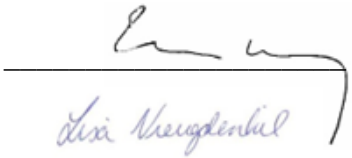





Medical Directive

Title:	Nicotine Cessation for Adults 18 Years of Age and Older	Assigned Number:	015
Activation Date:	July 1, 2011	Review due by:	December 2025
Approval Signature & Date			
Medical Director:		Date Reviewed:	Feb 23, 2024
Clinical Services Director:		Date Reviewed:	Feb 23, 2024
Order and/or Delegated Procedure:	Appendix Attached: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		
	Title:		
Initiation and renewal of nicotine (including both conventional cigarette/cigar and/or alternative delivery systems e.g. e-cigarettes) cessation products by Registered Pharmacists and Registered Nurses/Registered Practical Nurses for patients 18 years of age or older.			
Recipient Patients:	Appendix Attached: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		
	Title:		
All active adult patients of Thames Valley Family Health Team, who require medications to assist in nicotine cessation.			
Authorized Implementers:	Appendix Attached: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		
	Title:		
<p>* Thames Valley Family Health Team Registered Nurses, Registered Practical Nurses, and Registered Pharmacists. (RN/RPN, RPh)* herein referred to as implementer.</p> <p>The implementer must receive orientation from the Educator with regards to the task. The implementer must have completed orientation and educational requirements of Prescription Medications for Nicotine Cessation for Adults 18 Years of Age and Older medical directive. The implementer must sign the Implementer Performance Readiness Form electronically via HR Downloads after successful completion of the orientation (and quiz, if applicable) indicating acceptance of this medical directive.</p>			

Indications:	Appendix Attached: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Title: Appendix 1 - List of Medications for Nicotine Cessation with Detailed Indications/ Contraindications
<ol style="list-style-type: none"> 1. Verbal consent received from the patient for the implementer to implement this directive. 2. Medication is offered as a nicotine cessation aid option in conjunction with behavioural modification strategies and support. 3. Patient willing and able to follow up with the implementer on a predetermined date. 	
Contraindications:	Appendix Attached: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Title: Appendix 1 - List of Medications for Nicotine Cessation with Detailed Indications/ Contraindications
<ol style="list-style-type: none"> 1. No verbal consent from the patient for the implementer to implement this medical directive. 2. Patient is under 18 years old. 3. Patient is pregnant or lactating. 4. Specific contraindications for each product as outlined in List of Medications for Nicotine Cessation with Detailed Indications/Contraindications (Appendix 1). 	
Consent:	Appendix Attached: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Title:
<ol style="list-style-type: none"> 1. Patients of Thames Valley Family Health Team. 2. The implementer obtains verbal consent prior to the implementation of care. 	
Guidelines for Implementing the Order/ Procedure:	Appendix Attached: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Title: Appendix 1 - List of Prescription Medications Appendix 2 - The Fagerstrom Test for Nicotine Dependence Appendix 3 - Nicotine Replacement Dosing Information Appendix 4 - Decision Tree to address Nicotine Withdrawal: Increasing dosage beyond 21mg patch Appendix 5 – The Fagerstrom Test for E-Cigarette Dependence
<p><u>Conventional Tobacco (e.g. Cigarettes, cigars)</u></p> <ol style="list-style-type: none"> 1. Assess patient’s readiness to change nicotine use habits and history of nicotine cessation including past attempts. Assessments completed by other members of the Family Health Team may be used. 2. If the patient is in preparation/action stage set Quit Date. 3. Assess nicotine addiction using Revised Fagerstrom Nicotine Addiction Scale (Appendix 2): 	

- If rating is greater than 3 out of 10, review Pharmaceutical Options, including Nicotine Replacement Therapy (NRT)
 - If rating is less than 3 out of 10, patient may not require medication
4. Assess for any contraindications to Zyban (bupropion), Champix (varenicline), NRT, (Appendix 3) and precautions (Appendix 1)
 5. Ensure other tobacco cessation strategies (behavior modification and supportive) are in place for Quit Date
 6. Arrange follow up appointment(s) as appropriate if patient requests.
 7. Order appropriate medication according to List of Medications for Nicotine Cessation (Appendix 1), as per usual standard with the patient's provider's name on the prescription.

Alternative Delivery Systems (e.g. e-cigarettes)

1. Assess patient's readiness to change vaping habits and history of nicotine cessation including past attempts. Assessments completed by other members of the Family Health Team may be used.
2. If the patient is in preparation/action stage, set Quit Date.
3. Assess Nicotine Addiction using The E-Cigarette Fagerstrom Test of Cigarette Dependence (Appendix 5):
 - If rating is greater than 3 out of 10, review pharmaceutical options, including Nicotine Replacement Therapy (NRT) as per Vaping Formula Determination for NRT (See Figure 1)
 - If rating is less than 3 out of 10, patient may not require medication
4. Vaping Formula Determination for NRT:

Figure 1 - Vaping Formula Determination for NRT

$$\frac{x \text{ mg}}{1 \text{ mL}} \times \frac{x \text{ mL}}{\text{day}} = x \text{ mg/day}$$

- The first part (x mg/1 mL) is the dose/strength of the e-juice being used, e.g. 3, 6, 10, 12, 18 mg/mL multiplied by the second part (the consumption of e-juice per day)
- For example, someone who is vaping 10 mg per mL e-juice and consuming 2 mL per day would have a recommended NRT dose of 20 mg per day
- Since usage patterns can be variable, calculations should be based on usage reported over the past week or month**

**** Note:** There is variation in nicotine content across e-cigarette products, and variations in use patterns across individuals. For example, there is a marked difference in nicotine delivery among e-cigarettes that use salt-based nicotine solutions (e.g. JUUL) and other brands that use freebase nicotine. **Salt-based nicotine solutions deliver dramatically higher levels of nicotine** without creating harsh, unpalatable effects.

- For patients who don't respond or only partially respond to NRT, other options can be considered (e.g. varenicline, bupropion) instead of, or in addition to, NRT. Note that these products should be started BEFORE the client's quit date ***

***** Dosage for varenicline and bupropion for vaping cessation are the same as those for smoking cessation (as per Appendix 1)**

Education and counselling for all clients (using traditional nicotine products OR e-cigarettes)

- Collaborate with the client to develop an individualized nicotine cessation plan addressing lifestyle changes and behavioural interventions and document the plan in the EMR.

- Provide education about appropriate use of NRT, if applicable. Including: proper application and/or use of the product, expected adverse effects and how to manage them, storage and disposal, recommended maximum dosing (for as-needed short-acting NRT), and identification of signs and symptoms of nicotine toxicity

Documentation and Communication:

Appendix Attached: Yes No

Title: Appendix 6 – Recommended Format for a Prescription or Requisition Completed Pursuant to a Directive

1. Documentation in the patient’s medical record needs to include name and number of the directive, name of the implementer (including credential), and name of the authorizer responsible for the directive and patient.
2. Information regarding implementation of the procedure and the patient’s response should be documented in the patient’s medical record, in accordance with standard documentation practice.
3. Dispensed NRT will be documented in EMRs and will include the date NRT was dispensed, type of NRT, amount – including number of boxes of patches, lozenges, gum, inhaler – and any adverse reactions.
4. Lot number(s) and expiry date(s) will be documented on the dispensed NRT.
5. Standard documentation is recommended for prescriptions, requisitions, and requests for consultation. *

* Potter, P.A. & Perry, A.G. (2006). Fundamentals of Nursing. St. Louis: Mosby. College of Nurses of Ontario (2008). CNO Practice Standard: Documentation

Review and Quality Monitoring Guidelines:

Appendix Attached: Yes No

Title:

1. The Directive remains in force until and unless amendment occurs. Review will occur biennially. In case the Medical Director identifies the need to change the Medical Directive, at least one TVFHT member of the implementing disciplines will be consulted.
2. At any such time that issues related to the use of this directive are identified, the team must act upon the concerns immediately by identifying these concerns to the Medical Director. The Medical Director will review these concerns and consult with at least one TVFHT member of the implementing disciplines, before necessary changes are made.
3. If new information becomes available between routine renewals, and particularly if this new information has implications for unexpected outcomes, the directive will be reviewed by the Medical Director and a minimum of one TVFHT member of the implementing disciplines.

Approving Authorizer(s):

Appendix Attached: Yes No

Title:

Authorizer Approval Form signed in HR Downloads.



Appendix 1 - List of Prescription Medications for Nicotine Cessation with Detailed Indications/Contraindications

Prescribing: Zyban (bupropion)

- If choosing Zyban prescribe 150 mg daily for 3 days (starting 1 week prior to quit date), then increase to 150 mg twice daily (to stop smoking between day 7 and 10).
- Renal Dysfunction: Use with caution; manufacturer's labeling suggests a reduction in dose and/or frequency be considered but does not provide specific dosing recommendations
- Advise patient to not take Zyban any closer than 8 hours apart due to increased seizure risk
- Ensure other nicotine cessation strategies (behaviour modification and support) are in place for Quit Date
- With close supervision, therapy may continue for 3-6 months. If within 3 months patient has not stopped using nicotine products, stop therapy, and offer alternatives, setting another stop date with support
- Can be used with NRT if strong physical component to nicotine addiction (moderate to high Fagerstrom score)

Contraindications:

- Known hypersensitivity to Bupropion
- Already being treated with Wellbutrin SR (bupropion), Wellbutrin XL or bupropion for depression
- Current treatment with MAO inhibitors (Isocarboxazid; Linezolid; Methylene Blue; Moclobemide; Phenelzine; Rasagiline; Safinamide; Selegiline; Tranylcypromine), Thioridazine (within 14 days), St. John's Wort
- Pregnant (1st Trimester)
- Lactation
- Under 18 years old
- Caution with recent MI, unstable heart disease, uncontrolled hypertension, risk of seizure (e.g., history of head trauma)
- Caution with medications that lower seizure threshold - e.g., antipsychotic, antidepressants, Lithium, Amantadine, Theophylline, systemic steroids, Quinolone antibiotics and antimalarials, OTC stimulants or anorectics, diabetes treated with oral hypoglycemic agents or insulin
- Caution with medical conditions that lower seizure threshold:
 - History of a seizure disorder
 - History of eating disorder- bulimia or anorexia nervosa
 - Impaired liver or kidney function (eGFR less than 60 mL/min)

- Undergoing abrupt discontinuation of ethanol or sedatives including anticonvulsants, barbiturates, or benzodiazepines

Precautions:

- Dosing considerations:
 - Do not administer doses less than 8 hours apart (increase seizure threshold)
 - Daily total dose may not exceed 300 mg
 - Insomnia may be minimized by avoiding bedtime doses (I.e., last dose by 1800)
- Smoking cessation with or without varenicline may alter pharmacodynamics or pharmacokinetics of some drugs for which dosage adjustment may be necessary (including but not limited to theophylline, clozapine, warfarin and insulin). Smoking cessation may result in increased plasma levels of CYP 1A2 substrates. The prescriber needs to be notified ASAP of smoking cessation if the patient is on any of the above medications.

Additional information regarding interaction with tobacco smoke:

https://www.helpthemquit.ca/sites/helpthemquit_ca/files/nrt_pharmacokinetic_drug_interactions_en_v13_final.pdf

Prescribing: Champix (varenicline)

- Prescribe 0.5 mg orally once daily for days 1-3 (starting 1-2 weeks prior to quit date), then increase to 0.5 mg orally twice daily for 4-7 days, then increase to 1 mg orally twice daily on day 8 for 11 weeks.
- Advise patients to follow-up with their provider if they experience side effects. The provider may counsel the patient to reduce their dose to 0.5 mg 1-2 times daily to improve tolerability.
- Patients to be advised to set a date to stop using nicotine products
- Dose to be adjusted in patients with severe renal impairment (CrCl less than 30mL per min).
 - CrCl less than 30 mL per minute: Initial: 0.5 mg once daily; maximum maintenance dose: 0.5 mg twice daily
- Duration of treatment is 12 weeks. For patients who have successfully stopped using nicotine products at the end of 12 weeks, an additional course of 12 weeks treatment with Champix may be considered
- Ensure other nicotine cessation strategies (behaviour modification and support) are in place for Quit Date

Contraindications:

- Patients who are hypersensitive to varenicline or to any ingredient in the formulation or component of the container
- Patients under 18 years of age
- Pregnancy or lactation

Precautions:

- Total daily dose may not exceed 2 mg
- The concomitant use of NRT may result in increase in adverse reactions including nausea, headache, vomiting, dizziness, dyspepsia, and fatigue
- Smoking cessation with or without varenicline may alter pharmacodynamics or pharmacokinetics of some drugs for which dosage adjustment may be necessary (including but not limited to theophylline, clozapine, warfarin and insulin). Smoking cessation may result in increased plasma levels of CYP 1A2 substrates. The prescriber needs to be notified ASAP of smoking cessation if the patient is on any of the above medications
- Caution patient -may cause mild to moderate nausea, most often transient but for some, may persist over several months
- May cause dizziness or somnolence

Prescribing: Nicotine Replacement Therapy (NRT)

- Patients will be offered the choice of NRT products available
- Product recommendations, including contraindications and dosages, based on **Appendix 3 - Table 1- Nicotine Replacement Dosing Information**

Precautions:

- Caution patients if they continue to use nicotine products while using NRT -may experience adverse effects due to peak nicotine levels higher than those experienced with smoking alone.
- Patients are asked to rotate the site of patch application daily to prevent/ minimize local irritation



Appendix 2 - The Fagerstrom Test for Nicotine Dependence

Score each of the following questions (the scores are given in brackets)

1. How soon after you wake up do you have your first cigarette?

- A. Within 5 minutes (3) B. 6-30 minutes (2)
C. 31-60 minutes (1) D. After 60 minutes (0)

2. Do you find it difficult to refrain from smoking in places where it is forbidden, e.g., in church, the library, the cinema, etc.?

- A. Yes (1) B. No (0)

3. Which cigarette would you hate most to give up?

- A. The first one in the morning (1) B. All others (0)

4. How many cigarettes do you smoke per day?

- A. 10 or fewer (0) B. 11-20 (1)
C. 21-30 (2) D. 31 or more (3)

5. Do you smoke more often during the first hours after waking than during the rest of the day?

- A. Yes (1) B. No (0)

6. Do you smoke even if you are so ill that you are in bed most of the day?

- A. Yes (1) B. No (0)

Now add up your score:

7 to 10 points = highly dependent on nicotine

4 to 6 points = moderately dependent on nicotine

less than 4 points = less dependent.

The higher your score, the more likely you are to have withdrawal symptoms if you give up smoking, and the withdrawal symptoms are likely to be stronger.



Appendix 3 - Nicotine Replacement Dosing Information

Medication/Dosage Nicotine Replacement Therapy:	Indications	Contraindications/Cautions	Max Dose per 24h
<i>Nicotine Patch: <u>Can be given alone or in combination with nicotine gum and inhaler</u></i>			
Nicotine Patch (21mg) per 24h	Smoking greater than 10 cigarettes per day (CPD) As a general rule for adults who are vaping, using more than 20mg of nicotine per day, can consider starting with 21mg patches to reduce background cravings.	Contact hypersensitivity to the patch. Signs and symptoms of these may include erythema, pruritis, edema, hives, or generalized rash or urticaria. *Pregnancy, recent cerebrovascular event, immediately post MI, angina, life threatening arrhythmias	**42mg
Nicotine Patch (14mg) per 24h	Smoking 7-14 CPD As a general rule, for adults who are vaping, using less than 20mg of nicotine/day, can consider starting with 14mg patches to reduce background cravings.	As above	**42mg
Nicotine Patch (7mg) per 24h	Less than 7 CPD or unable to tolerate higher doses of NRT For adults who are vaping, lower doses can be considered based on withdrawal symptoms.	As above	**42mg

Medication/Dosage Nicotine Replacement Therapy:	Indications	Contraindications/Cautions	Max Dose per 24h
<p><i>Nicotine Gum</i> <u>Can be used alone or in combination with nicotine patch and inhaler</u></p>			
<p>Nicotine Gum 4mg q 1h prn</p>	<p>Willing to learn the proper technique since nicotine must be absorbed across the buccal mucosa.</p>	<p>Unable to chew gum Wears dentures Immediately post MI, arrhythmias, angina, active TMJ dysfunction</p>	<p>20 pieces of Nicorette gum</p>
<p>Nicotine Gum 2mg q 1h prn</p>	<p>As above, use 2 - 4mg first, switch to 2mg if unable to tolerate 4mg gum- too strong, signs/symptoms of nicotine toxicity with 4mg gum (nausea, diaphoresis, irritated throat, etc.)</p>	<p>As above</p>	<p>20 pieces of Nicorette gum</p>
<p><i>Nicotine Inhaler: Can be used alone or in combination with nicotine gum or patch</i></p>			
<p>Nicotine Inhaler 10mg cartridge Q1h prn (delivers 4mg nicotine per cartridge)</p>		<p>Recent CVA, immediately post MI, angina, life-threatening arrhythmias.</p>	<p>6 cartridges</p>
<p><i>Nicotine Lozenge</i> <u>Can be used alone or in combination with nicotine gum, patch, or inhaler</u></p>			
<p>Nicotine Lozenge 2mg Q 1-2 hrs. PRN</p>	<p>Unable to tolerate or use nicotine gum or inhaler</p>	<p>Recent CVA, immediately post MI, angina, life threatening arrhythmias.</p>	<p>15 nicotine lozenges per day</p>
<p>Nicotine Lozenge 4mg Q 1-2 hrs. PRN</p>	<p>Unable to tolerate or use nicotine gum or inhaler</p> <p>Use 4mg first, switch to 2mg if unable to tolerate 4mg lozenge</p> <p>Signs and symptoms of nicotine toxicity with 4mg lozenge (nausea, diaphoresis, irritated throat, etc.)</p>	<p>As above</p>	<p>15 nicotine lozenges per day</p>

* Recent studies have shown that using NRT is safer than smoking/vaping. Any client who is pregnant or who has a history of heart disease, recent CVA or MI, or any arrhythmias should be initiated on NRT by a provider (MD/NP). The implementer can then continue these clients on NRT and reduce dosages accordingly. Any increase in dosage should be done by the patient's provider.

** Clients can be titrated up to and including 42mg patch dosage by the implementer (including in combination with PRN nicotine gum or inhaler). See Appendix 4 - DECISION TREE TO ADDRESS NICOTINE WITHDRAWAL: INCREASING DOSAGE BEYOND 21MG PATCH

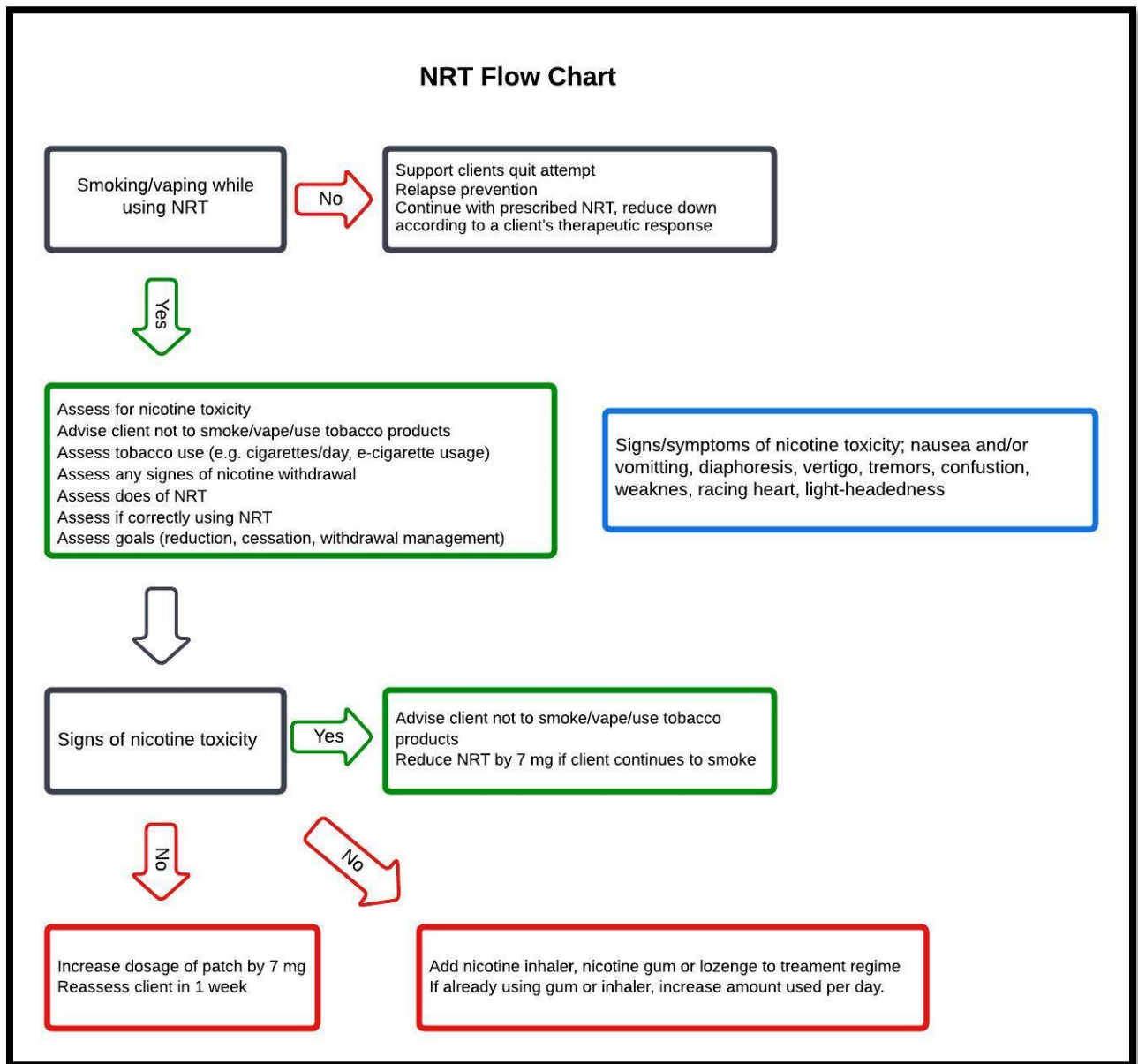
NOTE re: vaping – Can consider adding short-acting NRT (e.g. gum, lozenge, inhaler) to long-acting NRT to relieve breakthrough cravings

NB If a client experiences nausea or vomiting, diaphoresis, tremors, confusion, or weakness after using NRT, this could mean they are receiving too high a dose and the NRT product should be discontinued. Once the client's condition stabilizes, the implementer can try a lower dose and continue to monitor client closely for the above signs.



Appendix 4 - Decision Tree to Address Nicotine Withdrawal: Increasing Dosage Beyond 21 mg Patch

If client requires greater than 42mg dosage, refer client to see the provider. The implementer can then continue clients on dosages of 42mg or higher. Any additional increases beyond 42mg should be done by the provider.





Appendix 5 – The Fagerstrom Test for E-Cigarette Dependence

The E-cigarette Fagerström Test of Cigarette Dependence

Tool taken from: Piper, M.E., Baker, T.B., Benowitz, N.L., Smith, S.S., & Jorenby, D.E. (2020). E-cigarette dependence measures in dual users: reliability and relations with dependence criteria and e-cigarette cessation. *Nicotine and Tobacco Research*, 22(5), 756-763.

Scoring taken from: Johnson, J. M., Mulienburg, J. L., Rathbun, S. L., Yu, X., Naeher, L. P., & Wang, J. S. (2018). Elevated Nicotine Dependence Scores among Electronic Cigarette Users at an Electronic Cigarette Convention. *Journal of community health*, 43(1), 164–174.

<https://doi-org.myaccess.library.utoronto.ca/10.1007/s10900-017-0399-3>

1	How many times per day do you usually use your electronic cigarette? (Assume that one “time” consists of around 15 puffs or lasts around 10 minutes.)	<input type="radio"/> 0-4 times/day (0) <input type="radio"/> 5-9 (0) <input type="radio"/> 10-14 (1) <input type="radio"/> 15-19 (1) <input type="radio"/> 20-29 (2) <input type="radio"/> 30+ (3)
2	Do you find it difficult to refrain from vaping in places where it is forbidden (e.g. in church, at the library, in the cinema)?	<input type="radio"/> Yes (1) <input type="radio"/> No (0)
3	When would you hate most to give up e-cigarette use?	<input type="radio"/> In the morning (1) <input type="radio"/> During or after meals (0) <input type="radio"/> During or after stressful situations (0) <input type="radio"/> None of the above (0)
4	On days that you can use your electronic cigarette freely, how soon after you wake up do you first use your electronic cigarette?	<input type="radio"/> 0-5 mins (3) <input type="radio"/> 6-15 (2) <input type="radio"/> 16-30 (2) <input type="radio"/> 31-60 (1) <input type="radio"/> 61-120 (0) <input type="radio"/> 121+ (0)
5	Do you use your e-cigarette more frequently during the first two hours of the day than during the rest of the day?	<input type="radio"/> Yes (1) <input type="radio"/> No (0)
6	Do you use your e-cigarette when you are so ill that you are in bed most of the day?	<input type="radio"/> Yes (1) <input type="radio"/> No (0)

Scoring eFTND: Sum the items. Total score: 0-2 = low dependence, 3-4 = low to moderate dependence, 5-7 = moderate dependence, 8+ = high dependence

Appendix 6 – Recommended Format for a Prescription or Requisition Completed Pursuant to a Directive

Medical Directive # 015

A prescription or requisition for laboratory specimen completed pursuant to a medical directive must include:

- Name and Number of the Directive
- Name of Authorizer
- Name and Signature of the Implementer

The following sample illustrates the recommended format for including this information. The format readily signifies to pharmacists that they have the proper order, permitting them to dispense the prescribed medication, in accordance with legislative and regulatory requirements. Should there be questions about the prescription the pharmacist would contact the implementer. If questions cannot be resolved the authorizer will be contacted for clarification. The authorizer is recorded as the prescriber. Where requested a copy of the medical directive can be forwarded to the pharmacist. The sample prescription is appended to the directive.

The same convention would apply to requisitions received by medical laboratory technicians that are completed pursuant to a directive.

Dr. J.D. Authorizer, MD, CCFP.
Thames Valley Family Health Team
6-1385 North Routledge Park, London ON
N6H 5N5
519-473-0530

Date: March 1, 2010
Patient: Christa Jones, 100 Main Street, London

Champix 0.5 mg orally once daily for days 1-3 (starting 1-2 weeks prior to quit date), THEN increase to 0.5 mg orally twice daily for 4-7 days, THEN increase to 1 mg orally twice daily on day 8 for 11 weeks.

(Signature)

Dr. J.D. Authorizer, MD, CCFP /Jane Smith RN
(Jane Smith RN, TVFHT 015)

Medical Directive Available at: <https://thamesvalleyfht.ca/medical-directives>