Treating All Smokers: A 2014 Update

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Overview

- Treating all smokers
- Treating smokers from priority populations
  - Women
  - Low education/SES
  - Racial minorities
  - Behavioral health (mental illness & addiction) clients

Smoking in the U.S.

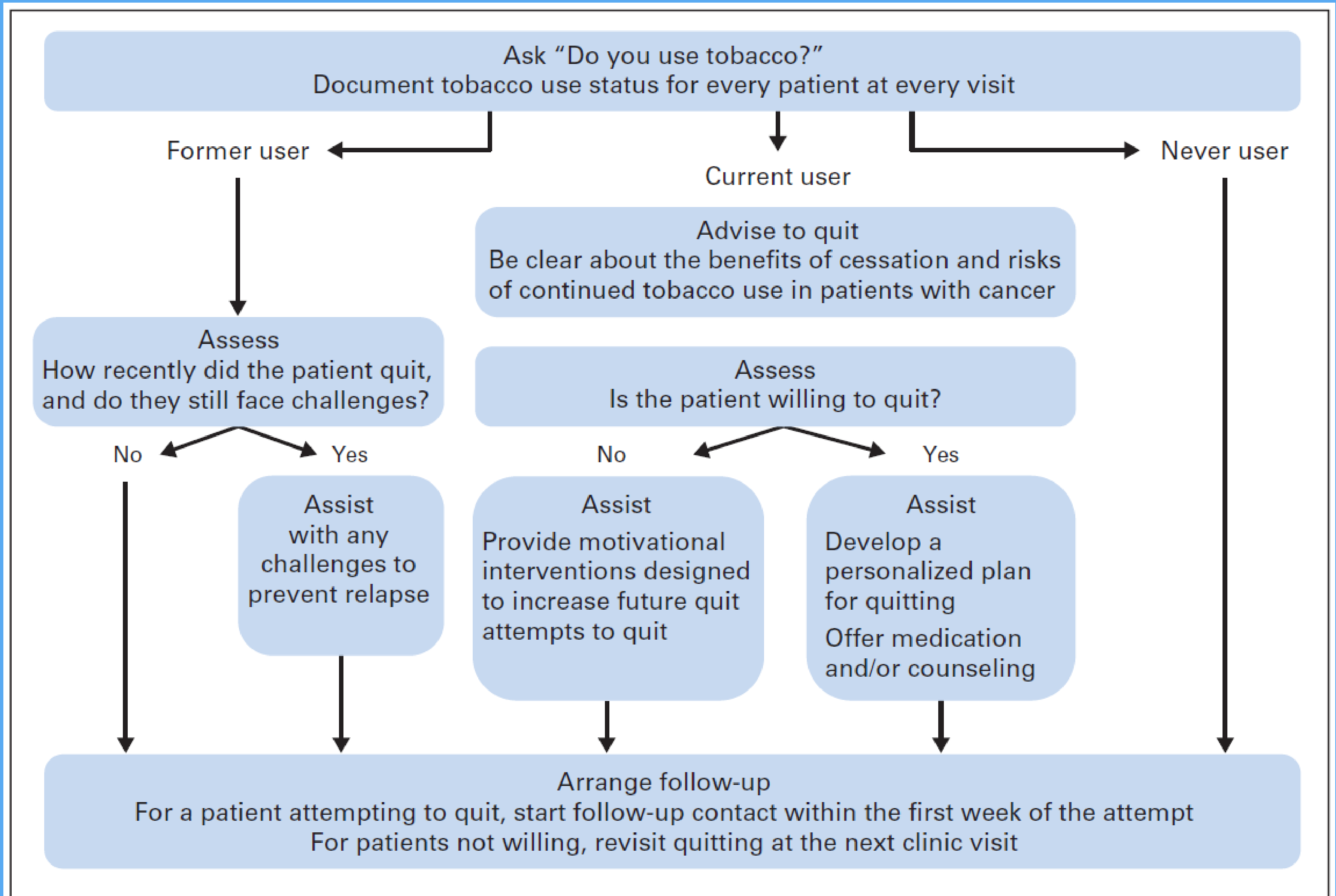
- 18% of adult Americans smoke (2012)
- 1 out of every 5 deaths in America is directly caused by smoking
- Kills more than 440,000 Americans each year
  - ⅓ to ½ of all tobacco users in this country will die prematurely from tobacco dependence
  - Smokers lose an average of 10-20 years of life

Treating Tobacco Use

- Tobacco dependence – chronic, relapsing disease
- Most smokers want to quit
  - > 50% try each year
- Effective treatments exist

2008 Public Health Service Guideline Update

The 5 A's



Assist Smokers Unwilling to Quit

- Motivational interventions
- 5 R's
  - Relevance
  - Risks
  - Roadblocks
  - Rewards
  - Repetition
- Is the patient willing to take a step toward a future quit attempt?
  - Cut down number of cigarettes?
  - Not smoke in certain areas?
  - Replace certain cigarettes with nicotine replacement?

Assist Smokers Willing to Quit

- Counseling
  - More is better
- Quit smoking medications
- Combining counseling and medication is best
  - Counseling + meds (22.1%) vs. counseling alone (14.6%): OR = 1.7
  - Counseling + meds (27.6%) vs. med alone (21.7%): OR = 1.4

Counseling 1-2-3

1. Set a quit date
   - Remove all tobacco products
   - No smoking, not even a puff, after you wake up
2. Learn from past quit attempts
   - What worked – build on that
   - What led to relapse – plan for that
3. Plan ahead – anticipate challenges and ways to cope
   - Craving and withdrawal symptoms
   - Triggers and smoking cues
   - Weight gain
   - Other smokers in the home
   - Alcohol use

Supplements to Clinician Counseling

- Maryland Quit Line
  - 1-800-QUIT-NOW
  - www.smokingstopshere.com
  - 4 calls and 4 weeks of free NRT (patch, gum)
  - Quit Coach, Web Coach, Text2Quit
  - Strong partnership with Medicaid to support cessation for Medicaid enrollees
- Smokefree.gov

Guideline Recommendation

- Clinicians should encourage medication for all patients attempting to quit smoking
  - EXCEPT when medically contraindicated
  - EXCEPT when there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers and adolescents)

FDA-Approved Cessation Medications

- Seven first-line medications (5 nicotine and 2 non-nicotine) reliably increase long-term smoking abstinence rates
  - Bupropion SR
  - Nicotine lozenge*
  - Nicotine inhaler
  - Varenicline
  - Nicotine gum*
  - Nicotine nasal spray
  - Nicotine patch*

*Available without a prescription

Relative Efficacy

Medication	Number of arms	Estimated odds ratio (95% C. I.)
Nicotine Patch (reference group)	32	1.0
Varenicline (2 mg/day)	5	1.6 (1.3, 2.0)
Patch (>14 weeks) + NRT (gum or spray)	3	1.9 (1.3, 2.7)
Patch + Bupropion SR	3	1.3 (1.0, 1.8)

Varenicline

Varenicline – Prescribing

- ***Dosing:*** Start one week before the quit date (quit tobacco on Day 8). Treatment for 14 weeks:
  - Days 1-3: 1 pill (0.5 mg) per day;
  - Days 4-7: 1 pill (0.5 mg) twice a day (am/pm)
  - Day 8 on: 1 pill (1 mg) twice a day (am/pm)
- Additional 12 week course for maintenance can be considered.
- Do **not** combine varenicline with NRT.
- Side Effects: nausea, insomnia, headache, abnormal dreams, and psychiatric symptoms including suicidal ideation and aggression

Varenicline – Safety

- FDA Warning (March 2008 and updated in 2011):
  - Reported depressed mood, agitation, changes in behavior, suicidal ideation and suicide.
  - If patient is feeling depressed while taking varenicline, stop the medication and call you.
  - Patients with CVD should notify health care providers of new or worsening cardiovascular symptoms and to seek immediate medical attention if they experience signs and symptoms of myocardial infarction.
- It is important to follow patients you put on varenicline, just like you follow patients with other medications.

NRT Dosing – Patch

- Patient smokes 10+ cigarettes per day
  - 4 weeks of 21 mg/day
  - 2 weeks of 14 mg/day
  - 2 weeks of 7 mg/day
- Patient smokes 9 or fewer cigarettes per day
  - 6 weeks of 14 mg/day
  - 2 weeks of 7 mg/day

NRT Dosing – Gum and Lozenge

- First cigarette smoked within 30 minutes of waking
  - 4 mg
- First cigarette smoked more than 30 minutes after waking
  - 2 mg
- Use enough – 5 to 20 pieces/day
- Use on a schedule and then prn for breakthrough cravings

Combination NRT

+

New FDA Label Changes

- From a safety perspective, it is now:
  - OK to use NRT while smoking or using other forms of tobacco
    - Pre-quit NRT
    - Continue NRT after lapsing/relapsing
  - OK to use more than one NRT
    - Combination NRT
  - OK to use NRT for more than 3 months
    - Extended duration

Guideline Recommendation

- Clinicians should also consider the use of certain combinations of medications identified as effective in this Guideline
  - Long-term (> 14 weeks) nicotine patch + other NRT (gum and spray)
  - Nicotine patch + the nicotine inhaler
  - Nicotine patch + bupropion SR.

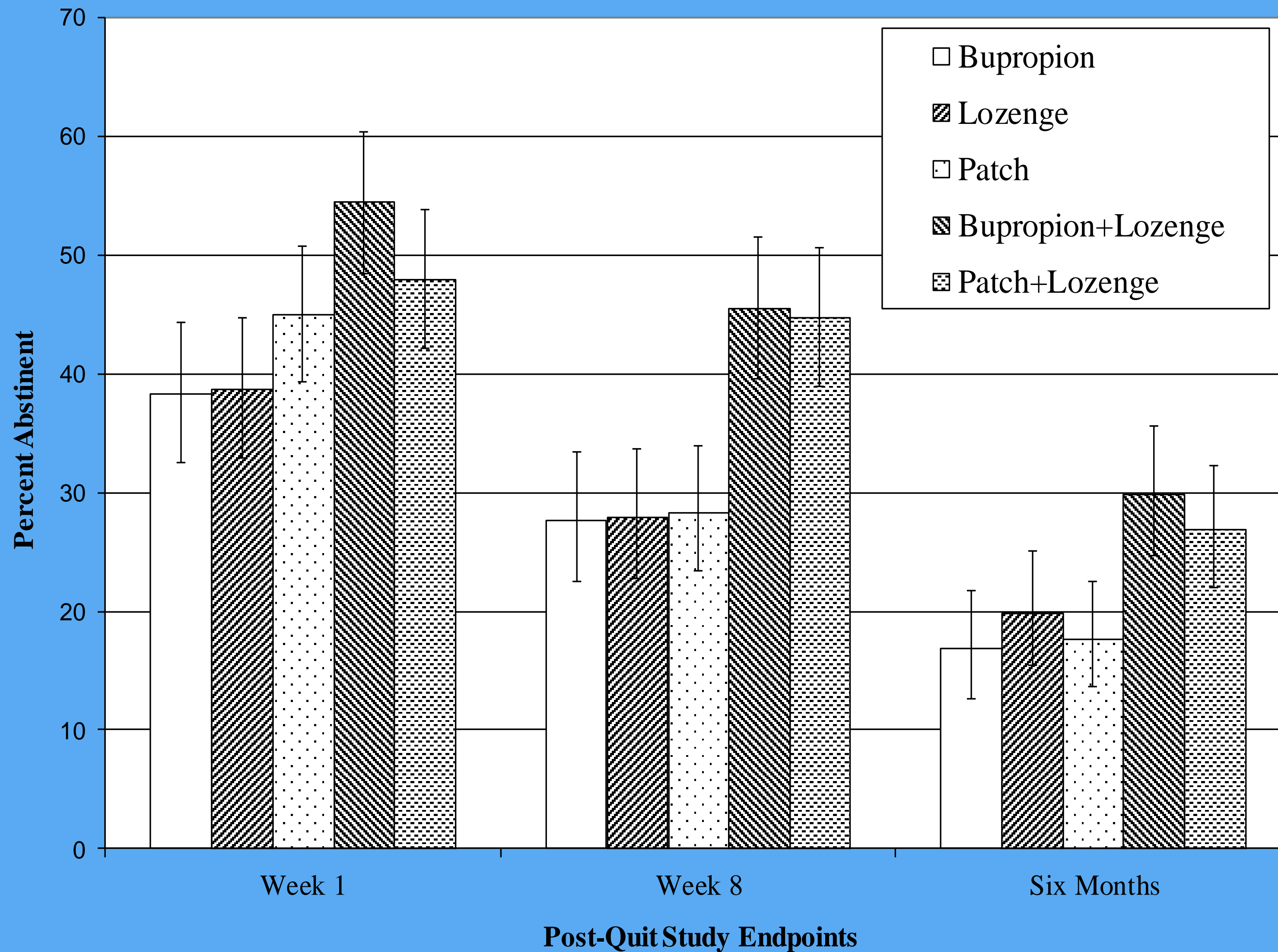
2012 Cochrane Meta-Analysis

- Combining a nicotine patch with a rapid delivery form of NRT was more effective than a single type of NRT
  - 9 trials
  - RR 1.34 (95% CI = 1.18 - 1.51)

Large Effectiveness Trial

- 1346 smokers who wanted to quit
- Recruited via primary care clinics
- Milwaukee, WI area
- All received a referral to the Wisconsin Tobacco Quit Line
- Randomized to receive:
  - Nicotine patch
  - Nicotine lozenge
  - Nicotine patch + lozenge
  - Bupropion
  - Bupropion + lozenge

Effectiveness Study: Cessation Rates

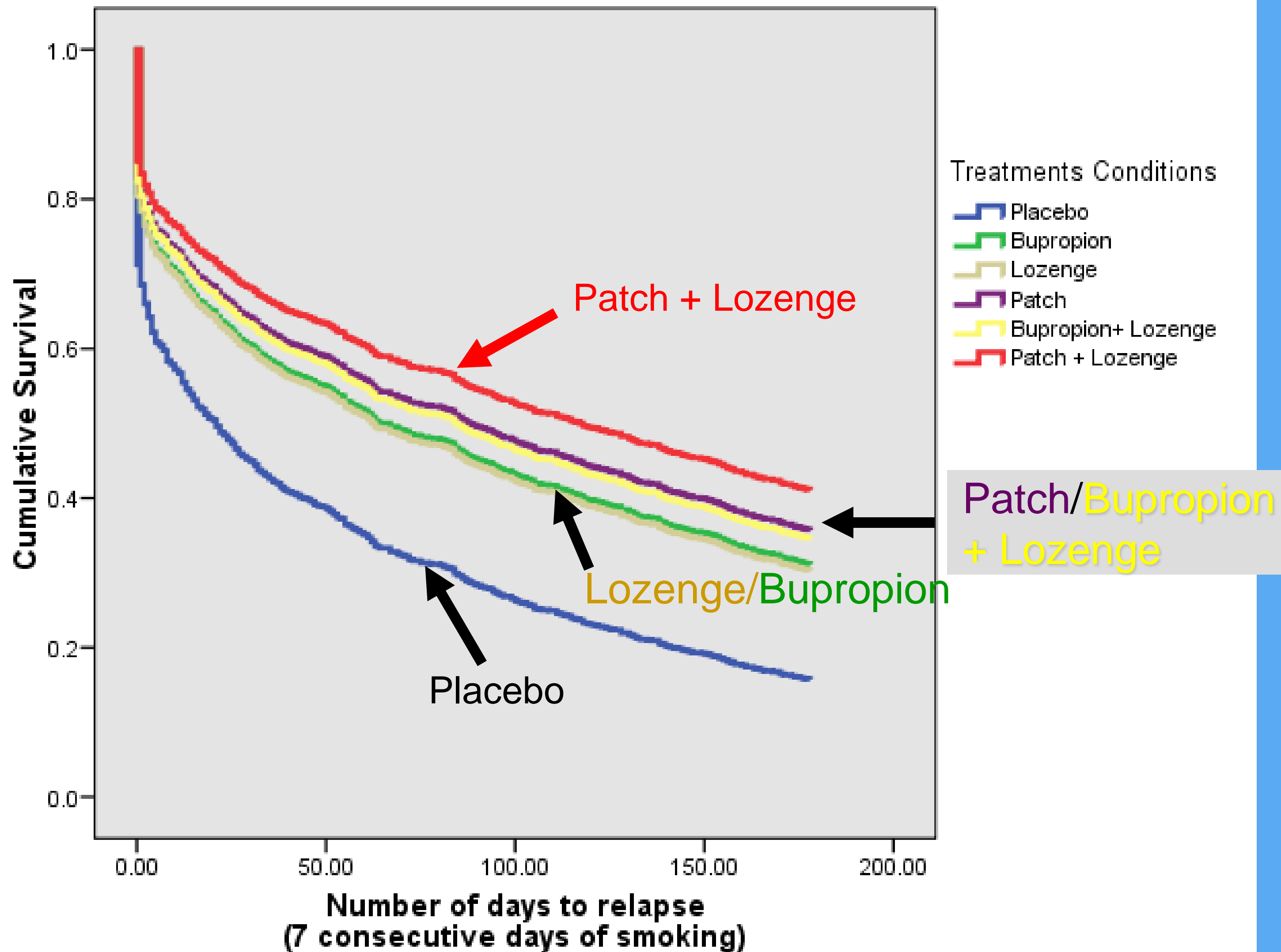


Smith et al., Archives of Internal Medicine, 2009

Large Efficacy Trial

- 1504 smokers motivated to quit
- Recruited via media
- Madison and Milwaukee, WI area
- All received in-person counseling
- Randomized to receive:
  - Placebo - Bupropion
  - Nicotine patch - Bupropion + lozenge
  - Nicotine lozenge - Nicotine patch + lozenge

Efficacy Study: Latency to Relapse



Piper et al., Archives of General Psychiatry, 2009

Conclusions

- Need systems to support clinicians
- All smokers should get evidence-based treatment
  - Motivation treatment – 5 R's
  - Cessation treatment
- Cessation treatment should include:
  - Counseling
    - Develop a concrete, proactive plan
  - Medication
    - Varenicline
    - Combination NRT (patch + ad lib)

Priority Populations

Smoking Rates in Priority Pops.

- Overall adult smoking rate in 2012 – 18%
- Women
  - 16.5%
- African-American
  - 19.4%
- Low education/low socio-economic status
  - No diploma = 25.5%
  - Below poverty level = 29.0%
- Behavioral health
  - 36.1%

MMWR, 2012 & 2013

Guideline Recommendation

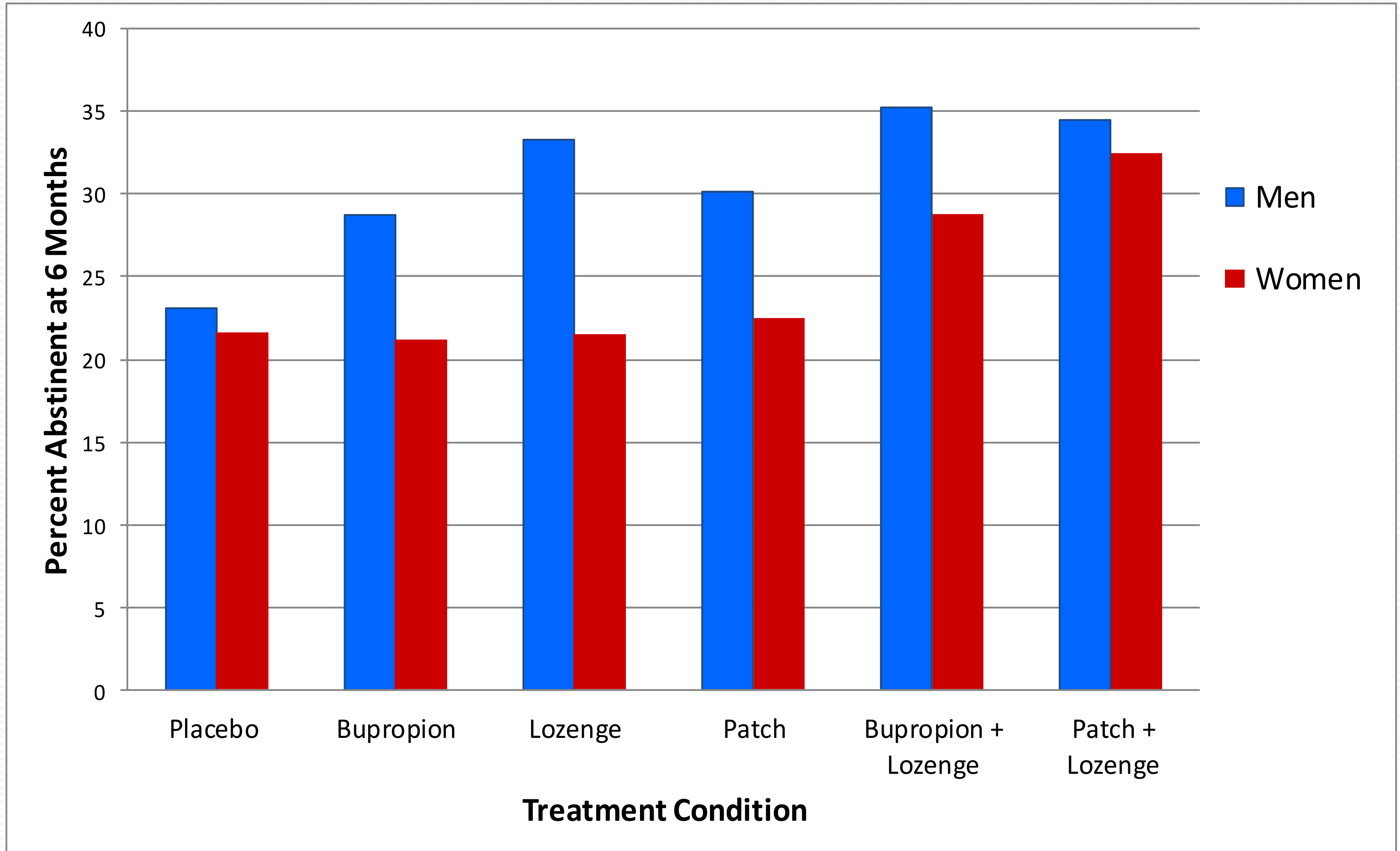
- The interventions found to be effective in this Guideline have been shown to be effective in a variety of populations. In addition, many of the studies supporting these interventions comprised diverse samples of tobacco users. Therefore, interventions identified as effective in this Guideline are recommended for all individuals who use tobacco, except when medication use is contraindicated or with specific populations in which medication has not been shown to be effective (pregnant women, smokeless tobacco users, light smokers, and adolescents).
  - Strength of Evidence = B

Combination NRT: Especially Effective for Women

- Women who received combination therapy were significantly more likely to be abstinent at 8 weeks and 6 months post-quit compared to those who received monotherapy
  - p-values < .001

Piper et al., NTR, 2010

Combination NRT for Women

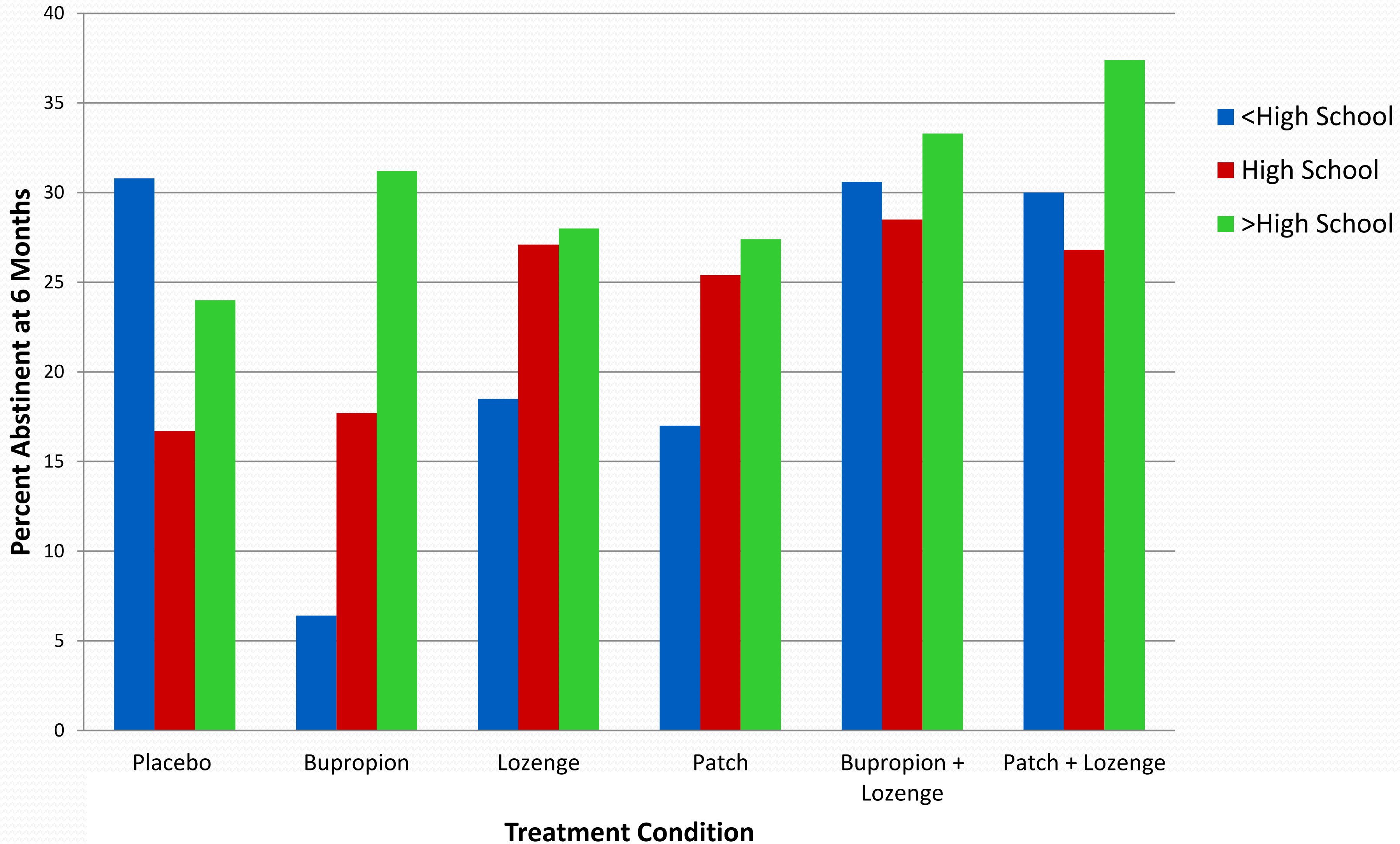


Combination NRT: Effective for Smokers with <HS Education

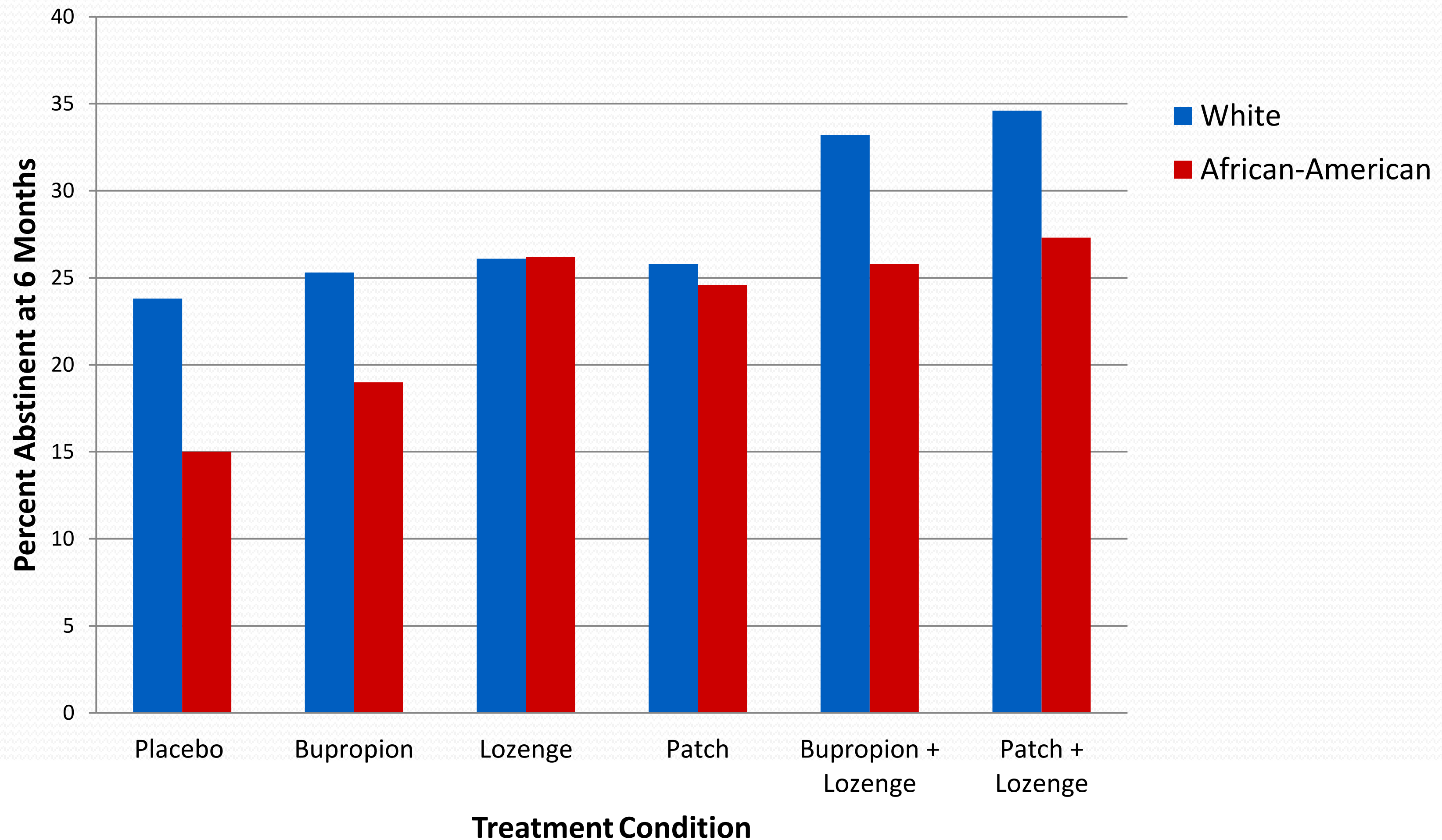
- Smokers with < high school education who received combination therapy were significantly more likely to be abstinent at 8 weeks and 6 months post-quit compared to those who received monotherapy
  - p-values = .01

Piper et al., NTR, 2010

Combination NRT for <HS Education



Combination NRT: No Differential Effects by Race



Combination NRT: Mechanisms of Action

- Compared to monotherapy, combination NRT has a stronger effect on:
  - **Post-quit craving**
  - Post-quit withdrawal
  - Post-quit smoking expectancies
- Sufficient replacement
- Use prn as a coping response

Bolt et al., JCCP, 2012

Conclusions

- Combination NRT (patch + ad lib) is a highly effective intervention for all smokers
- Specific priority populations respond especially well to combination NRT
  - Women
  - Those with < HS education

Behavioral Health and Smoking

Real AODA/
mental health
consumers

Behavioral Health Clients

- Smoking disproportionately affects behavioral health clients
- Almost twice as likely to be smokers
- Consume a disproportionate number of cigarettes
  - 44% of all cigarettes in US
- Smoke more heavily
- Over time, smoking rates have not declined as much as rates for smokers without behavioral health issues

(Cook et al., 2014; Grant et al., 2004; Gwynn et al., 2008; Kalman, Morissette, & George, 2005; Lasser et al., 2000; Wiesbeck, Kuhl, Yaldizli, & Wurst, 2008; Williams & Ziedonis, 2006)

Smoking Prevalence by Diagnosis

Major depression	45-50%
Bipolar disorder	46-70%
Schizophrenia	59.1-90%
ADD/ADHD	37.2%
1 BH diagnosis	31.9%
2 BH diagnoses	41.8%
3+ BH diagnoses	61.4%

2007 NHIS data; Grant et al., 2004; Lasser et al., 2000

Complications of Smoking and Behavioral Health

- More likely to die and die sooner
  - 7x higher risk of heart disease than peers
  - >7x higher rate of suicide rate
  - Lose 24 years of life
- Influences development of metabolic syndrome in patients on antipsychotic drugs
- Influences metabolism of psychotropic medications

NASMHPD Research Inst, 2006

Myths About Smoking and Behavioral Health

- Tobacco is necessary self-medication
  - Not necessary
- They are not interested in quitting
  - Same % want to quit as general population: 60-70%
- They can't quit
  - Quit rates same or slightly lower than general population
- Quitting worsens recovery from the mental illness
  - NO!
- It is a low priority problem
  - Smoking is the biggest killer in behavioral health population

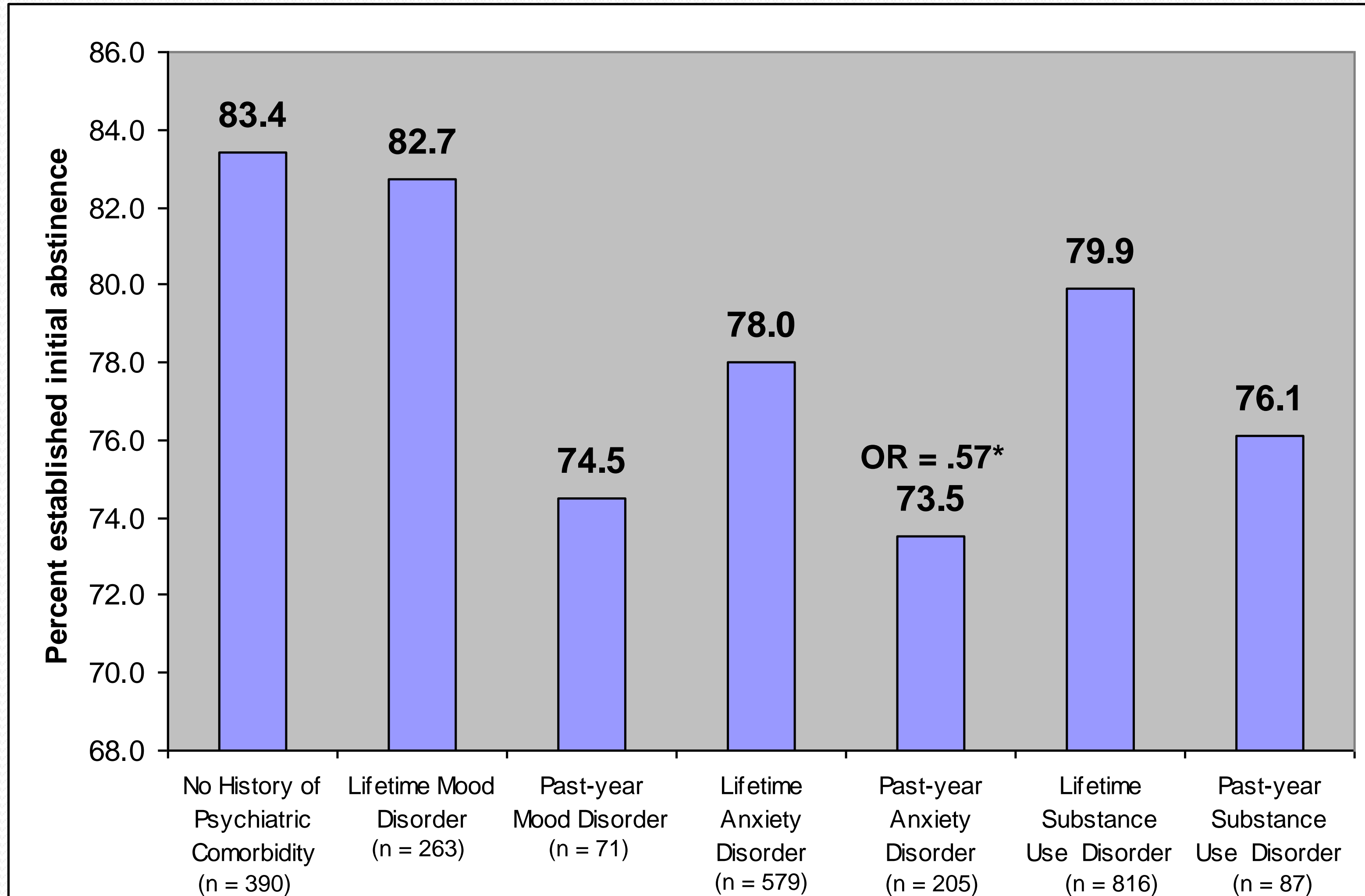
Prochaska, NEJM, 2011

Behavioral Health In RCT

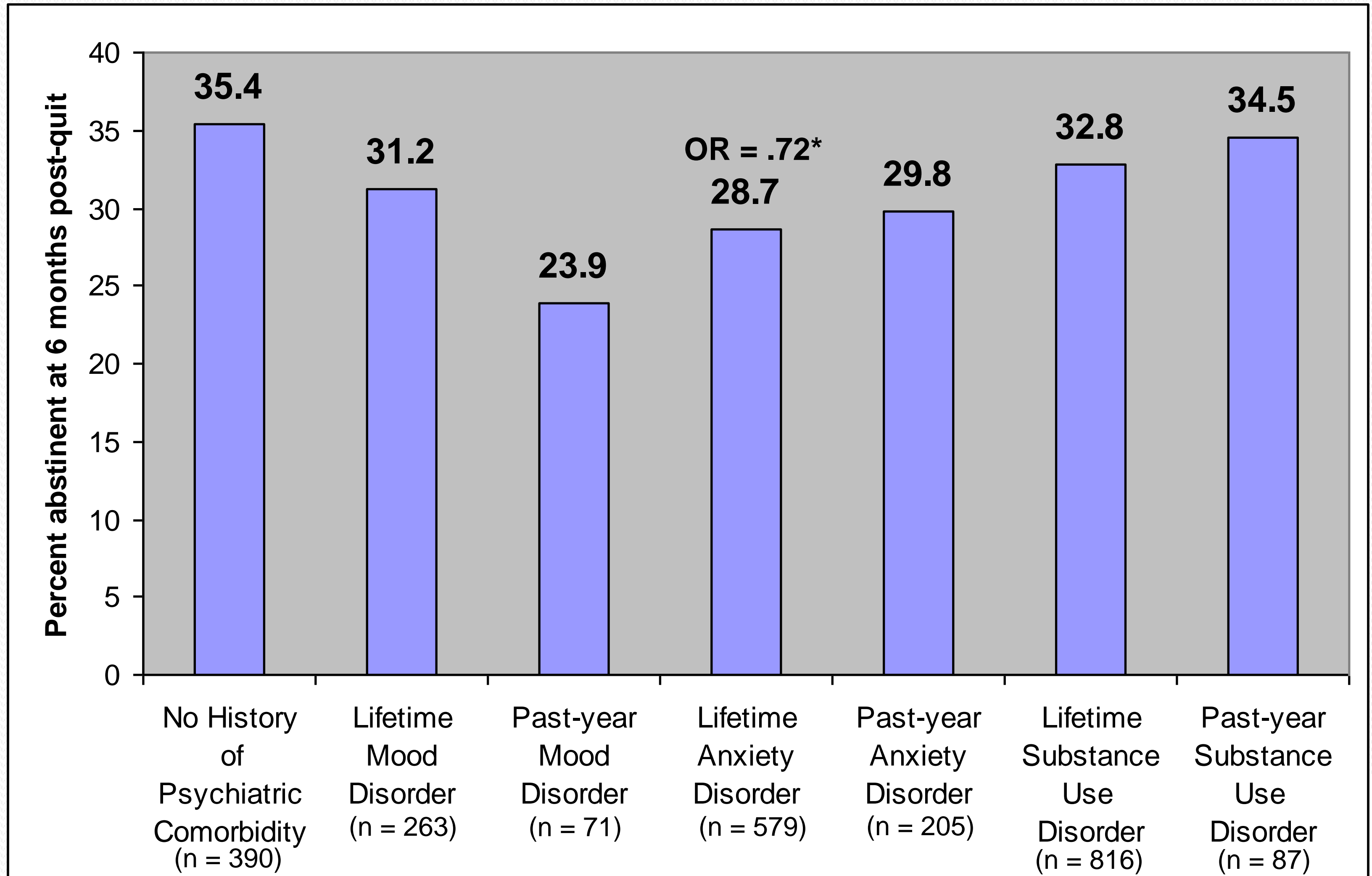
- From the Efficacy trial (Efficacy Trial; N = 1504)
- World Mental Health Survey Initiative Version of the Composite International Diagnostic Interview (CIDI)
- 74% history of mood, anxiety or substance use disorder
  - 18% mood
  - 39% anxiety
  - 56% substance use disorder
  - 45% more than one lifetime diagnosis

Piper, et al., JCCP, 2010

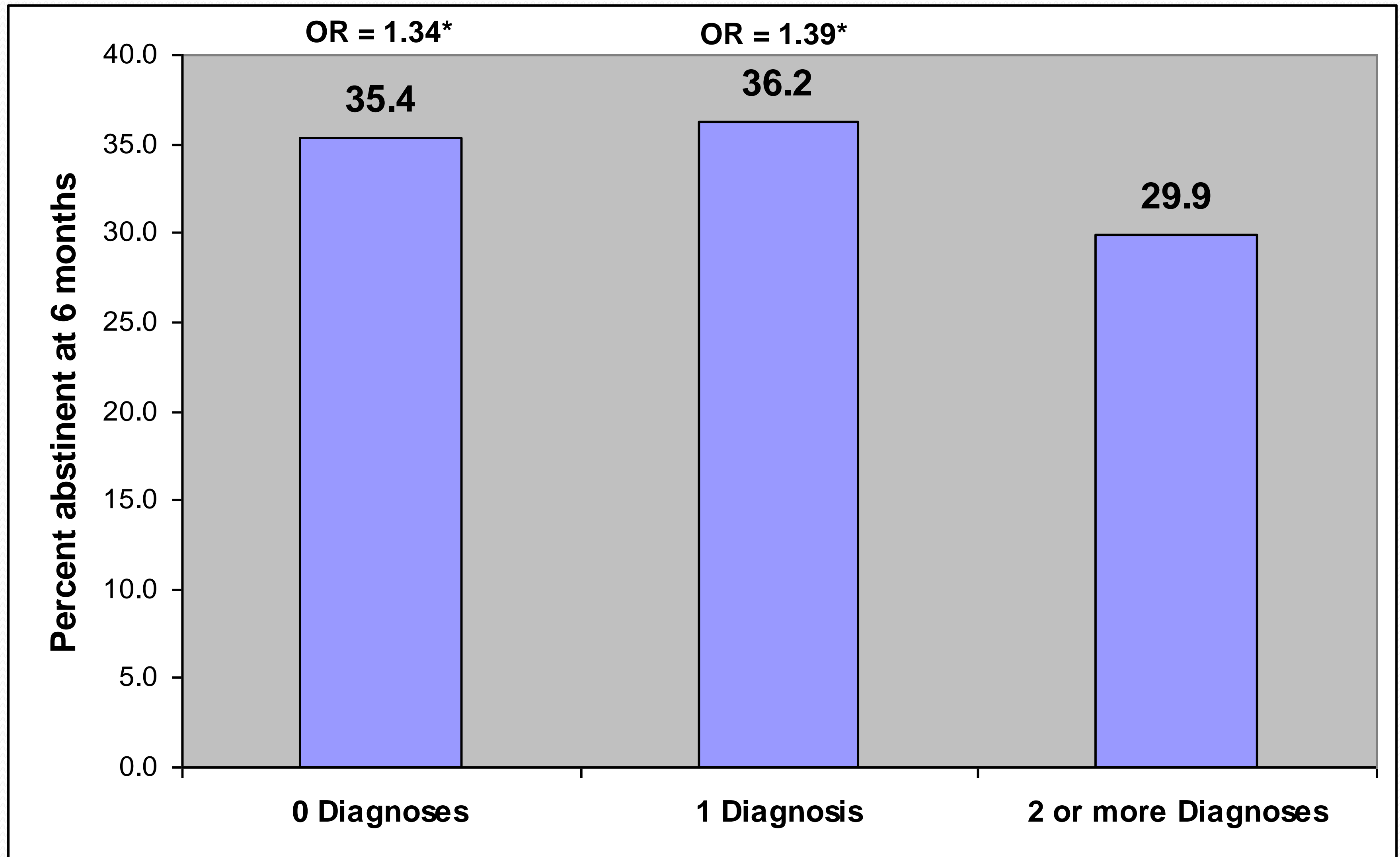
Initial Cessation



6 Months Post-Quit



6 Months Post-Quit

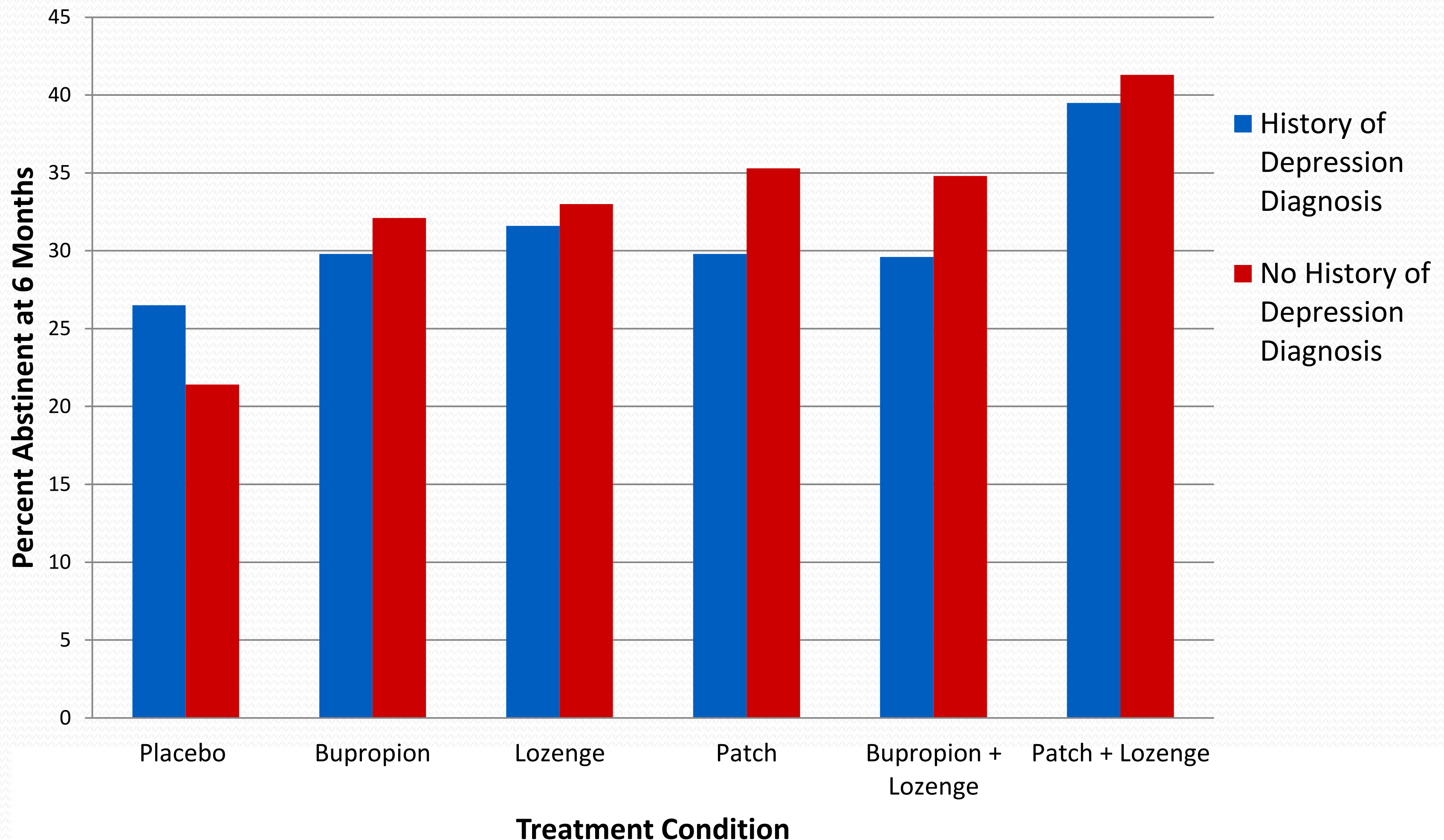


Lifetime Anxiety and Withdrawal

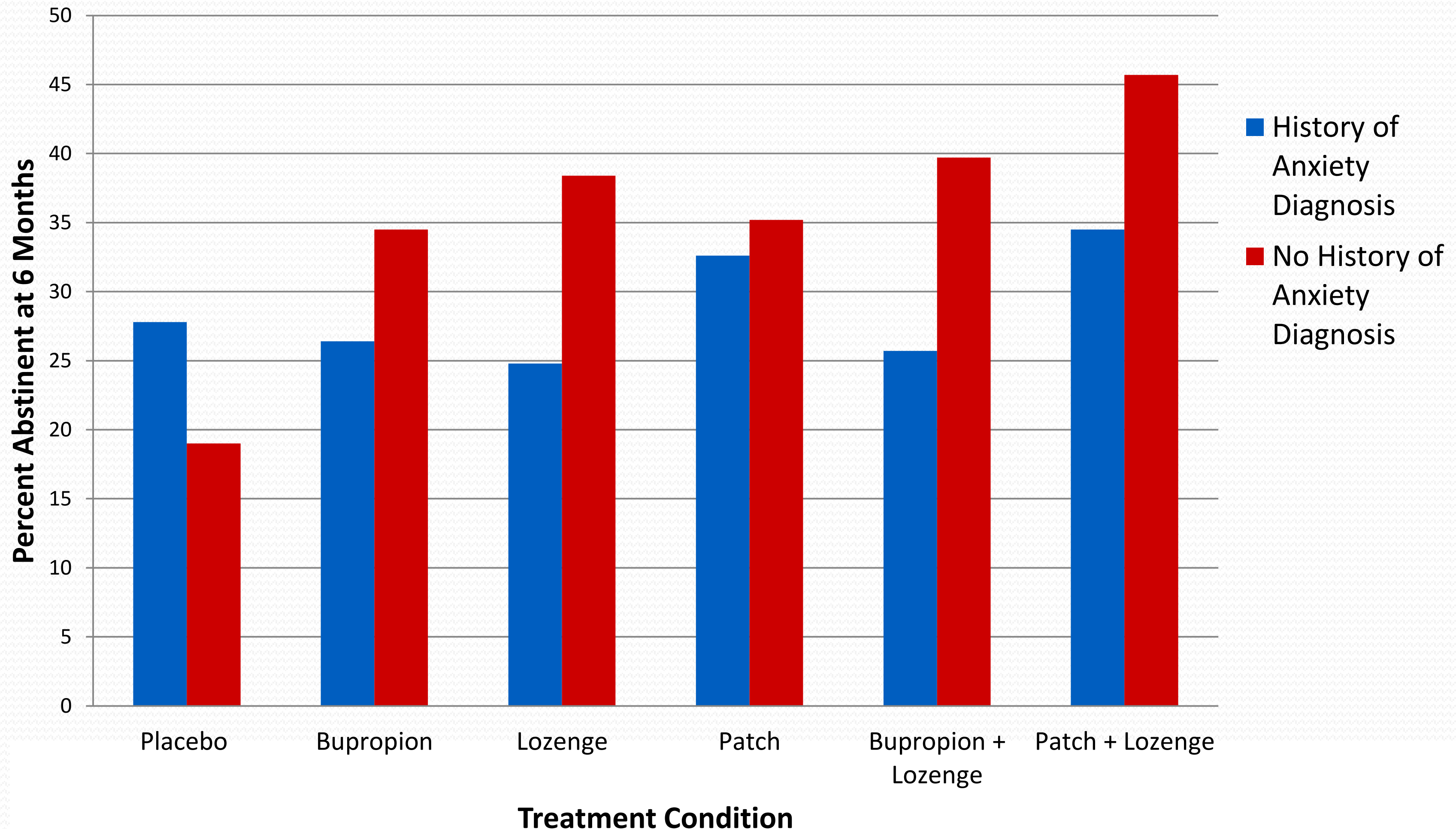
- Panic Attacks, GAD and Social Anxiety Disorder
  - Greater pre-quit negative affect and withdrawal
  - Significant increase in cessation fatigue over time
- GAD and Social Anxiety Disorder
  - Greater pre-quit craving
  - Greater anticipatory anxiety

(Piper et al., Addiction, 2011)

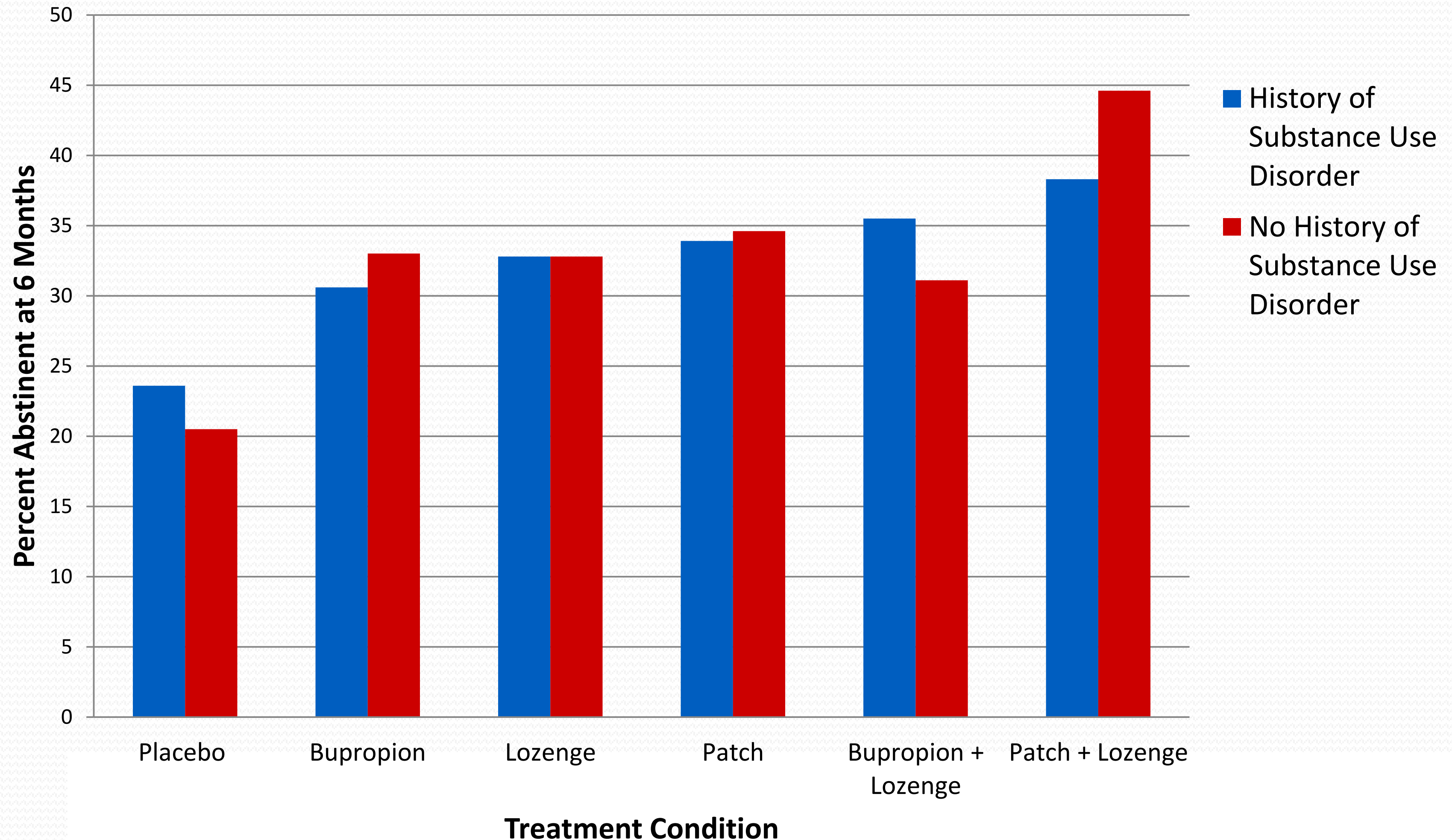
Combination NRT: Especially Effective for History of Depression



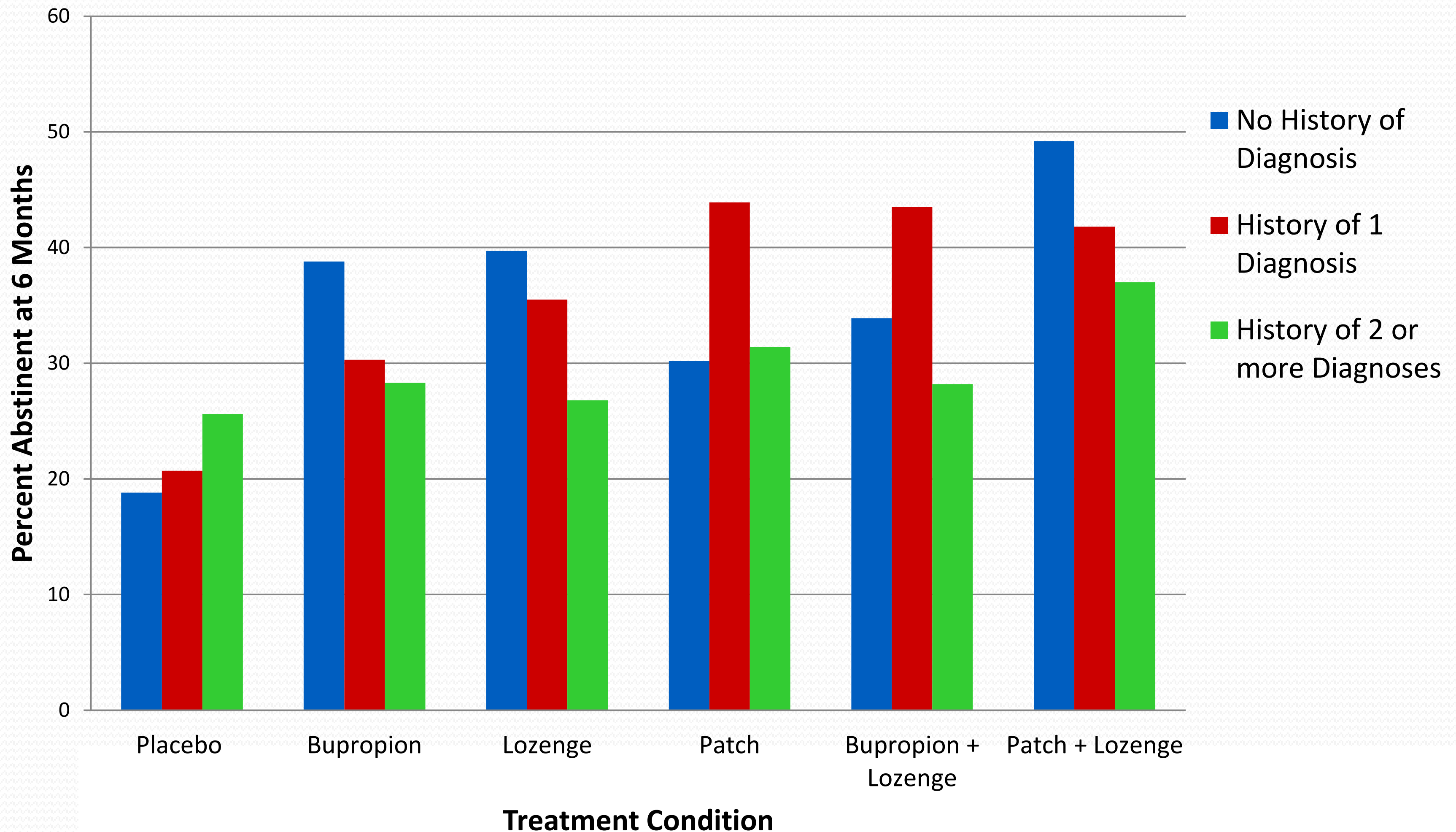
Combination NRT: No Increased Effectiveness for Anxiety



Combination NRT: Some Increased Effectiveness for SUD



Combination NRT: Increased Effectiveness with 2+ Diagnoses



Behavioral Health Diagnoses Over Time

- Mental health appears to improve following smoking cessation.
  - Quitters were less likely to develop and maintain SUD or Major Depression diagnoses over 3 years
- No results suggest quitting smoking has negative long-term behavioral health effects

Piper, et al., Drug & Alcohol Dependence, 2013

Conclusions

- Smokers with behavioral health issues:
  - Want to quit and present for treatment – 74% have hx of diagnosis
  - Can quit – only hx of anxiety predicted lower 6-month abstinence rates (29%) and maybe mood disorders in last 12 months (24%)
- Smokers with a history of anxiety may need help:
  - Getting started on their quit
  - Tolerating and coping with withdrawal symptoms, reducing cessation fatigue
- Combination NRT is especially effective for:
  - History of depression
  - History of 2+ behavioral health diagnoses
  - History of SUD?

What Can You Do?

- Work with every single smoker – including behavioral health clients
- Provide appropriate evidence-based interventions
  - Motivation treatment – 5 R's
  - Cessation treatment
- Counseling
  - Develop a concrete plan
  - For those with anxiety – help develop coping skills
- Medication
  - Varenicline: monitor for safety
  - Combo NRT: especially for women, low education, those with a history of mood and SUD diagnoses

Key UW-CTRI References

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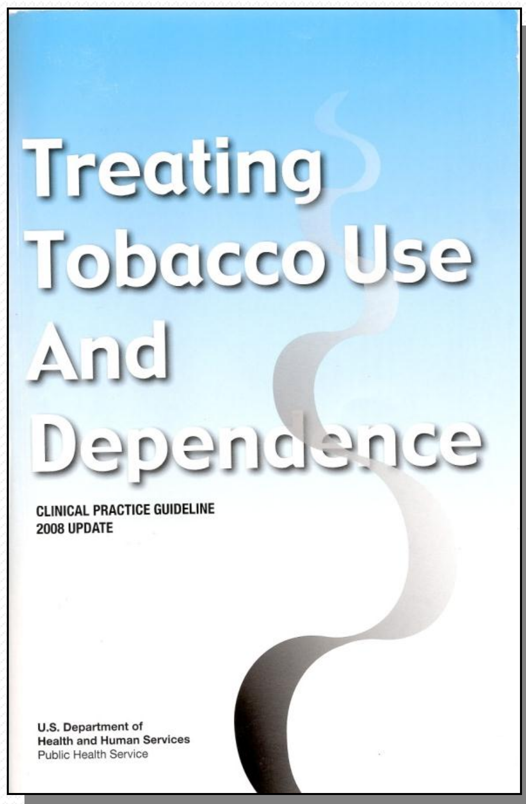
MDQuit.org
Maryland's Tobacco Resource Center - Linking Professionals to Best Practices

www.ctri.wisc.edu



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