Safe & Effective Pharmacological Tobacco Cessation Supports for Individuals with Behavioral Health Conditions

Presented by:
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Marc L. Steinberg, PhD
Jill M. Williams, MD
Trish Dooley Budsock, MA, LPC, CTTS

National Behavioral Health Network
For Tobacco & Cancer Control

Tuesday, November 28th, 2017, 2:00pm EDT

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Welcome!

Lea Simms

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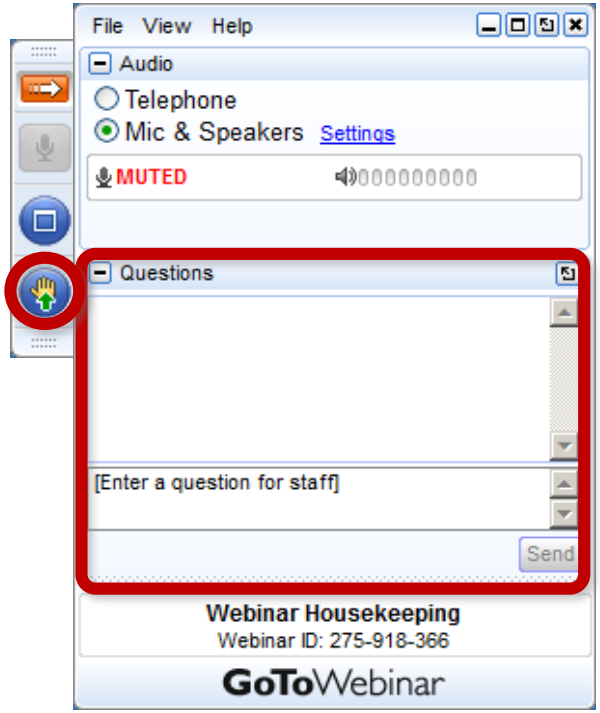

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National Behavioral Health Network
For Tobacco & Cancer Control

- Jointly funded by CDC's *Office on Smoking & Health* & *Division of Cancer Prevention & Control*
- Provides resources and tools to help organizations reduce tobacco use and cancer among people with mental illness and addictions
- 1 of 8 CDC National Networks to eliminate cancer and tobacco disparities in priority populations

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Special thanks to our webinar co-host!

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Today's Agenda

- Opening Remarks
- Tobacco Cessation Counseling for Behavioral Health Population
- Utilizing Pharmacotherapy for Tobacco Cessation for Behavioral Health Population
- Provider experience: Providing Treatment to Clients with Psychiatric Conditions
- Moderated Q&A

Opening Remarks

Anita Everett, MD, DFAPA

- Chief Medical Officer, Substance Abuse and Mental Health Services Administration (SAMHSA)
- Long-term community psychiatrist
- Formerly served as Division Director of Community Psychiatry Services at Johns Hopkins in Baltimore, MD

Substance Abuse and Mental Health Services Administration
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Guest Presenter #1

Marc L. Steinberg, PhD

- Clinical psychologist, and the Director of the Tobacco Research & Intervention lab
- Associate Professor of Psychiatry and Associate Director, Division of Addiction Psychiatry at Rutgers University-Robert Wood Johnson Medical School
- Member of the Motivational Interviewing Network of Trainers
- Actively serves on the Society for Research on Nicotine & Tobacco's (SRNT) Communications Committee and Advisory Committee
- Deputy Editor for the journal *Nicotine & Tobacco Research*

RUTGERS
Robert Wood Johnson Medical School

Tobacco Cessation Counseling for Behavioral Health Populations

Marc L. Steinberg, Ph.D.,

Associate Professor of Psychiatry

Director, Tobacco Research & Intervention lab

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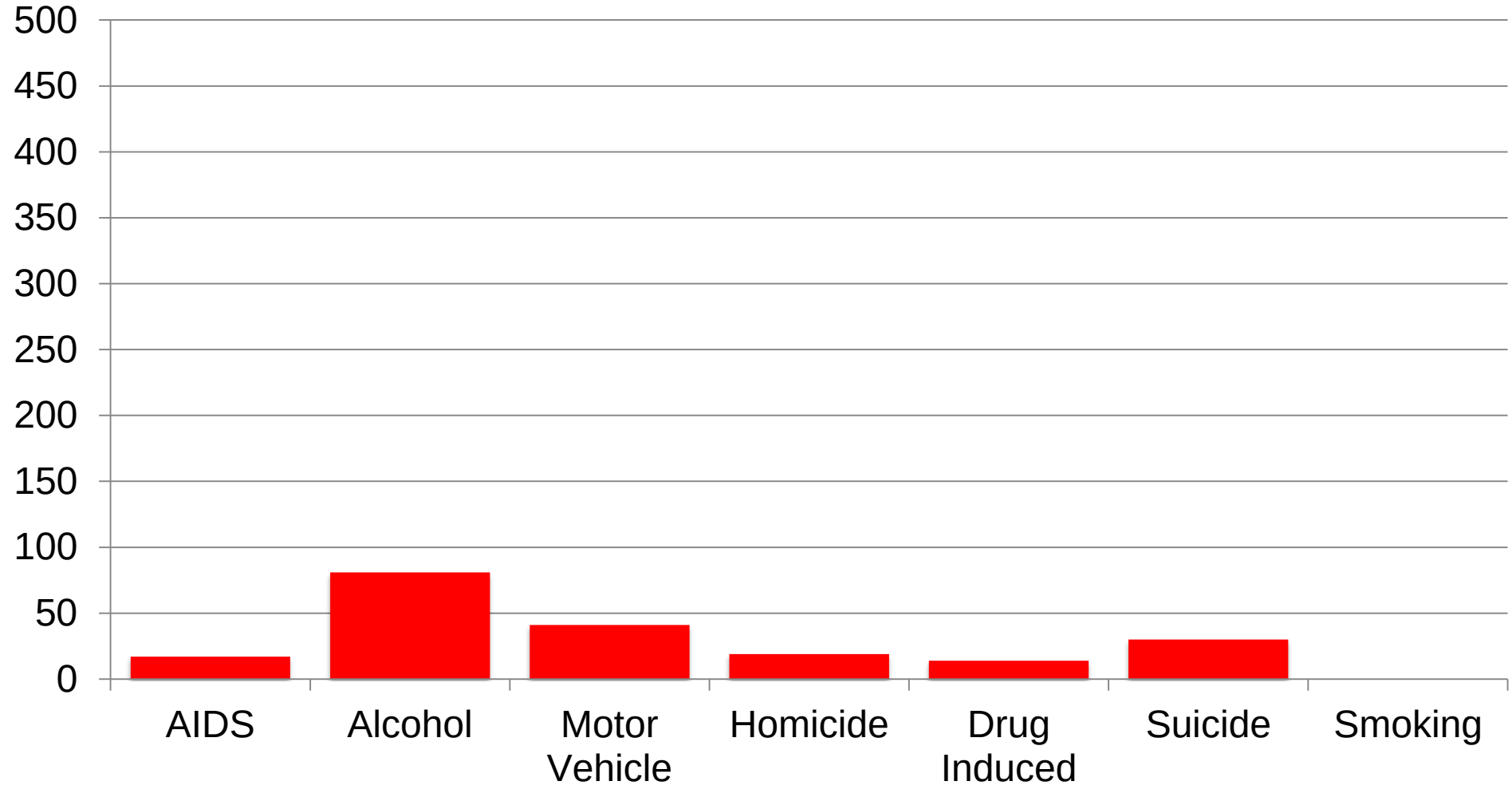
Comparative Causes of Annual Deaths in the U.S.

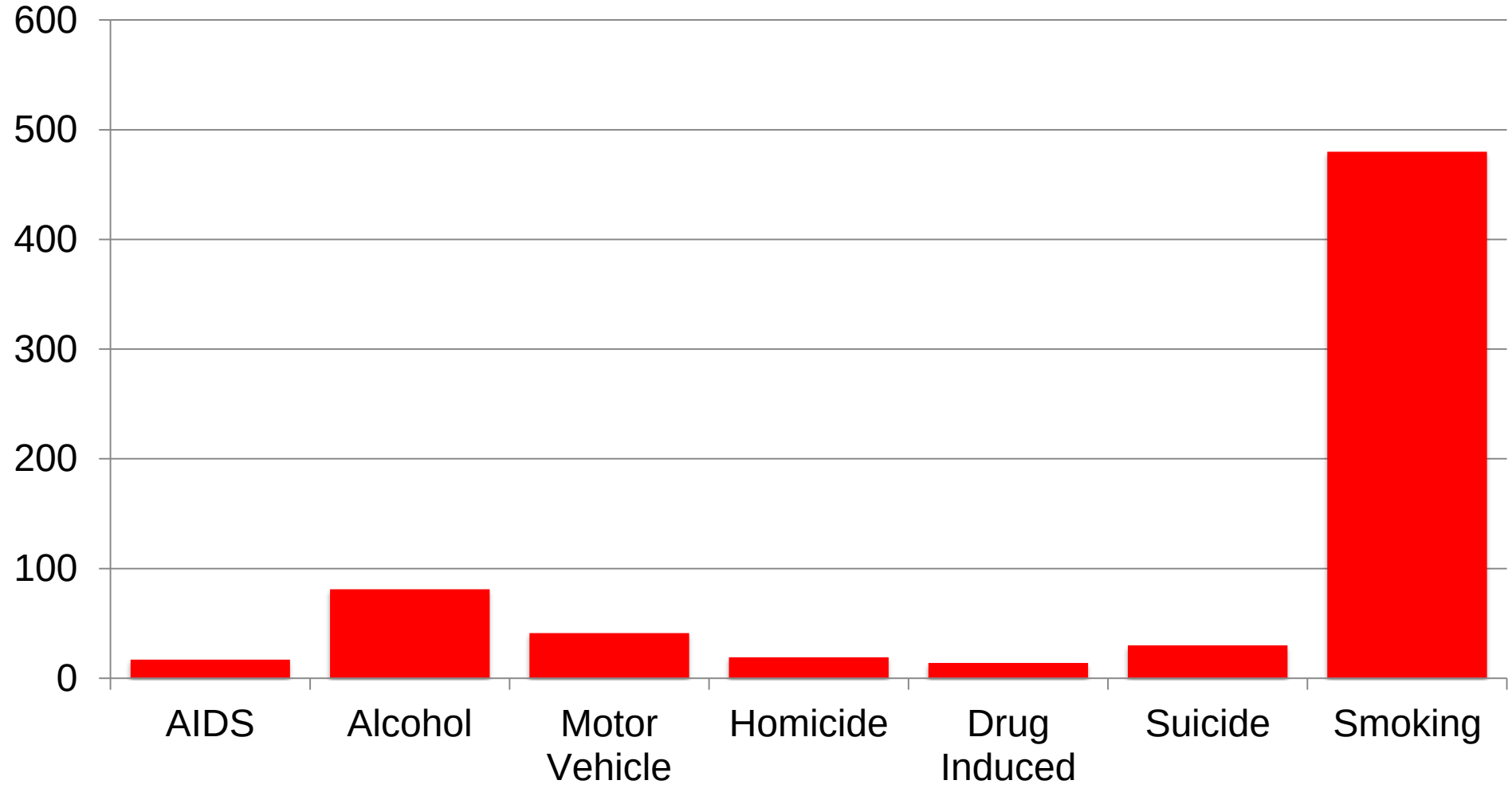
(In Thousands of Deaths)



Centers for Disease Control, Tobacco Information and Prevention Source (TIPS) 2000.

Comparative Causes of Annual Deaths in the U.S.

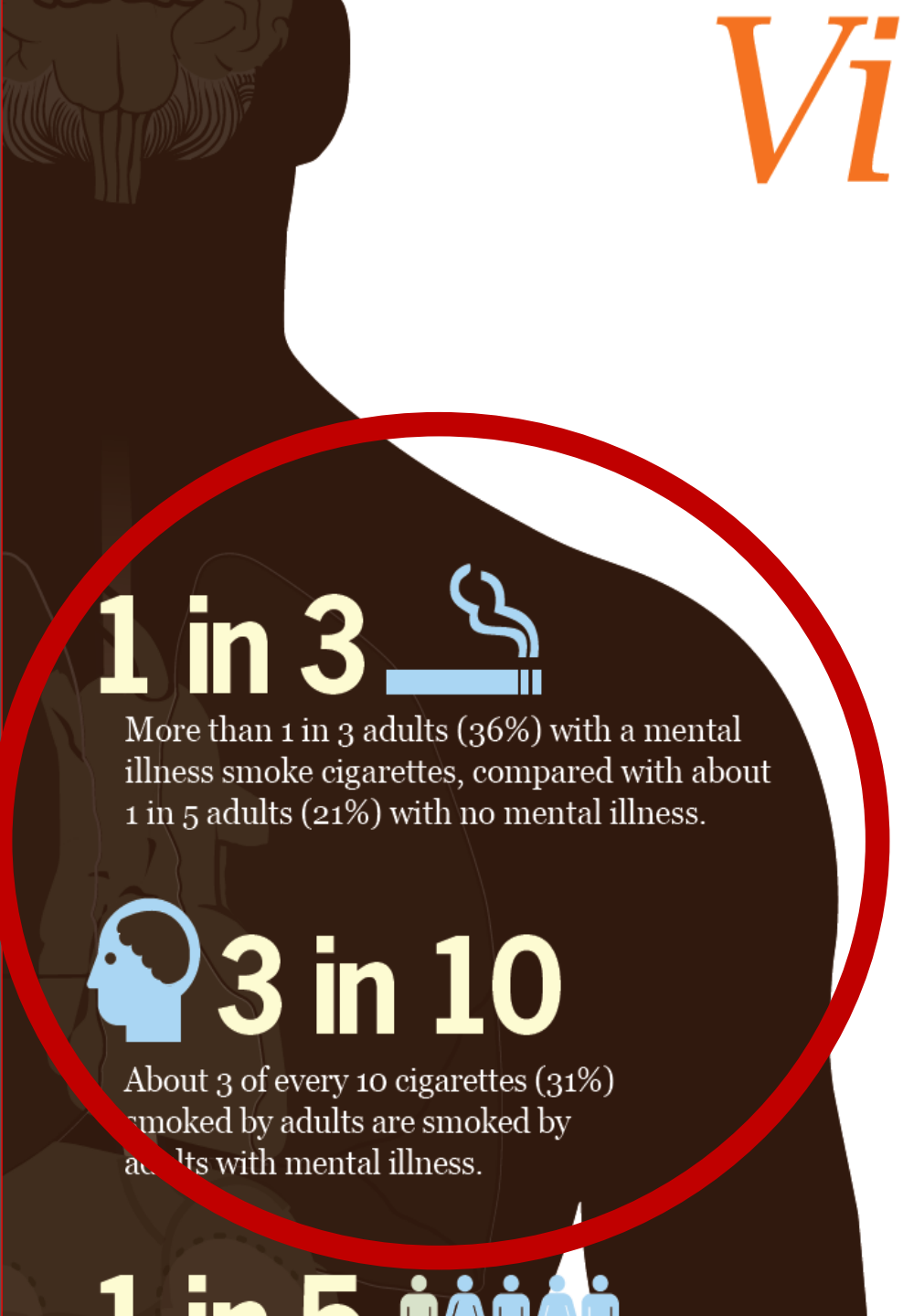
(In Thousands of Deaths)



Centers for Disease Control, Tobacco Information and Prevention Source (TIPS) 2000.

Smokers with mental illness?

CDC Vitalsigns™
February 2013



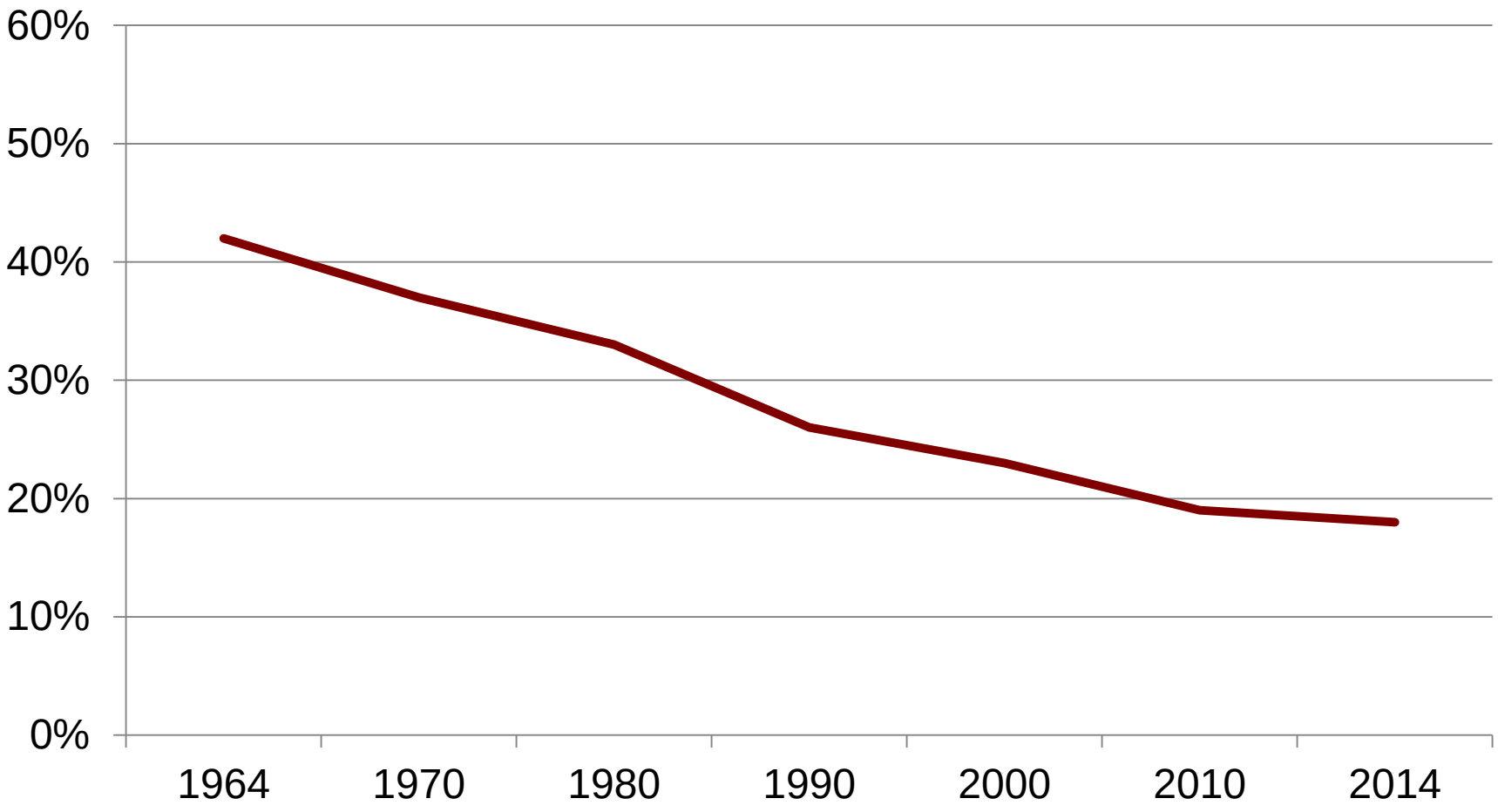
Adult Smoking

Focusing on People with Mental Illness

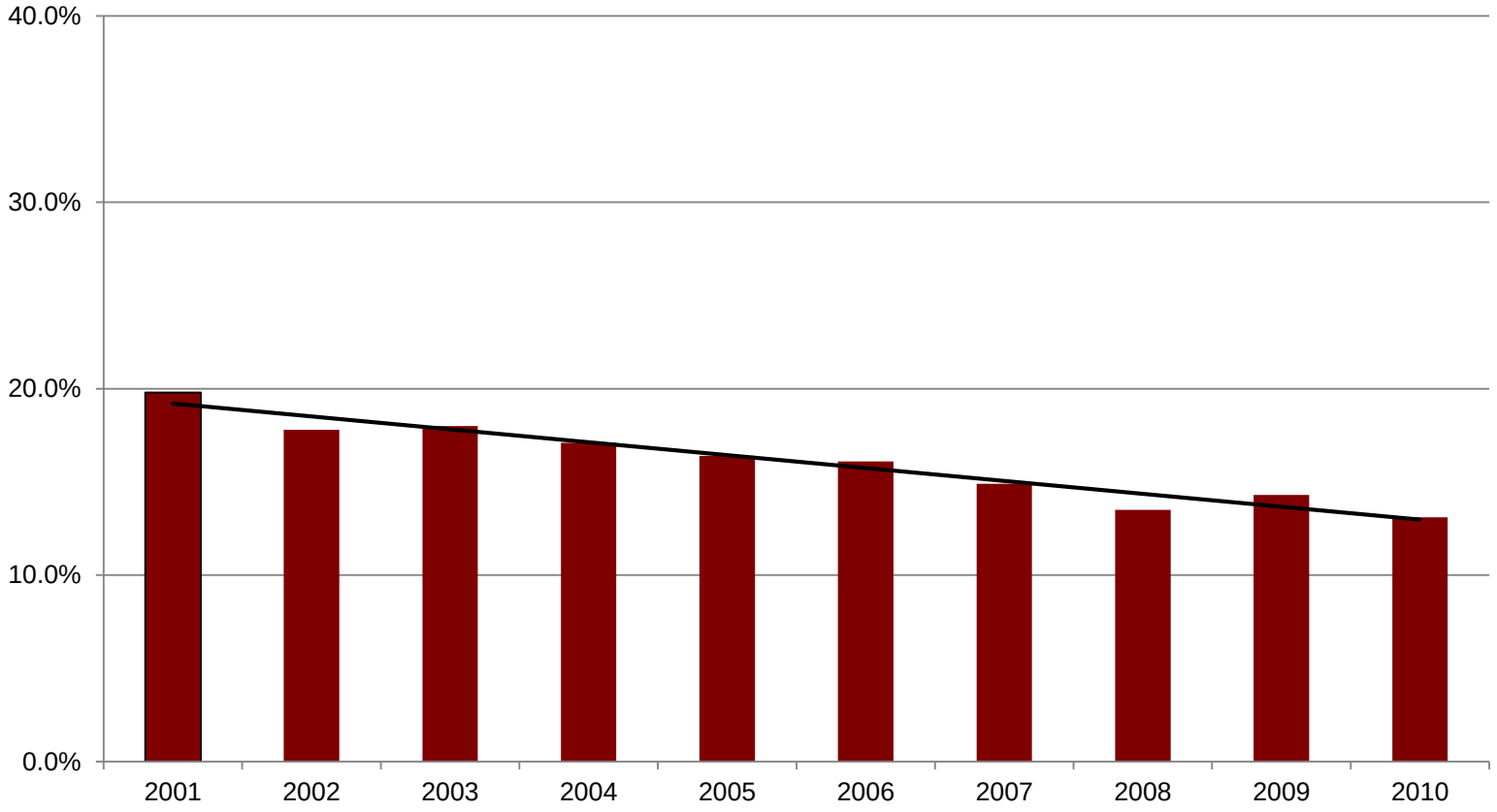
Cigarette smoking is the leading preventable cause of disease, disability, and death in the US. Despite overall declines in smoking, more people with mental illness smoke than people without mental illness. Because many people with mental illness smoke, many of them will get sick and die early from smoking.

Recent research has shown that, like other smokers, adults with mental illness who smoke want to quit, can quit, and benefit from proven stop-smoking treatments. Some mental health providers and facilities have made progress in this area, while others are now beginning to

Adult smoking prevalence in U.S.

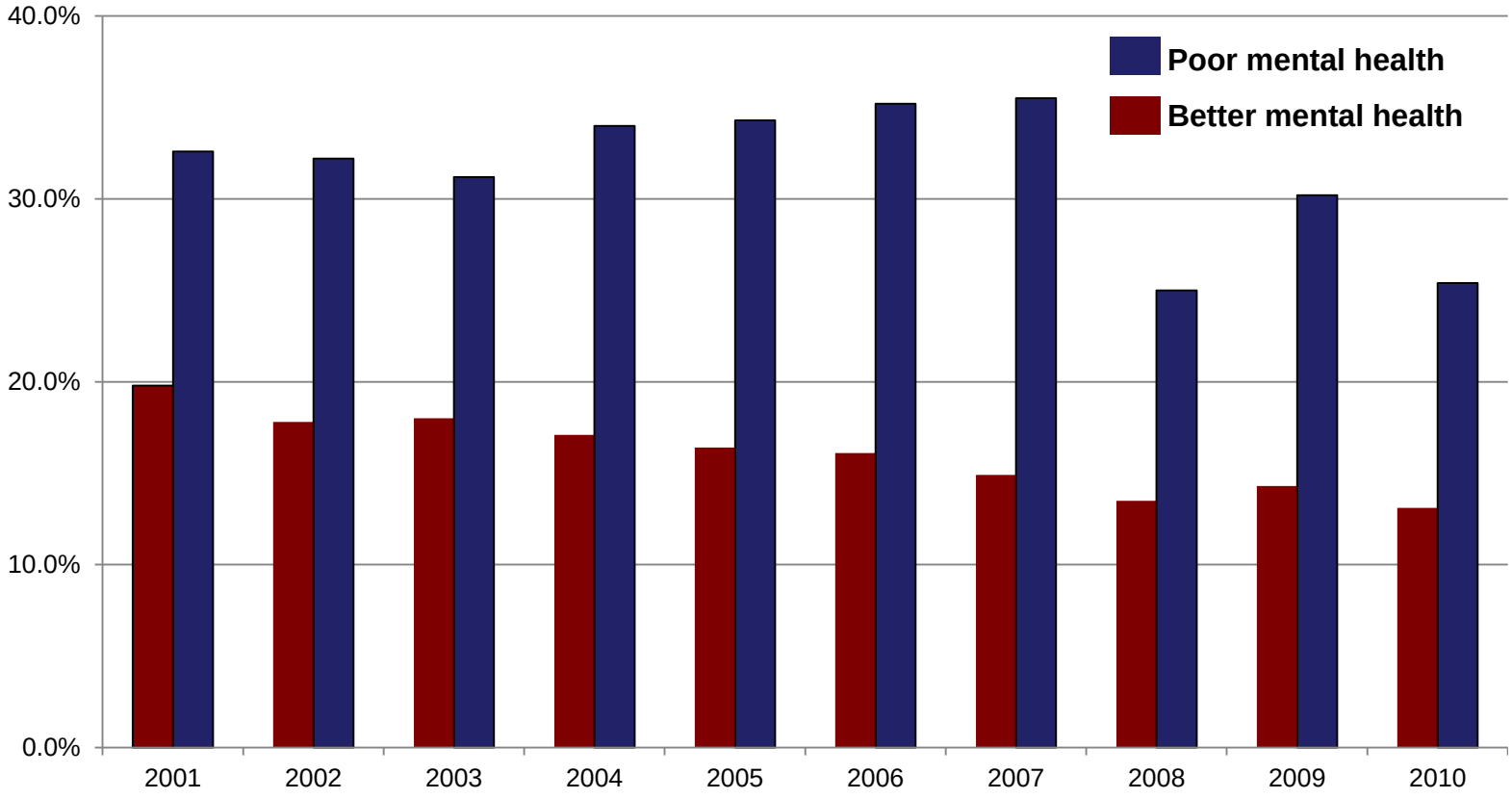


Smoking prevalence in New Jersey for those reporting good mental health 2001 – 2010



Steinberg ML, Williams JM, Li Y. Poor mental health and reduced decline in smoking prevalence. *Am J Prev Med*. 2015;49(3):362-369. doi:10.1016/j.amepre.2015.01.016

Smoking prevalence in New Jersey for those reporting good mental health 2001 – 2010



Greater smoking prevalence was found in those with poor mental health as compared to those without poor mental health, after adjusting for age, sex, race, income, and education (*OR* = 2.001 [95% CI: 1.836 – 2.181], p < 0.0001).

Steinberg ML**,** Williams JM, Li Y. Poor mental health and reduced decline in smoking prevalence. *Am J Prev Med*. 2015;49(3):362-369. doi:10.1016/j.amepre.2015.01.016

Need to Encourage Those In Behavioral Health to Quit

Steinberg ML, Ziedonis DM, Krejci JA, Brandon TH. (2004). Motivational Interviewing With Personalized Feedback: A Brief Intervention for Motivating Smokers With Schizophrenia To Seek Treatment for Tobacco Dependence. *Journal of Consulting & Clinical Psychology,* 72(4), 723-728.

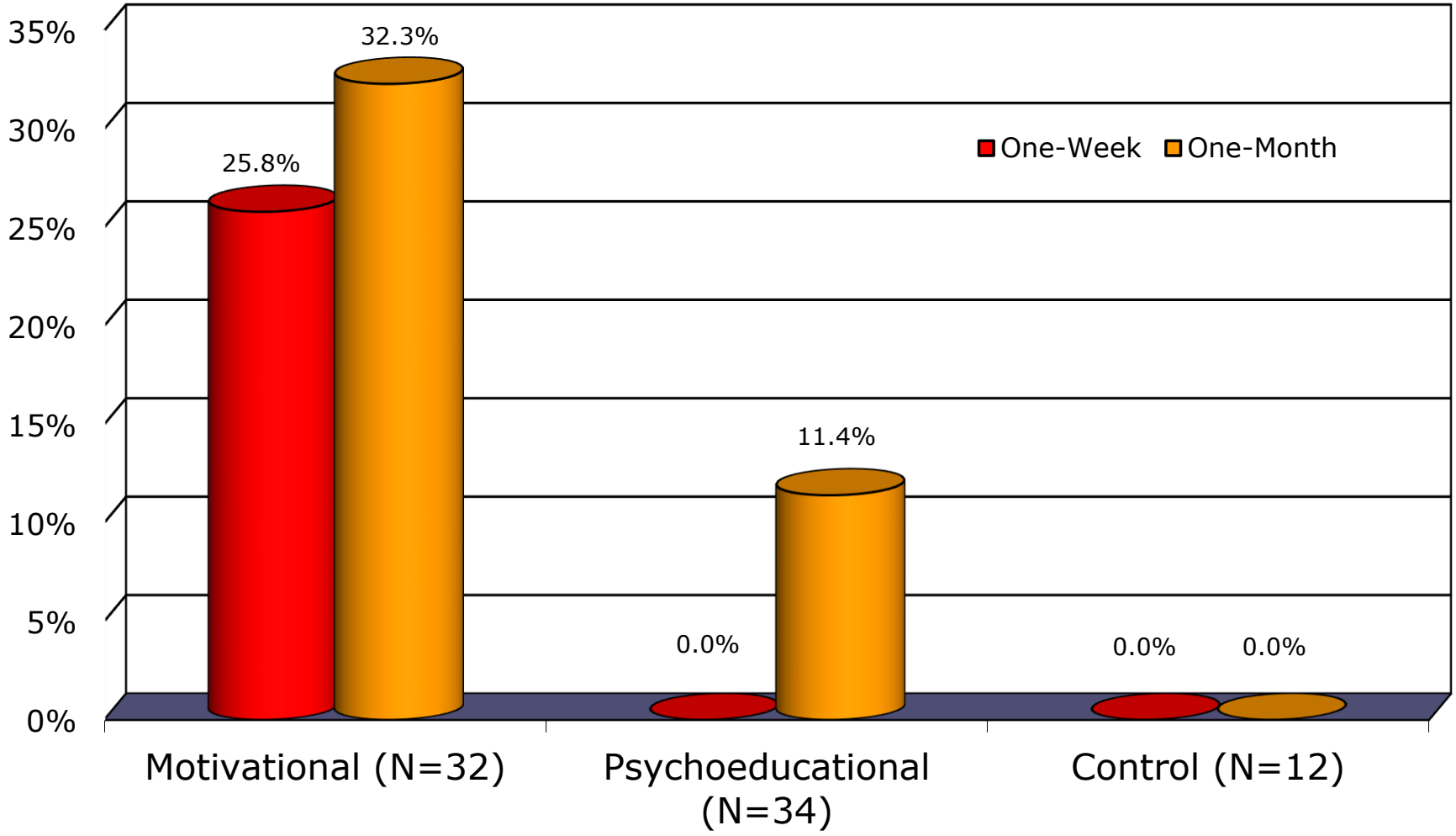
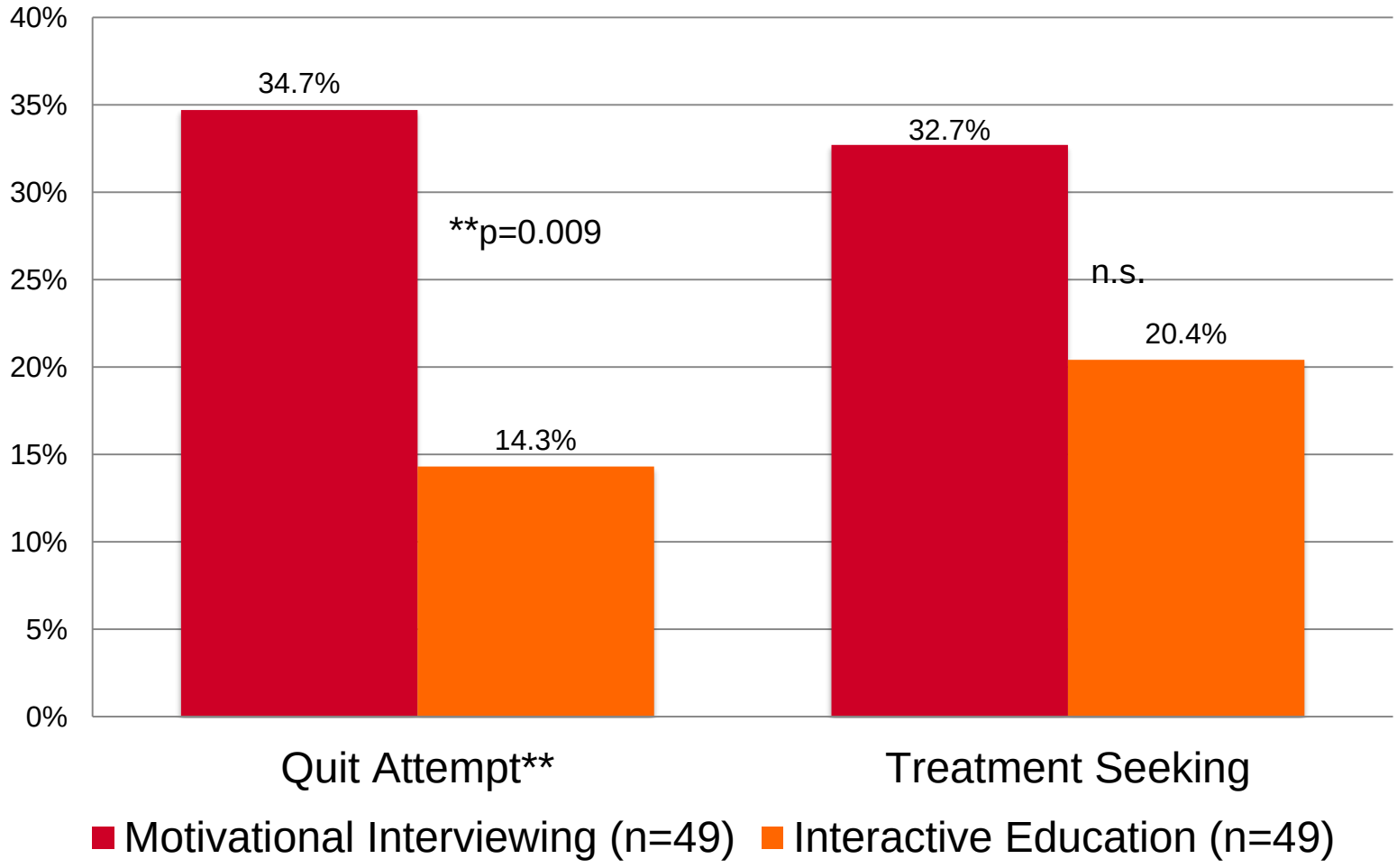


Figure 1. Percentage of participants receiving each intervention following up on referral to tobacco dependence treatment at one-week and one-month post-intervention

Motivational Interviewing produced more quit attempts, but not greater formal treatment seeking

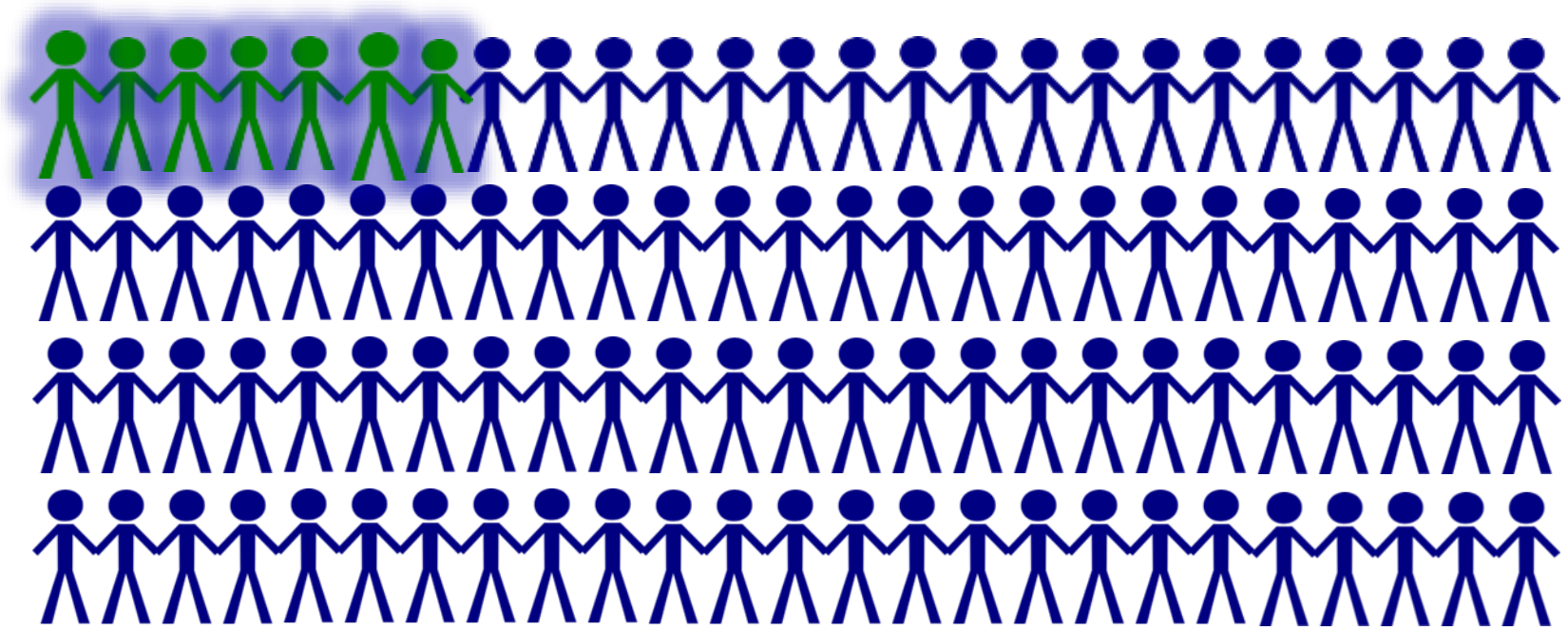


Steinberg ML, Williams JM, Stahl NF, Budsock PD, Cooperman NA. An adaptation of motivational interviewing increases quit attempts in smokers with serious mental illness. Nicotine & Tobacco Research, 8(3):243-250, 2016. doi: 10.1093/ntr/ntv043

Clinical Implications

- MI appears to be a better strategy than more commonly utilized techniques
- Indicates this population can benefit from brief interventions
- Should offer brief interventions to engage in treatment and initiate quit attempts

Only 6.8% of smokers making a 24-hour quit attempt receive any psychosocial treatment



Babb, Malarcher, Schauer, Asman, & Jamal, 2017

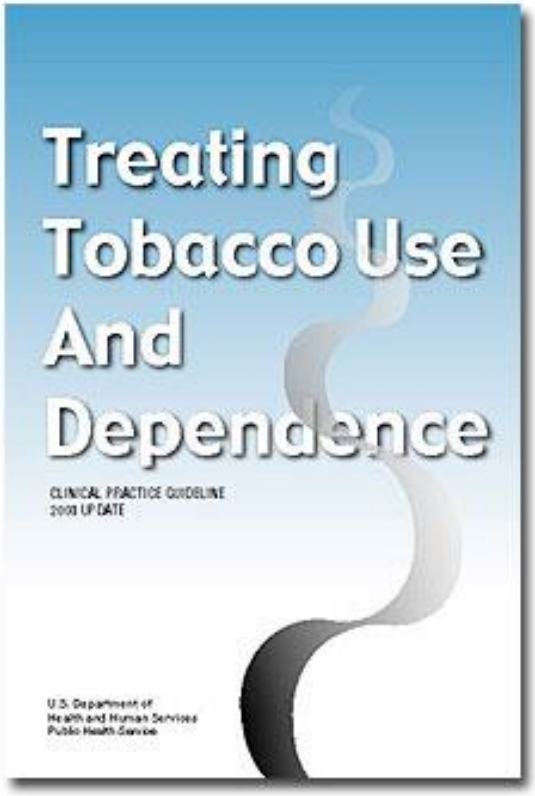
Psychosocial approaches

	Risk Ratio	95% CI	Sample Size	# of Studies
Group therapy vs. self-help only[4]	1.98	1.60 - 2.46	4,375	13
Individual Counseling vs. minimal contact control[5]	1.39	1.24 - 1.57	9,587	22
Physician advice to quit vs. No advice / Usual care[6]	1.76	1.58 – 1.95	22,240	26
Motivational Interviewing vs. Brief advice / Usual care[7]	1.27	1.14 - 1.42	10,538	14
Proactive phone counseling (multi-session) vs. self-help or brief counseling[8]	1.37	1.16 – 1.50	24,904	9

4. Stead LF, Lancaster T. Group behaviour therapy programmes for smoking cessation. Cochrane Database of Systematic Reviews 2005, Issue 2. Art. No.: CD001007.
5. Lancaster T, Stead LF. Individual behavioural counselling for smoking cessation. Cochrane Database of Systematic Reviews 2005, Issue 2. Art. No.: CD001292.
6. Stead LF, Bergson G, Lancaster T. Physician advice for smoking cessation. Cochrane Database of Systematic Reviews 2008, Issue 2. Art. No.: CD000165.
7. Lai DTC, Cahill K, Qin Y, Tang JL. Motivational interviewing for smoking cessation. Cochrane Database of Systematic Reviews 2010, Issue 1. Art. No.: CD006936.
8. Stead LF, Perera R, Lancaster T. Telephone counselling for smoking cessation. Cochrane Database of Systematic Reviews 2006, Issue 3. Art. No.: CD002850. DOI: 10.1002/14651858.CD002850.pub2.

Empirical Evidence:
Specific Psychosocial components

- Supportive Treatments
- Practical Counseling



Fiore MC, Jaen CR, Baker TB, et al. *Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline. Rockville, MD: U.S. Department* of Health and Human Services. Public Health Service. May 2008.

Supportive Treatment

- Encourage
- Communicate caring / concern
- Discuss quitting process

Practical Counseling

- Recognize high-risk situations
- Provide basic information about treatment
  - Quit date preparation

Behavioral Health providers have the required skill set

- You already help your patients with:
  - Problem-solving
  - Coping with difficult situations / emotions
  - Social skills training
  - Making better choices
  - Avoiding high risk situations

Unique Issues for Smokers with Mental Illness: Psychiatric Symptoms

- Assess patient concerns about smoking and their symptoms
- Dispel common myths
- Teach alternate coping skills
- Collaborate with treatment team

Unique Issues for Smokers with Mental Illness: Social Skills

- Drug refusal
- Problem solving
  - Reduce anger
  - Facilitate conversations
- Asking for social support
- Letting family / friends know they are quitting
  - Avoid “Happy Birthday! Here’s a carton of cigarettes”

Unique Issues for Smokers with Mental Illness: Cognitive Limitations

- Take extra time when warranted
- Use repetition
- Assess understanding of topics
- Enhance self-efficacy
  - Cognitive limitations may inflate OR deflate self-efficacy

Unique Issues for Smokers with Mental Illness: Therapeutic Alliance

- Show empathy – quitting is hard!
- Use Engaging skills of Motivational Interviewing

Unique Issues for Smokers with Mental Illness: Lower task persistence

- Behavioral manifestation of distress tolerance
- Continuing to work towards a difficult or effortful goal
- Need to teach skills related to ability to tolerate distress

Why Smokers with Mental Illness?

- High smoking prevalence
- Less likely to quit
- Devastating, and unique consequences
- Behavioral health professionals have the skills to help!

Guest Presenter #2

Jill M. Williams, MD

- Professor of Psychiatry & Director, Division of Addiction Psychiatry, Rutgers University-Robert Wood Johnson Medical School
- Faculty appointments at Cancer Institute of NJ and Rutgers Center for Alcohol Studies
- Board Certified in addiction psychiatry and member of the APA Council on Addictions
- Co-founder of CHOICES Program (Consumers Helping Others Improve their Condition by Ending Smoking)
- Started this work as clinical researcher, conducting clinical trials & human laboratory studies to improve smoking cessation rates in smokers with SMI

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Safe and Effective Pharmacological Tobacco Cessation Supports for Individuals with Behavioral Health Conditions

Pharmacology

Jill Williams, MD

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Disclosures

- Grant Support from Pfizer
- Consultant Pfizer
- Grant support from NIDA, NJDMHAS, ABPN, NYC DOHMH
- Consultant and Speaker for American Lung Association

Smoking is a Social Justice Issue

www.thetruth.com

Improved Mental Health with Quitting Smoking

- Meta-analysis 26 studies (14 gen pop, 4 psychiatric, 3 physical conditions, 2 psychiatric or physical, 2 pregnant, 1 post-op)

Table 1| Effect of smoking cessation on mental health. Sensitivity analysis after removal of studies of low quality (medium-l Newcastle-Ottawa scale)

Outcome	No of studies included	No of studies excluded	Standardised mean difference (95% CI)	
			Effect estimate	Original effect estimate
Anxiety	4	0	−0.37 (−0.70 to −0.03)	−0.37 (−0.70 to −0.03)
Depression	9	1	−0.29 (−0.42 to −0.15)	−0.25 (−0.37 to −0.12)
Mixed anxiety and depression	4	1	−0.36 (−0.58 to −0.14)	−0.31 (−0.47 to −0.14)
Psychological quality of life	4	4	0.17 (−0.02 to 0.35)	0.22 (0.09 to 0.36)
Positive affect	1	2	0.68 (0.24 to 1.12)	0.40 (0.09 to 0.71)
Stress	2	1	−0.23 (−0.39 to −0.07)	−0.27 (−0.40 to −0.13)

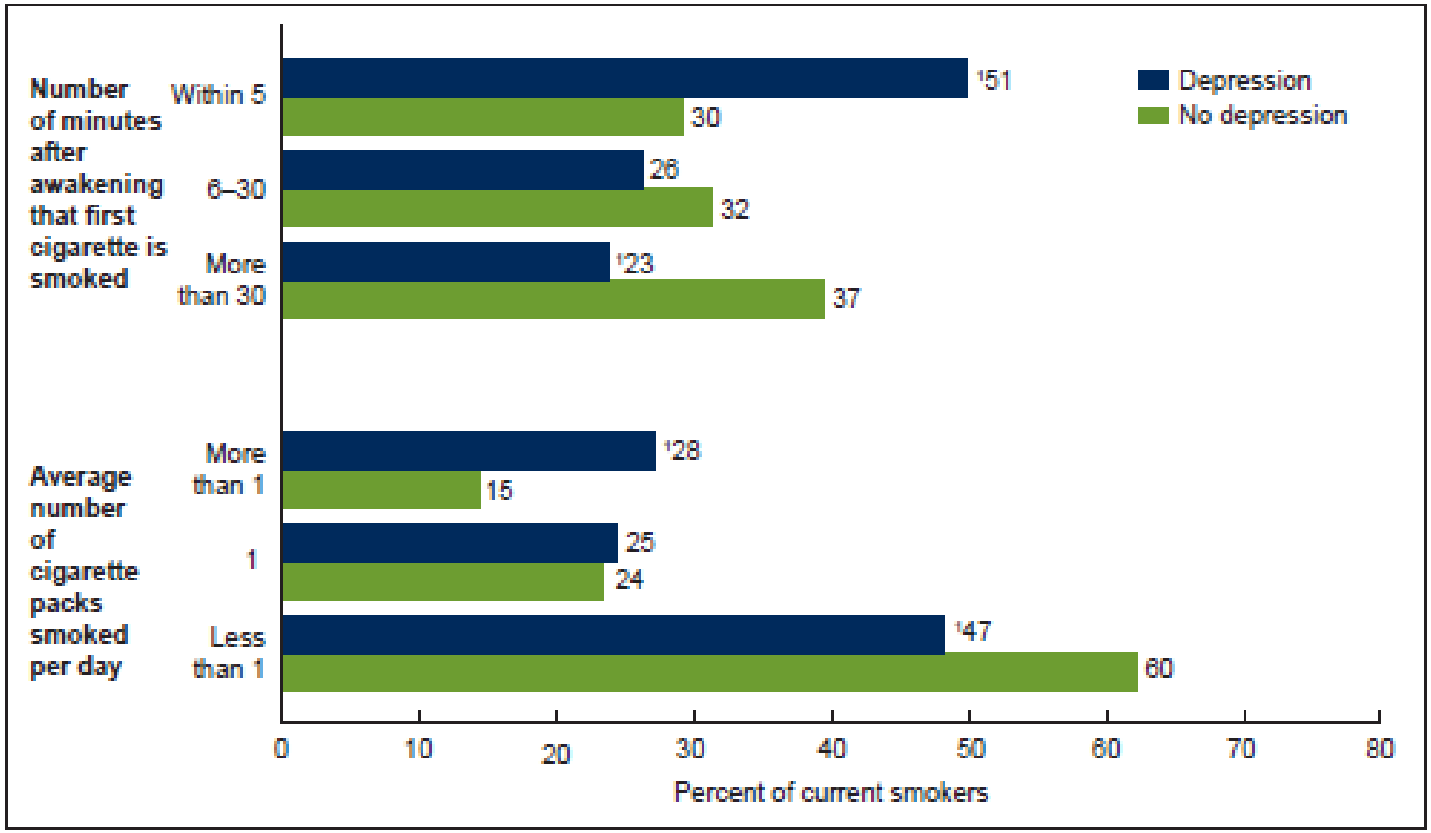
Taylor et al, BMJ, 2014

Why are Patients Not Quitting?

- Neurobiological
- Psychological
- Social & Environmental
- Spiritual & Advocacy
- Treatment System & Institutional
- Greater dependence
- Poor coping; low confidence
- Live with smokers
- No hope; No peers succeeding
- Limited access help

Smokers with depression smoke more cpd and are more dependent

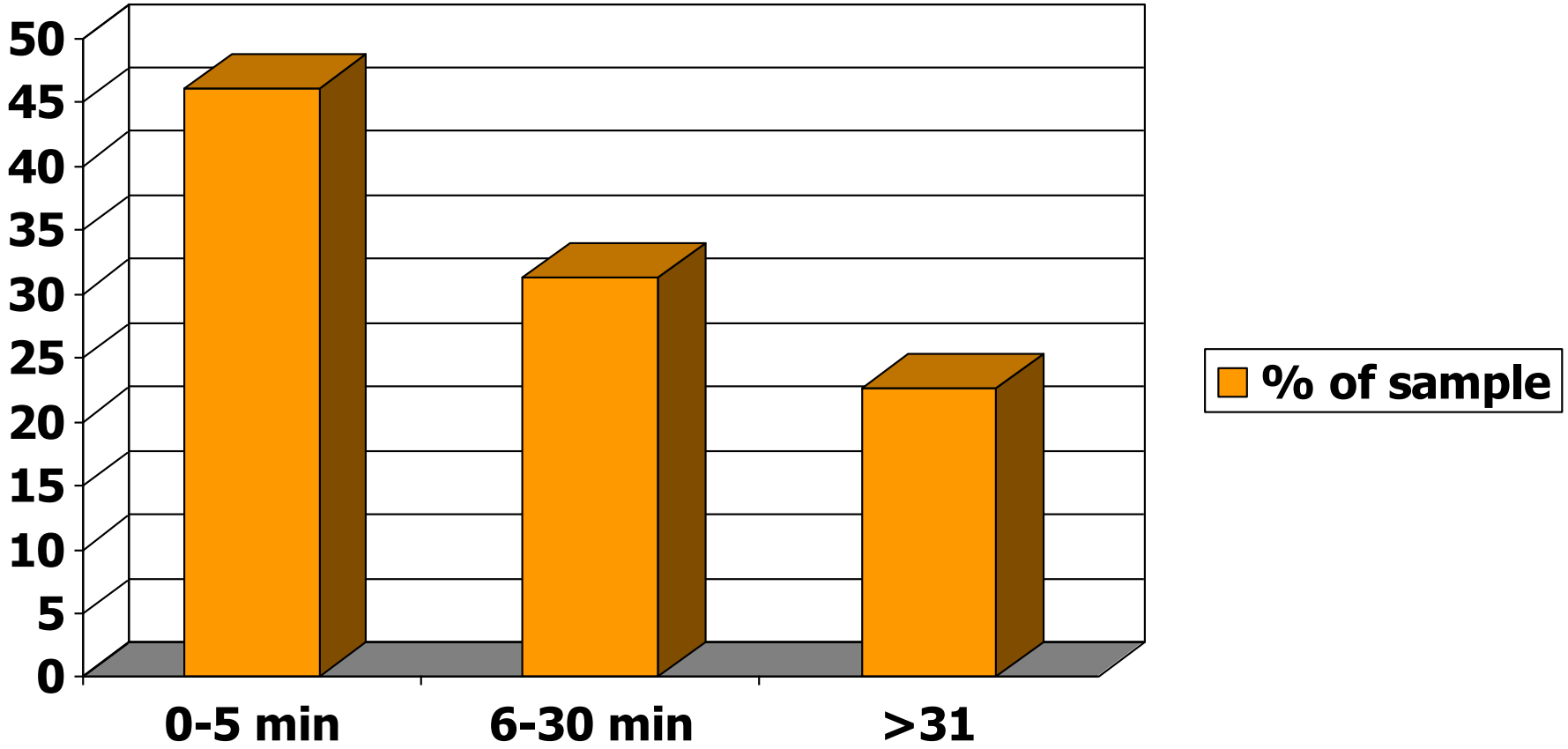
Figure 3. Percentage of current smokers aged 20 and over, by time of first cigarette and amount smoked per day, by depression status: United States, 2005–2008



[1]Significantly different from no depression.

SOURCE: CDC/NCHS, National Health and Nutrition Examination Surveys, 2005–2008.

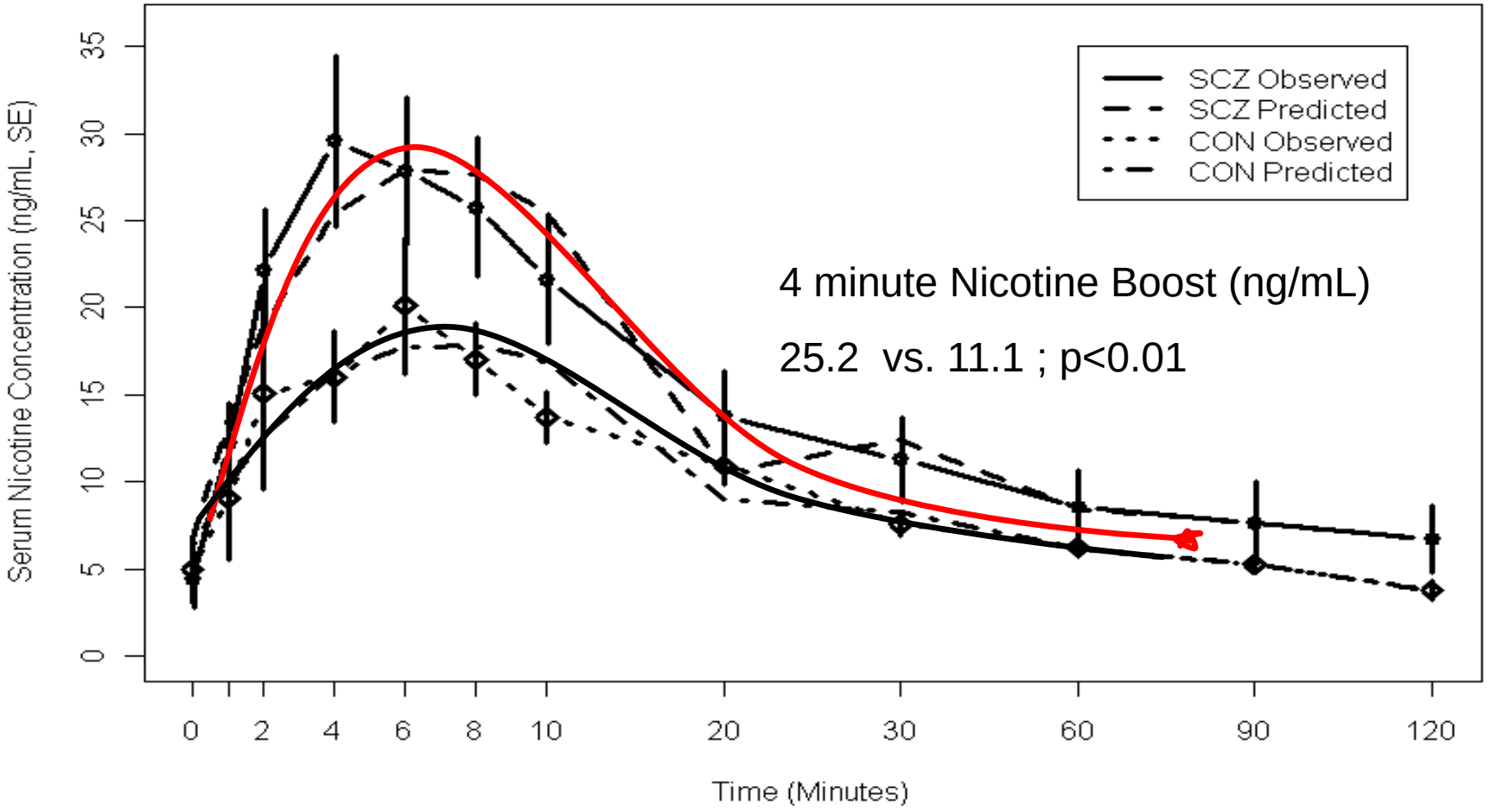
Smokers in Addiction Treatment are Moderately to Severely Addicted to Nicotine



N=1882 smokers in NJ addictions treatment, 2001-2002;

Williams et al., 2005

Individuals with schizophrenia highly addicted



Greater nicotine intake per cigarette

Williams NTR 2010

Tobacco Withdrawal

4 or more

Depressed mood

Insomnia

Irritability, frustration or anger

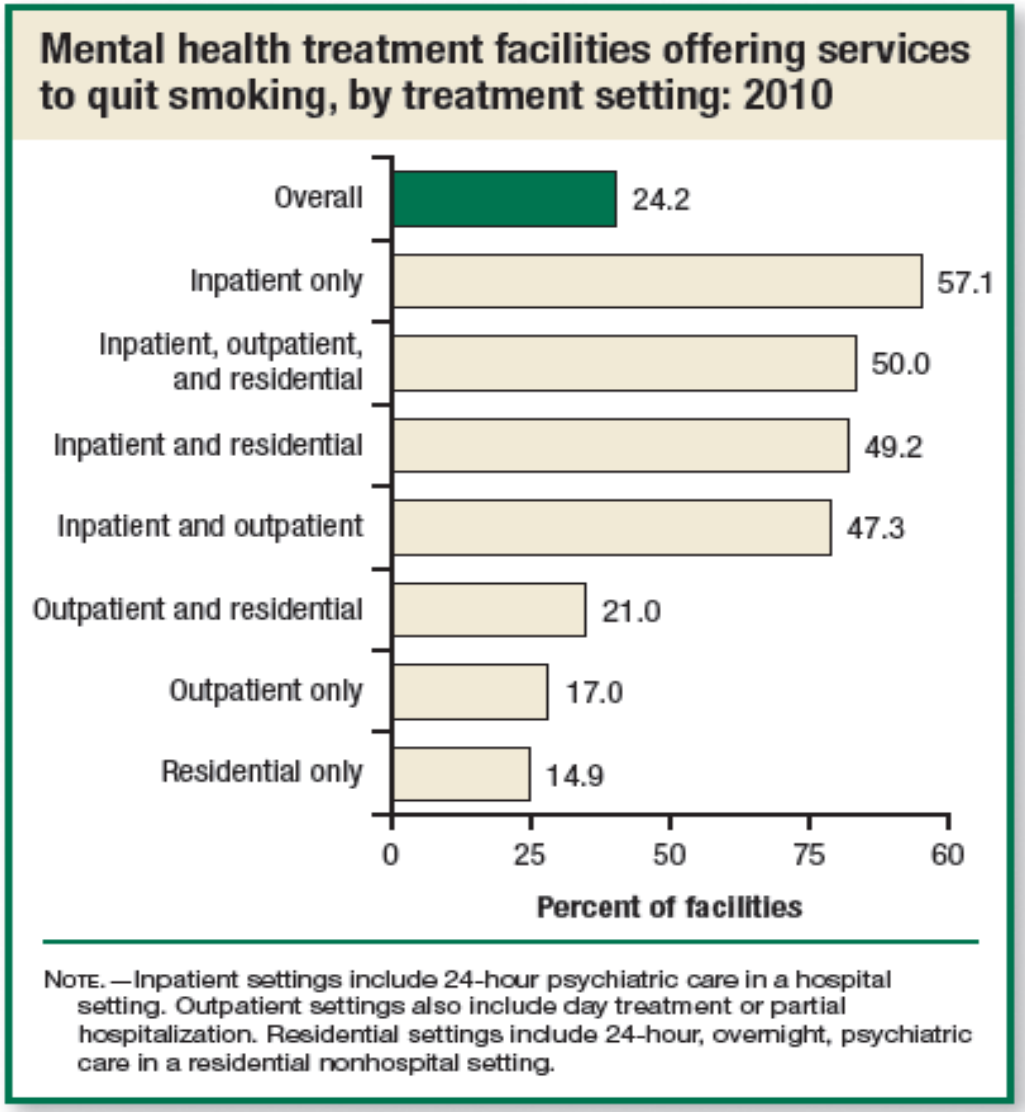
Anxiety

Difficulty concentrating

Restlessness

Increased appetite or weight gain

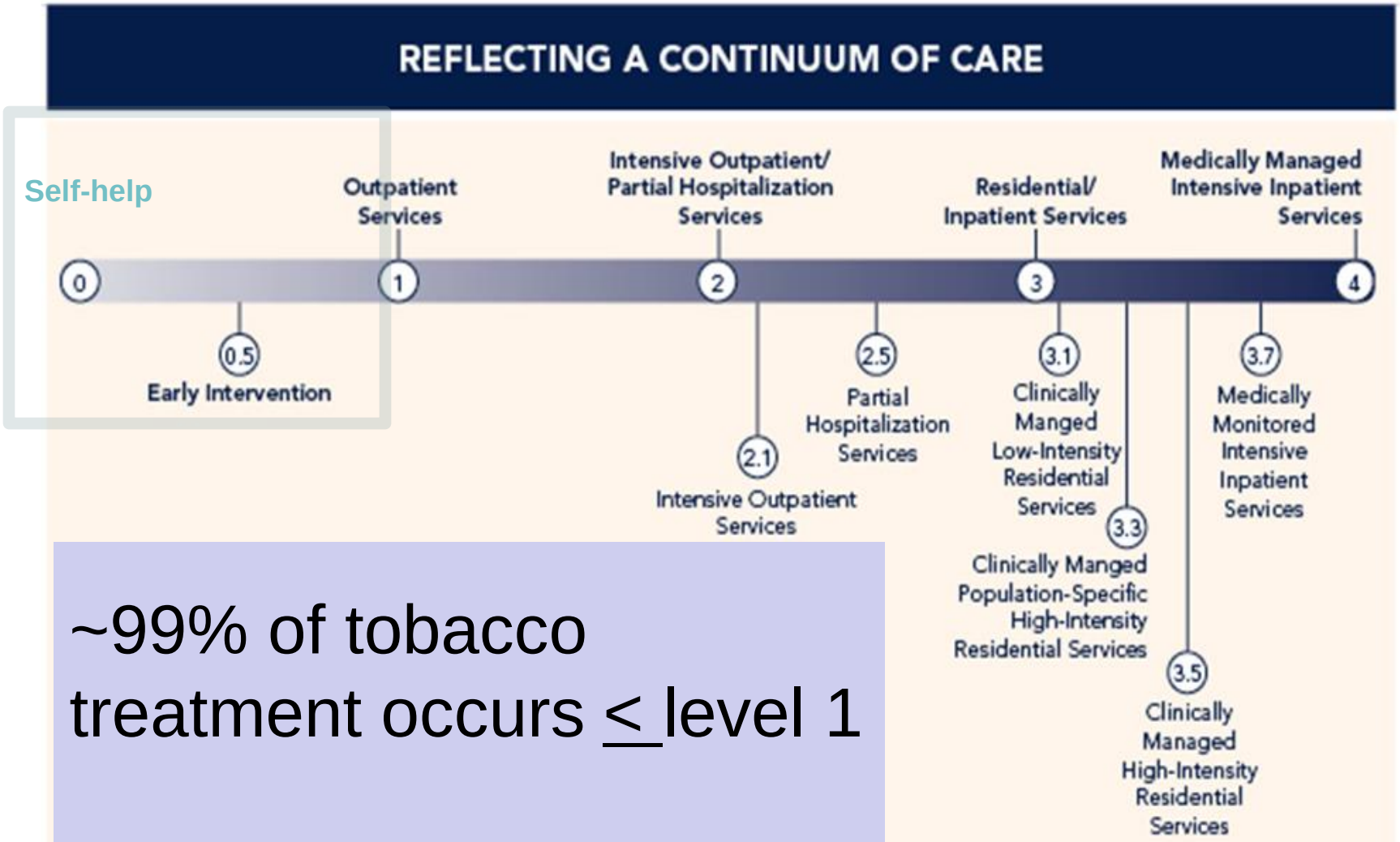
Only 1 in 4 Mental Health Treatment Facilities Offers Quit Smoking Services



Survey of 9048 MH facilities in US (2010)

N-MHSS Report, Nov 2014

ASAM Addiction Levels of Care



~99% of tobacco treatment occurs ≤ level 1

Williams et al., JAM, 2016

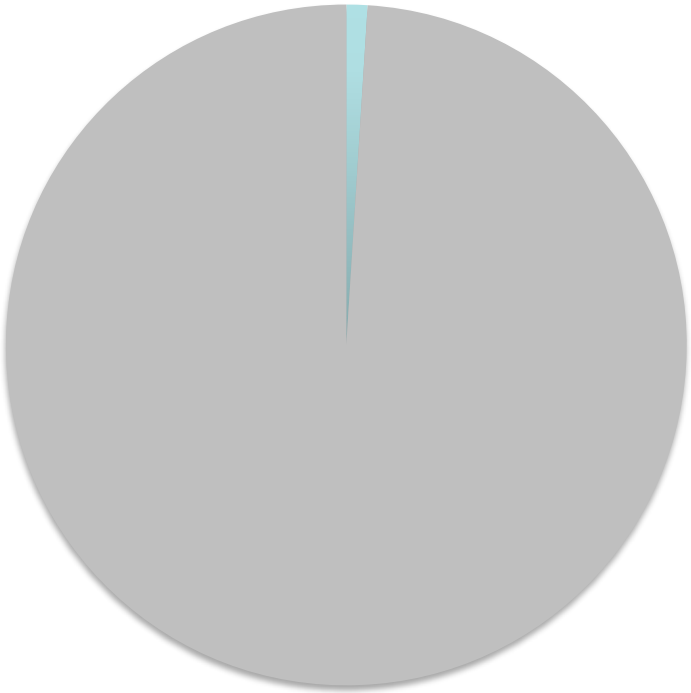
Reduced Access to Specialty Tobacco Treatment

23 million individuals need treatment for an drug or alcohol use problem

11% Access

51 million use cigarettes

1% Use Quitlines



12% received intensive outpatient (IOP)

Effectiveness of First Line Medications

Results from meta-analyses comparing to placebo (6 month F/U)

Medication	No. Studies	OR	95% CI
Nic. Patch (6-14 wks)	32	1.9	1.7-2.2
Nic. Gum (6-14 wks)	15	1.5	1.2-1.7
Nic. Inhaler	6	2.1	1.5-2.9
Nic. Spray	4	2.3	1.7-3.0
Bupropion	26	2.0	1.8-2.2
Varenicline (2mg/day)	5	3.1	2.5-3.8

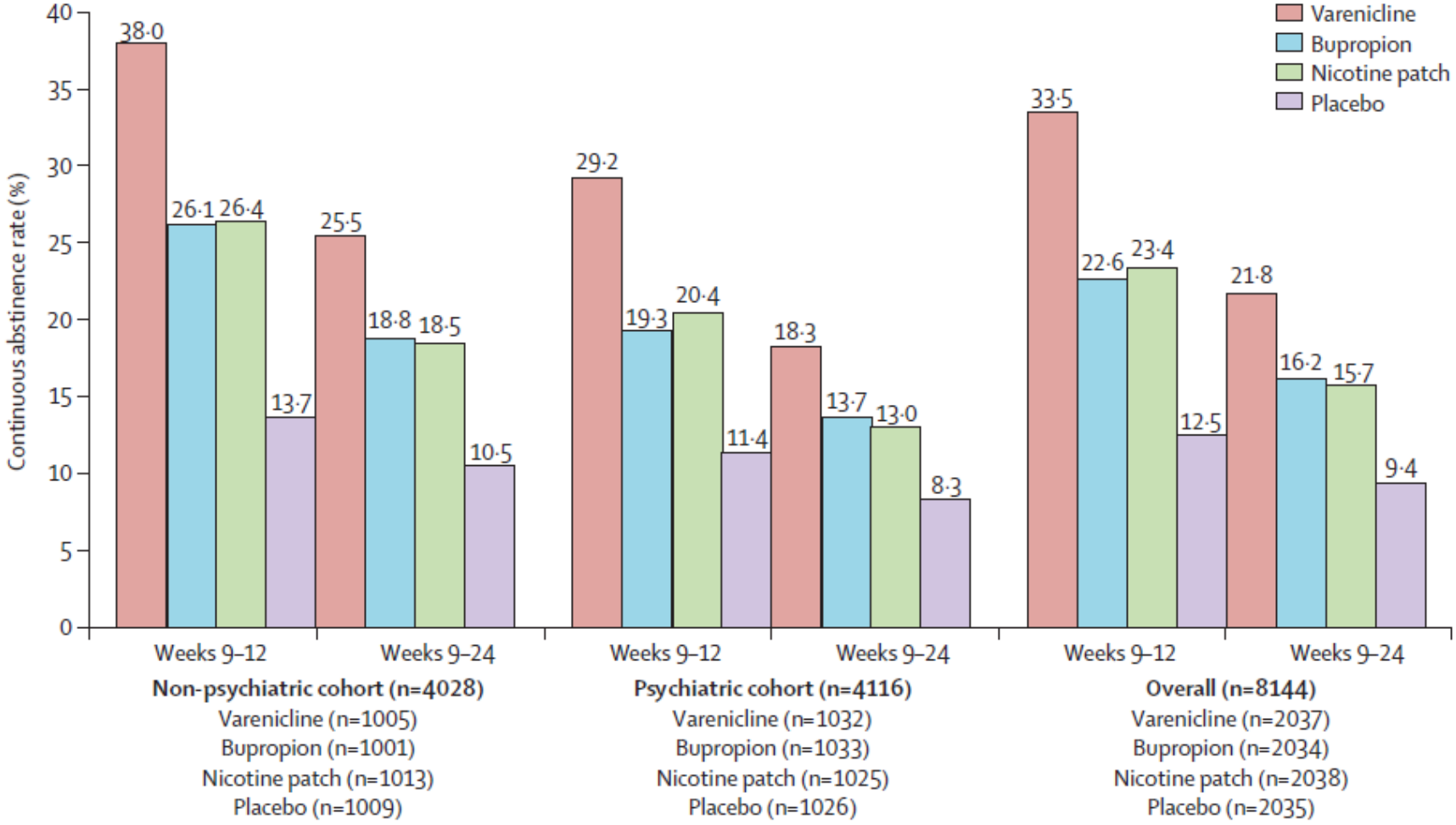
PHS Clinical Practice Guideline 2008 Update

Neuropsychiatric Safety and Efficacy
Varenicline, Bupropion, Nicotine Patch
Smokers with and without Psych Disorders (EAGLES)

- 8144 (4416 psych and 4028, non psych by SCID)
- Triple dummy (DB-PC) x 12 weeks
  - 21mg patch taper
  - Varenicline mg BID
  - Bupropion 150 BID
- Largest smoking cessation study
- 33% lifetime suicidal ideation (12% behavior); 50% on psych meds
  - 70% depression/ bipolar
  - 20% anxiety d/o
  - 10% psychotic
  - 1% personality disorder
- Brief weekly counseling
- Funded Pfizer and Glaxo (GSK)

Anthenelli et al., Lancet 2016

Varenicline superior to BUP and NP overall and in psych and non psych cohorts



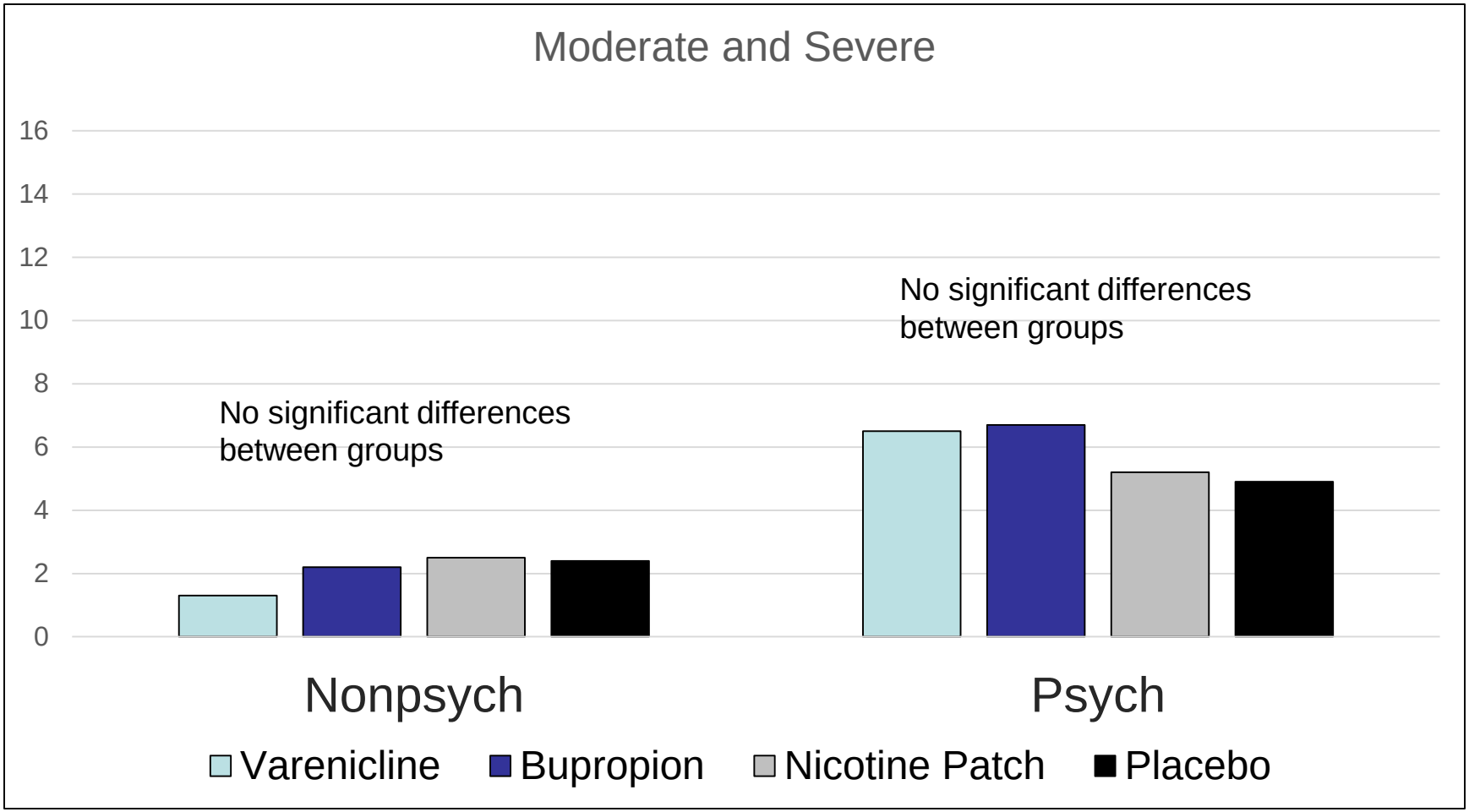
Anthenelli et al., Lancet 2016

Neuropsychiatric Composite

- Anxiety/ Panic
- Depression
- Feeling abnormal
- Hostility
- Agitation
- Aggression
- Delusions
- Hallucinations/ Paranoia/ Psychosis
- Homicidal ideation
- Mania
- Suicidal ideation or behavior

Anthenelli et al., Lancet 2016

Rates of Neuropsychiatric Adverse Events



VAR ↑ Side effects: Nausea, insomnia, abnormal dreams, headache

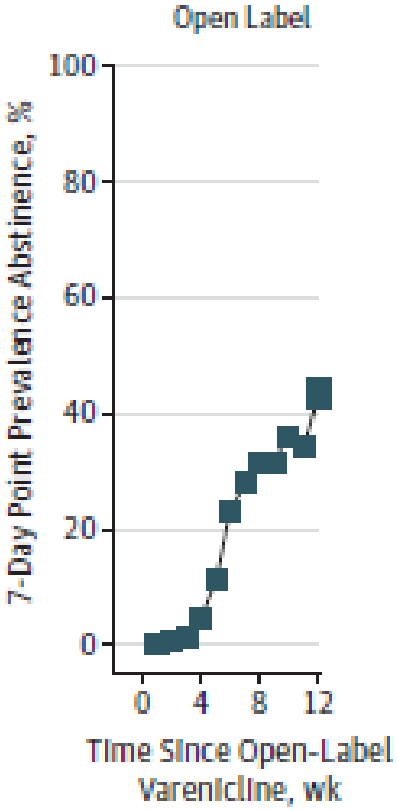
Anthenelli et al., Lancet 2016

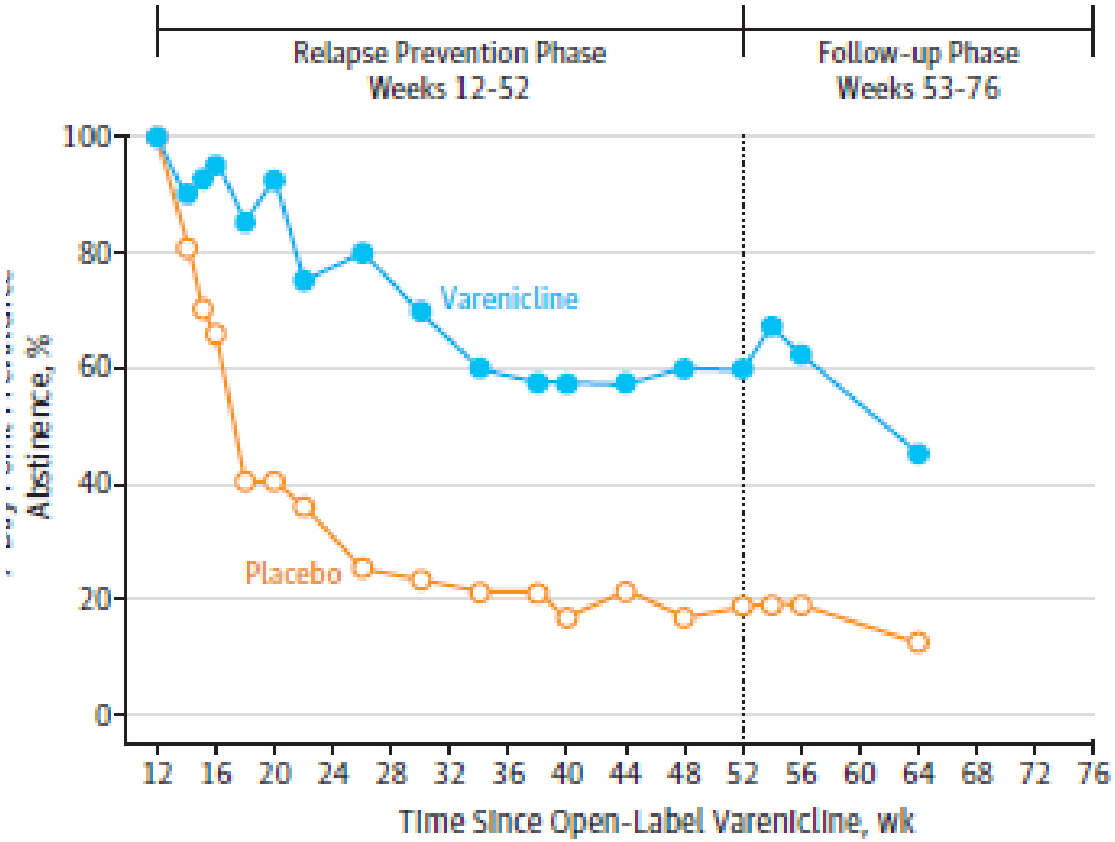
FDA Approves **Removal** Of Boxed Warning Regarding Serious Neuropsychiatric Events From CHANTIX® (varenicline) Labeling

- Based on a U.S. Food and Drug Administration (FDA) review of a large clinical trial that we required the drug companies to conduct, we have determined the risk of serious side effects on mood, behavior, or thinking with the stop-smoking medicines Chantix (varenicline) and Zyban (bupropion) is lower than previously suspected. The results of the trial confirm that the benefits of stopping smoking outweigh the risks of these medicines (December 2016)

http://www.fda.gov/Drugs/DrugSafety/ucm532221.htm

Maintenance Varenicline Greater abstinence at 1 year





87 smokers with SCZ/ BPD from open label phase

Randomized at week 12 to 1mg BID

Evins, JAMA 2014; Pachas et al., JDD 2012

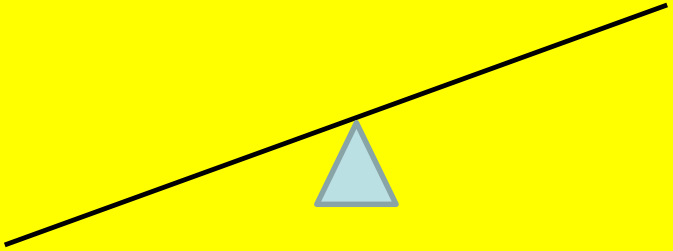
Yet…… The Medicaid PARADOX

Big Gaps Remain In Efforts To Get Smokers To Quit

In 2013 Medicaid spent **less than 0.25 %**
of the estimated **cost of smoking related diseases**

$ **22 billion** on
tobacco illnesses

$103 million
on cessation
medications



http://www.stateoftobaccocontrol.org; *Armour 2009; Ku et al., 2016*

Recommendations for Ideal Medicaid Benefit

- **Coverage of all 7 FDA approved meds**
  - **No Prior Authorization (PA)**
  - **No requirement to be in counseling**
  - **No stepped care**
  - **No time limits**
  - **No banning combinations**

- Coverage of multiple options for counseling
- Access to several courses of meds/ year
- Access to multi-session counseling/ year
- Low or no co-pay

ALA; PFP; Action to Quit 2010

NY Medicaid and Medications Used For Smoking Cessation

- Course limitations will not apply to enrollees with a SUD and/or a diagnosis of mental illness;
- MMC plans will allow for concomitant utilization of two (2) agents, defined as: two (2) Nicotine Replacement Therapies (NRT); a NRT and bupropion Sustained Release (SR); or a NRT and Chantix.
- Formulary coverage of all smoking cessation agents

https://www.health.ny.gov/health_care/medicaid/program/update/2015/2015-09.htm#cha

https://www.health.ny.gov/health_care/medicaid/program/update/2016/2016-06.htm#behav

Conclusions

Treatments increase the success rates and should be used in all smokers

Many behavioral health conditions associated with greater levels of tobacco dependence

Varenicline is safe and effective in the population and has greater efficacy than prior treatments

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Guest Presenter #3

Trish Dooley Budsock, MA, LPC, CTTS

- Mental health clinician, Division of Addiction Psychiatry
- Licensed Professional Counselor & Tobacco Treatment Specialist
- Director of CHOICES (Consumers Helping Others Improve their Condition by Ending Smoking)
- Has worked in fields of addictions & mental health since 1995
- Acted as clinician and clinical supervisor for many clinical trials specific to medications & behavioral therapies for tobacco dependence in SMI population

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Safe and Effective Pharmacological Tobacco Cessation Supports for Individuals with Behavioral Health Conditions

Provider Experience of Providing Treatment for Clients with Psychiatric Conditions

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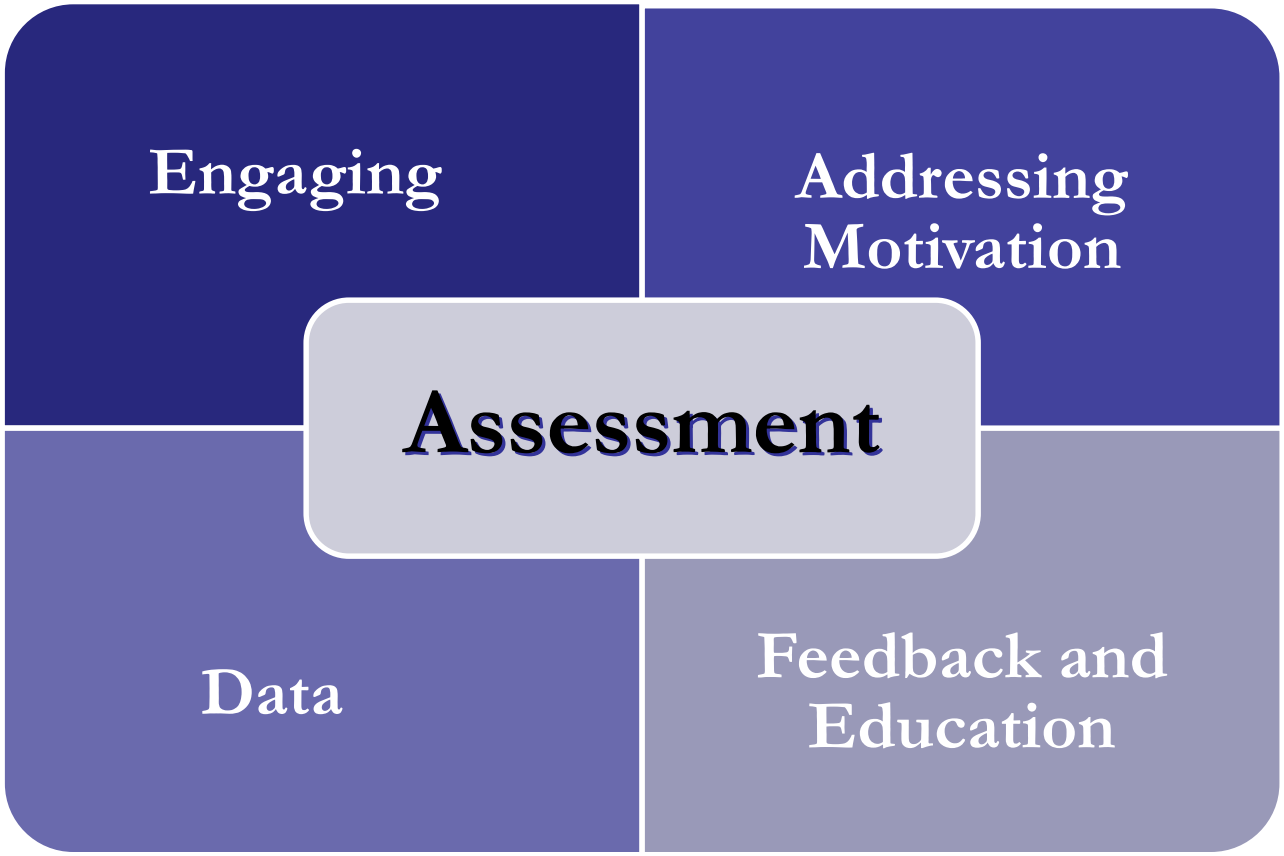
Engaging
Addressing Motivation
Assessment
Data
Feedback and Education

Biological Assessment

- Evaluate Tobacco Use Disorder
  - DSM V Codes 305.1
    - (Z72.0 Mild)
    - (F17.200 Moderate)
    - (F17.200 Severe)
  - ICD Diagnostic Codes
- Tobacco Smoke Exposure/ Expired CO
- FTND
- Quitting History/Nicotine Withdrawal
- Medical Consequences of Tobacco Use

Psychological Assessment

- **Motivation** to Quit
- Confidence
- Self-efficacy
- Coping Skills
- Mood Management

Social Assessment

- Smokers in Home
- Smoking Indoors
- Smokers in Social Network
- Smoke-Free Recreation
- Support for Quitting

Treatment Planning

Based on assessment, Treatment Plan ideally contains the following:

- **Diagnosis**
- **Problem Statements**
- **Goal Statements**
- **Objectives**
- **Therapies and activities (pharmacotherapies/behavioral therapies)**
- **Client preferences for treatment – should be done collaboratively, using Motivational Interviewing style.**

Available free online (2012 update)

rwjms.rutgers.edu/psychiatry/divisions/addiction

Learning About Healthy Living

TOBACCO AND YOU

Written in 2004, Contributors:

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Edited & Revised February 2012

RWJMS Division of Addiction Psychiatry

Group I: Learning About Healthy Living

- **20 Weeks**
- **Educational and Motivational**
- **Accepts all smokers with mental illness**
- **Smoking within the context of Healthy Living (Exercise, stress, & diet)**

Group II: Quitting Smoking Group

- **6 Weeks**
- **Focuses on quitting**
- **Uses evidence-based strategies with modifications**

Providing Education in the Context of Counseling

- **Cigarette Ingredients**
- **Health Consequences**
- **Why Cigarettes are so addictive**
- **Withdrawal Symptoms**
- **Nicotine Replacement Therapy and Medications**

Treatment modifications

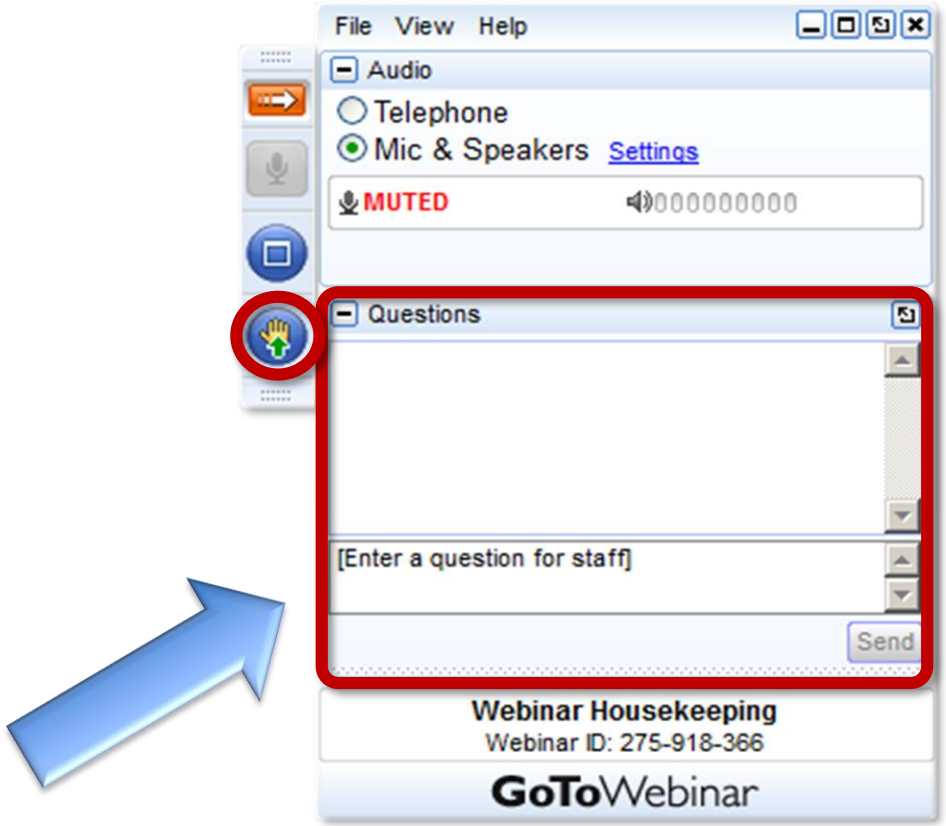
- **Include peers in treatment approach, whenever possible.**

- **If following a manual, provide scenarios for:**
  - Quitting
  - Reducing
  - Not quitting
  - Relapse.

Conclusion

- **Engage patients in discussion of tobacco**
- **Addressing motivation in an ongoing way is key**
- **Providing education**
- **Treatment planning designed to fit patient's motivation**
- **Don't give up! As with all addictions, relapse is a common clinical challenge, and should be addressed in an ongoing way.**
- **Treatment works!**

Questions?



To ask a question, type it into the Q&A box in your webinar window.

National Behavioral Health Network
For Tobacco & Cancer Control

- Jointly funded by CDC's *Office on Smoking & Health* & *Division of Cancer Prevention & Control*
- Provides resources and tools to help organizations reduce tobacco use and cancer among people with mental illness and addictions
- 1 of 8 CDC National Networks to eliminate cancer and tobacco disparities in priority populations

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Thank you for joining us!

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Questions? Please contact Lea Simms at LeaS@thenationalcouncil.org