STOP on the Road (SOR)

An arm of the STOP program (Stop smoking Therapy for Ontario Patients (STOP): The effectiveness of nicotine replacement therapy in Ontario smokers)

Operations Manual

For organizing and delivering SOR-VIII workshops

SOR-VIII: Summer 2017 – current

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Feb 2018
dd-mmm-yyyy

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dd-mmm-yyyy

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Feb 2018

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2. Definitions

NRT – Nicotine Replacement Therapy. In the context of STOP on the Road-VIII it usually refers specifically to nicotine patches.

Partnering Organizations – Organizations that have agreed to collaborate with the STOP Program to deliver STOP on the Road workshops in their communities.

Partnering Staff – Personnel from Partnering Organizations who are collaborating with the STOP team to organize and deliver the workshops.

SOR-VIII – STOP on the Road Cycle 8 (Starting July 2017)

STOP Staff – Personnel who work directly for the STOP Program. They are based at the Centre for Addiction and Mental Health (CAMH) in Toronto and can include the study investigators, program managers, coordinators, and research analysts.

TEACH-Trained Practitioner – Practitioners who have received training in delivering smoking cessation education and counselling from the Training Enhancement in Applied Cessation Counselling and Health (TEACH) certificate program. This term may also be used to refer to practitioners who have received training from other accredited programs in tobacco dependence and cessation.

Workshop Participants – Eligible individuals who participate in the workshops. They are also referred to as program or study participants or study subjects.

3. Introduction

STOP on the Road is a component of the STOP program wherein smoking cessation workshops are held in various localities across Ontario in partnership with local healthcare providers (Public Health Units – PHUs, and others). The workshops are essentially mobile clinics that allow the STOP team and its local partners, in a joint effort, to deliver a combination of pharmacotherapy (i.e. NRT) and health education/counselling (psychoeducation) to eligible smokers from the local community who wish to quit smoking. The STOP on the Road protocol has been reviewed and approved by the Centre for Addiction and Mental Health's Research Ethics Board (REB).

This manual is intended to communicate the details related to the organization and delivery of this round of workshops.

4. Key Elements of the Program

- The participants are daily cigarette smokers who are planning to quit in the next 30 days (in addition to satisfying other inclusion and exclusion criteria, as directed by the Screening Form)
- The workshops are typically 2-3 hours long
- Eligible participants receive a 1-hour group psychoeducational presentation and a 5-week kit of nicotine patches at the workshop
- Participants may be contacted by STOP Staff approximately 5 weeks and 6 months after the workshop to complete an evaluation survey.

5. History of STOP on the Road

After initial discussions with various stakeholders, the STOP program collaborated with a few PHUs in early 2007 to pilot an innovative approach to offering cessation workshops in areas typically far-removed from specialized smoking cessation clinics. This arm of the STOP program, called *STOP on the Road,* delivered 39 workshops in 28 towns and cities during that first round of workshops (February and March 2007).

Encouraged by its success, a 2nd round of STOP on the Road was completed between September 2007 and March 2008 in partnership with a larger group of PHUs, Community Health Centres (CHCs) and Family Health Teams (FHTs). During this period, 75 workshops were conducted in 54 different localities. Driven by increasing local interest, a 3rd round of STOP on the Road was conducted from August 2008 to March 2009, when 96 workshops were offered in 78 towns and cities across Ontario. A campaign of similar magnitude was carried out in the 4th round of STOP on the Road, between October 2010 and March 2011, wherein 100 workshops were delivered across 76 cities and towns throughout Ontario.

In the 5th round of STOP on the Road (Oct 2011–May 2012), a pilot project was initiated which allowed Public Health Units the opportunity and flexibility to conduct STOP on the Road workshops on their own. Seven Health Units successfully implemented 33 workshops in 22 communities in this pilot. An additional 86 workshops were delivered in 61 cities and towns through the traditional implementation method. Encouraged by the success of the 5th round pilot, and confident in the growing expertise in local

communities, the previously piloted CAMH-Assisted Model became the default implementation model in the 6th round of STOP on the Road. Twenty Health Units successfully implemented 121 workshops in 67 communities using the CAMH-Assisted Model. A further 34 workshops in 29 communities were conducted using the traditional "CAMH-Led Model".

In order to further engage Health Units in the delivery of workshops, a third implementation option was developed and piloted for those Health Units that had TEACH-trained practitioners on staff but were limited in their ability to deliver workshops due to the lack of authorized personnel to deliver NRT. This third implementation option, the CAMH-Mailed Model, has trained Health Unit staff to deliver the workshop without the on-site presence of STOP staff (similar to the CAMH-Assisted Model). However, instead of dispensing NRT kits to participants in person at the workshops, STOP staff mail eligible participants their NRT kit following the workshop. The 7th round of workshops (Jan 2014-June 2017) saw all three implementation options – the CAMH-Assisted Model, CAMH-Mailed Model and CAMH-Led Model – offered to Public Health Units in an effort to increase access to the program. During this time period, 1279 workshops were successfully implemented. Due to the success of this round of workshops, the 8th round of STOP on the Road was approved for launch in July 2017.

6. Program Implementation Models

There are three streams of program implementation available in this round of STOP on the Road. All three streams share many of the same features of implementation and rely on a strong collaborative effort between STOP Staff and the Partnering Staff at Partnering Organizations. As part of the transition to a more flexible, patient-centred, locally-based approach, the CAMH-Assisted Model will be the default model of implementation for all Partnering Organizations that meet its requirements. The CAMH-Mailed Model will be encouraged for all Partnering Organizations that are currently unable to dispense NRT but whose staff is trained in smoking cessation. This implementation option will allow for more frequent workshops than the third option, the CAMH-Led Model, which will be implemented in a limited capacity for Health Units without the resources to deliver workshops on their own.

CAMH-Assisted Model

The CAMH-Assisted Model is the default model of SOR-VIII. STOP Staff are not present at the workshop; therefore, the responsibilities traditionally carried out by STOP Staff are now addressed by the Partnering Staff. Dispensing of NRT and data collection by Partnering Staff requires a signed collaborative agreement (i.e., a contract). The Partnering Organization may require a Medical Directive for its staff to dispense NRT at SOR workshops. The psychoeducational presentation is delivered by trained staff from the Partnering Organization or TEACH-trained practitioner(s) from the local area (if necessary). Since the majority of program responsibilities are assumed by the Partnering Staff, the Partnering Organization has more flexibility to schedule workshops on an on-going, as-needed basis in response to the needs of the communities it serves. Testimonials from some of the Partnering Organizations who implemented the CAMH-Assisted Model in the past have been assembled (see Appendix A).

CAMH-Mailed Model

The CAMH-Mailed Model is an alternative for Partnering Organizations who have TEACH-trained practitioners able to deliver the workshops on their own. STOP Staff are not present at the workshops so Partnering Staff are responsible for data collection, delivering the presentation, and preparing participant documentation for courier immediately following the workshop. A signed collaborative agreement is required. A medical directive may not be applicable since STOP Staff will be responsible for the mailing of NRT kits to participants following the workshop. Due to the work associated with the administration of

NRT by STOP Staff, there may be less flexibility in the scheduling of workshops as compared to the CAMH-Assisted Model.

CAMH-Led Model

The CAMH-Led Model continues to be an option for Partnering Organizations who do not have the resources to deliver workshops without on-site STOP presence. A signed collaborative agreement is required between the Partnering Organizations and CAMH. Staff from the Partnering Organizations are responsible with securing the workshop venue, workshop promotions and participant screening prior to the workshop. At each of these workshops, STOP staff are to carry out several responsibilities including data collection, transporting and dispensing of NRT, assisting collaborating staff with room setup and crowd management, and delivering the psychoeducational presentation (if necessary).

	Advantages	Disadvantages
CAMH-Assisted Model	• Partnering Organizations can schedule workshops on an on-going, as-needed basis in response to local demand and are not restricted by a pre-set STOP workshop schedule • Partnering Organizations may plan for workshops until March 31 2018 • Partnering Organizations can set their workshops' minimum registration requirements which may allow for the targeting of special populations • Partnering Staff have the opportunity to utilize their TEACH-training to provide more comprehensive cessation treatment directly to their communities • By leveraging local expertise, the program becomes more sustainable	• Increased responsibility on Partnering Staff requiring additional staff resources from the Partnering Organization • Time and resources needed to get Collaborative Agreements signed • Additional time and resources maybe needed for signing of a Medical Directives, (if necessary) and internal Ethics Board approval (if necessary) • Increased liability on Partnering Organization

CAMH -Mailed Model	• Partnering Organizations can schedule more frequent workshops to meet the needs of their region • Partnering Staff have the opportunity to utilize their TEACH-training to provide more comprehensive cessation treatment directly to their communities • By leveraging local expertise, the program becomes more sustainable • Reduced liability since Partnering Organization is not responsible for NRT administration	• Increased responsibility on Partnering Staff requiring additional staff resources from the Partnering Organization • Time and resources needed to get Collaborative Agreements signed, and internal Ethics Board approval (if necessary) • Workshop participants are not able to receive NRT at workshop and may have to postpone their quit date until their NRT has been received • Partnering Staff's preparation of participant documentation for courier back to CAMH must be expedited • Demand on STOP Staff time reduces flexibility in workshop scheduling •

	Advantages	Disadvantages
CAMH-Led Model	• On-site support from STOP Staff • Reduced workload and reduced responsibility on the Partnering Staff • Minimal liability on Partnering Organization	• Time and resources needed to get Collaborative Agreements signed, and internal Ethics Board approval (if necessary) • Demand on STOP Staff time limits flexibility in number and dates of when workshops can be offered • Workshops may be cancelled if minimum registration targets are not met (minimum of 25 participants)

7. CAMH-Assisted Model: Operational Details

Please refer to Appendix B for a comprehensive timeline and checklist for the CAMH-Assisted Model. This document should help to ensure that all required steps have been taken.

7.1 Organizational Details

7.1.1 Venue: Partnering Staff will secure an appropriate venue for conducting the workshop. This venue may be onsite at the Partnering Organization's facility or offsite at a third party location. A venue should be chosen that has a room large enough to comfortably seat the expected maximum number of participants in front of a presentation screen, while still having space to set up a projector and laptop, have a table at the door for signing-in participants, and tables to conduct the individual counselling and dispensing of medication to participants in a confidential manner. Please see Appendix C for more information regarding the workshop room set-up.

7.1.2 Refreshments: Light refreshments may be provided by Partnering Staff at the workshop. If refreshments are provided, they should be healthy (e.g. fresh fruit/vegetables, water) to promote good eating habits, and ideally not be common smoking triggers (e.g. coffee or cola).

7.1.3 Storage Space for NRT: STOP will supply the NRT for the workshops in pre-assembled kits. The kits will be shipped to the main contact at the Partnering Organization prior to the workshop date. Partnering Staff and the STOP Coordinator will coordinate the quantity and timing of NRT shipments. Partnering Staff will store the NRT in a locked, restricted-access space until dispensed to the workshop participants. Following the workshop, any leftover NRT kits must be stored in a locked, restricted-access space until they are couriered back to the STOP Coordinator.

7.1.4 Staffing: Typically 2-3 staff members are required to implement a workshop (this may vary depending on the expected number of participants and the experience of the staff). Prior to the workshop, 1-2 staff members may be responsible for organization of the workshop including recruitment and screening of potential participants, transporting NRT, documentation and refreshments to the workshop, setting up the workshop room etc. For the first 20 minutes of the workshop, 1-2 staff members may run the sign-in desk and 1-2 staff members may answer questions and help participants complete their forms. For approximately the next hour, 1-2 staff members may give the presentation while 1 staff member reviews and organizes the completed participant documentation. Following the presentation, 2 staff members may do the one-to-one counselling and NRT dispensing while 1 staff member directs participants, answers any participant questions and discusses any additional resources. Following the workshop, 1 staff member may be responsible for transporting NRT and documentation back to Partnering Organization offices and preparing it for courier.

7.1.5 Staff Training: All Partnering Staff delivering the workshop presentation and conducting one-to-one counselling and dispensing at the workshop should have expertise in providing smoking cessation interventions. If a local TEACH-trained practitioner is required for delivery of the presentation, the STOP Coordinator may be able to assist with this.

All Partnering Staff implementing the workshop should attend a webinar-based Operations Training session (dates/times to be scheduled as needed) so that they are familiar with the processes and documentation involved and can proficiently implement the protocol.
Partnering Organizations are responsible with providing a list of trained staff that have attended the Operations training. Partnering Organizations are to inform the Coordinator of any changes in staff that are dispensing the NRT and to request additional Operations Training when new staff start delivering workshops.

7.2 Pre-Workshop Procedures

7.2.1 Requesting a Workshop: After the Partnering Organization's collaborative agreement has been approved and signed by CAMH (see section 7.5 on Legal/Ethical Requirements), the Partnering Organization may submit requests to hold workshop(s) by emailing completed Workshop Request Form(s) to the STOP Coordinator (see Appendix D). Partnering Organizations are encouraged to contact and collaborate with local organizations on workshops in order to maximize recruitment of smokers who are unable to access cost-free smoking cessation treatment and to make the workshops as cost-effective as possible. Local Canadian Mental Health Association branches and other care provider organizations may be potential sources of partnerships (see Appendix E). While staff should be allocated and a tentative location/date identified, no room rental deposits should be paid or participant recruitment begun until the workshop request has been approved. The workshop request should be submitted at least 1 month before

the workshop to give sufficient time for recruitment and to ensure that there is enough time to have NRT kits and documentation prepared and couriered.

7.2.2 Recruitment: Workshop participants will be recruited by the Partnering Organization. Recruitment strategies may involve the use of posters, advertisements in local community venues, newspapers and on the radio, as deemed appropriate by the Partnering Organization and CAMH. All advertisements must use the CAMH REB-approved poster template (see Appendix F), media release template (see Appendix G), radio script template (see Appendix H), or Twitter template. The approved Twitter template is:

> *STOP on the Road workshop for smokers who want to quit: <workshop date> - <workshop city or town>. Call <screening phone number> to see if you're eligible.*

Due to the time it takes to get regulatory, institutional and Ministry approval of any changes to the approved templates, it is not recommended that any changes be made to the text of these templates.

7.2.3 Screening and Registration: Partnering Staff will screen all prospective workshop participants in person or over the telephone using the Screening Form (see Appendix I). Should there be collaboration between two or more local agencies to deliver the workshop(s), only one agency should conduct the screening in order to avoid enrolling the same person more than once.

Individuals are eligible to participate if they meet all of the following inclusion and exclusion criteria, as determined by the Screening Form.

7.2.3.1 Eligibility Criteria

Inclusion Criteria

- Males and females who are 18 years of age or older
- Ontario resident
- Current daily smoker
- Smokes 10 or more cigarettes per day
- Wants to quit smoking within next 30 days
- Capable and willing to provide informed consent and comply with the program's protocol

Exclusion Criteria

- Individuals under the age of 18 years
- Have a medical condition that would make participation medically hazardous as determined by the list of cautions and warnings in the product license (Appendix J) For this program, it is necessary to adhere to the warnings listed on the NRT package and the product license.
- If the subject has a known allergy or intolerance to NRT, or a general skin disorder (e.g. eczema, rash) that would prevent them from using nicotine patches, then they should not participate in the program.
- Pregnancy and breast-feeding are listed as warnings in the product license. These individuals are not able to receive NRT through STOP on the Road. If a program participant becomes pregnant during the program, she will be withdrawn from the program and will be asked to return all unused NRT. She will be advised to discontinue all use of NRT provided by STOP.

- Have been enrolled in another arm of the STOP program within the past 6 months.

7.2.3.2 Screening Script: If an individual indicates interest in participating in the workshop, they will be informed that the workshop is part of a study conducted by the Centre for Addiction and Mental Health in Toronto and that if they are eligible for the program they will be required to attend a local smoking cessation workshop (up to 3 hours in duration) where they will be asked to complete a consent form and a questionnaire regarding their smoking behaviour, medical history, and demographic characteristics. They will receive information about quitting smoking and nicotine patches at the workshop and may be contacted for evaluation follow-up surveys approximately 5 weeks and 6 months after the workshop by staff at the Centre for Addiction and Mental Health.

7.2.3.3. Screening Process: If the individual is interested in participating after hearing the Screening Script (see above), the Partnering Staff will screen the individual by asking all of the questions on the Screening Form (see Appendix I). Prospective participants may not complete the form on their own. The form must be completed in full for each prospective participant (even if they are deemed ineligible) and the eligibility criteria should not be revealed to any prospective participants. Partnering Staff will decide if the individual is eligible based on the screening criteria without seeking approval from the STOP team unless they are unsure or unclear about the specific individual. If they require a consultation about an individual's eligibility, they may consult with the STOP Coordinator prior to informing the prospective participant of their eligibility status.

Individuals who meet the eligibility criteria on the Screening Form and are interested in participating in the workshop: These individuals will be told the time, date and location of the workshop. It is important that registrants are made aware that they must arrive at the start of the workshop and attend the full workshop, and that the workshop is only offering nicotine patches. It is recommended that registrants to be reminded to bring their reading glasses and that they must be eligible at the time of the workshop in order to receive NRT. At the discretion of the Partnering Organization, Partnering Staff may contact eligible participants in the days immediately prior to their workshop to remind them of the date and time. Completed Screening Forms for eligible individuals should be stored alphabetically at the front of the Screening Folder.

Individuals who do not meet the eligibility criteria on the Screening Form or are not interested in participating in the workshop: Partnering Staff will provide these individuals with the Smokers' Helpline phone number and website, and if available and feasible, a list of smoking cessation resources (see Appendix K). The Screening Forms of these individuals should be stored at the back of the Screening Folder.

7.2.3.4 Registration List: When registration for the workshop closes, a registration list should be created with the first and last names of all *eligible* participants. It is helpful for the staff at the workshop sign-in desk if the names are listed alphabetically. This list should be brought to the workshop and used for signing-in registrants.

7.2.4 Ordering Documentation and NRT: Approximately 10-14 days prior to the workshop, Partnering Staff will inform the STOP Coordinator of the number of current and projected workshop registrants. The STOP Coordinator will have sufficient documentation (Consent Forms, Baseline Questionnaires, Change Plan workbooks, Ontario Health Study bookmarks) and NRT kits shipped to the Partnering Organization prior to the workshop. Alternately, if secure storage space is available at the Partnering Organization, Partnering Staff may arrange with the STOP Coordinator to have documentation and NRT kits for multiple workshops delivered and stored at the Partnering Organization. As part of this arrangement, Partnering Staff are responsible for ensuring that they have sufficient documentation and NRT for all registered participants at each approved workshop and that any requests for additional NRT

and documentation are submitted to the STOP Coordinator at least 2 weeks prior to the date the materials are required.

7.2.4 Tracking NRT Shipments: Upon arrival of the NRT kit shipment, Partnering Staff will verify that the correct quantities of NRT kits have arrived and update the NRT Inventory Log (see Appendix L) with this change in inventory. When the NRT Inventory Log has been updated with this new shipment, it should have the date of the shipment arrival in the first column, "NRT received" in the second column, the number of each type of NRT Kit that the Partnering Organization currently has (not necessarily the quantities in the shipment) in the third and fourth columns, and the name of the staff member receiving the NRT shipment in the last column.

7.3 Workshop Procedures

7.3.1 Room Set-up: Please see Room Set-up in the Venue section above (including Appendix B)

7.3.2 Program Documents and Materials: Partnering Staff should be prepared to provide each participant with the following at the workshop: 1 number, 1 blue pen, 2 Consent Forms (see Appendix M), 1 Baseline Questionnaire (see Appendix N) and 1 My Change Plan workbook.

7.3.3 Workshop Agenda

First 20 minutes	Participants sign in and are given program materials to immediately complete. Participants complete and hand in a Consent Form and Baseline Questionnaire.
Next 1 hour	Group psychoeducational presentation
Remainder of time	Authorized staff from Partnering Organization consult with - and dispense NRT kits individually to - participants in order of their arrival (by the number assigned to them at sign-in). Participants are free to leave the workshop after receiving their NRT kit.

7.3.4 Participant Sign-in and Handing out of Program Materials: The first 20 minutes of the workshop will be spent signing in participants and allowing participants time to complete and hand in their program documents.

When individuals arrive at the workshop Partnering Staff will confirm that they are listed on the Registration List.

If the person's name is on the Registration List: Partnering Staff will assign them a number on a first-come, first-served basis (starting at number 1) and write down that number beside the person's name on the registration list to indicate that the person attended the workshop. (Numbers are assigned and given to participants so that they can be called up during the one-to-one consult and dispensing without having their confidentiality breached by having their name called out). Partnering Staff should take note of who might have to legitimately leave early (not before the end of the presentation) so that they can be seen for NRT dispensing first.

Write the participant's assigned number in the top right-hand corner of a Baseline Questionnaire. Give the participant the number assigned to them, 2 Consent Forms, the Baseline Questionnaire (with assigned number written on it), a blue pen to fill out the forms and a My Change Plan workbook. Give them instructions on how to fill out the forms (see below) and direct them to one of the chairs set up for the workshop.

If the person's name is not on the Registration List: Partnering Staff should assume that the individual has not been screened yet (even if they say they have). Partnering Staff will use a blank Screening Form to screen the individual for eligibility.

If the newly screened person is deemed eligible, Partnering Staff will:	*If the newly screened person is deemed ineligible, Partnering Staff will:*
Add their name to the registration list. The Screening Form should be safely stored and transported back to the Partnering Organization (for filing in the Screening Folder) and the procedure for registered participants followed.	Inform them that they are not eligible for the program and give them Smokers' Helpline contact information (and local community resources if available) to help them in their quit attempt. Their Screening Form should be safely stored and transported back to the Partnering Organization (for filing in the Screening Folder).

Instructions to participants when providing program forms at workshop

"Here is your number. Please keep this number with you because you will be called up by this number after the presentation. You are receiving 2 Consent Forms and 1 Baseline Questionnaire. The Consent form tells you about the study. If you consent to participate in this study, complete 1 of the Consent Forms (initial the bottom of the front side and complete the back side); the other Consent Form is for you to keep for your own records. Then complete the entire Baseline Questionnaire. It is important that you read and provide an answer for every question on the form (including your contact information). Once you have filled out 1 Consent Form and the Baseline Questionnaire, please hand them back to one of our staff. If you have any questions at all, please feel free to ask at any time."

7.3.5 Review of Program Documentation: While the presentation is taking place, 1 Partnering Staff can review and organize the handed-in forms (1 Consent form and 1 Baseline Questionnaire per participant) to make the one-to-one portion of the workshop more time-efficient.

Partnering Staff can review the forms for completeness and indicate with large arrows all questions which suggest ineligibility, or are not complete, or which have been filled out incorrectly. The arrows will indicate to the staff doing the individual consult and dispensing any problematic/incomplete areas of the form(s) which need to be addressed at the beginning of the one-to-one session. The Consent Form should be tucked into the corresponding Baseline Questionnaire so that they are kept together. The Partnering Staff can complete the footer section on the first page of the Baseline Questionnaire during this time: Partner Name, Workshop City/Town, Workshop Start Time, Workshop Date, Participant Initials.

Once all of the submitted forms have been reviewed, the reviewer should put the forms (Consent Form and Baseline Questionnaire) in order by the number assigned. Participants will be called up in order of these numbers.

7.3.6 Presentation

7.3.6.1 The presentation covers a brief overview of the study procedures, a brief discussion about other unhealthy lifestyle behaviours that often cluster with smoking, information on developing a Quit Plan, behavioural strategies for quitting smoking, and education on Nicotine Replacement Therapy including its proper use. The presentation should take approximately 1 hour with at least the last 20 minutes left to deliver the NRT section and answer any questions.

It is helpful for the flow of the presentation if questions that are very specific to the participant (i.e. related to a previous personal experience) are left for the one-on-one time, and only questions that would benefit the entire group to hear are asked during the presentation. As well, it is recommended that any incorrect information or inflammatory comments from participants are addressed immediately (e.g. anything that might make other participants fearful or weary of using NRT or of quitting smoking). The presenter(s) should ensure that everyone in the audience understands how to use the Nicotine Patches correctly.

7.3.6.2 Speaker's Notes will be prepared as a resource to the presenter. The Speaker's Notes are not meant to be read and/or memorized by the presenter and are meant to help the presenter understand the slide progression and the topics that must be covered. The presenter should review and familiarize themselves with the speaker's notes and slides in advance to ensure that their presentation covers all of the relevant information. The presenter does not need to present the information exactly as written in the Speaker's Notes and is encouraged to adjust the language and examples so that they are appropriate and relevant to the participants.

7.3.6.3 Smokers' Helpline (SHL): At the end of the presentation, a Smokers' Helpline Representative (if in attendance), may speak to the audience for a few minutes about their support services. If a SHL Representative is not available to attend the workshop, Partnering Staff should speak briefly about SHL services, in particular the SHL Fax Referral Program. Partnering Staff should contact their SHL Regional Coordinator to inform them of their upcoming workshops and to determine how information and resources will be disseminated to participants (see Appendix O). Smokers' Helpline Fax Referral forms should be available at the workshops for participants who would like to sign up (the forms will be provided by SHL). Fax referral forms may either be faxed directly to SHL by Partnering Staff or can be sent to the STOP Team with the rest of the participant documentation to be faxed later on. If Partnering Staff are faxing completed Fax Referral forms directly to SHL, the hard copies do not need to be sent to the STOP team.

7.3.6.4 Local Programs/Supports/Resources: Partnering Staff may inform the participants about any smoking-cessation related programs and/or resources offered at their organization at the end of the presentation during the Brief Individual Consult and Dispensing of NRT.

7.3.7 Brief Individual Consult and Dispensing of NRT: Following the presentation, all of the reviewed Consent and Baseline Questionnaires should be given to the Partnering Staff who are doing the brief one-to-one consult and dispensing of NRT. In order to maintain confidentiality and in the interest of fairness, participants should be called up one at a time by their assigned number (starting with number 1).

The general steps to the one-to-one consult are as follows:

General Steps	Partnering Staff will:
1. Answer participant questions	Ask participant if they have any questions relating to the study or NRT and answer them to the participant's satisfaction. If participant requires more intensive counselling or support, they may be referred to their family physician, services at Partnering Organization, or Smokers' Helpline.
2. Confirm consent	Ask participant if they still agree to participate. If participant says yes, ensure that participant has initialed front side of Consent Form and completed the entire back side of Consent Form. It is extremely important that the participant initials that they provide consent to participate in the study on the back of the Consent Form. Complete the bottom section of the back of the Consent Form (for the staff obtaining consent). Then check "Yes" to the 1st question on the last page of the Baseline Questionnaire in the section *To Be Completed By Study Staff Only.*
3. Confirm eligibility	Ensure that the entire top section of the last page of the Baseline Questionnaire is complete. Ensure that the participant has entered a quit date within 30 days of the workshop date. Review participant's responses to the questions at the top of the last page of the Baseline Questionnaire and determine whether participant is currently eligible to receive NRT (all but the last 2 questions relate to eligibility). If participant is still eligible, check off "Yes" to the 2nd question on the last page of the Baseline Questionnaire in the section *To Be Completed By Workshop Staff Only.*

	Clarification on cigarettes per day smoked at the time of the workshop: All participants are required to smoke 10 cigarettes per day (CPD) at the time of screening. <u>If participants reduce to less than 10 CPD at the time of the workshop they are still eligible to receive the kit</u>. Please double check that participants reported smoking 10 CPD at the time of screening and record the amount of cigarettes smoked at screening on the form under eligibility comments.
4. Ensure form completeness	Ensure that the entire Consent Form and Baseline Questionnaire are complete and legible.
5. Select appropriate NRT Kit	Review top section of last page of Baseline Questionnaire, ask any other relevant questions and make recommendation to participant with regards to kit type. The 2 Kit options are (see Appendix P): **<u>Kit H</u>** – Higher-dose patch kit 3 weeks of 21mg patch (Step 1) 1 week of 14mg patch (Step 2) 1 week of 7mg patch (Step 3) **<u>Kit L</u>** – Lower-dose patch kit 3 weeks of 14mg patch (Step 2) 2 weeks of 7mg patch (Step 3)
6. Dispense NRT and document dispensing.	Once Partnering Staff and participant are in agreement about kit selection, select kit. Check label to confirm correct kit was selected and that final dispensing date has not passed. On last page of Baseline Questionnaire in the section *To Be Completed by Workshop Staff Only*, check off whether kit is dispensed, check off which kit type is dispensed and record Kit Lot Number. If kit is not dispensed, indicate so and provide the reason why it was not dispensed. Print name of staff member doing the consult and complete the footer of last page of Baseline Questionnaire (Partner Name, Workshop City/Town, Workshop Start Time, Workshop Date, Participant Initials, Participant #). The "STOP Portal ID#" can be left blank. Ensure that all applicable sections of the Consent Form and Baseline Questionnaire are complete before proceeding with the next participant's consult.

Please note: The participant may not receive another STOP kit if they lose their NRT or require more NRT, or exchange the kit for the other type at a later time. NRT may not be dispensed to a participant who has not been deemed eligible or for an individual who has not attended the workshop that day.

<u>Unusual situations resulting in no kit being dispensed</u>:

a) Participant does not provide proper informed consent or no longer consents to participate or does not want to receive the STOP Patch Kit
b) Participant is no longer eligible to receive STOP Patch Kit based on Baseline Questionnaire responses and/or individual consultation with practitioner
c) Participant leaves workshop without coming up for one-to-one consultation/receiving STOP Patch Kit

Partnering Staff will document the above scenarios on the last page of the Baseline Questionnaire in the section *To Be Completed By Workshop Staff Only*.

7.4 Post-Workshop Procedures

7.4.1 Documentation and NRT Accountability and Transport: Before leaving the workshop venue, Partnering Staff will put all the forms in numerical order. They will confirm that they have a completed Consent Form and Baseline Questionnaire for each workshop attendee. Partnering Staff will ensure the safe transport of these documents along with the Registration List, any newly completed Screening Forms,

leftover NRT kits, blank documentation, My Change Plan workbooks, pens, and numbers (if they are being reused) back to the Partnering Organization office. The completed documents now contain Personal Health Information so Partnering Staff should take extra care to ensure that they are all accounted for and transported safely and securely.

7.4.2 Tracking NRT and couriering back workshop documentation and NRT: Following the workshop, Partnering Staff will review documentation and current NRT stock. Partnering Staff will enter a new row on the NRT Inventory Log to reflect the reduction in NRT inventory caused by dispensing kits at the workshop (in the 2nd column of Log, enter "Workshop - <name of workshop location>).

Within a week of the workshop, Partnering Staff must complete a Workshop Courier Form (see Appendix Q) and prepare the completed documentation (and leftover NRT and documentation if not holding another workshop in the near future) for courier pick-up. Once the packages are ready for pick-up, Partnering Staff will email the completed Workshop Courier Form to the STOP Coordinator so that courier pick-up can be scheduled and arranged by STOP. In general, two envelopes with unique shipping labels (one containing consent forms and the other, containing baseline questionnaires) will be expected. The envelopes should not be attached to each other in any way, thereby ensuring that identifying information (on the consent) remains independent of any data (on the baseline). If NRT kits are being sent back to STOP, a new row will be entered on the NRT Inventory Log to reflect the reduction in NRT Inventory (in the 2nd column of Log, enter "NRT Returned"). Workshop documentation must be couriered back within a week of the workshop to ensure that participant follow-ups can occur on schedule.

7.4.3 Participant Follow-up Surveys: Follow-up surveys to evaluate the effectiveness of the treatment will be conducted by STOP Staff at the end of treatment and at 6 months after the end of treatment (see Appendices R and S, respectively). STOP Staff may contact participants who have received STOP NRT using the email address and/or phone number provided by the participant.

7.5 Legal/Ethical Requirements

7.5.1 Collaborative Agreement and Medical Directives: As the program's data collection, treatment intervention and NRT accountability will be the responsibility of Partnering Staff, a contract between CAMH and the Partnering Organization is required. A template of the contract has been provided to Partnering Organizations. Changes to the contract may be negotiated via CAMH's Legal Counsel.

A Medical Directive may be required by the Partnering Organization, indicating which Partnering Staff have been authorized to dispense NRT kits to STOP on the Road participants and under what conditions. If requested, a template of a medical directive can be provided to Partnering Organizations; this may be modified by the Partnering Organization to meet their organizational and professional requirements.

7.5.2 Ethics Board Approval: This study has been approved by the CAMH Research Ethics Board. If a Partnering Organization requires its own internal Ethics Board's approval before implementation of SOR-VIII, approval from such Ethics Board must be obtained by the Partnering Organization in order for the CAMH Collaborative Agreement to be valid.

Partnering Organizations should always enquire about Ethics Board requirements during discussions with local community partners. It is the responsibility of the Partnering Organization to obtain applicable Ethics Board approvals prior to requesting a workshop for a particular community group or booking a particular venue. The STOP on the Road-VIII research protocol and CAMH REB approval letter may be used in a Partnering Staff's preparation of an internal Ethics Board submission to implement STOP on the Road. These documents can be requested from the STOP Coordinator.

8. CAMH-Mailed Model: Operational Details

Please refer to Appendix T for a comprehensive timeline and checklist for the CAMH-Mailed Model. This document should help to ensure that all required steps have been taken.

8.1 Organizational Details

The information in the Organizational Details section of the CAMH-Assisted Model (–section 7.1) applies to the CAMH-Led Model except for the section on Storage Space for NRT. Partnering Organizations implementing the CAMH-Mailed Model are not required to store NRT kits as NRT administration will be the responsibility of STOP Staff.

8.2 Pre-Workshop Procedures

The information in the Pre-Workshop Procedures section of the CAMH-Assisted Model (section 7.2) applies except for the sections on Requesting a Workshop, Screening Script, Ordering Documentation and NRT and Tracking NRT Shipments.

Requesting a Workshop: After the Partnering Organization's collaborative agreement has been approved and signed by CAMH (see section 8.5 on Legal/Ethical Requirements), the Partnering Organization should submit a proposed workshop schedule by emailing a completed Workshop Request Form (see Appendix D) to the STOP Coordinator. The STOP Coordinator and Partnering Staff will finalize a mutually agreeable workshop schedule and plan that takes into consideration the resources available at the Partnering Organization and at the STOP Team. No room rental deposits should be paid or participant recruitment begun until the workshop schedule has been finalized and approved by both parties.

Partnering Organizations are encouraged to notify local organizations once the workshop schedule has been finalized in order to maximize recruitment of smokers who are unable to access cost-free smoking cessation treatment and to make the workshops as cost-effective as possible. Local Nurse Practitioner-Led Clinics (NPLCs) and Canadian Mental Health Association branches may be potential sources of partnerships (see Appendix E).

Screening Script: The Screening Script is similar to that used for the CAMH-Assisted Model except that potential participants should be told that eligible participants will have nicotine patches mailed to their address following the workshop.

Ordering Documentation: Prior to the first workshop, the STOP Coordinator will send an initial shipment of participant documentation (Consent Forms, Baseline Questionnaires, My Change Plan workbooks) to the Partnering Staff. Following the initial shipment, Partnering Staff will be responsible for ensuring that they have sufficient documentation for all registered participants at each approved workshop. Any requests for additional documentation should be submitted to the STOP Coordinator 2 weeks prior to the date the documentation is required.

Approximately a week before each workshop, Partnering Staff will inform the STOP Coordinator of the number of current and projected workshop registrants so that sufficient NRT and staffing resources are available to process the participant documentation and send out NRT kits in a timely manner.

Tracking NRT Shipments: NRT kits will not be sent to the Partnering Organization for the CAMH-Mailed Model so no tracking is required.

8.3 Workshop Procedures

The information in the Workshop Procedures section of the CAMH-Assisted Model (–section 7.3) applies for the most part except for the changes described below.

Workshop Agenda: Following the group psychoeducational presentation, authorized staff from the Partnering Organization will consult individually with participants in order of their arrival (by the number assigned to them at the sign-in). No NRT will be dispensed during this consult although a brief discussion about the appropriate NRT kit type will occur between Partnering Staff and the participant.

Participant Sign-in and Handing out of Program Materials: At sign-in, Partnering Staff should take note of who might have to legitimately leave early (not before the end of the presentation) so that they can be seen for their brief consult first. Participants who leave before their brief consult may not receive an NRT kit.

Presentation: During the presentation, participants will be informed that they should pick a Quit Date 2-4 weeks after the workshop date to allow enough time to receive their NRT kit by mail. Partnering Staff will provide them with the appropriate date range for their Quit Date selection.

Brief Individual Consult: Confirm eligibility: Ensure that the participant has entered a quit date that is 2 weeks after the workshop date and no later than 30 days after the workshop. The date they have selected may need to be changed. Based on the questions at the top of the last page of the Baseline Questionnaire, check off the appropriate response to the 2nd question in the To Be Completed by Workshop Staff Only section of the last page of the form.

Ensure form completeness: It is extremely important that all information on the Consent Form and Baseline Questionnaire (including contact information on the Consent Form) is complete, correct, and legible so that unnecessary delays due to incomplete/incorrect/illegible data are minimized.

Select and document NRT recommendation: Once Partnering Staff and participant are in agreement about the kit selection, circle on the form which kit is being recommended. If Kit L is being recommended, provide a brief explanation in the Comment section. Do not check off that NRT has been dispensed. If NRT is not being recommended, provide the reason why. Print name of staff member doing the consult and complete the footer of the last page of the Baseline Questionnaire (Partner Name, Workshop City/Town, Workshop Start Time, Workshop Date, Participant Initials, Participant #). The "STOP Portal ID#" can be left blank. Ensure that all applicable sections of the Consent Form and Baseline Questionnaire are complete before proceeding with the next participant's consult.

8.4 Post-Workshop Procedures

Only the section in the CAMH-Assisted Model on Participant Follow-up Surveys (section 7.4.3) is completely accurate in the context of the CAMH-Mailed Model. See below for other Post-Workshop Procedures relevant to the CAMH-Mailed Model.

Documentation Accountability and Transport: Before leaving the workshop venue, Partnering Staff will put all the participant forms in numerical order. They will confirm that they have a completed Consent Form and Baseline Questionnaire for each workshop attendee. Partnering Staff will ensure the safe

transport of these documents along with the Registration List, any newly completed Screening Forms, and blank documentation, My Change Plan workbooks, pens and numbers (if they are being reused) back to the Partnering Organization office. The completed documents now contain Personal Health Information so Partnering Staff should take extra care to ensure that they are all accounted for and transported safely and securely.

Couriering back workshop documentation: By the day following each workshop, Partnering Staff must complete a Workshop Courier Form (see Appendix U) and prepare the completed documentation (and leftover documentation if not holding another workshop in the near future) for courier pick-up. In general, two envelopes with unique shipping labels (one containing consent forms and the other, containing baseline questionnaires) will be expected. The envelopes should not be attached to each other in any way, thereby ensuring that identifying information (on the consent) remains independent of any data (on the baseline). Once the packages are ready for pick-up, Partnering Staff will email the completed Workshop Courier Form to the STOP Coordinator so that courier pick-up can be scheduled and arranged by STOP Staff for either the following day or 2 days later (as determined by the courier's standard pick-up times for that location). It is particularly important in the CAMH-Mailed Model workshops that documentation be picked up by courier within 3 days of the workshop to ensure that eligible participants receive their NRT kit within 2 weeks of their workshop.

8.5 Legal/Ethical Requirements

The information in the Legal/Ethical section of the CAMH-Assisted Model (section 7.5) applies to the CAMH-Mailed Model except for the section on the Collaborative Agreement and Medical Directive.

Collaborative Agreement: As the program's data collection and transfer, and psychoeducation component of the intervention will be the responsibility of Partnering Staff, a contract between CAMH and the Partnering Organization is required. A template of the contract has been provided to Partnering Organizations. Changes to the contract may be negotiated via CAMH's Legal Counsel.

A Medical Directive may not be applicable for this implementation option as Staff from Partnering Organizations are not required to dispense NRT.

9. CAMH-Led Model: Operational Details

Please refer to Appendix V for a comprehensive timeline and checklist for the CAMH-Led Model. This document should help ensure that all required steps have been taken.

9.1 Organizational Details

The information in the Organizational Details section of the CAMH-Assisted Model (–section 7.1) applies to the CAMH-Led Model except for the sections on Storage Space for NRT, Staffing and Staff Training.

Storage Space for NRT: If STOP Staff are travelling to the workshop location by air or do not have sufficient space to transport all required workshop materials, the Partnering Organization may be required to receive and store in a locked, restricted-access space, NRT kits and participant documentation for their workshop(s). Otherwise, STOP Staff will bring the NRT and documentation with them to the workshop.

Staffing: A minimum of 1 Partnering Staff should attend the workshop. If registrants are identified through screening as needing individual help in filling out their program forms, it is recommended that

additional Partnering Staff attend the workshop to assist in this task. If at all possible, TEACH-trained staff in the Partnering Organization are requested to deliver the psychoeducation presentation during the workshop.

Staff Training: Information teleconferences will be held prior to the start of the workshops to discuss details pertaining to this round of workshops. There will be no specific Operations Training for staff implementing the CAMH-Led Model. STOP Staff will be at the CAMH-Led Model workshops and will be primarily responsible for delivering the various components of the workshop.

9.2 Pre-Workshop Procedures

The information in the Pre-Workshop Procedures section of the CAMH-Assisted Model (section 7.2) applies except for the sections on Requesting a Workshop, Ordering Documentation and NRT, and Tracking NRT and Documentation.

Requesting a Workshop: Workshop requests may be made using the SOR-VIII Interest and Capacity Survey. Once all surveys have been submitted, the STOP Coordinator will schedule the CAMH-Led Model workshops and inform Partnering Staff of the locations, dates and times.

Ordering Documentation and NRT: Approximately 7-10 days prior to each workshop, Partnering Staff will inform the STOP Coordinator of the number of current and projected workshop registrants so that sufficient quantities of NRT and documentation can be prepared and brought to the workshop(s).

Tracking NRT Shipments: STOP Staff will bring the NRT and documentation with them to the workshop unless travel restrictions require advance courier of the materials. In the case of advance courier of materials, documentation of the receipt of the correct and full shipment of NRT will be required (this will be arranged with the STOP Coordinator).

9.3 Workshop Procedures

The information in the Workshop Procedures section of the CAMH-Assisted Model (–section 7.3) applies for the most part. STOP Staff will assist Partnering Staff in setting up the venue prior to the workshop and cleaning up the venue following the workshop. Partnering Staff are encouraged to assist STOP Staff in the Sign-in Procedures and in helping participants with their program documentation. They may also be asked to help in ensuring an efficient NRT dispensing process. TEACH-trained Partnering Staff are requested to deliver the presentation if possible (with the aid of STOP Staff if necessary). STOP Staff will be solely responsible for reviewing program documentation, the brief consults and NRT dispensing.

9.4 Post-Workshop Procedures

Only the section in the CAMH-Assisted Model on Participant Follow-up Surveys (section 7.4) applies to the CAMH-Led Model. STOP Staff will be responsible for transport of NRT and documentation back to CAMH.

9.5 Legal/Ethical Requirements

The section in the CAMH-Assisted Model on Ethics Board Approval (section 7.5) also applies to the CAMH-Led Model. A contract between CAMH and the Partnering Organization is required. A template of the contract has been provided to Partnering Organizations. Changes to the contract may be negotiated via CAMH's Legal Counsel.

10. Appendices

Appendix	Document Name	Document
A	Public Health Unit Testimonials: The CAMH-Assisted Model Experience	Public Health Unit Testimonials - The CA
B	Checklist for CAMH-Assisted Model	SORVIII CAM checklist
C	Workshop Room Set-up	SORVIII Workshop Room Set-up
D	Workshop Request Form	SORVIII Workshop Request Form
E	Canadian Mental Health Association Branches	Ontario CMHA Branches Jun2017
F	Approved Poster Template	SORVIII Poster Template ENG
G	Approved Media Release Template	SORVIII CAMH Media Release Template EN
H	Approved Radio Script Templates	SORVIII Radio Script Template ENG
I	Screening Form	SOR 8 - Screening Form v2.0 ENG
J	NRT Product Licenses	2016 Nicorderm 7-14-21 mg license.p
K	List of Smoking Cessation Resources	SORVIII List of Smoking Cessation Re

L	NRT Inventory Log	SORVIII NRT Inventory Log
M	Consent Form	SORVIII Consent Form ENG
N	Baseline Questionnaire	SORVIII Baseline Questionnaire v1.0a
O	Smokers' Helpline Regional Coordinator Contacts	Smokers' Helpline Regional Coordinators
P	Information Sheet inside NRT Kits (unchanged)	Package Inserts H and L for SORVIII wo
Q	Workshop Courier Form (CAMH-Assisted Model)	SORVIII CAM Workshop Courier Fo
R	End-of-Treatment (5-week) Follow-up Questionnaire	SOR 8 - 5 Week Follow-up ENG.pdf
S	6-month Post-Treatment Follow-up Questionnaire	SOR 8 - 6 month Follow-up ENG.pdf
T	Checklist for CAMH-Mailed Model	SORVIII CMM Checklist
U	Workshop Courier Form (CAMH-Mailed Model)	SORVIII CMM Workshop Courier Fo
V	Checklist for CAMH-Led Model	SORVIII CLM Checklist