



# TOBACCO PREVENTION AND CESSATION UPDATES

---

KAYLA HSU, MPH, CHES<sup>®</sup>, NCTTP

KMHSU@IU.EDU

COMMUNITY OUTREACH MANAGER

[WWW.RETHINKTOBACCOINDIANA.ORG](http://WWW.RETHINKTOBACCOINDIANA.ORG)

# CDC OFFICE ON SMOKING & HEALTH: 2019 – YEAR OF CESSATION!

Q1

FOCUS: People who smoke and quit attempts

OPPORTUNITY: New Year's Resolutions

Q2

FOCUS: Health conditions improved by quitting; Health systems

OPPORTUNITY: Launch of 2019 *Tips From Former Smokers*<sup>®</sup> Campaign

Q3

FOCUS: Quitlines; Cessation interventions; Linkage with broader tobacco control policies

OPPORTUNITY: National Conference on Tobacco or Health

Q4

FOCUS: Clinicians and real-world use of evidence-based cessation interventions

OPPORTUNITIES: Great American Smokeout<sup>®</sup>; Pharmacy Month; Health Literacy Month



# Prevalence of Tobacco Use in Behavioral Health Populations

- Nicotine dependence most prevalent substance use disorder among persons with behavioral health conditions.
- Adults living with behavioral health conditions:
  - Smoke more cigarettes/month than persons without such conditions (326 vs. 284)
  - Almost 40% of all cigarettes are smoked by people with BH conditions.
  - Account for nearly half of 480,000 annual tobacco-related deaths in U.S.

# PHS: Clinical Practice Guidelines

Treating  
Tobacco Use  
And  
Dependence

U.S. Department of  
Health and Human Services  
Public Health Service

The *Clinical Practice Guidelines for Treating Tobacco Use and Dependence* (updated) strongly recommend the *combination use* of:

- Medication treatments **and**
- Tobacco dependence counseling
- The combination of medication and counseling are more effective than either alone.
- Tobacco dependence treatments are both clinically and cost-effective.

# Why Behavioral Health Providers?



- Often the clinician for whom contact is the most frequent and who knows the patient best.
- Able to combine psychopharmacological and behavioral/counseling treatment.
- Trained in substance abuse treatment.
- Trained in motivational interviewing.
- Able to identify and address any changes in psychiatric symptoms during the quit attempt.

# Indiana Medicaid Coverage

Indiana Health Coverage Programs (IHCP) offers tobacco dependence treatment, including pharmacotherapy and counseling services.

## 1. Tobacco dependence counseling services

- Up to 10 “units” of counseling per member / calendar year
  - One Unit = 15 mins
  - Minimum of 30 mins (two units) of counseling must be provided

## 2. Tobacco cessation drug treatment

- Up to 180 days per member / calendar year unless prior authorization obtained
- All seven FDA-approved treatment medications available on formulary

**UPDATES EFFECTIVE MARCH 1, 2019 – IHCP Bulletin BT201921**

# Tobacco Treatment Medications\*

## UPDATES – IHCP Bulletin BT201921

- Nicotine Gum
- Nicotine Lozenge
- Nicotine Patch
- Nicotine Nasal Spray
- Nicotine inhaler
- Bupropion SR (Zyban)
- Varenicline (Chantix)
  - ✓ May be used as first-line therapy
  - ✓ May be used in combination with other NRT

Combination NRT may be especially helpful for highly dependent smokers or those with a history of severe withdrawal.

**\*Patients must participate in smoking cessation counseling in order to receive prescriptions for cessation medications**

# Bupropion and Varenicline: Warnings and Precautions - 2009

- Neuropsychiatric symptoms and suicide risk
  - Changes in mood (including depression and mania)
  - Psychosis/hallucinations/paranoia/delusions
  - Homicidal ideation
  - Aggression/hostility/anxiety/panic
  - Suicidal ideation, suicide attempt, completed suicide

**FDA  
boxed  
warning  
removed  
December  
2016**

**Advise patients to stop taking bupropion SR and contact a health care provider immediately if symptoms such as agitation, depressed mood, or changes in behavior or thinking that are not typical are observed or if the patient develops suicidal ideation or suicidal behavior.**



# Neuropsychiatric safety and efficacy of varenicline, bupropion, and nicotine patch in smokers with and without psychiatric disorders (EAGLES): a double-blind, randomised, placebo-controlled clinical trial



Robert M Anthenelli, Neal L Benowitz, Robert West, Lisa St Aubin, Thomas McRae, David Lawrence, John Ascher, Cristina Russ, Alok Krishen, A Eden Evins

## Summary

**Background** Substantial concerns have been raised about the neuropsychiatric safety of the smoking cessation medications varenicline and bupropion. Their efficacy relative to nicotine patch largely relies on indirect comparisons, and there is limited information on safety and efficacy in smokers with psychiatric disorders. We compared the relative neuropsychiatric safety risk and efficacy of varenicline and bupropion with nicotine patch and placebo in smokers with and without psychiatric disorders.

**Methods** We did a randomised, double-blind, triple-dummy, placebo-controlled and active-controlled (nicotine patch; 21 mg per day with taper) trial of varenicline (1 mg twice a day) and bupropion (150 mg twice a day) for 12 weeks with 12-week non-treatment follow-up done at 140 centres (clinical trial centres, academic centres, and outpatient clinics) in 16 countries between Nov 30, 2011, and Jan 13, 2015. Participants were motivated-to-quit smokers with and without psychiatric disorders who received brief cessation counselling at each visit. Randomisation

*Lancet* 2016; 387: 2507–20

Published Online

April 22, 2016

[http://dx.doi.org/10.1016/S0140-6736\(16\)30272-0](http://dx.doi.org/10.1016/S0140-6736(16)30272-0)

See [Comment](#) page 2481

University of California,  
San Diego, CA, USA

(Prof R M Anthenelli MD);  
University of California,  
San Francisco, CA, USA

(Prof N L Benowitz MD);  
University College, London, UK

# Bupropion and Varenicline: Safety Update

## EAGLES Study –FDA-mandated clinical trial

24-week, double-blind, randomized; active and placebo-controlled:

- Varenicline: standard dosing, 12 wks
- Bupropion SR: standard dosing, 12 wks
- Nicotine patch: 21 mg/day with standard taper, 12 wks
- Placebo, 12 wks
- All treatment arms: 13 counseling visits, 11 telephone calls

Follow-up through 24 wks; outcome = continuous abstinence

# Bupropion and Varenicline: Safety Update (cont'd)

## Incidence of Moderate or Severe Neuropsychiatric Adverse Events

Patient cohort	Varenicline	Bupropion SR	Nicotine patch	Placebo
Non-psychiatric	1.3%	2.2%	2.5%	2.4%
Psychiatric	6.5%	6.7%	5.2%	4.9%

**No significant differences in neuropsychiatric events by treatment arm**

# Treatment Arms: Efficacy, weeks 9-24

## Continuous abstinence (95% confidence interval)

Patient cohort	Varenicline	Bupropion SR	Nicotine patch	Placebo
Non-psychiatric	25% (23–28)	19% (16–21)	18% (16–21)	11% (9–13)
Psychiatric	18% (16–21)	14% (12–16)	13% (11–15)	8% (7–10)

**Highest efficacy with varenicline**

**Drugs**

Home > Drugs > Drug Safety and Availability

<b>Drug Safety and Availability</b>	
Drug Alerts and Statements	
Medication Guides	
Drug Safety Communications	
Drug Shortages	▼
Postmarket Drug Safety Information for Patients and Providers	▼
Information by Drug Class	
Medication Errors	
Drug Safety Podcasts	▼
Safe Use Initiative	▼
Drug Recalls	
Drug Supply Chain Integrity	▼

# FDA Drug Safety Communication: FDA revises description of mental health side effects of the stop-smoking medicines Chantix (varenicline) and Zyban (bupropion) to reflect clinical trial findings

f SHARE | t TWEET | in LINKEDIN | p PIN IT | e EMAIL | p PRINT

This is an update to the [Drug Safety Communication](#) issued on March 9, 2015.

## Safety Announcement

**[12-16-2016]** Based on a U.S. Food and Drug Administration (FDA) review of a large clinical trial that we required the drug companies to conduct,<sup>1</sup> we have determined the risk of serious side effects on mood, behavior, or thinking with the stop-smoking medicines Chantix (varenicline) and Zyban (bupropion)<sup>\*</sup> is lower than previously suspected. The risk of these mental health side effects is still present, especially in those currently being treated for mental illnesses such as depression, anxiety disorders, or schizophrenia, or who have been treated for mental illnesses in the past. However, most people who had these side effects did not have serious consequences such as hospitalization. The results of the trial confirm that the benefits of stopping smoking outweigh the risks of these medicines.

As a result of our review of the large clinical trial, we are removing the *Boxed Warning*, FDA's most prominent warning, for serious mental health side effects from the Chantix drug label. The language describing the serious mental health side effects seen in patients quitting smoking will also be removed from the *Boxed Warning* in the Zyban label.<sup>†</sup> We are also updating the existing warning section in both labels that describes the side effects on mood, behavior, or thinking to include the results from the clinical trial. This decision is consistent with the recommendations of external experts at a September 2016 FDA Advisory

**FDA  
boxed  
warning  
removed  
December  
2016**



An abstract graphic on the left side of the page consists of several overlapping, semi-transparent blue circles and arcs of varying shades, creating a sense of depth and movement. The background is a solid, vibrant blue.

# QUITLINE UPDATES

---

UPDATES TO THE INDIANA TOBACCO QUITLINE

# Indiana's Tobacco Quitline



**1.800.QUIT.NOW**  
Indiana's Tobacco Quitline  
QuitNowIndiana.com



**QUIT COACH™**  
Specialized  
Training

**MEDICATION**  
Direct Mail NRT,

**WEB COACH™**  
Fully Integrated

**QUIT GUIDES**  
Stage Based

**FREE** and **CONFIDENTIAL** telephone-based counseling service to help Indiana tobacco users quit with a professional Quit Coach®.

Programs by Population	PLUS the Following:
4 Prearranged calls for Adults	<ul style="list-style-type: none"> <li>▪ Unlimited call-ins to the ITQL</li> <li>▪ Text messages to connect with Quit Coach</li> <li>▪ Free nicotine replacement therapy (NRT) products (patch, gum, or lozenge), if eligible.</li> <li>▪ Access to online tools, videos, and educational materials on <a href="http://www.QuitNowIndiana.com" style="color: green;">www.QuitNowIndiana.com</a></li> </ul>
5 Prearranged calls for Youth	
10 Prearranged calls for Pregnant Women	

NEW

# Behavioral Health Program

  
**1.800.QUIT.NOW**  
Indiana's Tobacco Quitline  
QuitNowIndiana.com

Behavioral Health Program includes:

Programs by Population	PLUS the Following:
<p><b>7</b> Prearranged calls with Quit Coach for Behavioral Health consumers.</p> <p><i>Quit Coaches have received additional training on mental illness and tobacco cessation.</i></p>	<ul style="list-style-type: none"><li>▪ <b>Free 12-week regimen of <i>combination therapy</i> NRT (patch + gum or lozenge)</b></li><li>▪ <b>Letter sent to MH provider informing of quit attempt</b></li><li>▪ Unlimited call-ins to the ITQL</li><li>▪ Text messages to connect with Quit Coach</li><li>▪ Access to online tools, videos, and educational materials on <a href="http://www.QuitNowIndiana.com">www.QuitNowIndiana.com</a></li></ul>



# Tobacco Quitlines: Systematic Review

## Impact of Tobacco Quitlines on Smoking Cessation in Persons With Mental Illness: A Systematic Review

Rhonda Schwindt<sup>1</sup>,  
Karen Suchanek Hudmon<sup>2</sup>,  
Mitchell Knisely<sup>3</sup>, Lorie Davis<sup>4</sup> and  
Caitlin Pike<sup>5</sup>

### Abstract

Persons with mental illness smoke at rates two to four times higher than do persons without mental illness and comprise 30.9% of the U.S. tobacco market. Given the prevalence of mental illness and the known detrimental effects of tobacco, concerted efforts are needed to promote the use of evidence-based treatment options. We conducted a systematic review of studies that examined the impact of tobacco quitline interventions

Journal of Drug Education: Substance  
Abuse Research and Prevention  
0(0) 1–14  
© The Author(s) 2018  
Reprints and permissions:  
sagepub.com/journalsPermissions.nav  
DOI: 10.1177/0047237918762104  
journals.sagepub.com/home/dre



- N = 4 published studies (over period of 11 years)
- **Results:**
  - Positive impact of quitline counseling
  - Compared to usual care (telephone counseling alone), customized telephone counseling was significantly more likely to generate positive outcomes
  - Persons with co-occurring mental illness might respond more positively to a **multi-modal approach** to tobacco dependence treatment

# www.QuitNowIndiana.Com

- Access free educational resources
- Order free quitline materials (palm cards, brochures, posters, etc.)
- Join the Quit Now Indiana “Preferred Provider” Program
  - Direct referral privileges
  - Status reports on referred patients
  - Ongoing communications on the latest tobacco research and news



# Save the Date: TTS Core Training



RETHINK TOBACCO INDIANA PRESENTS



## UMASS TOBACCO TREATMENT SPECIALIST CORE TRAINING

**OCTOBER 8 - 11, 2019**

**9 AM - 4:30 PM CT**

SOUTHWESTERN BEHAVIORAL HEALTHCARE  
410 MULBERRY STREET, EVANSVILLE, INDIANA

*Registration cost and details to follow*

**Overview:** The TTS Core Training is an intensive four-day, in-person, evidence-based training program. The training is designed for persons who work with tobacco dependent clients or deliver tobacco treatment services within a healthcare or community setting. Completion of this training qualifies as the training requirement to apply for the National Certificate in Tobacco Treatment Practice.

**Target Audience:** Physicians, advance practice providers, mental health counselors, addiction counselors, nurses, social workers, pharmacists, respiratory therapists, peer recovery coaches, and other health care professionals who work with tobacco and nicotine users.

*This curriculum is developed by the University of Massachusetts Medical School and is accredited by the Council for Tobacco Treatment Training Programs.*



Questions? Contact Kayla Hsu at [kmhsu@iu.edu](mailto:kmhsu@iu.edu)

## Tobacco Treatment Specialist (TTS) Core Training

**October 8-11**

**9:00am-4:30pm**

**Evansville, IN**

***Registration to  
Open Soon!***



An abstract graphic on the left side of the page, consisting of several overlapping, semi-transparent blue circles and arcs of varying shades, creating a sense of depth and movement.

# QUESTIONS?

---

VISIT [WWW.RETHINKTOBACCOINDIANA.ORG](http://WWW.RETHINKTOBACCOINDIANA.ORG)  
FOR MORE INFORMATION.