

**HASTINGS PRINCE EDWARD PUBLIC HEALTH
MEDICAL DIRECTIVES**

Section:	TOBACCO CONTROL
Directive Title:	Delegation to Determine Eligibility for and to Dispense Nicotine Replacement Therapy
Directive #:	TC-01
Approved by:	Medical Officer of Health
Date:	October 7, 2019

ORDER / DELEGATED PROCEDURE:

The Medical Officer of Health (MOH) for Hastings Prince Edward Public Health (HPEPH) delegates the authority to Authorized Implementers to determine eligibility for and to dispense over-the-counter, combination system Nicotine Replacement Therapy (NRT), off-label, to Recipient Clients, as per the NRT Decision-Making Algorithm (Supporting Documents) and Appendix - Guidelines for Titration of Combination System NRT.

RECIPIENT CLIENTS:

Adults and youth who have requested smoking cessation assistance, have undergone assessment, and have been found to be eligible for NRT.

AUTHORIZED IMPLEMENTERS:

Registered Nurses (RNs), Registered Practical Nurses (RPNs), and Health Promoters (HPs) who accept the delegation to determine eligibility for and to dispense combination system NRT and have completed the core course from the Centre for Addiction and Mental Health TEACH (Training Enhancement in Applied Cessation Counselling and Health) program or other recognized organization.

INDICATIONS:

Determine eligibility for and dispense the appropriate dose of combination system NRT—continuous transdermal patches, short-acting NRT gum, lozenges, inhaler, or oral spray—for Recipient Clients, who must

- currently, on a regular basis, attend either a support group, smoking cessation class, clinic, meeting, or home visit, with an Authorized Implementer:
 - under special circumstances, to be determined by Authorized Implementer, a Recipient Client who cannot attend a smoking cessation clinic visit, due to, but not limited to, illness or mobility issues, may undergo a phone / video conference interview / consultation, then NRT may be dispensed on their behalf to a designated substitute
- have an individualized smoking cessation plan, addressing lifestyle changes and behavioural interventions
- be educated about the proper uses of NRT

Clients on prescription medications on Drug Interactions with Tobacco Smoke list

- agree to have their health care provider (HCP) notified by fax if they are commencing NRT and are on prescription medications listed on Drug Interactions with Tobacco Smoke (Related Links), since some drugs may require monitoring during smoking cessation due to an altered pharmacologic response; fax notification should include
 1. Notification of Initiation of NRT about enrolment in the We Can Quit Initiative, with a potential maximum daily patch dose of 84 mg NRT
 2. Notification of HCP about Drug Interactions with Tobacco Smoke and Smoking Cessation
 3. Drug Interactions with Tobacco Smoke list
- agree to allow HPEPH to share medical records with HCP, as noted in Penelope

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- if client does not have an HCP, give them the list to take with them to the clinic on their next visit and note “Client does not have HCP” in Penelope

Clients with medical conditions identified in Table 1

- agree to have their HCP notified by fax, including
 1. Notification of Initiation of NRT—about enrolment in the We Can Quit Initiative, with a potential maximum daily patch dose of 84 mg NRT
 2. Notification of HCP about Drug Interactions with Tobacco Smoke and Smoking Cessation, if they are on prescription medications on the list
 3. Drug Interactions with Tobacco Smoke list
- client will also agree to allow HPEPH to share medical records with HCP, as noted in Penelope
- if client does not have an HCP, give them the list to take with them to the clinic on their next visit and note “Client does not have HCP” in Penelope

Table 1

Medical conditions requiring notification of HCP

- | |
|--|
| <ul style="list-style-type: none">• heart attack in the last 2 weeks• severe or worsening angina• life-threatening arrhythmias• recent cerebral vascular incident• severe psychiatric condition,¹ not well controlled |
|--|

Pregnancy

- Pregnant clients² will agree to
 - have their HCP notified by means of a faxed form—Notification of Initiation of NRT—about enrolment in the We Can Quit Initiative, with a maximum daily dose of 49 mg NRT, which may include two 21 mg day-only patches
 - allow HPEPH to share medical records with HCP, as noted under Comments in Penelope
- If the client does not have an HCP or obstetrician, the RN or RPN will arrange an appointment with the Sexual Health Clinic for a referral to a Community Obstetrician, as per the Sexual Health procedure Pregnancy Management, as soon as possible
- The benefits of NRT to aid smoking cessation in pregnant women, who cannot stop smoking without such therapy, substantially outweigh the risks of either continual smoking or NRT.^{3 4}
- The benefits of cessation are greatest if the cessation occurs early in pregnancy.⁵
- First line treatment: Smoking cessation counselling about lifestyle and behavioural changes.

¹ Anthenelli 2016. Randomised, double-blind, placebo-controlled study with 8144 participants showed NRT, including patches, does not appear to increase incidence of serious neuropsychiatric side effects.

² Leung, 2015. Seventeen percent of Canadian women continue to smoke during pregnancy

³ NHS Health Scotland. 2013. Maternal and early years

⁴ Cooper, S. 2014. Infants born to women who used NRT for smoking cessation in pregnancy were more likely to have unimpaired development.

⁵ Society for the Study of Addiction 2016

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- Second line treatment: The Society of Obstetricians and Gynecologists of Canada suggest offering NRT at the lowest effective dose if counselling alone fails, along with an informed discussion of the benefits and risks of NRT therapy,⁶ keeping in mind that any smoker is safer with NRT (Pipe 2012):
 - Patch(es) may be considered to a maximum daily dose of 42 mg; the patch(es) should be removed at bedtime to reduce fetal nicotine exposure (Leung, 2015) unless the pregnant woman wakes up at night to smoke.
Note: If an increased dose is indicated, the Recipient Client will agree to consult with their HCP prior to the increase.
 - Patches may be preferred if the client is suffering from nausea during the pregnancy.
 - Studies have shown that there are no significant adverse effects from using the NRT patch(es) during pregnancy, and smoking cessation leads to healthier pregnancies and deliveries and fewer developmental impairments.⁷
 - Studies of the effectiveness of NRT in pregnant clients are inconclusive to date, but real-world studies suggest effectiveness in clinical practice. In one large non-randomised study in a clinical setting, clients who were prescribed combination NRT had twice the quit rate of those receiving no medication or monotherapy.⁸ Additionally, the Mayo Clinic reports that nicotine replacement products are safe during pregnancy, and counselling, with NRT, is the most effective way to quit.
 - Effective titration of NRT in pregnant clients should be considered since the rate of metabolism of nicotine may be increased by 40% or more during pregnancy,⁹ according to the University of Ottawa Heart Institute (Pipe, 2012).

Lactation

- Breastfeeding clients will agree to have their HCP notified by means of a faxed form— Notification of Initiation of NRT—about enrolment in the We Can Quit Initiative with a maximum daily dose of NRT of 49 mg.
- The benefits of NRT for breastfeeding clients and their infants outweigh the risks of smoking and offer great potential benefit to the infant because of reduced exposure to harmful second-hand smoke, according to the Society for the Study of Addiction. In addition, the amount of nicotine from NRT is less than that from cigarettes (Quit Victoria 2016).
- First line treatment: Smoking cessation counselling about lifestyle and behavioural changes is recommended.
- Second line treatment: short-acting NRT / patch(es) at the lowest effective dose may be considered to a maximum daily dose of 49 mg, along with an informed discussion of the benefits and risks of NRT, keeping in mind that any smoker is safer with NRT (Pipe 2012).
Note: If an increased dose is indicated, the Recipient Client will agree to consult with their HCP prior to the increase.
- Short-acting NRT should be avoided, if possible, for at least one hour before breastfeeding; instead, it should be used, if needed, immediately after breastfeeding.

⁶ CDC.2015.Tobacco smoke contains more than 7,000 chemicals, at least 70 of which are known to cause cancer.

⁷ University of Ottawa Heart Institute 2016

⁸ Australia Family Physician 2012

⁹ Benowitz 2009. Study results showed a 60% higher rate of nicotine metabolism from 18 weeks until 4 weeks postpartum. The study also showed a 28% higher rate in participants on oral contraceptives suggesting that sex hormones may be a causal factor.

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- The patch(es) should be removed at bedtime to reduce the infant's nicotine exposure unless the client wakes up at night to smoke.

Precautions

- Past history of adverse effects to NRT such as rash or serious cardiovascular symptoms, advise the client to consult with HCP.
- If there are concerns about the accuracy of the medical information provided, e.g. list of medications or physical and mental health status, advise the client to consult with HCP.
- Smoking reduces the effects of caffeine, so once the client quits smoking, the side effects from caffeine will likely increase:
 - **caffeine consumption should be reduced by 50%** (or more, during pregnancy) while quitting smoking to reduce the side effects of too much caffeine, e.g. palpitations, sweating, anxiety, insomnia, difficulty concentrating, impatience, restlessness.
 - it is not advisable to stop smoking and abruptly stop drinking all caffeinated beverages at the same time, as the symptoms of caffeine withdrawal—headache and fatigue—may be mistaken for nicotine withdrawal.
- The dosage of NRT may need to be reduced if the client experiences side effects of **excess nicotine** such as racing or irregular heartbeat or (listed in decreasing rate of frequency) headaches (15%), insomnia (11%), dizziness (7%), depression (5%), irritability, fatigue / weakness (5%), nausea (5%), drowsiness (4%), stomach upset (3%), diarrhea (3%) or anxiety (2%)¹⁰. Some symptoms are similar to those from nicotine withdrawal.
- **Nicotine overdose** is unlikely, but if it occurs, vomiting is the most common symptom. Other signs and symptoms include pallor (unhealthy, pale appearance), cold sweat, nausea, salivation, abdominal pain, diarrhoea, headache, dizziness, disturbed hearing and vision, tremor, mental confusion and weakness.
- Patch(es) should be removed immediately if the client shows signs of excess nicotine or overdosage and they should seek immediate medical care by contacting a physician or local poison-control centre. The skin surface should be flushed with water and dried. Soap must not be used since it may increase nicotine absorption.¹¹ Nicotine will continue to be delivered into the bloodstream for several hours after removal of the system because of a depot of nicotine in the skin.
- **Keep new or used short-acting NRT or long-acting NRT patches out of the reach of children and pets to avoid swallowing, chewing or sucking** since a small amount of nicotine can produce severe toxicity. The lethal dose of nicotine in a small child is approximately 10 to 15 mg.¹²
- Dispose of patches as directed, with sticky sides together. Each patch contains up to 114 mg of nicotine; approximately 60% of that amount is absorbed transdermally, which could leave up to 68 mg of available nicotine on the discarded patch.
Note: If nicotine is ingested, contact poison control; activated charcoal should be given as soon as possible.
- Patch(es) should be removed at night if the client experiences vivid dreams, insomnia or a sleep disturbance. Day-only patches result in a reduction of the daily dose of NRT.

¹⁰ Nicoderm. CPS. McNeil Consumer Healthcare. Controlled clinical trials with 2141 participants

¹¹ Johnson & Johnson, 2012. WebMD, 2018

¹² Pfizer, Mar 2016

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- Up to 50% of clients will have a local skin reaction to the patch; it is usually mild and self-limiting. Suggest rotating sites and using hydrocortisone cream to continue use of this method.
- Patch(es) should be removed prior to magnetic resonance imaging (MRI) testing as a burn may occur underneath the patch(es).
- Short-acting NRT gum should be avoided in clients with an active jaw disorder, such as temporomandibular joint disorder (TMJ), dentures or dental problems.
- Short-acting NRT should be reduced if it results in dyspepsia or irritation of the oral mucosa.
- Inhalers should be used with caution in clients with chronic throat diseases or asthma.
- NRT lozenges and gum are sugar free.
- Transferred dependence on NRT is possible, but it is rare, less harmful, and easier to overcome than smoking dependence. The amount of nicotine in NRT products is low, and compared with cigarettes, it takes longer for the nicotine in NRT products to get to the brain and produce the rush that is a big part of nicotine dependence.¹³

CONTRAINDICATIONS:

- Severe hypersensitivity or allergy to any components of the NRT.¹⁴
- NRT is not contraindicated in pregnancy. The decision to use NRT should be made with a risk benefit assessment as early on in the pregnancy as possible with the aim of discontinuing use as soon as possible.¹⁵
- NRT is not contraindicated in lactation. Nicotine from smoking and NRT is found in breast milk; however the amount of nicotine the infant is exposed to is relatively small and less hazardous than the second-hand smoke they would otherwise be exposed to.¹⁶

CONSENT:

Informed consent will be obtained as per the current College of Nurses of Ontario (CNO) Practice Guidelines and the HPEPH Policy, Consent to Treatment.

GUIDELINES FOR IMPLEMENTATION:

- Follow the guidelines in the procedure Tobacco Cessation Clinics – We Can Quit Initiative
- Review the NRT Clinic Follow-up Assessment at each support group, smoking cessation class, clinic, meeting, or home visit to reconfirm eligibility.
- Determine eligibility for and dispense Recipient Client's NRT supply, during, but not prior to, a regularly scheduled support group, smoking cessation class, clinic, meeting or home visit, following the guidelines in the NRT Decision-Making Algorithm (Supporting Documents) and Guidelines for Titration of Combination System NRT - Appendix, based on the client's individual needs and high trigger times. Currently, the maximum recommended dose of NRT from patches is 84 mg.¹⁷
- Advise the client
 - to follow Authorized Implementer's specific directions for applying or taking NRT

¹³ camh, 2018

¹⁴ Components of specific NRTs are listed on the NRT Fact Sheets.

¹⁵ Nicorette, Mar 2016, p.7

¹⁶ Ibid

¹⁷ camh, 2018. PFSD, 2018. Recommended by OMSC, 2018.

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- to follow the NRT Fact Sheet and the Inhaler / Oral Spray Information, Set-Up and Directions Fact sheet.
- to understand that the word *inhaler* is misleading, since the “inhaler” NRT should **not** be inhaled into the lungs; instead it should be absorbed by the oral mucosa by means of shallow intakes / puffs of air, similar to the way one smokes a cigar
- that about 50 % of the released nicotine in an inhaler cartridge is systemically available, so a 4 mg cartridge will deliver 2 mg during 20 minutes of frequent puffing at 20°Celsius. This is the equivalent to once hourly chewing of NRT 2 mg gum. The inhaler dose increases by almost 30% if the surrounding temperature is 30°C, and about 50% at 40°C.¹⁸
- to contact HPEPH, consult their HCP, remove the patch(es) or stop using the gum, lozenges, inhaler or oral spray if they experience symptoms of **excess nicotine**, as per the NRT Fact Sheets
- If, despite maximizing the daily patch dose to 84 mg NRT, the client is still experiencing symptoms of nicotine withdrawal, consult with the MOH for reassessment of the maximum dose of NRT or advise the client to contact their HCP as another approach may be considered
 - common symptoms of **nicotine withdrawal** due to smoking cessation include irritability, frustration, anger, anxiety, difficulty concentrating, restlessness, trouble sleeping, increased appetite, headaches or a strong desire to smoke
 - withdrawal symptoms should resolve once the proper balance of NRT is achieved
- Support the client in gradually reducing their NRT daily dosage, for example
 - suggest that they use NRT for fewer hours each day
 - if they are using 2 mg lozenges / gum, suggest that they try 1 mg lozenges / gum
 - if they are using the inhaler cartridges, suggest they gradually reduce the number and length of their sessions
 - if they are using the Oral Spray, suggest they gradually reduce the number and frequency of their sprays
 - if they are wearing two patches and smoke the majority of their cigarettes per day (CPD) in the morning, suggest removing one patch during the afternoon
 - if they smoke the majority of their CPD after work, suggest applying the patch(es) near the end of the work day
 - if they are reluctant to reduce their NRT, suggest that they reduce the amount of continuous nicotine by removing a patch and adding some short-acting NRT, if symptomatic; reassure them that they can always return to their previous dose the following day, if necessary

DOCUMENTATION AND COMMUNICATION:

- Dispensed NRT will be documented in electronic medical records and will include the client's name, date NRT was dispensed, type of NRT, amount—including number of boxes of lozenges, gum, inhaler or spray—and any adverse reactions.
- Lot number(s) and expiry date(s) will be documented on the dispensed NRT

REVIEW AND QUALITY MONITORING GUIDELINES:

Review annually as per the Medical Directives Policy.

¹⁸ Ibid, p 2

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ATTACHMENTS:

Appendix - Guidelines for Titration of Combination System NRT

SUPPORTING DOCUMENTS:

- Clinic / Prenatal Follow-up Assessment Form (Penelope EMR)
- Medical Notification of Initiation of NRT (Penelope)

CDSshare / Tobacco / CESSATION / Doctor referral program

- Smoking Cessation Fax Referral Forms – Physician, Pharmacist, CHC, RCC

CDSshare / Tobacco / CESSATION / Forms Guidelines Algorithm

- NRT Decision-Making Algorithm
- NRT Fact Sheet
- NRT Inhaler / Oral Spray Information, Set-Up and Directions Fact Sheet

CDSshare / Tobacco / CESSATION / Procedure

- Tobacco Cessation Clinics – We Can Quit Procedure

RELATED LINKS:

Drug Interactions with Tobacco Smoke - The University of California. Zevin, S. & Benowitz, N.L. Revised 2016.

<https://smokingcessationleadership.ucsf.edu/sites/smokingcessationleadership.ucsf.edu/files/A4%20DI%20TABLE.pdf>

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**HASTINGS PRINCE EDWARD PUBLIC HEALTH
MEDICAL DIRECTIVES**

Section: TOBACCO CONTROL
Directive Title: **Delegation to Determine Eligibility for and to Dispense Nicotine Replacement Therapy**

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Oct 7, 2019

Date

Replaces: MD-008
Created: Jan 2011
Revised: June 2011
Apr 2016
29 Nov 2016
26 June 2017
03 August 2018
20 Dec 2018
14 Feb 2019
Oct 7, 2019

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Appendix - Guidelines for Titration of Combination System NRT

Authorized Implementers should use their clinical judgment on a case-by-case basis

First visit / meeting

Start by replacing each cigarette with 1 mg NRT from patch plus a maximum of 20 mg short-acting
If using more than 20 mg short-acting daily (e.g. 10 cartridges), consider additional 7 mg patch

<10 cigarettes per day(CPD) Light smoker	10 – 29 CPD Moderate smoker	30+ CPD Heavy smoker
<ul style="list-style-type: none"> • Offer lifestyle counselling & behavioural interventions • Start with 7* -14 mg patch and / or short-acting NRT, as needed, to maximum of 20 mg (may combine types) <ul style="list-style-type: none"> ○ 10 pieces of gum or lozenges per day (1 or 2 mg each); / ○ 10 inhaler cartridges (4 mg each but only release 2 mg each); / ○ 1 oral spray per hour (1 mg each) during the day 	<ul style="list-style-type: none"> • 14* - 21 mg patch along with lifestyle counselling / behavioural interventions • Consider adding short-acting NRT, as needed, to a maximum of 20 mg (may combine types) <ul style="list-style-type: none"> ○ 10 pieces of gum or lozenges per day (1 or 2 mg each), / ○ 10 inhaler cartridges (4 mg but only release 2 mg), / ○ 20 oral sprays (1 mg each) during the day 	<ul style="list-style-type: none"> • 21* - 28 mg patch (21 + 7); or 35 (21 + 14); or 42 (21 x 2); or 63 (21 x 3); or (84 (21 x 4) along with lifestyle counselling / behavioural interventions • Consider adding short-acting NRT, as needed, to a maximum of 20 mg <ul style="list-style-type: none"> ○ 10 pieces of gum or lozenges per day (1 or 2 mg each); / ○ 10 inhaler cartridges (4 mg each but only release 2 mg each); / ○ 20 oral sprays (1 mg each) during the day

*If client weighs less than 45 kg (99 lb), start at lowest recommended dose for patch and adjust, as necessary

Pregnant or Breastfeeding Clients

- First-line treatment: lifestyle counselling and behavioural interventions
- Second-line treatment: NRT - short-acting and / or day-only patch(es) up to 49 mg, **as indicated above**, in lowest effective dose, since research shows that medicinal NRT is safer than smoking



Subsequent visits / meetings (every 1 to 2 weeks)

- NRT Follow-up Assessment and NRT Decision-Making Algorithm
- If still smoking, adjust NRT daily dose:
 - 1 – 5 CPD - Add 7 mg patch to current dose plus short-acting NRT
 - 6 – 9 CPD - Add 14 mg by patch to current dose plus short-acting NRT
 - 10+ CPD - Add 1 or more 21 mg patch(es) to current dose plus short-acting NRT

NRT maximum daily dose from patch is 84 mg (21 x 4) plus short acting*
- If client still has withdrawal symptoms, despite maximum dose of **84+ mg**, consult MOH or advise client to consult HCP to reassess
- When client is ready to reduce NRT, reduce by 7 mg patch every 1 to 2 weeks until off patches, if possible; then reduce short-acting NRT until no longer needed

Pregnant or Breastfeeding Clients

- Continue **as indicated above** (if appropriate patch dose will exceed 42 mg, consult HCP)
- NRT should be discontinued if pregnant / breastfeeding client does not reduce number of CPD

Modeled after University of Ottawa Heart Institute – OMSC; Adapted from Centre for Addiction and Mental Health (camh)