

**City of Hamilton Public Health Services
MEDICAL DIRECTIVES**

Subject	Provision of Nicotine Replacement Therapy Products (Nicotine Patch, Nicotine Gum, and Nicotine Lozenge)	
Section	Medical Directives	Page 1 of 11
Approved by:	<hr/> Dr. Ninh Tran <hr/> Dr. Hamidah Meghani	2013-Jul-04
Date to be reviewed:		

Purpose: To ensure the provision of nicotine replacement therapy (NRT) products to those who meet the eligibility criteria within the City of Hamilton Public Health Services (HPHS) catchment area and (a) who are 16 years of age and over (b) who require titration beyond 21 mg (c) who are pregnant and/or breastfeeding women. Registered Nurses (RN's) will be authorized to provide NRT products (Nicotine Patch, Nicotine Gum, and Nicotine Lozenge) at no cost according to the program policies and procedures.

Medical Directive

The undersigned Associate/Medical Officers of Health, as agents of the Board of Health of the City of Hamilton, delegate authority to designated Registered Nurses (RN's) employed by the City of Hamilton Public Health Services to provide Nicotine Replacement Therapy (NRT) Products (Nicotine Patch, Nicotine Gum, and Nicotine Lozenges) to clients including pregnant and/or breastfeeding women in accordance with this directive.

This directive is for designated Registered Nurses employed by the City of Hamilton Public Health Services providing client service through:

- *Becoming Smoke-Free: A Quit Smoking Clinic*
- *Hamilton Public Health Services, Family Health Division*

Eligibility Criteria

The designated Registered Nurse (RN) may provide NRT products to clients if the following eligibility criteria are met:

- The individual is currently a client of Hamilton Public Health Services.
- The individual is currently smoking and is attempting to quit smoking by developing a quit plan with the RN.
- The individual cannot afford the cost of NRT.
- The individual is greater than 12 weeks gestation.
- The individual is not currently using Varenicline Tartrate (Champix®)*.
- The individual does not have a known skin condition or allergy to the nicotine patch*.
- The individual does not have oral conditions (e.g. TMJ, dentures, Sicca syndrome) or a known allergy to the nicotine gum or aspartame*.
- The individual has received health teaching by the RN related to the proper use, dosage, duration of treatment, possible medication interactions, and possible side-effects.*
- The individual provides full disclosure and signature on the "Client Agreement and Consent to Treatment" form.

*For detailed information refer to the **Policy and Procedure for the Medical Directive** "Provision of Nicotine Replacement Therapy Products (Nicotine Patch, Nicotine Gum, and Nicotine Lozenge)"

Consult with the AMOH Responsible for Pharmacotherapy:

The designated RN will consult with the AMOH responsible and provide the client with a letter to inform his/her family physician regarding the use of NRT in the following cases^{5,6,7, 8}:

- Accelerated or severe hypertension (greater than 140/90) as taken by the RN.
- Recent (3 week) cerebral vascular accident
- Immediate (2 week) post-myocardial infarction period
- Uncontrolled cardiac arrhythmias
- Poorly controlled insulin dependent diabetes
- Pheochromocytoma
- Hepatic insufficiency
- Severe or worsening angina
- Vasospastic diseases (Buerger’s disease)
- Active peptic ulcer disease
- Uncontrolled hyperthyroidism
- Under the age of 16
- Renal insufficiency

Other Reasons for RN to Consult with AMOH:

- The individual experiences side-effects associated with the use of NRT.*
- The individual is currently using subcutaneous insulin to control his/her diabetes and notes a change in his/her blood sugar readings.
- The client is currently using tricyclic antidepressants, benzodiazepines or antipsychotic medications and experiences changes in mood as reported by the client or assessed by the RN.

*For detailed information refer to the **Policy and Procedure for the Medical Directive** “Provision of Nicotine Replacement Therapy Products (Nicotine Patch, Nicotine Gum, and Nicotine Lozenge)”.

Nicotine Replacement Therapy Dosage Guideline (NON-PREGNANT)

Treatment Plan One- (Patient smoking less than 15 cigarettes per day or weighing less than 45 kg)	Treatment Plan Two- (Patient smoking 15-30 cigarettes per day)	Treatment Plan Three- (Patient smoking 30-40 cigarettes per day)	Treatment Plan Four- (Patient smoking greater than 40 cigarettes per day)
Nicotine Transdermal Patch 14 mg applied once daily for 6–8 weeks followed by,	Nicotine Transdermal Patch 21 mg applied once daily for up to 6 weeks followed by,	Nicotine Transdermal Patch 28 mg (14 mg + 14 mg or 21 mg + 7 mg) applied once daily for up to 6 weeks followed by,	Nicotine Transdermal Patch 42 mg (21 mg + 21 mg) applied once daily for up to 6 weeks followed by,
Nicotine Transdermal Patch 7 mg applied once daily for 2 weeks.	Nicotine Transdermal Patch 14 mg applied once daily for 2-4 weeks followed by,	Nicotine Transdermal Patch 21 mg applied once daily for up to 4 weeks followed by,	Nicotine Transdermal Patch 35 mg (21 mg + 14 mg) applied once daily for 2 weeks followed by,
	Nicotine Transdermal Patch 7 mg applied once daily for 2 weeks.	Nicotine Transdermal Patch 14 mg applied once daily for up to 2 weeks followed by,	Nicotine Transdermal Patch 28 mg (14 mg + 14 mg) applied once daily for 2 weeks followed by,
		Nicotine Transdermal Patch 7 mg applied once daily for up to 2 weeks.	Nicotine Transdermal Patch 21 mg applied once daily for 2 weeks followed by,
			Nicotine Transdermal

			Patch 14 mg applied once daily for 2 weeks followed by,
			Nicotine Transdermal Patch 7 mg applied once daily for 2 weeks.
If after initial application, withdrawal or cravings persist, add short acting NRT and/or increase to Nicotine Patch 21 mg and follow next protocol.	If after initial application, withdrawal or cravings persist, add short acting NRT and/or increase to Nicotine Patch 28 mg and follow next protocol.	If after initial application, withdrawal or cravings persist, add short acting NRT and/or increase to Nicotine Patch 35-42 mg and follow next protocol.	If after initial application, withdrawal or cravings persist, add short acting NRT.

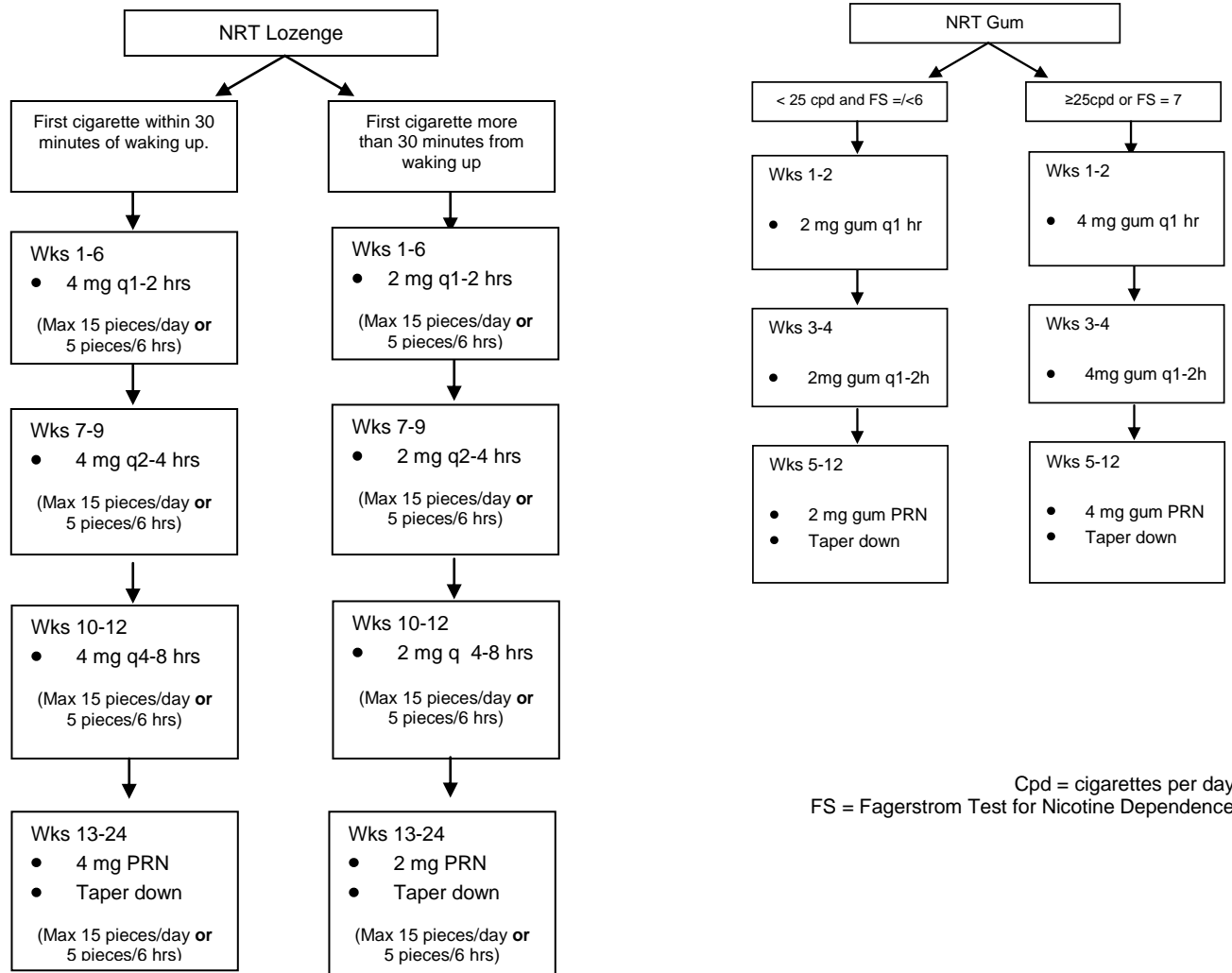
Note: It may be necessary for some patients to remain on NRT for longer than the above schedule.

Combination Therapy

Depending on how a cigarette is smoked, 1 to 3.5 milligrams is absorbed into the body therefore short-acting NRT (gum, lozenge) may be needed to address cravings as necessary. The nicotine patch may be used alone or in combination with nicotine gum or lozenge, as per the discretion of the designated RN based on the number of cigarettes smoked per day and client’s needs. Always review and assess proper use of short acting NRT. Combination pharmacotherapy is indicated for patients based on: failed attempt with monotherapy; clients with breakthrough cravings; client’s level of dependence; multiple failed attempts; clients with nicotine withdrawal. The combination of pharmacotherapies can be a helpful response for managing nicotine withdrawal symptoms. The use of two or more forms of NRT has the strongest evidence base and is the most commonly used form of combination therapy. There is a high level of confidence that this combination can be used safely, effectively and permits optimal titration (Bader et al, 2009).

Add 1 other form of Nicotine Replacement Therapy to address cravings as necessary.
Nicotine 2 mg Gum q 30 minutes as needed for up to 12 pieces/day
Nicotine 2 mg Lozenge q 30 minutes as needed for up to 12 pieces/day

Mono Therapy- Nicotine Gum or Lozenge



Note: Provide lozenge based on client's preference, is unable to chew gum, wears dentures, or has active TMJ dysfunction.

Monitoring

At each visit, the RN will assess clients using NRT for signs and symptoms of a nicotine overdose and possible side effects of NRT. The RN will make dose adjustments for too much or insufficient nicotine. Clients will be advised to monitor for nicotine toxicity (too much nicotine) and/or nicotine withdrawal (not enough nicotine). If the client experiences nausea, vomiting, sweating, tremors, light headedness, confusion, racing heart, or weakness, they will be advised to *stop using NRT and notify their pharmacist or doctor to have the dose reassessed.*

Discontinuing Use of NRT:

The RN will advise the client to discontinue the use of NRT and seek medical attention if:

- The individual experiences new cardiovascular symptoms.
- The individual develops a severe and persistent local skin reaction (if on the nicotine patch) or generalized skin reaction.
- The individual experiences signs and symptoms of nicotine overdose (as above).

Clients will cease to receive NRT when they:

- Cease to regularly attend programming through which they obtain NRT.

-
- Fail to follow through with commitments made in their quit plan.
 - No longer require NRT due to significant reduction or elimination of cravings.

Nicotine Replacement Therapy Dosage Guidelines for Pregnant Women

NRT is safer than smoking for the pregnant woman and her fetus if she is unable to quit smoking with a behavioural intervention (CAN-ADAPTT, 2011; OMA, 2008; Selby & Dragonetti, 2007; US Department of Health and Human Services, 2008). NRT is considered safe in breastfeeding women. While some nicotine will be found in breast milk with NRT use, the amounts are minimal compared to the levels obtained through continued smoking, and should not cause any adverse effects (CAN-ADAPTT, 2011; Hale, 2010; OMA, 2008; Selby & Dragonetti, 2007; US Department of Health and Human Services, 2008)

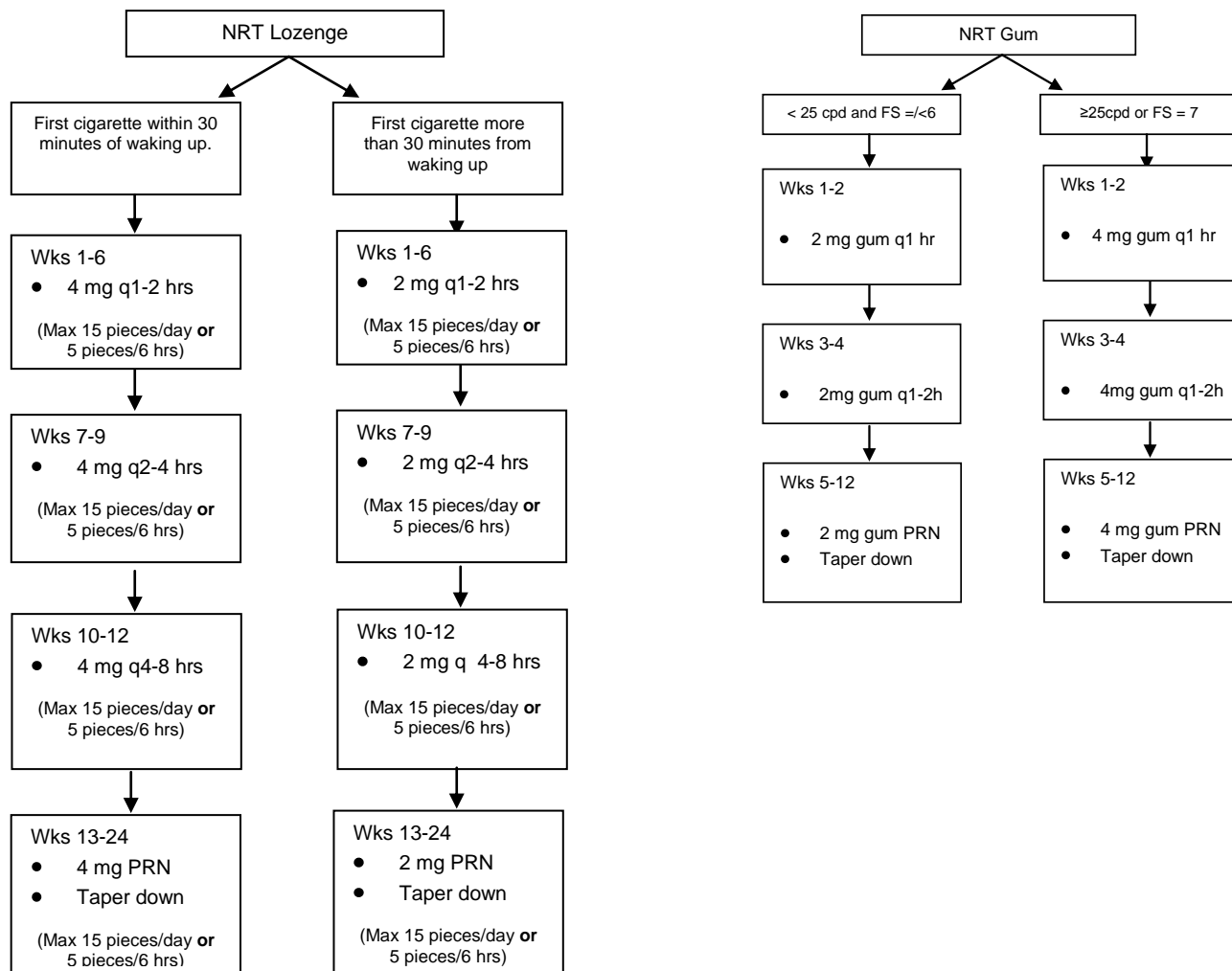
A discussion regarding the risks and benefits of any form of nicotine to the developing fetus should be discussed with the pregnant woman. However, it should be stressed that NRT removes the risk of other highly toxic chemicals from the developing fetus. Dosing should be based on an individual's needs.

First Line of Treatment: Evidence-Informed Intensive Behavioural Counselling.

During pregnancy and breastfeeding, counselling is recommended as first line treatment for smoking cessation (CAN-ADAPTT, 2011). Treatment should start as early as possible in the pregnancy (CAN-ADAPTT, 2011). **NRT will not be provided during the first trimester.**

Second Line of Treatment: Intermitting Dosing of Nicotine Replacement Therapy

To be used if first line of treatment is ineffective, in that the client is unable to remain abstinent from smoking due to cravings and/or withdrawal symptoms. The literature also recommends ensuring intensive counselling (e.g. motivational interviewing techniques) is combined with NRT (Urquhart et al, 2012; National Health Service, 2010; Selby & Dragonetti, 2007). Consider factors such as patient preference, history, and experience when deciding on quit smoking medications (Bader et al, 2009). **Follow Mono Therapy - Nicotine Gum or Lozenge method as below.**



Cpd = cigarettes per day
 FS = Fagerstrom Test for Nicotine Dependence

Note: Provide lozenge based on client’s preference, is unable to chew gum, wears dentures, or has active TMJ dysfunction.

Monitoring

At each visit, the RN will assess clients using NRT for signs and symptoms of a nicotine overdose, as well as possible side effects of NRT. The RN will make dose adjustments for too much or insufficient nicotine. Clients will be advised to monitor for nicotine toxicity (too much nicotine) and/or nicotine withdrawal (not enough nicotine). If the client experiences nausea, vomiting, sweating, tremors, light headedness, confusion, racing heart, or weakness, they will be advised to *stop using NRT and notify their pharmacist or doctor to have the dose reassessed.*

At each visit, the RN will assess pregnant client’s blood pressure. The RN will consult with the AMOH responsible and provide the client with a letter to inform her family physician/primary care health care provider.

Discontinuing Use of NRT:

The RN will advise the client to discontinue the use of NRT and seek medical attention if:

- The individual experiences new cardiovascular symptoms.

- The individual develops a persistent and severe local skin reaction (if on nicotine patch) or generalized skin reaction.
- The individual experiences signs and symptoms of nicotine overdose (as above).

Clients will cease to receive NRT when they:

- Cease to regularly attend programming through which they obtain NRT.
- Fail to follow through with commitments made in their quit plan.
- No longer require NRT due to significant reduction or elimination of cravings.

Third Line of Treatment: Continuous Dosing of Nicotine Replacement Therapy

To be used if first and second line of treatment is ineffective; client is unable to remain abstinent from smoking due to breakthrough cravings and/or withdrawal symptoms. Consider pregnancy-related symptoms in selecting mode of NRT (e.g. patch for a woman experiencing high levels of nausea) (Schnoll et al, 2007). Pregnant women should be advised to wear the patch for 16 hours each day, removing the patch at bed time and applying a new patch in the morning when they awake (National Health Service, 2010; Schnoll et al, 2007). **Follow Nicotine Replacement Therapy as below.**

Treatment Plan One- (Patient smoking less than 15 cigarettes per day or weighing less than 45 kg)	Treatment Plan Two- (Patient smoking 15-30 cigarettes per day)
Nicotine Transdermal Patch 14 mg applied once daily for 6–8 weeks followed by,	Nicotine Transdermal Patch 21 mg applied once daily for up to 6 weeks followed by,
Nicotine Transdermal Patch 7 mg applied once daily for 2 weeks.	Nicotine Transdermal Patch 14 mg applied once daily for 2-4 weeks followed by,
	Nicotine Transdermal Patch 7 mg applied once daily for 2 weeks.
If after initial application, withdrawal or cravings persist, add short acting NRT and/or increase to Nicotine Patch 21 mg and follow next protocol.	If after initial application, withdrawal or cravings persist, consult responsible Associate/Medical Officers of Health.

Combination Therapy

Depending on how a cigarette is smoked, 1 to 3.5 milligrams is absorbed into the body therefore short-acting NRT (gum, lozenge) may be needed to address cravings as necessary. The nicotine patch may be used alone or in combination with nicotine gum or lozenge, as per the discretion of the designated RN based on the number of cigarettes smoked per day and client’s needs. Always review and assess proper use of short acting NRT.

Combination pharmacotherapy is indicated for patients based on: failed attempt with monotherapy; clients with breakthrough cravings; client’s level of dependence; multiple failed attempts; clients with nicotine withdrawal. The combination of pharmacotherapies can be a helpful response for managing nicotine withdrawal symptoms. The use of two or more forms of NRT has the strongest evidence base and is the most commonly used form of combination therapy. There is a high level of confidence that this combination can be used safely, effectively and permits optimal titration (Bader et al, 2009).

Add 1 other form of Nicotine Replacement Therapy to address cravings as necessary.

Nicotine 2 mg Gum q 30 minutes as needed for up to 12 pieces/day

Nicotine 2 mg Lozenge q 30 minutes as needed for up to 12 pieces/day

NOTE: Pregnant women demonstrate increased nicotine metabolism in the late second and third trimester (Selby & Dragonetti, 2007; National Health Service, 2010). They may require forms of NRT that can be titrated to match metabolism, such as NRT lozenges or gum (National Health Service, 2010; Schnoll et al, 2007; Stead et al, 2007).

Training and Certification

Prior to implementing this medical directive, designated RN's employed by the City of Hamilton Public Health Services providing intensive smoking cessation services are required to complete the *Quit Smoking Program* orientation, Public Health Nurse Orientation Checklist, and obtain certification by the University of Toronto in the delivery of intensive tobacco dependence interventions*.

*For detailed information refer to the ***Policy and Procedure*** for "Orientation of New Staff", and Nursing Orientation Checklist)

Quality Assurance

The medical directive "Provision of Nicotine Replacement Therapy Products (Nicotine Patch, Nicotine Gum, and Nicotine Lozenge)" and the pursuant Policy and Procedure for the Medical Directive "Provision of Nicotine Replacement Therapy Products (Nicotine Patch, Nicotine Gum, and Nicotine Lozenge)" will be reviewed annually by the Tobacco Control Program Manager, and/or the Reproductive Health Manager and the AMOH responsible for the *Becoming Smoke Free Hamilton Public Health Services Quit Smoking Clinic**.

For detailed information refer to the *Policy and Procedure*** for "Quality Assurance, Documentation, Medical Directive Provision of Nicotine Replacement Therapy Chart Audit Tool, Nursing Documentation Chart Audit Tool: Quit Smoking Clinic."

References

- Bader, P., McDonald, P & Selby, P (2009). An Algorithm for Tailoring Pharmacotherapy for Smoking Cessation: Results from a Delphi Panel of International Experts Tobacco Control, 18(1), 32-48.
- Brant Community Health Care System (2012). Adult Nicotine Replacement Therapy Pre – Printed Order Sheet.
- CAN-ADAPTT (2011). Canadian smoking cessation guideline specific populations: Pregnant & breastfeeding women [document on the internet]. Available from: <https://www.nicotinedependenceclinic.com/English/CANADAPTT/Documents/Guideline/Pregnant%20and%20Breastfeeding%20Women.pdf>.
- Canadian Pharmacists Association. (2007). Compendium of pharmaceuticals and specialties: The Canadian drug reference for health professionals.
- Center for Addiction and Mental Health (CAMH) (2010). Primary Care Addiction Toolkit for Smoking Cessation: Recommending nicotine replacement therapy (NRT)
- Elbirt, K, & Luckmann, R. (2006). University of Massachusetts Tobacco Treatment Specialist Training Manual. Unit One: The biology and pharmacology of nicotine dependence. University of Massachusetts Medical School.
- Hale TW. Mini medications and mothers' milk. 14th ed. Amarillo, TX: Hale Publishing; 2010.
- Hamilton Health Sciences (2011). Physician Guidelines to Titration of Nicotine Replacement Therapy.
- Hamilton Public Health Services (2011). Policy and Procedure for the Medical Directive "Provision of Nicotine Replacement Therapy Products (Nicotine Patch, Nicotine Gum, and Nicotine Lozenge)".
- Heatherton TF, Kozlowski LT, Frecker RC, Fagerstrom KO. The Fagerstrom Test for Nicotine Dependence: A revision of the Fagerstrom Tolerance Questionnaire. *British Journal of Addictions* 1991;86:1119-27.
- Hurt, R.D., Ebbert, J.O., Hays, T., & McFadden, D.D. (2009) Treating tobacco dependence in a medical setting. *A Cancer Journal for Clinicians* 59 (5), 313-326.
- Kingston, Frontenac and Lennox & Addington Public Health : Medical Directive to Start an Individual on Nicotine Replacement Therapy in the Take Control Baby Steps Program
- McKenry, L. & Salerno, E. (1992). *Mosby's pharmacology in nursing*. (19th ed.). St. Louis, MO: Mosby.
- McNeil Consumer Healthcare. (2007). Nicoderm: Nicotine transdermal system USP. [Product Monograph]. Markham, ON.
- McNeil Consumer Healthcare. (2007). Nicorette gum: Nicotine polacrilex gum USP. [Product Monograph]. Markham, ON.
- McIvor, A. et al (2009). Best Practices for smoking cessation interventions in primary care. *Canadian Respiratory Journal*. 16 (4), 129-134.
- National Institute for Health and Clinical Excellence [NICE]. (2010). Quitting smoking in pregnancy and following childbirth: NICE public health guidance 26. Retrieved May 7, 2013 from <http://www.nice.org.uk/nicemedia/live/13023/49345/49345.pdf>
- Novartis Consumer Health, Inc. (2010). Transdermal Nicotine System. [Patient Information Insert].
- Ontario Medical Association. (2008). Rethinking stop-smoking medications: Treatment myths and medical realities. *Ontario Medical Review*, 75 (1): 22-34.
- Pfizer Canada Inc. (2003). Nicorette inhaler: Nicotine inhalation system. [Product Monograph]. Markham, ON.
- Pfizer Canada Inc. (2007). Champix: Varenicline tartrate tablets. [Product Monograph]. Kirkland, Quebec.
- Porcupine Health Unit (2012). "Chronic Disease/Injury Prevention Quit Smoking Clinic Manual Nicotine Replacement Therapy Medical Directive."
- Schnoll, R. A., Patterson, F., & Lerman, C. (2007). Treating tobacco dependence in women. *Journal of Women's Health*, 16(8), 1211-1218.
- Selby P., Dragonetti R. Pragmatic strategies to help pregnant smokers quit [document on the internet]. Smoking Cessation Rounds; 2007 October [cited 2011 Jun 30]. Available from: <http://www.smokingcessationrounds.ca/crus/140-009%20English.pdf>.
- Stead L.F., Perera R., Bullen C., Mant D., Lancaster T. (2007). Nicotine replacement therapy for smoking cessation (review). *The Cochrane Library*, 4.
- Tatro, DS. (2006). Update: The effects of smoking on drug therapy. *Drug Facts and Comparison News*. February.

Trillium Health Centre (2011). Nicotine Replacement Therapy Dosing.

University of Ottawa Heart Institute (2010). Titration of nicotine replacement therapy. Ottawa Model for Smoking Cessation In Patient Workplan.

Urquhart, C., Jasiura, F., Poole, N., Nathoo, T. & Greaves, L. (2012). *Liberation! Helping Women Quit Smoking: A Brief Tobacco Intervention Guide*. Vancouver, BC: British Columbia Centre of Excellence for Women's Health.

U.S. Department of Health and Human Services. (2008). Clinical practice guideline: Treating tobacco use and dependence. [Online]. Retrieved April 3, 2007 from:
http://www.surgeongeneral.gov/tobacco/treating_tobacco_use.pdf

Questions regarding the use of this medical directive can be directed to Dr. Ninh Tran (AMOH), Dr. Hamidah Meghani (AMOH) or a covering physician. During office hours Dr. Ninh Tran can be reached at 905-546-2424 Ext. 7113, and Dr. Meghani can be reached at Ext. 5581.

Approved by:

Dr. Ninh Tran, Associate Medical Officer of Health

Date

Dr. Hamidah Meghani, Associate Medical Officer of Health

Date

Dr. Julie Emili, Associate Medical Officer of Health

Date

Dorothy Barr-Elliott, Senior Nurse Leader

Date

Ellen Pezzetta, Director, Healthy Living Division

Date

Kevin McDonald, Manager, Tobacco Control Program

Date

Jen Vickers-Manzin, Manager, Reproductive Health Program

Date

Original copy is signed and housed with the Tobacco Control Program, at the City of Hamilton Public Health Services, Healthy Living Division.