to another chronic disease like hypertension, the management of tobacco dependence appears dismal.

The development of comprehensive approaches to tobacco addiction as a chronic disease, including the orphan of tobacco control policy development, will save lives and dollars. It is of fundamental importance that policy makers are made aware that assistance with cessation will be more effective and more cost efficient than programmes designed to ensure that smoking is never commenced. Both are obviously important but the magnitude of the health and economic benefits of cessation programmes delivered to the current cohort of smokers make the former strategy an important, and heretofore largely neglected, element of a contemporary approach to the tobacco disease epidemic. At a time of heightened economic pressure, such an approach will produce significant savings through reduced re-admissions, recurrences of illness, and progression of disease than any other preventive intervention.

Cessation interventions are markedly more cost-effective than virtually all other preventive treatments or interventions. It is no longer acceptable to use outdated techniques, or to permit antiquated attitudes that preclude the development and implementation of best practice solutions for the management of the leading cause of preventable disease, disability, and premature death in Canada. As is the case with other chronic diseases, the identification and treatment of tobacco addiction is now seen as a standard-of-care in Canada, and there is an implied element of negligence when clinicians deliberately ignore this duty-of-care related to tobacco addiction.

Persons suffering from tobacco addiction, a chronic medical condition, deserve nothing less than a systematic, empirically informed, and qualified approach, as discussed in this manuscript. This should be on par with treatment and approaches developed to treat other chronic diseases, some of which were considered untreatable only a few decades ago. The single most important factor in achieving this will be the full recognition of tobacco addiction as a bona fide, treatable medical condition. Empirically driven cessation policies, guiding safe and effective treatment interventions, within a healthcare system accountable to its consumers, have a tremendous potential to save healthcare dollars.

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