Taddle Creek
Family Health Team

MEDICAL DIRECTIVE

Title:	Nicotine Replacement Therapy	**Number:**	TCFHT-MD10
Activation Date:	14-June- 2011	**Review Date:**	1-November- 2017
Next Review Date:	1-November- 2018		

Sponsoring/Contact Person(s) *(name, position, contact particulars):*

Jessica Lam, RPh, CGP, BScPhm – jlam@tcfht.on.ca
Shawn Goodman, RPh, PharmD – sgoodman@tcfht.on.ca
790 Bay Street, Suite 522,
Toronto, Ontario M5G 1N8
416-591-1222 x #8513

Dr. Vivienne Lemos
790 Bay Street, Suite 522
Toronto, Ontario M5G 1N8
416-960-1366

Sherry Kennedy, Executive Director – skennedy@tcfht.on.ca
790 Bay Street, Suite 306,
Toronto, Ontario M5G 1N8
416-260-1315, x307

Order and/or Delegated Procedure:

Appendix Attached: __X__ **No** ___ **Yes**
Title:

Under this medical directive, authorized implementers may prescribe and dispense nicotine replacement therapy (NRT). NRT includes nicotine patches, gum, lozenges, inhalers, and mouth spray. The source of NRT may be over-the-counter, samples from pharmaceutical companies (e.g. Johnson & Johnson), or from the CAMH STOP-FHT study (enrolled patients only).

Recipient Patients:

Appendix Attached: ___ **No** __X__ **Yes**
Title: Appendix A – Authorizer Approval Form

Recipients must:

- Be active patients of a TCFHT primary care provider who has approved this directive by signing the Authorizer Approval Form
- DEP Community Patients can participate as long as it has been authorized by their community physician (by signing as an authorizer to this medical directive)
- Meet the conditions identified in this directive

Authorized Implementers:

Appendix Attached: ___ **No** __X__ **Yes**

Title: Appendix B – Implementer Approval Form

Implementers must be TCFHT employed Regulated Health Care Providers (RN, Pharmacist) or Physician Assistant (under the supervision of a physician).

Implementers must complete the following preparation and sign the Implementer Approval Form:

- Online or in-class Smoking Cessation Training TEACH Core Course with the Centre for Addiction and Mental Health (CAMH). This training will include indications for use of NRT, contraindications, signs, and symptoms of nicotine withdrawal and overdose and actions to be taken if the client presents with the below contraindications and considerations. This course will help practitioners screen, assess and treat patients with tobacco dependence using evidence-based pharmacotherapies.

Indications:

Appendix Attached: __X__ No __ Yes
Title:

Implementers may prescribe, and/or adjust doses of NRT for appropriate clients engaged in smoking cessation counselling according to the parameters of this directive.

Contraindications:

- Known history of or newly presenting adverse side effects, drug sensitivity or allergy
- Recent MI, CVA, angina, or arrhythmias. This is not an absolute contraindication; recent studies have shown that using NRT is safer than smoking. Any client with a history of heart disease, recent CVA or MI, or any arrhythmias should be initiated on NRT by a doctor. The implementer can then continue these clients on NRT and reduce dosages accordingly. Any increase in dosage should be done by the Physician/NP.
- Pregnancy. This is not an absolute contraindication; recent studies have shown that using NRT is safer than smoking. Any client who is pregnant should be initiated on NRT by a doctor. The implementer can then continue these clients on NRT and reduce dosages accordingly. Any increase in dosage should be done by the Physician/NP.

Considerations:

- Clients can be titrated up to and including a 63 mg NRT patch dosage by the implementer (plus the combination with PRN nicotine gum, lozenge, inhaler, or mouth spray if needed). If clients require greater than 63 mg NRT patch, they should be referred to a physician. The implementer can then continue clients on dosages of up to a maximum of 84 mg NRT patch in consultation with the physician.

Consent:

Appendix Attached: __X__ No __ Yes
Title:

The implementer will obtain verbal consent from the patient or legal substitute decision maker, and explain any potential risks and benefits prior to prescribing or changing doses of NRT.

Guidelines for Implementing the Order/Procedure:

Appendix Attached: __ No __X__ Yes
Title: Appendix C - List of NRTs covered by TCFHT-MD10
Appendix D – STOP Program Sample NRT Algorithm
Appendix E – What Withdrawal Symptoms Can I Expect

Under the Regulated Health Professions Act: Controlled Act: #8: Prescribing, dispensing, selling or compounding a drug as defined in clause 113 (I)(d) of the Drug and Pharmacies Regulation Act, or supervising the part where such drugs are kept, requires a medical directive when such acts are delegated to other health care professionals. Therefore, under this medical directive:

1. Implementers providing smoking cessation counseling, on the authority of this medical directive, may prescribe and dispense NRT directly to clients of TCFHT (or community patients of the DEP), without prior consultation with a physician under defined circumstances, as indicated in the Appendices. The implementer must believe that she/he has the knowledge, skill, and judgment to implement this medical directive, and must have completed the educational requirements as outlined.
2. The implementer providing smoking cessation counseling may continue and/or adjust a client's NRT orders if previously implemented by a physician.
3. Implementers providing smoking cessation counseling possess advanced knowledge regarding the use of NRT. As such, this medical directive allows the Regulated Health Care Provider or Physician Assistant to initiate and continue NRT above the usual recommended dosages or in combinations of different NRT formulations, as appropriate. If clients require a dosage greater than 63 mg of NRT patch, a physician should be consulted.
4. Any medication ordered by the implementer as per this medical directive, should be brought to the attention of the patient's primary care provider within 72 hours.
5. In situations where the implementer is unsure of whether it falls under this medical directive, he/she should consult the authorizing primary care provider for the patient.
6. A list of medications covered by this Medical Directive is included in Appendix C. Please refer to the Stop Program Sample NRT Algorithm in Appendix D to determine which NRT to use.
7. The implementer will dispense a quantity of NRT not to exceed 1 month's supply, except in extenuating circumstances that must be documented into the EMR.
8. The implementer is responsible for thoroughly checking that the correct amount, strength, and dosage form of NRT is being dispensed and that these details (including lot # and expiry dates) are documented into the EMR.
9. For clients enrolled in the CAMH STOP-FHT study, the implementer is responsible for ensuring all required documentation is provided on the STOP Portal.
10. The implementer will ensure that the TCFHT supply of NRT is securely stored within a locked cabinet and that the medication is regularly checked for good dating and supply level.
11. The NRT inventory may consist of NRT provided by the CAMH STOP-FHT study (for enrolled clients only) and samples from Johnson & Johnson (for non-enrolled clients or additional dosage forms not provided by CAMH).

Preexisting Criteria:

Prior to dispensing any nicotine replacement within this medical directive, implementers must assess client status including:

- Allergies
- Smoking status - number of cigarettes per day
- Length of use (cigarettes)
- Readiness to change
- Goals (reduction, abstinence)
- Prior experience with any NRT or other pharmacotherapy for smoking cessation (e.g. Bupropion (Zyban©), Varenicline (Champix©), or Cytisine, including efficacy, duration, and side effects
    - Note: Pharmacists in Ontario, as part of their expanded scope of practice, may

provide counseling and prescriptions for Bupropion or Varenicline for the indication of smoking cessation

Documentation and Communication:

Appendix Attached: __X__ No __ Yes
Title:

- Implementers that are applying this medical directive will be required to document the NRT dispensed in the prescribing portion of the EMR.
- Details of the prescription to be documented include: date, time, drug, dosage, route, frequency, and quantity dispensed. "As per Medical Directive" should also be indicated in the EMR.
- The implementer must also document in the Progress Notes of the EMR. The implementer must document what assessment he/she has completed to determine the need to apply the directive and what was discussed with the client. For follow-up encounters, an evaluation of the client's response to the treatment must be documented in the EMR.

Review and Quality Monitoring Guidelines:

Appendix Attached: __X__ No __ Yes
Title:

- Educational requirements: a current or updated list of those certified to implement this medical directive must be maintained by TC FHT's Executive Director.
- The implementer is expected to maintain competency by regular use of the medical directive once a month or more.
- This medical directive will be monitored by a TCFHT Pharmacist.
- The implementer will seek consultation from FHT physicians/NPs (or DEP community physicians) regarding individual client issues/care as needed.
- Routine review will occur annually on the anniversary of the activation date. Reviews will involve a collaboration between the authorizing primary care providers and the authorized implementers.
- If new information becomes available between routine reviews, such as the publishing of new clinical practice guidelines, and particularly if this new information has implications for unexpected outcomes, the directive will be reviewed by an authorizing primary care provider and a mimimum of one implementer.
- At any such time that issues related to the use of this directive are identified, TCFHT must act upon the concerns and immediately undertake a review of the directive by the authorizing primary care providers and the authorized implementers.
- This medical directive can be placed on hold if routine review processes are not completed, or if indicated for an ad hoc review. During the hold, implementers cannot perform the procedures under authority of the directive and must obtain direct, patient-specific orders for the procedure until it is renewed.

NOTE:

This medical directive is based on TCFHT's previous medical directive "Provision of Nicotine Replacement Medications by Registered Nurses During Smoking Cessation Counselling," which required revision in formatting to reflect the growth of the TCFHT organization. The majority of the content of "Provision of Nicotine Replacement Medications by Registered Nurses During Smoking Cessation Counselling" has remained the same for the revised TCFHT-MD10 version. Therefore, all approved Implementers and Authorizers for medical directive "Provision of Nicotine Replacement Medications by Registered Nurses During Smoking Cessation Counselling" have grandfathered approval for TCFHT-MD10 "Nicotine Replacement Therapy."

Appendix A:

Authorizer Approval Form

Name	Signature	Date

Appendix B:

Implementer Approval Form

To be signed when the implementer has completed the required preparation, and feel they have the knowledge, skill, and judgement to competently carry out the actions outlined in this directive.

Name	Signature	Date

Appendix C: List of NRTs Covered by TCFHT-MD10

Medication & Dose	Indications	Precautions	Contraindications*	Max Dose/24hr
Nicotine Patch (e.g., Nicoderm, Habitrol, generics) • Can be used alone or in combination with nicotine gum, lozenge, inhaler, or mouth spray				
Nicotine Patch 21mg/24hr	Smoking >10-29 cigarettes per day (CPD) (Use 28 mg if smoking > 29 CPD)	Patch may cause contact hypersensitivity. Patch may cause Insomnia/nightmares – remove patch at night if not tolerated.	Pregnancy, recent CVA, immediately post-MI, angina, life-threatening arrhythmias	63 mg (as per medical directive) Absolute maximum of 84 mg (4 x 21 mg) daily
Nicotine Patch 14mg/24hr	Smoking < 10 CPD or unable to tolerate higher doses of NRT			
Nicotine Patch 7mg/24hr	Smoking <5 CPD or unable to tolerate higher doses of NRT			
Nicotine Gum (e.g., Nicorette, Thrive, generics) • Can be used alone or in combination with nicotine lozenge, inhaler, mouth spray, or patch				
Nicotine Gum 2 mg or 4 mg q1hr PRN (Note: only 2mg strength available via STOP-FHT study)	Smoking Cessation or Reduction Start with 2 mg if smoking < 20 cpd or using combination therapy with patches. Start with 4 mg if smoking > 20 cpd and not using patches.	Must be able to learn proper chewing technique to ensure proper buccal absorption. Not ideal choice for denture-wearers or patients with TMJ dysfunction. Use caution in patients with esophageal or peptic ulcers.	Pregnancy, recent CVA, immediately post-MI, angina, life-threatening arrhythmias	20 pieces of gum
Nicotine Inhaler (e.g.,Nicorette, Nicotrol) • Can be used alone or in combination with nicotine gum, lozenge, mouth spray, or patch				
Nicotine Inhaler 10mg cartridge q1hr PRN (delivers 4mg of nicotine per cartridge)	Smoking Cessation or Reduction	Must be able to learn proper inhalation technique to ensure proper buccal absorption. Use with caution in patients with bronchospastic disease.	Pregnancy, recent CVA, immediately post-MI, angina, life-threatening arrhythmias	12 cartridges
Nicotine Lozenge (e.g.,Nicorette, Thrive) • Can be used in combination with nicotine gum, inhaler, mouth spray, or patch.				

Nicotine Lozenge 2mg or 4 mg q1-2hr PRN (Note: only 2mg strength available via STOP-FHT study; Thrive brand 1mg strength also available without a prescription)	Smoking Cessation or Reduction Start with 2 mg if smoking < 20 cpd or using combination therapy with patches. Start with 4 mg if smoking > 20 cpd and not using patches.	Must be able to learn proper technique to ensure proper buccal absorption.	Pregnancy, recent CVA, immediately post-MI, angina, life-threatening arrhythmias	15 lozenges
Nicotine Mouth Spray (e.g., **Nicorette QuickMist)** • Can be used in combination with nicotine gum, lozenge, inhaler, or patch. • Administration Note: Spray must be primed with first use or after 2 days of not using				
Nicotine spray 1 mg Use 1-2 sprays PRN	Smoking Cessation or Reduction	Must be able to learn proper technique to ensure proper buccal absorption.	Pregnancy, recent CVA, immediately post-MI, angina, life-threatening arrhythmias	2 sprays at a time, 4 sprays per hour, 64 sprays in 24 hours Maximum 32 sprays/24 hours when combined with Nicotine patch

***Not absolute contraindications – speak with client's physician**

N.B. If client experiences nausea or vomiting, diaphoresis, tremors, confusion or weakness after using NRT, this could mean they are receiving too high a dose. Discontinue its use, ensure client does not resume smoking, monitor client and notify a doctor. Once client's condition stabilizes, the doctor can try a lower dose and continue to monitor client closely for the above signs.

Appendix D: STOP Program Sample NRT Algorithm

**Note that these are guidelines only. Practitioners should use their clinical judgment where appropriate for each patient case.

Appendix E: Recognizing Nicotine Withdrawal Symptoms

Appendix F: Protocol – Implementing Smoking Cessation Treatment in Ontario Family Health Teams

Background and Rationale

Smoking remains the leading preventable cause of death in Canada and the US, accounting for one in every five deaths each year (Fiore, Jaen, Baker, et al., 2008). As such, there needs to be a concerted effort to encourage Ontario smokers to quit. The Ontario Ministries of Health Promotion and Sport and Health and Long Term Care have partnered with the Nicotine Dependence Clinic at the Centre for Addiction and Mental Health to implement and evaluate a smoking cessation program within Family Health Teams (FHTs). The purpose of the program is to build capacity for the treatment of tobacco dependence through the training of FHT clinical practitioners in smoking cessation counseling through the TEACH project. This, coupled with the provision of free smoking cessation medications for those patients who are interested in using pharmacological aids to help them quit smoking may significantly decrease the prevalence of smoking in the FHT patient population. Previous clinical research has established that cessation medications coupled with behavioural counseling is a very efficacious treatment strategy that more than doubles long-term quit rates over unaided quit attempts. Furthermore, advice and assistance from healthcare professionals around smoking cessation is very effective in motivating patients to quit.

Primary care and especially Family Health Teams are invested in chronic disease prevention and management. The most effective chronic disease prevention strategy is quitting smoking. However, barriers to effective treatment for tobacco dependence exist such as lack of adequate training and knowledge among health professionals about tobacco dependence and how to treat it, as well as barriers to the patient such as the high cost of the medication and the lack of adequate insurance coverage for them. As such, the FHT setting and structure with its rostered patients and multi-disciplinary approach to health care and disease prevention is the optimal setting for this project.

Methodology

Smoking cessation interventions will follow the 5 A's model. Patients will be **asked** if they smoke. Patients who smoke will be **advised** to quit and their interest in quitting using free Nicotine Replacement Therapy (NRT) will be **assessed**. Those who wish to quit using NRT will be **assisted** in doing so and follow-up appointments **arranged** as deemed appropriate by the practitioner and patient.

Treatment will be provided via the Individual or Group implementation models. FHTs are free to choose one or both models to incorporate into their practice. FHTs that have committed to participating in either the Ottawa Model or 'Stanford' model will implement the program using a protocol that integrates both programs' requirements.

Practitioners implementing the program are responsible for ensuring that all applicable program documents have the Participant ID and initials and the date of the intervention recorded correctly. Clinical documentation standards (e.g. no pencil or liquid paper) should be upheld.

Enrollment

Patients must read or have read to them the *Patient Information and Consent Form* and complete the 'Agreement to Participate' section of the form in order to participate in this program. All patients who enroll in the program should be provided with a copy of the consent form to retain for their own records. Patients who wish to enroll in the program must also complete a *Baseline Questionnaire*. It is the responsibility of the practitioner who is providing the treatment intervention to verify that the patient has consented to participate

in the program and to ensure that the *Patient Information and Consent Form* and *Baseline Questionnaire* are complete and up-to-date prior to the patient receiving any Nicotine Replacement Therapy. The FHT has the option to scan the completed *Patient Information and Consent Form* and *Baseline Questionnaire* into the patient's Electronic Medical Record.

Note: The original completed hard copies of the *Patient Information and Consent Form* and *Baseline Questionnaire* will be couriered to the program coordinator at CAMH on a monthly basis.

Smoking Cessation Interventions
At the initial visit, practitioners will complete an *Intervention Form*. They will confirm on the form that a completed and signed *Patient Information and Consent Form* and a *Baseline Questionnaire* for the participant are in their possession. They will collect and record information pertaining to the participant's current smoking status (7-day point prevalence of abstinence, cigarettes per day, time to first cigarette) and dispensing of NRT on the *Intervention Form*.

At every subsequent smoking cessation intervention for enrolled participants where either individual counseling and/or dispensing of NRT occurs, practitioners will complete an *Intervention Form*. As on the initial Intervention Form, information pertaining to the participant's current smoking status and dispensing of NRT will be recorded.

Nicotine Replacement Therapy
The Nicotine Replacement Therapies available to participants in this program are: nicotine patch, nicotine inhaler, nicotine 2mg gum, nicotine 2mg lozenge, and nicotine 1mg spray (while quantities allow).

Dispensing NRT
Nicotine Replacement Therapy will be dispensed by authorized Family Health Team staff to enrolled, medically suitable participants. Prior to dispensing NRT to an enrolled participant, the participant's smoking status must be assessed and recorded on the *Intervention Form*. NRT dispensing information must be recorded on the *Intervention Form*. It is the responsibility of the practitioner dispensing the NRT to ensure that expired product is not dispensed. NRT dispensing should also be tracked on the NRT Inventory Log at this time (see below).

Individual Model - After consultation with the participant, the authorized practitioner will use their clinical judgment (and FHT's algorithm for dispensing NRT, if applicable) to determine the appropriate dose, type and quantity of NRT to meet the participant's needs. Authorized FHT practitioners may dispense a maximum of 4 weeks' worth of NRT at a time to enrolled participants. Participants may receive up to 26 weeks of NRT in a year if deemed appropriate by their practitioner.

Group Model – A prepared 5-week kit of Nicotine Replacement Therapy may be dispensed to participants who are receiving a group psychoeducation intervention. After consultation with the patient, the authorized practitioner will use their clinical judgment (and FHT's algorithm for dispensing NRT, if applicable) to determine the appropriate kit to dispense to the patient. The practitioner may not break a prepared kit, dispense more than one 5-week kit at the time to one patient, or create a new 5-week kit using off-label combination therapy through this dispensing option.

Inventory Control
The *NRT Inventory Log* is to be used to keep track of current available stocks of NRT at the FHT/Site and should be kept up to date at all times. Each change in the FHT/Site's current NRT inventory should be reflected on their *NRT Inventory Log*. This includes program NRT that has been received, returned or transferred by a FHT/Site, or dispensed to an enrolled participant. The *NRT Inventory Log* should not reflect any previously dispensed NRT that has been returned to the Family Health Team by a participant. Any NRT, even if unopened,

that has been returned to the FHT by an enrolled participant should be recorded in the Comments section of the participant's *Intervention Form* and marked for destruction and/or destroyed by the FHT using appropriate measures. On occasion, requests may be made to have the *NRT Inventory Log* faxed to the program coordinator at CAMH for tracking and medication reconciliation purposes.

Ordering NRT

Designated FHT staff are responsible for ensuring that their FHT/Site's NRT stock is kept at adequate levels and for re-ordering NRT in a timely manner so that inventory of each type of NRT does not run out. Additional NRT can be ordered by faxing a completed *NRT Order Form* with an up-to-date *NRT Inventory Log* to CAMH (contact information on form).

Training

Smoking cessation interventions – Training and support of different durations and intensities will be offered throughout the year to FHT staff.

Operations– Operations training in the implementation model being provided at the FHT is mandatory for each FHT practitioner who will be implementing the program (i.e. counseling and/or dispensing NRT).