Expert Considerations in the Off-label use of NRT

Meeting Proceedings from the Expert Review on
Commercial Tobacco/Nicotine Cessation Treatment (November 7, 2022)

This document summarizes the proceedings of a session held with various tobacco and nicotine treatment experts who discussed several case studies and potential treatments for patients who need help quitting or reducing their use of nicotine products. This document aims to support STOP implementers and other clinicians who are supporting patients who want to quit or reduce their nicotine use including for products other than commercial cigarettes (e.g., e-cigarettes) by providing pharmacotherapy. This summary may be helpful in your practice as you begin or continue to treat your patients who use nicotine with nicotine replacement therapy (NRT). However, this is not an exhaustive list of all treatment strategies, nor will it be tailored advice for your individual patients. It provides a starting point based on how clinicians in our community are treating patients with similar nicotine use patterns at the time this resource was developed (November 2022).

Expert Review on Commercial Tobacco/Nicotine Cessation Treatment

On November 7, 2022, the Nicotine Dependence Service within the Intrepid Lab at the Centre for Addiction and Mental Health (CAMH) convened a group of clinicians for a two-hour virtual session to discuss different types of nicotine use and treatment measures. The main objectives of this session were: (1) to identify treatment strategies for patients seeking cessation support for nicotine products other than commercial cigarettes; and (2) commitment to an ongoing dialogue among participants regarding evolving practices to treat patients using nicotine products (not including NRT) other than commercial cigarettes.

The session included a series of case studies focused on patients looking for nicotine cessation support. The case review took an adaptive expertise approach, a training framework that emphasizes clinicians as adaptive experts, inviting them to apply their current knowledge and skills as well as develop new knowledge by focusing on various patient needs and context.[1] The discussion began with a core case study of a patient with minimal comorbidities. Participants discussed how they would treat the patient described, drawing on their clinical expertise and experience treating patients with similar nicotine use patterns and profiles. As the session progressed, additional complexities (e.g., comorbidities, psychosocial characteristics) were introduced to each case, and the group discussed how they might adapt their treatment strategies in light of this new information. While this session was primarily focused on vaping and dual use (vaping and smoking) cessation, it was the first engagement of an ongoing discussion, which will be continued as new evidence continues to emerge regarding cessation treatment of nicotine products other than commercial cigarettes.

Twelve clinicians attended the virtual session, and one clinician responded to the case studies during a one-on-one meeting with a Research Coordinator from the Nicotine Dependence Service. We have combined the responses from all participating clinicians throughout this document. This document is not

[1] Mylopoulos, M, Kulasegaram, K, Woods, NN. Developing the experts we need: Fostering adaptive expertise through education. J Eval Clin Pract. 2018; 24: 674– 677. https://doi.org/10.1111/jep.12905

a verbatim transcript of the meeting, but rather a high-level summary of the meeting proceedings. It includes a summary of considerations for nicotine use treatment, as well as a series of patient cases and high-level treatment strategies. Each case includes several potential treatment strategies discussed by the expert group, including special considerations for the adaptations discussed (e.g., pregnancy, depression, in-patient settings, social isolation, and gender considerations).

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Disclaimers:

1. In Canada, the indication of NRT is for commercial cigarettes only. Any discussion of the use of NRT for nicotine products other than commercial cigarettes is considered off-label at this time.
2. The treatment strategies outlined in this document are not formal recommendations from CAMH; rather, they represent how clinicians in our community are treating patients who are looking to quit or reduce their use of nicotine products at this time (November 2022).

Expert Review Participants

The following is a list of clinicians who attended the Expert Review on Commercial Tobacco/Nicotine Cessation Treatment.

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Summary of Considerations for Treating Tobacco/Nicotine Product Use

This section provides a list of considerations that emerged during the Expert Review case discussion. You can use them to help inform your treatment plan when working with patients who are seeking support to quit or reduce their use of any nicotine product. We have categorized these considerations into three overarching themes: assessment and follow-up, provision of NRT for nicotine products other than commercial cigarettes, and behavioural support.

Assessment and Follow-up

All participating clinicians endorsed the following general considerations when working with someone who presents for nicotine treatment:

- A comprehensive history should be taken at the start of treatment, including but not limited to:
  - Factors that led the patient to start using nicotine product(s)
  - Length of time the patient has been using nicotine product(s)
  - Patient's motivation and readiness to quit
  - Nicotine use patterns and triggers, including dual use
  - Dependence on nicotine (please refer to Appendix A for a list of standardized tools for assessing nicotine dependence)
  - Treatment goals (e.g., quit or reduce use of nicotine product(s)) and interests (e.g., counselling, medication, combination)
  - Comorbidities, history of mental illness and substance use
- Healthcare providers should always monitor patients' nicotine use and withdrawal symptoms throughout the course of treatment.

Provision of NRT for Nicotine Products other than Commercial Cigarettes

- Approaches involving NRT for commercial cigarette cessation can be adapted for other nicotine products. However, given the variability of products on the market, it is difficult to standardize dosing. Therefore, when initiating NRT for non-cigarette nicotine cessation, use short-acting forms of NRT or use lower doses of patches to prevent nicotine toxicity.
- Health Canada has not approved the use of NRT for nicotine products other than commercial cigarettes. In all cases using NRT for nicotine cessation other than commercial cigarettes, healthcare providers must obtain informed consent from patients when using NRT off-label.

Behavioural Support

- If possible, healthcare providers should offer counselling and behavioural support along with other treatment strategies, including pharmacotherapy.
- For patients who have no history of quitting nicotine, counselling and behavioural strategies may be an effective first line treatment.
- Consider asking the 5 A's at the first session (refer to Appendix B).

Cases & High-level Treatment Strategies

This section summarizes the discussion of high-level treatment strategies recommended for a series of patient cases. The group provided multiple potential treatment options for each case study, as there is no one-size-fits-all approach. Each core case begins with a case description, followed by several potential treatment options for the core case. Following each set of treatment options, are a series of considerations for different adaptations applied to the case (i.e., psychosocial factors and comorbidities).

Case 1: Exclusive Vaping

SAMIR (Adult)

- **Age**: 41 years
- **Sex**: Male
- **Smoking**: 0 CPD; No history of smoking commercial cigarettes
- **Vaping**: 2 pods per day, 20mg/ml pods of 1ml each; takes breaks to vape throughout the day, but consistently grazes in the evening and on the weekend
- **Comorbidities**: None
- **Current medications**: None
- **History of quitting nicotine**: None
- **Looking for help to**: Quit vaping

Approach	Treatment Options

Behavioural Support	**Counselling & Behavioural Support Only:**
	• Start by providing counselling and behavioural support, without the use of NRT
	• Behavioural strategies:
	  ○ Slowly decrease use of e-cigarettes
	  ○ Ask patient to treat e-cigarettes as one might treat commercial cigarettes; go outside at a special time to use it (vs. anywhere, anytime); decrease the number of puffs patient takes
	  ○ Journal exercise to identify triggers
	  ○ 24 hour abstinence trial
	  ○ Please see Appendix A for additional resources on behavioural strategies
	• If patient is not able to reduce their use of e-cigarettes after 2 to 4 weeks, discuss other treatment options, such as NRT

NRT	**Start with Short-acting NRT:** • Offer patient's choice of short-acting NRT (e.g., gum, lozenge, mouth spray, inhaler) • Instruct patient to use as much as they feel they need to manage cravings and withdrawal • Follow up in 1 to 2 weeks post quit date and assess e-cigarette use

	• If patient is not able to reduce their use of e-cigarettes after 2 to 4 weeks, discuss other treatment options • Recommendation to include counselling and behavioural support in addition to providing NRT **Start with Nicotine Patch:** (if confident the patient tolerates 20mg or more of vaping liquid per day) • Start with a 21mg patch • Follow up in 1-2 weeks post quit date and assess e-cigarette use • Option to provide patient's choice of short-acting NRT (gum, lozenge, mouth spray, inhaler) for breakthrough cravings as needed (may not be necessary) • Continue to evaluate e-cigarette use and response to treatment on an ongoing basis • Recommendation to include counselling and behavioural support in addition to providing NRT • Titrate dose of NRT up (e.g., add 7mg patch) or down, depending on patient needs
Other Pharmacotherapy	**Varenicline:** (if patient would like to set a quit date and wait a few weeks) • Please refer to the Algorithm for Tailoring Pharmacotherapy for details on Varenicline dosing • Recommendation to include counselling and behavioural support in addition to Varenicline
Case Adaptations	
Gender Considerations	• Healthcare providers may offer the same treatment strategies outlined above for patients of any gender. • Please see Appendix A for additional resources on how to include a Sex- and Gender-based Analysis (SGBA+) approach with your patients.
Pregnancy Considerations	• Healthcare providers should offer counselling and behavioural support to people who are pregnant as a first line treatment. They can consider offering NRT as a second line treatment.

Case 2: Exclusive Vaping – Youth

Please note: we initially presented this case as an adaptation to the first core case. However, given the number of special considerations for treating youth for nicotine cessation, we present a separate case for the purpose of this document.

SAMIR (Youth)

- **Age**: 15 years
- **Sex**: Male
- **Smoking**: 0 CPD; No history of smoking commercial cigarettes
- **Vaping**: 2 pods per day, 20mg/ml pods of 1ml each; consistently grazing throughout the day
- **Comorbidities**: None
- **Current medications**: None
- **History of quitting nicotine**: None
- **Looking for help to**: Quit vaping
- **Additional information**: Clinical visits accompanied by father (parents divorced). When clinician offers to see Samir alone or with his father present, he says he is happy for his father to be present (however, seems somewhat tentative when sharing his history).

Special Considerations for Youth

- Healthcare providers should normalize the confidential assessment with youth. If possible, acquire nicotine use history with youth patients without the presence of a parent/guardian.
- When treating youth for nicotine cessation, healthcare providers should assess patients for concurrent mental health issues and other substance use.
- Counselling and behavioural strategies may be an effective first line treatment for youth. However, healthcare providers can offer NRT to this population if they deem NRT to be an appropriate treatment option.
- Tailor behavioural strategies to the youth population, where possible.
- Healthcare providers should consider following up with youth more frequently than adults.

Approach	Treatment Options
Behavioural Support	**Counselling & Behavioural Support Only*:** • Start by providing counselling and behavioural support, without the use of NRT • Assess patients for concurrent mental health issues that often co-occur with youth vaping, and ensure patients are being supported for any psychological comorbidities • If patient is not able to reduce their use of e-cigarettes after 2 to 4 weeks, discuss other treatment options such as NRT • Provide behavioural support using an app, group or individual therapy depending on individual interest and capacity and resources available **Recommended first line treatment for youth*

NRT	**Start with Short-acting NRT:** Can apply the same strategy as the case above **Start with Nicotine Patch:** Can apply the same strategy as the case above
Case Adaptations	
In-patient Settings	• Given increased opportunities to monitor patients in-inpatient settings (i.e., daily), treatment with NRT for youth can start at the same dose as an adult (21 mg) or at a lower dose (7mg or 14mg patch), to be adjusted as necessary.

Case 3: Dual use of commercial cigarettes and e-cigarettes

DEBRA

- **Age**: 56 years
- **Sex**: Female
- **Smoking**: 12 CPD
- **Vaping**: 1 Juul pod per day
- **Comorbidities**: None
- **Current medications**: None
- **History of quitting nicotine**: None
- **Looking for help to**: Quit smoking, quit vaping

Special considerations for dual use of commercial cigarettes and e-cigarettes:

- Healthcare providers should seek to understand why someone is using commercial cigarettes and e-cigarettes at the same time (i.e., vaping recreationally, using e-cigarettes to help them quit smoking, etc.), as this has implications for treatment.
- Healthcare providers should seek to understand the patient's motivations for quitting, and how they want to approach next steps (i.e., what they want to eliminate, whether they want to quit both products at the same time or sequentially).
- The recommended approach for dual use is to prioritize smoking cessation by switching entirely to e-cigarettes. Once the patient has quit smoking, they can work towards vaping cessation.

Approach	Treatment Options
Behavioural Support	**Counselling & Behavioural Support Only:** • Start by providing counselling and behavioural support to address smoking, without the use of NRT • Encourage patient to reduce their smoking, while not increasing their e-cigarette use (to eventually switch entirely to vaping) • Address e-cigarette cessation after patient has quit smoking • If patient is not able to entirely switch to e-cigarettes after 2 to 4 weeks, discuss other treatment options such as NRT • Refer to the Vaping Cessation Guidance Resource for additional behavioural strategies to address dual use
NRT	**Nicotine Patch & Short-acting NRT:** • Start with a 21mg patch to address 12 CPD (patient can continue using e-cigarettes) • Offer patient's choice of short-acting NRT (gum, lozenge, mouth spray, inhaler) for breakthrough cravings, as needed • Follow up within 2 weeks post quit date and assess commercial cigarette and e-cigarette use • Continue to evaluate commercial cigarette and e-cigarette use, and response to treatment on an ongoing basis • Titrate dose of NRT up (e.g., add 7mg patch) or down, depending on patient needs and response to treatment • Address e-cigarette cessation after patient has quit smoking • Recommendation to include counselling and behavioural support in addition to providing NRT
Other Pharmacotherapy	**Varenicline:** (if patient would like to set a quit date and wait a few weeks) • Please refer to the Algorithm for Tailoring Pharmacotherapy for details on Varenicline dosing • Recommendation to include counselling and behavioural support in addition to Varenicline
Case Adaptations	
Depression	• Before engaging in cessation work, healthcare providers should ensure treatment for concurrent mental health issues, especially if unstable and if it interferes with quitting the use of nicotine. • Healthcare providers should closely monitor any medication to address depression or other concurrent mental health issues during and after nicotine cessation treatment. • Healthcare providers should consider following up with patients with concurrent mental health issues more frequently than other patients due to the effects of nicotine withdrawal on depression and mood changes.

	• Healthcare providers may consider the use of bupropion as an antidepressant and smoking cessation medication. Please refer to the Algorithm for Tailoring Pharmacotherapy for details on bupropion dosing.
Social Isolation	• Healthcare providers may recommend group counselling, which may help patients feel less socially isolated.

Appendix A: Resources for Practitioners

Nicotine Dependence Service Website

- Resources for Providers
- E-Cigarettes and Vaping Resources
- Self-help Resources

Nicotine Product Cessation

- Lower-Risk Nicotine Use Guidelines (LRNUG)
- Vaping Cessation Guidance Resource
- Animated Video Vignettes for clinicians depicting e-cigarette treatment
- TEACH Vaping Webinars

Behavioural Strategies

- 5 A's Model (refer to Appendix B)
- My Change Plan Workbook
- Motivational Interviewing (MI) Toolkit

Pharmacotherapy Algorithm

- Algorithm for Tailoring Pharmacotherapy

Assessment Tools:

- List of Assessment Tools for vaping/nicotine dependence

Sex- and Gender-based Analysis (SGBA+)

- Sex, Gender and Equity Analysis Information Sheet
- Sex, Gender & Vaping Information Sheet

Appendix B: 5 A's Model

The 5 A's model (based on Fiore et al.[2]) is a common approach used among healthcare providers to integrate tobacco/nicotine cessation into practice. This model is very brief and can be offered in one to three minutes. Providing brief or minimal interventions can help some people who use tobacco/nicotine make significant changes in their tobacco/nicotine use.

The 5 A's model consists of:

ASK	Ask your patients about their nicotine use *E.g., "Tell me about your nicotine use."*
ADVISE	Advise your patients to quit by providing information on the impact of nicotine use on their health and well-being *E.g., "I am concerned about your nicotine use and advise you to quit. Quitting your tobacco/nicotine use is the single most important health behaviour change you can do to protect and improve your health."*
ASSESS	Assess your patients' readiness to quit, including their level of motivation and how important quitting is to them *E.g., "On a scale from 0 to 10, where 10 is the most important, how important is it for you to quit or cut down your nicotine use?"* *"On a scale from 0 to 10, where 10 is the most confident, how confident are you in your ability to quit or cut down your nicotine use?"*
ASSIST	Assist your patients by offering support during their quit attempts *E.g., Set a quit date.* *Tell friends, family, and coworkers; request understanding and support.* *Anticipate challenges during a quit attempt.* *Remove nicotine products from the environment.*
ARRANGE	Arrange to follow-up with your patient 1 to 2 weeks post quit date

[2] Fiore MC, Jaén CR, Baker TB, et al. *Treating Tobacco Use and Dependence: 2008 Update*. Clinical Practice Guideline. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service. May 2008.