

Exploring Combination Therapy for Smoking Cessation: A Provider and Quitline Intervention



Tuesday, June 11, 2019

Moderated by:

Tony Astran, MPA, APR
Public Information Specialist, New York State Smokers' Quitline

WEBINAR OBJECTIVES

1. Learn how the New York State Smokers' Quitline (NYSSQL) supports healthcare providers in their efforts

- a) Resources available to aid in assisting tobacco users
- b) Listen to a mock call between a tobacco user and a Quit Coach

2. Explore combination therapy for smoking cessation

- a) Greater effectiveness versus using one nicotine replacement therapy (NRT) product or going "cold turkey"
- b) Recommendations for using the seven FDA-approved NRT products
- c) Possible side effects to consider

YOUR PRESENTERS



Paula Celestino, MPH
Client and Outreach Director



*Dr. Daniel Croft, MD, MPH*Physician Task Force Member

PAULA CELESTINO, MPH



ABOUT ROSWELL PARK

Roswell Park Comprehensive Cancer Center:

- Over 60 years of work in the field of tobacco control and today is considered a leader in the field
- Administers state and community-based programs and conducts research on the local, state, national, and international level
- Employs experts in the fields of cessation, policy, ENDS, tobacco product marketing and countermarketing, and product regulation



ABOUT ROSWELL PARK

Roswell Park Comprehensive Cancer Center:

- Located in Buffalo, New York
- Administering the NYSSQL since its launch in 2000
- Offers and provides telephonic and web-based cessation services for health plans and employer groups
- Administers the national Gilda Radner Ovarian Line, the NYS HIV/AIDS Hotline, and the NYS Prison HIV Counseling Hotline



ABOUT THE NYSSQL

The New York State Smokers' Quitline:

- began as an informational service and materials clearing house with six (6) information specialists
- evolved to offer coaching along with a patient fax referral program for healthcare professionals
- through research, was a pioneer in establishing the efficacy of nicotine replacement therapy (NRT) distribution through a quitline
- is one of the busiest quitlines in the nation



ABOUT THE NYSSQL

Today's NYSSQL

As a component of the New York State Bureau of Tobacco Control's comprehensive program, the NYSSQL works to carry out activities that support a broader goal: to improve reach and evidencebased cessation delivery through Health Systems Change throughout New York State.

Supporting Activities

Participant Intervention

Provide Education & Messaging
Web & Social Media Messaging
Ancillary Messaging

Provider Outreach & Services

Adjunct Patient Referral Program

Marketing & Public Relations

Support, Resources, &

Technical Assistance

Operations

Specialized Training
Standardized Messaging
Interface Prompts & Support
QuitSite Enhancements

Outcome Monitoring

Intervention Measures

Marketing Measures

QuitSite Measures

NYSSQL Services

- Cessation coaching: up to 2 (two) coaching sessions and unlimited incoming calls
- Email or text support messages
- Nicotine Replacement Therapy
 - (phone and online registrations)
- Self-help materials
- QuitSite: <u>www.nysmokefree.com</u>
 - interactive and informational
- Refer or triage to other cessation services
 - (e.g., health plan, local or healthcare program, Asian Smokers Quitline)



NYSSQL NRT Availability*

- Eligibility criteria:
 18 years or older, NYS resident, no contraindications
 - Most are eligible!
- Can receive supply two (2) times in 12 months with 3-month interval
- 2- or 4-week supply available depending on resources (currently 4 weeks)
- Mailed out in 2-week shipments
- Moderate and heavy smokers receive a combination of nicotine patch and the gum or lozenge (combination therapy)

*Criteria subject to change per NYS BTC supply/discretion & NYC supply

NYSSQL Services for Healthcare Professionals

- Patient Referral Program
 - Call within 24-72 hours of referral receipt
 - Materials and referral forms
 - Technical assistance
- QuitSite resources (www.nysmokefree.com)
- E-Newsletters
 - Quitters Always Win & The Check-Up
- Webinars and CME trainings
- Connections to local NYS Health Systems Change programs



Links to Other Provider Resources

NYS Bureau of Tobacco Control:

Talk to Your Patients

CDC:

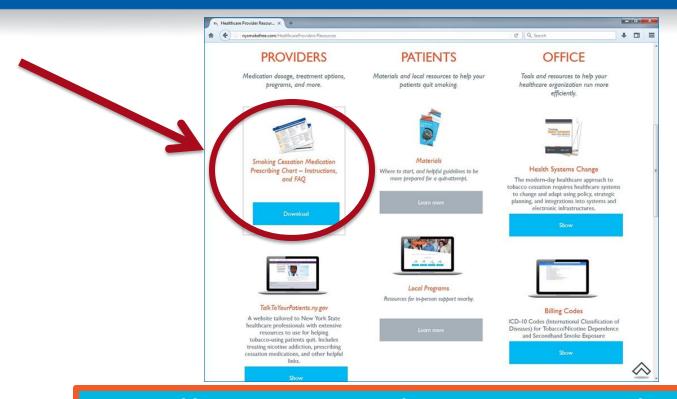
Healthcare Providers: Tools and Resources



NYC Health:

Information on Smoking and Tobacco Use for Clinicians

RESOURCES: HCPs WEBSITE



https://nysmokefree.com/HealthcareProviders/Resources

RESOURCES: DOSING CHART

Smoking Cessation Medication Prescribing Chart

These highlights do not include all information needed for safe and effective use. See full prescribing information for each medication.

N	Aedication*	Suggested Regimen	Precautions	Contraindications	Potential Adverse Effects	
(NRT)	Patch [†] Long-acting NRT	≤10 cig/d, start with 14 mg/qd x 6 weeks, followed by 7 mg/qd x 2 weeks >10 cig/d, start with 21 mg/qd x 6 weeks, followed by 14 mg/qd x 2 weeks, followed by 7 mg/qd x 2 weeks,	Pregnancy Class D* Uncontrolled hypertension Skin disorders (patch) Allergy to adhesive tape (patch) MRI (patch)	Heart attack within 2 weeks Serious cardiac arrhythmia Unstable angina	Symptoms of too much nicotine, e.g., nausea, headache dizziness, fast heartbeat Skin irritation, insomnia (patch Jaw pain, dry mouth (gum) Hiccups, heartburn (gum,	
t Therapy	Gum [†] Short-acting NRT	1st cig >30 mins after awakening, 2 mg/hr 1st cig ≤30 mins after awakening, 4 mg/hr (both up to 24 pcs/day)	Advise starting with the highest-dose patch available except for patients weighing less than 100 lbs. TMJ disease, dental work, dentures (qum)		Triccups, heartourn (gum, lozenge) Ronchospasm (nasal spray, inhaler) Nasal irritation, tearing, sneezing (nasal spray) Mouth and throat irritation (inhaler)	
Replacement Therapy (NRT	Lozenge† Short-acting NRT	1st cig >30 mins after awakening, 2 mg/hr 1st cig ≤30 mins after awakening, 4 mg/hr (both up to 20 pcs/day)	Tinu disease, dental work, dentures (gum) Sodium-restricted diet (gum, lozenge, nasal spray) Stomach ulcer (gum, lozenge, nasal spray,			
Nicotine Re	Nasal spray Short-acting NRT	1–2 sprays/hr, as needed (max 40/d up to 3 mos)	inhaler) Sinusitis, rhinitis (nasal spray)			
Nico	Inhaler Short-acting NRT	Frequent continuous puffing for up to 20 mins at a time every hour, as needed (6 –16 cartridges/d up to 6 months)	 Reactive ainway disease (nasal spray, inhaler) 			
		Long-acting NRT (patch) can be used in combinat	tion with short-acting NRT (gum, lozenge, nasa	spray or oral inhaler) or with	h bupropion SR.	
(2	upropion SR Eyban*, (dellbutrin*)	Days 1-3:150 mg po qd Day 4 to 7-12 weeks (or end of treatment): 150 mg po bid Can be maintained up to 6 months (24 weeks) Can be combined with the NRT patch	Pregnancy Class C¹ Pregnancy Class C¹ Severe cirrhosis – dose adjustment required Mild-mod hepatic & mod-severe renal impairment – consider dose adjustment	MAO inhibitor in past 14 days Seizure disorder, bulimia/anorexia Abrupt discontinuation of ethanol or sedatives	Insomnia, dry mouth, headache pruritis, pharyngitis, tachycati seizures, neuropsychiatric effects and suicide risk As of December 18, 2018, the FDA removed the Bosed Warming for this medication. https://www.dda.gov/brugs/DrugSafety/ ucm\$3221.htm	
Varenicline (Chantix*)		Starting month pack: (start I week before quit date*) 0.5 mg po qa 3 days;THEN 0.5 mg po bid x 4 days;THEN 1 mg po bid x 4 days;THEN 1 mg po bid x 3 weeks Continuing month pack: Week 5 to 1 core and of treatment): 1 mg po bid Can be maintained up to 6 months (24 weeks) CANNOT be combined with NRI.	Pregnancy Class C¹ Seizure disorder CrCl <30 or Halpsis – dose adjustment required May increase risk of CV events in patients with CVD Operate heavy machinery May lower alcohol tolerance	Known history of serious hypersensitivity or skin reactions to varenicline	Nausea, insomnia, abnormal dreams, constipation, neuropsychiatric effects, seizures, suicide risk and cardiovascular events As all December 1, 2018, the Tol removed the constitution of the constitution of the https://www.files.gov/Dusys/Enugs/akey/ ucm533221.hdm Nauseans and Constitution of the Constitu	

medications, including OTC next medications with a percopagation proper intring, without gird visioning review from Early Fed Great Health installation, and in 2011, the TEAR did not identify any advitory disk associated with longer earns used OTC NRT products. Tailer to partiest in seek if the great duration is May consider if convincing alone in ineffective, the patient to highly motivated to quit and the risk-benefit has been controlly assessed with patient. A Retensive regimen for varietistic in to instruct, patient to take Implied the needs capture date between Days 3 and 3.5 of the setting of the patient.

Note: Zuban" and Wellburtist" are resistened trademarks of Glass Smith Bline Chantis" is a resistened trademark of Place Inc. The use of brand cames does not imply endursement of any conduct by the New York City Department of Health and

Smoking Cessation Medication Brief Instructions and FAQs

Product	Nicotine Patch	Nicotine Gum	Nicotine Lozenge	Nicotine Nasal Spray	Nicotine Inhaler	Bupropion SR (Zyban*, Wellbutrin*)	Varenicline (Chantix ^o)
Brief Instructions	Apply 1 patch to clean, dry, hairless skin like upper arm, upper back, shoulders, lower back or hip, Avoid moisturizers under patch and wash hands after use. Replace daily after waking and rotate site daily.	Chew until a peppery taste and slight tingle occurs, then park between cheek and gum. When taste fades, chew again, then park in another area of mouth. Avoid eating and drinking for 15 mins before and after use.	Allow lozenge to dissolve slowly without chewing or swallowing. Avoid eating and drinking for 15 mins before and after use.	Blow nose if not clear and tilt head back. Insert bottle tip as far in nostril as far in nostril as comfortable, angling toward wall of nostril. Do not sniff while spraying, Walt 2-3 mins before blowing nose.	Inhale using short breaths or puffs to get vapor in mouth and throat but not lungs. Store cartridges at temperature range 60F-77F for maximum effectiveness.	Take with food. Take I pill x 3 days, then 2 pills starting day 4, Take second pill at least 8 hours after the first, but as early as possible to avoid insomnia. Can be used in combination with nicotine patch.	Take with food and water as directed. Do not make up a missed dose by doubling up the next dose. Avoid using NRT with varenicline.

Questions You May Receive from Your Patients and Examples of Responses

What should I do if the patch does not stick?

Place the patch on non-hairy skin with the heel of your hand and press for 10 seconds. Do not use moisturizing soap or lotion before applying the patch. You can use medical tape to help the patch stick better.

Can I become addicted to the patch?

Nicotine from the patch is delivered in a much steadier and lower quantity than nicotine from cigarettes, so the chance of becoming addicted is much lower.

If I have had major dental work done or wear dentures, should I use the

You should use the lozenge. The gum should generally be avoided if you have had major dental work and/or have dentures, braces or temporary crowns.

Can I use the patch and gum (or lozenge) at the same time?

Yes. Using the patch and gum (or lozenge) together helps many smokers guit. The patch provides a stable dose of nicotine throughout the day, while the gum or lozenge is short-acting and may help with withdrawal symptoms.

Can I use the patch, gum or lozenge after a brief relapse? Yes, continued use of these medications after relapse is safe and can increase your

How do I know if I'm getting too much or too little nicotine?

If you're getting too much nicotine, you may have a fast heartbeat, headache, upset stomach and/or feel dizzy or nauseous. If you have these symptoms, stop using the patch right away and call your doctor.

If you're getting too little nicotine, you may feel anxious, irritable, have difficulty concentrating, feel strong cravings, experience insomnia and/or have an increased appetite.

Do you have any medication that does not have nicotine?

Yes, bupropion and varenicline are two non-nicotine prescription medications that have been shown to be very effective in helping people quit. Bupropion is more effective when used in combination with the nicotine patch.

I need more help to stop. How can I get it?

Talk to your health care provider for additional counseling and medications. Call or visit the NYS Smokers' Quitline (nysmokefree.com) at 1-866-NY-QUITS (1-866-697-8487) for quit coaching support and resources. In NYC, you can also call 311 to find guit smoking programs or visit NYC Quits, an online resource for smokers and recent quitters.

Note: Zyban* and Wellbuttin* are resistered trademarks of Glass/smithKine. Chaotis* is a resistered trademark of Pizze Inc. The use of brand names does not imply endorsement of any product by the

New York City Department of Health and Mental Hypigene or the New York City State Department of Health, Please county person their join formation for complete usage and safety information. To report SUSPECTED ADVERSE REACTIONS, contact the manufacturer or the FDA at 1-800-FDA-1088 (1-800-332-1088) or <u>xnovafda.govimedowstch</u>.

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MEDITERAL TIT

DR. DANIEL CROFT, MD, MPH



NICOTINE REPLACEMENT THERAPY

- Safe and Effective!
- Evidence shows NRT has <u>low risk</u> of side effects and interference with existing medications.

Adverse effects with use of nicotine replacement therapy among quitline clients <u>Nicotine & Tobacco Research</u>, Volume 11, Number 4 (April 2009) 408–417

"The majority of adverse effects reported were rated as mild, and only 4.4% – 5.4% of subjects (across the 2-week and 3-month follow-ups) reported discontinuation of NRT as a result of adverse effects."

Always use NRT as directed and use a full course; connect to a health plan for more supply.

FDA-APPROVED NRT & STOP-SMOKING MEDICATIONS



AFTER ENSURING READINESS...



"I'm prescribing a patch to help you quit smoking. Wear it over your mouth."

FDA-APPROVED NRT & STOP-SMOKING MEDICATIONS



COST AND ACCESS

- Especially with the cost of healthcare for chronic conditions, over time, quitting smoking is still less expensive than smoking.
- Tobacco users have access to free and reduced-cost resources:
 - ✓ Health plans
 - Quitlines
 - ✓ Discount coupons
 - ✓ Generic versions of medications



NICOTINE PATCH

- Delivers a continuous supply of nicotine all day
- Slow-release product
- Typically in 21 mg, 14 mg, and 7 mg;
 1 mg equates to 1 cigarette
- Typically used for 8 to 12 weeks
- Place above the waist, preferably on the chest, back, shoulder, or upper arm
- Apply to clean, smooth skin in the morning

NICOTINE GUM

- Use as needed; should last about 20 to 30 minutes
- Fact-acting product
- Typically in 4 mg or 2 mg;
 much thicker than typical chewing gum
- Typically used for 8 to 12 weeks;
 but should be weaned after 4 to 6 weeks
- Chew a few times, then park it along the cheek;
 nicotine will be released and slowly absorbed
- Use 1 piece per hour at the 4 mg level



NICOTINE LOZENGE

- Use as needed; should last about 20 to 30 minutes
- Fact-acting product
- Typically in 4 mg or 2 mg;
 has 25% more nicotine than gum
- Typically used for 8 to 12 weeks;
 but should be weaned after 4 to 6 weeks
- Dissolve slowly in the mouth
- 4 mg for smokers who smoke immediately upon waking;
 recommended not to use more than 20 lozenges a day



NICOTINE INHALER

- Use as needed throughout the day; mimics a cigarette
- A typical cartridge equates to 2 cigarettes;
 about 6 to 16 cartridges can be used per day
- Typically used for up to 6 months;
 but should be weaned after 4 to 6 weeks
- Puff gently, up to 80 puffs per cartridge
- Requires a prescription



NICOTINE NASAL SPRAY

- Use as needed throughout the day
- Use 1 to 2 sprays in each nostril per hour;
 nicotine gets into the system very fast
- 1 dose equates to 1 spray per nostril;
 maximum 40 doses per day = pack of cigarettes
- Typically used for up to 6 months;
 but should be weaned after 4 to 6 weeks
- Pump the bottle, then tilt head back and spray
- Requires a prescription



FDA-APPROVED STOP-SMOKING MEDICATION

VARENICLINE

- Non-nicotine pill form of smoking cessation
- Reduces cravings by fooling receptors in the brain
- Start 1 week before quit-date
- 0.5 mg a day for three days; then 0.5 mg twice daily (AM and PM) for four days; then 1 mg twice a day



- Typically used for 6 months
- Requires a prescription

FDA-APPROVED STOP SMOKING MEDICATION

BUPROPION

- Non-nicotine pill form of smoking cessation
- Also doubles as an anti-depressant
- Start 1 to 2 weeks before quit-date
- 150 mg per day for three days, then twice daily;
 or take 300 mg once a day
- Never double dose
- Typically used for 3 to 6 months
- Requires a prescription

NICOTINE PATCH

- Rash / skin reaction
 - Be sure to rotate location daily
 - Press and hold firmly for 10 seconds when applying; avoid moisturizers
- Insomnia or vivid dreams
- Mild headache
- Overall, side effects tend to be minimal and not severe



NICOTINE GUM

- Hiccups
- Dizziness
- Indigestion
- Heartburn
- Mouth irritation
- Sore jaw / throat
- Overall, side effects tend to be minimal and not severe



NICOTINE LOZENGE

- Indigestion
- Heartburn
- Diarrhea
- Mouth and throat irritation
- Sore jaw
- Possible hiccups
- Do not eat or drink for 15 to 30 minutes prior to use or during use; do not chew, break, or crush it
- Side effects are still generally rare/minimal



NICOTINE INHALER

- Irritation of throat and nasal passages
- Coughing
- Inflammation of mouth and lips
- Side effects are typically rare/minimal and generally caused by inappropriate use



NICOTINE NASAL SPRAY

- Sneezing
- Cough
- Teary eyes
- Nasal irritation
- Not recommended for those with chronic nasal disease (nasal polyps, sinusitis)
- Wait 2 to 3 minutes before blowing nose



VARENICLINE

- Nicotine toxicity
- Nausea
- Jitteriness
- Insomnia or vivid dreams
- Possible negative interaction with psychiatric medications
- Contraindication: hypersensitivity / skin reactions
- <u>OASAS</u>: Proven to be safe and without serious adverse events or exacerbation of psychiatric symptoms, both in general and for patients with severe mental illness



BUPROPION

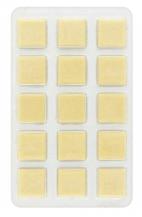
- Possible negative interaction with psychiatric medications
- Anxiety or mood changes
- Headaches
- Dry mouth
- Insomnia or vivid dreams
 - Take the PM dose earlier in the evening
- Be sure to monitor blood pressure
- Contraindications: seizure disorder, eating disorder, alcohol dependence, head trauma



CONTRAINDICATIONS

- Heart attack within two weeks
- Unstable angina
- Serious cardiac arrhythmia



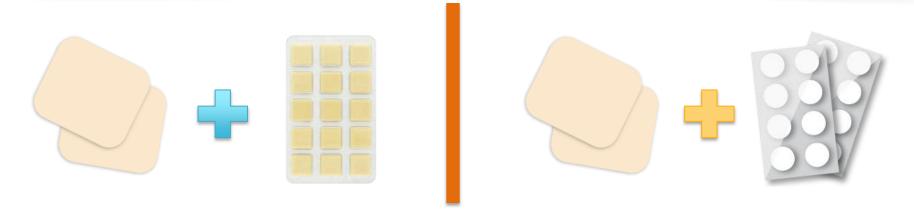








COMBINATION THERAPY

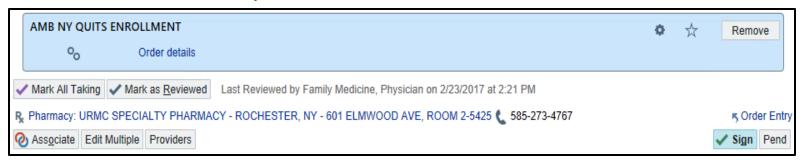


Most research studies show combination therapy can <u>double the odds</u>* for helping a tobacco user quit, compared to using just one NRT product!

* Rigotti, Nancy A MD. "Pharmacotherapy for smoking cessation in adults." <u>UpToDate</u>. 22 December 2017. Web. 21 February 2019.

ELECTRONIC REFERRAL TO THE QUITLINE

- Type smoking in the order box
- Ordering should take 6 seconds or less
 - Consent box is already checked, just 'Alt-A' it
- The patient's phone number and name are automatically sent to the Quitline (will be called in 2-3 days)
- No additional steps by your clinic team are necessary.
- Line added automatically to the AVS: 'You were referred to NYSSQL'







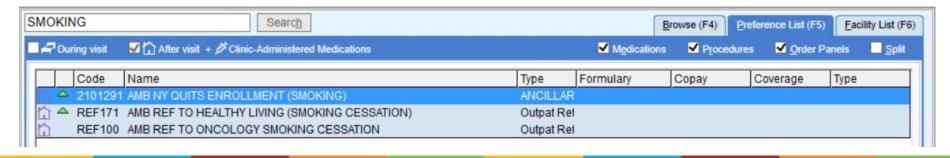
REFERRAL TYPE

- 'Connecting' patients to Quitline is key
- 'Passive' referral is less effective
- 7.8% of all identified smokers enrolled in treatment versus 0.6% in AAR

Vidrine, J. I., (2013). JAMA Internal Medicine, 173(6), 458-464.

URMC SMOKING CESSATION RESOURCES

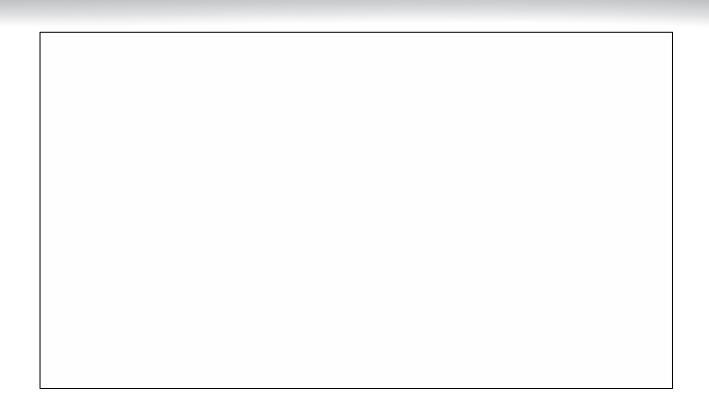
- Healthy Living Center: Geoffrey Williams MD/PhD
- Wilmot Cancer Center: Chunkit Fung MD
- Inpatient smoking cessation: John Grable MD/PhD
- Research team:
 Scott McIntosh PhD, Deborah Ossip PhD, et al.



A NOTE ON ENDS

- Electronic nicotine delivery systems (ENDS)
 are not FDA-approved for smoking cessation
- Fewer toxins ≠ Safe
- Reserved as last resort for 'switching'
- Inflammatory and immune effects in cells
 - Lung, Heart, Vessels
- Short/Long term effects being studied

MOCK CALL



QUESTIONS?



CONTACT US ANYTIME!

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