Nicotine Addiction, Tobacco Use and Cessation Strategies for People with Mental Illness

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Financial Disclosures:

- Principal Investigator on US Federal and State research awards:
  - NHLBI R01, NCI R01, NIDA R34
  - CA TRDRP Research Awards
- Ad hoc consultant with Pfizer
- Expert witness in litigation against tobacco companies
Tobacco & Mental Illness: A Health Disparity Issue

AGENDA

Prevalence
Morbidity & Mortality
Status Quo
Treatment Efficacy & Safety
Policy Efforts
“My doctor told me I’m too stressed out to quit smoking.... Well, 43 years later, I’m still stressed and I’m still smoking.”

-- Woman diagnosed with severe depression
DEATH of a 56-YEAR-OLD MAN with SERIOUS MENTAL ILLNESS

- 56-year-old, gay-identified Caucasian man
- 15+ psychiatric hospitalizations over a 10-year span
- Severe depressive symptoms, suicidal ideation, and auditory hallucinations criticizing him and/or commanding him to commit suicide
- Tested positive for stimulants
- Diagnosed with schizoaffective disorder, major depression with or without psychotic features, PTSD, and polysubstance or stimulant dependence

DEATH of a 56-YEAR-OLD MAN with SERIOUS MENTAL ILLNESS

- Smoked 2 packs of cigarettes per day for 25 years
- 10 attempts to quit smoking, 2 in the past year
  - Each attempt unassisted, without clinical support or use of FDA-approved cessation medications
- Longest period of being tobacco-free was 7 days
- No advice to quit smoking in the past year by a mental health or general medical provider

Died 20 years prematurely from complications of pulmonary emphysema due to smoking
Tobacco & Mental Illness: A Health Disparity Issue

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- Prevalence
- Morbidity & Mortality
- Status Quo
- Treatment Efficacy & Safety
- Policy Efforts
“60% of People with Schizophrenia Smoke”

- Meta-analysis of 42 studies on tobacco smoking among schizophrenia subjects found an average smoking prevalence of 62% (range = 14-88%)

- Studies reporting higher smoking rates were more commonly cited in the research literature
  - A 10% increase in reported smoking prevalence was associated with a 61% increase in citation rate

- This bias was mirrored on the Internet

SMOKING PREVALENCE by PSYCHIATRIC DIAGNOSIS

41.0% Overall

- Panic Disorder
- PTSD
- GAD
- Dysthymia
- Major Depression
- Bipolar Disorder
- Nonaffect Psychosis
- ASPD
- Alcohol Abuse/Dep
- Drug abuse/dep

Source: Lasser et al., 2000 JAMA
SMOKING & MENTAL ILLNESS: PREVALENCE over TIME

<table>
<thead>
<tr>
<th>Year</th>
<th>No mental illness</th>
<th>Lifetime disorder</th>
<th>Past month/year disorder</th>
</tr>
</thead>
<tbody>
<tr>
<td>1991-1992</td>
<td>35%</td>
<td>30%</td>
<td>41%</td>
</tr>
<tr>
<td>2000-2001</td>
<td>25%</td>
<td>35%</td>
<td>44%</td>
</tr>
<tr>
<td>2001-2003</td>
<td>27%</td>
<td>30%</td>
<td>45%</td>
</tr>
<tr>
<td>2009-2011</td>
<td>25%</td>
<td>30%</td>
<td>36%</td>
</tr>
</tbody>
</table>

Source: National Comorbidity Survey, Lasser JAMA 2000
Healthcare for Communities survey Ong AJ PH 2010
National Survey of American Life, Hickman NTR 2010
CDC Vital Signs MMWR, 2012
SMOKING in PSYCHIATRY:
ADULTS in SAN FRANCISCO, CA

<table>
<thead>
<tr>
<th></th>
<th>Cigarettes/day</th>
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<tbody>
<tr>
<td>Public Psych Inpatient</td>
<td>21 (15)</td>
</tr>
<tr>
<td>Private Psych Inpatient</td>
<td>17 (12)</td>
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<td>Private Psych Outpatient</td>
<td>14%</td>
</tr>
<tr>
<td>SF Adults</td>
<td>15</td>
</tr>
</tbody>
</table>

Acton, Prochaska, Kaplan, Small & Hall. (2001) Addict Behav
POST-MORTEM STUDY with YOUNG ADULTS in FINLAND (N=1623)

Smoking Prevalence in Finland 18.6%

Launiainen et al. (2011) NTR

% Cotinine+ (Recent Tobacco Use)

- Antipsychotics: 70%
- Antidepressants: 72%
- Anxiolytics: 78%
- Hypnotics/sedatives: 75%
- Illicit Drug: 85%
SMOKING and MENTAL ILLNESS
AUSTRALIA

1 in 3 people with mental illness smokes (32%)\(^1\)

- Twice as likely to smoke as those without mental illness (16%)\(^1\)
- Smoking rates increase with severity of mental illness\(^2,3\)
  - Depression: 36%
  - Bipolar disorder: 61%
  - Schizophrenia: 70%

1. Australian National Survey of Mental Health and Wellbeing. ABS 2008
2. Cooper J. Aust NZJ Psych 2012
3. AIHW. National Drug Strategy Household Surveys
4. Bowden J. ANZJ Psych 2011
SMOKING RATES in PSYCHOSIS UNC HANGED: AUSTRALIA 1977/8-2010

SMOKING RATES in PSYCHOSIS UNCHANGED: AUSTRALIA 1977/8-2010

Jablensky A. Aust NZJ Psych 2000; Cooper J. Aust NZJ Psych 2012
Menthol Use & Serious Mental Distress

- 2008-2009 National Survey on Drug Use and Health
- 24,157 adult smokers
- Severe psychological distress associated with menthol use:
  
  \[ \text{adj-OR}=1.23, \ p=0.02 \]

- Controlling for socio-demographic factors: ethnicity, SES, gender, age, education, marital, health insurance, cpd

Hickman, Delucchi, Prochaska (2014) Tobacco Control
Nicotine enters the brain and stimulates nicotine receptors. This leads to dopamine release. The primary areas involved in the dopamine reward pathway are the Prefrontal cortex, Nucleus accumbens, Ventral tegmental area, and Amygdala.
NEUROCHEMICAL and RELATED EFFECTS of NICOTINE

- **Dopamine** ➔ Pleasure, reward
- **Norepinephrine** ➔ Arousal, appetite suppression
- **Acetylcholine** ➔ Arousal, cognitive enhancement
- **Glutamate** ➔ Learning, memory enhancement
- **β-Endorphin** ➔ Reduction of anxiety and tension
- **GABA** ➔ Reduction of anxiety and tension
- **Serotonin** ➔ Mood modulation, appetite suppr.
NICOTINE WITHDRAWAL EFFECTS

- Dysphoric or depressed mood
- Insomnia and fatigue
- Irritability/frustration/anger
- Anxiety or nervousness
- Difficulty concentrating
- Impaired task performance
- Increased appetite/weight gain
- Restlessness and impatience
- Cravings
NICOTINE ADDICTION CYCLE

![Graph showing plasma nicotine concentration over time.](image)

- **Pleasure/Arousal**
- **Neutral Zone**
- **Abstinence symptoms**

**Plasma Nicotine Concentration (ng/ml)**

8am, 6pm, 4am

**Hour**
PLASMA NICOTINE CONCENTRATIONS for NICOTINE-CONTAINING PRODUCTS

![Graph showing plasma nicotine concentrations over time for different nicotine-containing products.](image-url)
WHAT ABOUT E-CIGARETTES?
(vape pens, e-hookahs, hookah pens)

- Cigarette-shaped device consisting of a battery and a cartridge containing an atomizer to heat a solution, often with nicotine

By January 2014 there were 466 brands (each with its own website) and 7764 unique flavors (Zhu, 2014)
E-CIGARETTES and MENTAL HEALTH

N=10,041

Cummins et al. (2014) Tobacco Control
E-CIG USE: SMOKERS with SERIOUS MENTAL ILLNESS (N=956)

Growth in Reported E-cig Use by Year of Study Enrollment

% reporting recent e-cigarette use

Year Entered Study

Prochaska & Grana (2014) PLOS ONE
PREDICTORS of E-CIG USE

- **Later year of enrollment**: OR=29.2 (95% CI 10.5 - 80.7)
- **Younger age** (18-25): OR =2.6 (1.2 - 5.7)
- **nonHispanic** vs. Hispanic: OR=4.0 (1.8 - 8.9)
- **Preparation** vs. precontemplation: OR=2.7 (1.4 - 5.2)

NS: gender, race, employment status, hospital site, study condition, psychiatric or substance use diagnosis, mental health severity, time to 1st AM cig, cigs/day

Prochaska & Grana (2014) PLOS ONE
E-CIG USE & SMOKING (N=956)

- **Not more likely to be tobacco free** @ follow-up:
  - 21% for EC users and 19% for non-EC users, $p = 0.726$

- **Not more likely to reduce cigarettes/day** @ follow-up:
  - $>50\%$ reduction in cigarettes/day (cpd)
    - EC (51%) vs. non-EC users (51%), $p = 0.978$
  - Median reduction in cpd: 7.1 (EC) vs. 6.6 (non-EC), $p = 0.730$
  - CPD at latest FU: 10.0 (EC) vs. 10.1 (non-EC), $p = 0.915$

- **All smoking outcomes NS by EC use** in adjusted models

Prochaska & Grana (2014) PLOS ONE
Looking Upstream...
MAJOR TARGET MARKET

- Estimates that 44% to 46% of cigarettes consumed in US by smokers with psychiatric or addictive disorders (Lasser, 2000; Grant, 2002)

- 175 billion cigarettes and $39 billion in annual tobacco sales (USDA, 2004)
Project SCUM 1995-1997

- RJ Reynolds’ SubCulture Urban Marketing Campaign for
  - Gay people in the Castro and “street people” in the Tenderloin
  - Noted the high incidence of smoking and drugs in these subcultures

- Plan was to introduce Camel cigarettes into less traditional retail outlets, like “head shops”

- Eventually changed the campaign to Project Sourdough
PAIRED with ALCOHOL USE
ENABLING ENVIRONMENTS

A PRIMER FOR
PSYCHOTHERAPISTS

BEHAVIOR DURING THE INTERVIEW

Should the therapist smoke during the interview? Why not? It will help drain the small amount of undischarged tension which is always present during an interview, and it contributes to the naturalness of his behavior.
A search of the Truth Tobacco Industry Library:

- 28 proposals to TI relating to schizophrenia
  - 7 funded, all on self-medicating effects
  - 21 unfunded, study of the high smoking prevalence, health harms (e.g., cancers, medication interactions), and nicotine withdrawal effects

Re: Research Proposal for July/83 - June/84
"Tobacco Smoking As a Coping Mechanism in Psychiatric Patients: Psychological, Behavioral and Physiological Investigations"
Phase I

The latest request is addressing the problems that restriction on smoking in the workplace or elsewhere may have on inducing stress on the smoker. Once again he seems to be looking at this from our point of view.
Department of Health, Education, and Welfare
National Institute of Mental Health
Washington, DC
August 4, 1980

Mr. G. H. Long
R. J. Reynolds Tobacco Company
Winston Salem, North Carolina 27102

Dear Mr. Long:

I am writing to request a donation of cigarettes for long-term psychiatric patients... because of recent changes in the DHHS regulations, Saint Elizabeth Hospital can no longer purchase cigarettes for them.

Over the years the Hospital provided tobacco and occasionally cigarettes for these patients. Many became strongly addicted and in fact look upon smoking as their greatest (and often their only) pleasure.

Recent changes in Department of Human Services regulations and their enforcement abruptly terminated the Hospital's practice of providing a modest number of cigarettes to these patients who have no funds with which to purchase their own. Of our 240 patients, approximately 100 are in this category. The result has been nicotine withdrawal (which can be very unpleasant) and the loss of one of the greatest pleasures for patients who have very few, if any, alternatives. Many of the staff have been providing patients with cigarettes out of their own pocket, but this gets extremely expensive.

I am therefore requesting a donation of approximately 5,000 cigarettes a week (8 per day for each of the 100 patients without funds).

Sincerely yours,

E. Fuller Torrey, M.D.
Medical Director
A. P. Noyes Division
March 21, 1991

Lawrence Tilton
Tilton's Log Cabin
P.O. Box 657
Skowhegan, ME 04976

Dear Larry:

This letter is to inform you that the smoking in restaurants bill (L.D. 603) is now set for hearing on Wednesday, April 3, 1991, at 9:30 a.m. at the Elks Lodge in Augusta. In fact, the following smoking bills also have been set for hearing on that day:

LD 463 - An Act to Exempt Substance Abuse and Psychiatric Patients from the Prohibition against Smoking in Hospitals

3. LD 542 - An Act to Ban Smoking in Laundromats
4. LD 603 - An Act to Amend the Laws Concerning Smoking in Restaurants
5. LD 1134 - An Act to Protect Citizens from the Effects of Environmental Tobacco Smoke

With the above bills all scheduled on one day, it is difficult to know exactly when each of them will be reached. It is vital that you, or a representative, attend the hearing to speak on the legislation and we would appreciate it if you would either give me a call or my paralegal, Susan Mitchell.

Thank you.

Kind regards,

JON R. DOYLE
**HOSPITAL SMOKING BAN EXEMPTION for MENTAL HEALTH**

The article discusses the issue of mental patients fighting to smoke when they are in the hospital. It highlights the efforts of Helen Konopka, a 71-year-old retired New York teacher who organized a tidal wave of letters and petitions to the Joint Commission. The article notes that this was part of a larger national alliance for the mentally ill, an influential advocacy group of patients and their families. It also mentions that the group has not had any contact with the tobacco industry.

JCAHO ultimately "yielded to massive pressure from mental patients and their families, relaxing a policy that called on hospitals to ban smoking."
NY TIMES COMMENTING
FEB 2013

• ...Seem arrogant and cruel to take that [smoking breaks] away. If you were incarcerated in one of these institutions, you might not see it as a problem to shave 5-10 years off your sentence.

• let's see: these people are in a sense terminally ill. there is no cure for their mental disease. they will not have enjoyable, productive, creative lives. so their cigarettes should be withheld so they can live LONGER?
Are e-cigarettes good for your mental health?

Patients with mental health problems are far more likely than others to become dependent on cigarettes. Can 'vaping' reduce symptoms without the risks?

Jack Dutton
theguardian.com, Monday 5 May 2014 12.17 EDT
Jump to comments (24)

“Giving psychiatric patients access to e-cigarettes, particularly on closed wards, is definitely something to consider.”
‘CIGARETTES ARE MY GREATEST ENEMY’

- Statewide social marketing campaign in California by Billy DeFrank Lesbian and Gay Community Center, the Center OC, and the American Legacy Foundation

- Real-life triumphs over adversities to quit smoking
Rebecca struggled with depression. She thought smoking would help, but it just made her more depressed. When she quit smoking it changed her life, mentally and physically. Now she runs 5Ks and hopes to live to be a hundred.

You can quit smoking.

For free help, call 1-800-QUIT-NOW.
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- Status Quo
- Treatment Efficacy & Safety
- Policy Efforts
COMPARATIVE CAUSES of ANNUAL DEATHS in the UNITED STATES

Individuals with mental illness or substance use disorders

Source: CDC, ACS
TOBACCO KILLS

- Individuals with mental illness die, on average, 25 years prematurely (Colton & Manderscheid, 2006)
- Elevated risk for respiratory and CVD and cancer, compared to age-matched controls
  - (Brown et al., 2000; Bruce et al., 1994; Dalton et al., 2002; Himelhoch et al., 2004; Lichterman et al., 2001; Sokal, 2004)

- Smoking is predictive of future suicidal behavior
  - Independent of depressive symptoms, prior suicidal acts, & other substance use
    - (Breslau et al., 2005; Oquendo et al., 2004, Potkin et al., 2003).
TOBACCO USE ISOLATES and is COSTLY

- 75% of psychiatric patients who smoke report smoking most or all of their cigarettes while alone (Prochaska et al., 2005)

- Median of $142.40 per month spent on cigarettes among an outpatient sample of smokers with schizophrenia (Steinberg et al., 2004)

- 27% of their monthly incomes
PHARMACOKINETIC DRUG INTERACTIONS with SMOKING

Drug that may have a decreased effect due to induction of CYP1A2:

- Caffeine
- Clozapine
- Fluvoxamine
- Haloperidol
- Olanzapine
- Phenothiazines
- Propanolol
- Tertiary TCAs
- Other medications: estradiol, naproxen, riluzole, ropinirole, tacrine, theophyline, verapamil, r-warfarin (less active), zolmitriptan

Smoking cessation may reverse the effect
Secondhand Smoke in MH Settings

PM$_{2.5}$ of 10 μg/m$^3$ is the lowest level at which total cardiopulmonary and lung cancer mortality has been shown to increase in response to long-term exposure (WHO).

Balbe et al. (2013) Int J Epi
Tobacco & Mental Illness: A Health Disparities Issue

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STATUS QUO IS CHANGING!
2005-2011

Percent of Smoke Free State Psychiatric Hospitals

Response Rate: 2005 - 55%, 2006 - 82%, 2008 - 75%, 2011 - 80%

NASMHPD Surveys 2005-2011
SMOKING BAN ≠ TREATMENT

- Langley Porter, 100% smokefree since 1988
- N=100 smokers
- 70% used NRT during hospitalization
- 1 patient had tobacco on their treatment plan
- 2 were advised to quit smoking
- 3 received a DSM-IV diagnosis of Nicotine Dependence or Withdrawal
- 4 were provided NRT at discharge

RETURN to SMOKING:
SMOKE-FREE ACUTE PSYCH HOSPITAL

FIGURE 1. Return to Smoking Following a Smoke-Free Hospitalization in Days Since Discharge

RESIDENTIAL EXPOSURES

Tobacco retailer density near persons with Serious Mental Illness living in SF Bay Area – 2xs more dense than average

Young-Wolf, Henriksen, Delucchi & Prochaska (2015). AJPH

Median # of retailers within the service areas of participants’ residences was: 3 (within 500m) and 12 (within 1km)

Median distance to a retailer was: 247m (IQR: 115, 527)
GREATER TO BACCO RETAILER DENSITY

**Greater:**
- Psychosis 500m: $B = 2.9, p < .01$; 1km: $B = 2.5, p = .01$
- Self-harm 500m: $B = 2.6, p = .01$; 1km: $B = 2.1, p = .03$
- Interpersonal problems 500m: $B = 2.0, p = .04$
- Nicotine dependence 500m: $B = 3.0, p < .01$

**Lower:**
- Self-efficacy 500m: $B = -2.1, p = .01$
- Motivation/Stage of Change: PC vs. C\(^1\), P\(^2\)
  - 500m: $B = 1.5, p = .04$
  - 1km: $B = 2.0, p = .02$
LOWER ACCESS TO TREATMENT

2006 AAMC SURVEY: PSYCHIATRISTS

- **62%** Ask about tobacco & Advise to quit
- **44%** Assess readiness to quit
- **13-23%** Assist
  - NRT (23%), other Rx (20%), cessation materials (13%)
- **14%** Arrange follow up
- **11%** Refer to others

Psychiatrists least likely to address tobacco use with their patients relative to other specialties (family medicine, internal medicine, OB/GYN)
SMOKERS with BI POLAR DISORDER: ONLINE SURVEY (N=685)

Few reported a psychiatrist (27%), therapist (18%), or case manager (6%) ever advised them to quit smoking.

Several reported discouragement to quit from mental health providers.

Prochaska, Reyes, Schroeder, et al. (2011). Bipolar Disorders
CLINICIANS’ PERCEPTIONS

- Meta-Analysis of 38 studies: 16,369 MH professionals
- 51% believe MH patients are disinterested in quitting
- 45% have permissive attitudes toward smoking
- 42% perceive barriers to treating tobacco
- 41% have negative attitudes toward treating tobacco
- 38% believe quitting smoking is too much for MH patients to take on

Sheals et al. (2016) Addiction
Just as Ready to Quit Smoking as the General Population

- Intend to quit in next 6 mo
- Intend to quit in next 30 days

**General Population**
- 40%
- 20%

**General Psych Outpts (Acton, 2001 Addict Bx)**
- 43%
- 28%

**Depressed Outpatients (Prochaska 2004, Drug Alc Dep)**
- 55%
- 24%

- 41%
- 24%

**Methadone Clients (Nahvi, 2006, Addict Bx)**
- 48%
- 22%

* No relationship between psychiatric symptom severity and readiness to quit
While 96% of current smokers believed they needed to be mentally healthy to quit, most ex-smokers were not in good or excellent mental health when they quit.

Quitting & MH Symptoms

Meta-analysis found quitting smoking is associated with long-term reductions in depression, anxiety, and stress and improved positive mood states and quality of life, including among those with poor mental health.

- Poor: 10%
- Excellent: 7%
- Good: 29%
- Fair: 54%
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US TOBACCO TREATMENT
CLINICAL PRACTICE GUIDELINES

- Literature base of more than 8,700 research articles

- <30 randomized clinical trials treating tobacco dependence in smokers with mental illness or addictive disorders

CA QUITLINE

- Takes < 3 minutes to Ask, Advise, Refer
- Nearly 1 in 4 callers met criteria for current major depression
- At 2-months, those with depression much less likely to be quit (19%) than callers without depression (28%)

VA TeleQuitMH COORDINATION PROGRAM EVALUATION

- EMR electronic consult
- Program marketing to providers
- Proactive outreach
- Medication coordination
- Self-help materials
- Smoking cessation counseling
  - VA
    - Quitline w/ warm transfers
- Follow-up

N = 577

- 26% vs. 18% quit (30-day) at 6-months follow-up
- Higher satisfaction

Rogers et al. (2013). Addict Sci Clin Practice (Study protocol); Rogers et al. (2016) AJ PM
TREATING TOBACCO USE in INPATIENT PSYCHIATRY

- 100% smoke-free unit
- Stage-tailored expert system, stage-tailored manual, 10 wk nicotine patch vs. Usual care
- 224 patients enrolled
- Full range of psychiatric diagnoses
- 79% recruitment rate
- 81% retention at 18 months

Prochaska et al., 2014, Am J Pub Health
Intervention Components

- Stage-tailored Expert System @ Intake, 3 & 6 months
- Stage-tailored Manual
- Counseling Session 15 to 30-minutes
- 10 weeks Nicotine Patch
SAMPLE (N=224)

- Dx: 47% unipolar depression, 25% bipolar depression, 15% schizophrenia spectrum, 13% other
- 88% involuntarily admitted
  - Suicidal (75%), homicidal (2%), gravely disabled (10%)
- Functioning (SF12): mental health (M=28±13)
  - physical health (M=49±13)
- Length of hospitalization, M = 7 days ± 6
- Regular smoker M = 20 years (±14)
- Cigarettes/day M = 19 (±13)
- 75% smoked ≤30 min of waking
Objective: We evaluated the efficacy of a motivational tobacco cessation treatment combined with nicotine replacement relative to usual care initiated in inpatient psychiatry.

Methods: We randomized participants (n = 224; 79% recruitment rate) recruited from a locked acute psychiatry unit with a 100% smoking ban to intervention or usual care. Prior to hospitalization, participants averaged 19 (SD = 12) cigarettes per day; only 16% intended to quit smoking in the next 30 days. Results: Verified smoking 7-day point prevalence abstinence was significantly higher for intervention than usual care at month 3 (13.9% vs 3.2%), 6 (14.4% vs 6.5%), 12 (19.4% vs 10.9%), and 18 (20.0% vs 7.7%; odds ratio [OR] = 3.15; 95% confidence interval [CI] = 1.22, 8.14; $p = .018; retention > 80%). Psychiatric measures did not predict abstinence; measures of motivation and tobacco dependence did. The usual care group had a significantly greater likelihood than the intervention group of psychiatric rehospitalization (adjusted OR = 1.92; 95% CI = 1.06, 3.49).


OR = 3.15, $p = 0.018$ for condition in a GEE-based logistic regression

Significantly greater rehospitalization rate for UC (140) than Tx (94), $p = 0.036$

Highly cost-effective: $428 per QALY*

* Barnett et al. (in press). J Clinical Psychiatry
IMPACT on MENTAL HEALTH SERVICE UTILIZATION

- 46% psychiatric re-hospitalization rate
  - State data: 44% psychiatric re-hospitalization rate

- 234 Re-hospitalizations:
  - Unrelated to quit status
  - Related to African American race, psychosis symptoms at baseline, prior psych hospitalizations, unstable housing, & study condition (p=.036)
  - Usual care = 140 vs. Treatment = 94
# Model Predicting Rehospitalization

<table>
<thead>
<tr>
<th>Parameter</th>
<th>OR (95% CI)</th>
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</thead>
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<tr>
<td>Condition (usual care)</td>
<td>1.92 (1.06, 3.49)</td>
</tr>
<tr>
<td>Race (African American)</td>
<td>3.04 (0.97, 9.58)</td>
</tr>
<tr>
<td>Psychotic Symptoms (BASIS-24)</td>
<td>1.43 (1.09, 1.89)</td>
</tr>
<tr>
<td>Education in years</td>
<td>1.06 (0.97, 1.16)</td>
</tr>
<tr>
<td>Unstably housed</td>
<td>2.09 (1.12, 3.92)</td>
</tr>
<tr>
<td>Quit during 18-month trial</td>
<td>0.56 (0.28, 1.14)</td>
</tr>
<tr>
<td>Psychiatric Hospitalization History</td>
<td></td>
</tr>
<tr>
<td>First hospitalization (reference)</td>
<td></td>
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<tr>
<td>1 to 2 prior hospitalizations</td>
<td>1.60 (0.70, 3.63)</td>
</tr>
<tr>
<td>3 to 7 prior hospitalizations</td>
<td>2.13 (0.95, 4.77)</td>
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<tr>
<td>8+ prior hospitalizations</td>
<td>3.21 (1.37, 7.54)</td>
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### Urban Public Hospital: Inpatient Psychiatry

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<tr>
<td><strong>N</strong></td>
<td>224</td>
<td>100</td>
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<tr>
<td>Recruitment Rate</td>
<td>79%</td>
<td>71%</td>
</tr>
<tr>
<td>Age in years</td>
<td>40 (14)</td>
<td>40 (11)</td>
</tr>
<tr>
<td>Female</td>
<td>40%</td>
<td>35%</td>
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<tr>
<td>Ethnicity</td>
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</tr>
<tr>
<td>White</td>
<td>63%</td>
<td>44%</td>
</tr>
<tr>
<td>African American</td>
<td>9%</td>
<td>27%</td>
</tr>
<tr>
<td>Hispanic</td>
<td>5%</td>
<td>9%</td>
</tr>
<tr>
<td>Asian American</td>
<td>7%</td>
<td>11%</td>
</tr>
<tr>
<td>Multiethnic/other</td>
<td>16%</td>
<td>9%</td>
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<tr>
<td>Education in years</td>
<td>14 (3)</td>
<td>13 (3)</td>
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<tr>
<td>Income &lt;$20,000</td>
<td>60%</td>
<td>81%</td>
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<tr>
<td>Homeless</td>
<td>5%</td>
<td>39%</td>
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<tr>
<td>Private/self-pay</td>
<td>53%</td>
<td>1%</td>
</tr>
</tbody>
</table>

Hickman et al. (2016) NTR
REPLICATION / TRANSLATION STUDY

Private Hospital, N=224

Public Hospital, N=100

Baseline 3 mo 6 mo 12 mo

3.9% 14.4% 19.4% 26.2%

Usual Care

12.5% 17.5% 8.5% 16.7%
STAR Study Research Questions

- Would 6-mo extended counseling + combination NRT (patch + gum/lozenge) be of interest and outperform our brief treatment?

- Would quit rates differ by diagnosis?
  - Unipolar
  - Bipolar
  - Psychotic Disorders
  - Other

3 Group Additive Design

- G1: Usual Care (on-unit NRT)
- G2: Brief Treatment: 3 mo
- G3: Extended Treatment: 6 mo

10 CBT counseling sessions + 6-months NRT
SETTIMG S

- Langley Porter Psychiatric Institute (SF): 1 unit
- Alta Bates, Herrick (Berkeley): 3 units
- Stanford Hospital (Stanford): 2 units

All with 100% smoking bans
Screened (N=1996)

Declined to Participate (n=349)
Baseline & Randomization (N=956)

Usual Care Control (N=132)
- 3 Month (89%, n=118)
  - 0 withdrew
  - 0 deceased
  - 12 lost to follow-up
- 6 Month (89%, n=116)
  - 0 withdrew
  - 2 deceased
  - 14 lost to follow-up
- 12 Month (92%, n=118)
  - 0 withdrew
  - 4 deceased
  - 10 lost to follow-up
- 18 Month (90%, n=115)
  - 0 withdrew
  - 4 deceased
  - 13 lost to follow-up

Brief Treatment (N=416)
- 3 Month (92%, n=380)
  - 0 withdrew
  - 2 deceased
  - 34 lost to follow-up
- 6 Month (92%, n=380)
  - 0 withdrew
  - 3 deceased
  - 33 lost to follow-up
- 12 Month (86%, n=350)
  - 2 withdrew
  - 8 deceased
  - 55 lost to follow-up
- 18 Month (89%, n=360)
  - 3 withdrew
  - 10 deceased
  - 42 lost to follow-up

Extended Treatment (N=408)
- 3 Month (89%, n=359)
  - 1 withdrew
  - 3 deceased
  - 43 lost to follow-up
- 6 Month (88%, n=353)
  - 2 withdrew
  - 5 deceased
  - 47 lost to follow-up
- 12 Month (89%, n=355)
  - 2 withdrew
  - 9 deceased
  - 40 lost to follow-up
- 18 Month (87%, n=341)
  - 2 withdrew
  - 15 deceased
  - 48 lost to follow-up

Ineligible (n=691)
- Smoking < 5 cpd (n=391)
- Cognitively impaired/failed capacity screener (n=80)
- NRT contraindications (n=51)
- Violence/sexual precaution (n=44)
- Moving out of area (n=34)
- Discharged before randomized (n=28)
- Non-cigarette tobacco user (n=21)
- No contact details (n=19)
- Pregnant (n=7)
- Planned discharge to non-smoking facility (e.g. jail, n=7)
- Non-English speaking (n=6)
- Other (n=3)

*Study deaths (3% of the sample, n=29) are not included in the denominator for calculation of study attrition.
SAMPLE DESCRIPTION

- N = 956, 73% Recruitment Rate
- 50% Men, Age M = 39 years old (SD = 14)
- 51% Caucasian, 24% African American, 25% Other
- Diagnoses:
  - 27% unipolar and 32% bipolar depression
  - 27% nonaffective psychotic disorders
  - 68% substance use disorder
- 80% prior psychiatric hospitalization
- At admission, M = 17 cigs/day (SD = 10) for 19 yrs (SD = 14)
  - 79% smoked within 30 min of waking
  - 24% intended to quit in the next 30 days
NRT USE

- **During hospitalization:**
  - No difference by hospital in on-unit NRT provision
  - A minority (13%) refused NRT during hospitalization
    - Lower FTND score, no prior NRT use (Schuck Tob Control 2014)
  - NW symptoms more severe for women, African American patients, & polysubstance abusers (Soyster Prev Med in press)

- **Post-Hospitalization:**
  - Most (88%) participants in brief and extended treatment groups used study-NRT post-hospitalization
  - Those preparing to quit and with more severe psych symptoms more likely to request NRT at discharge
NRT Requested @ Hospital D/C and Smoking Status @ 1 week

- **54%** requested
- **14%** requested and quit within 24 hours
- **25%** quit at 1 week
- **4%** did not quit

The chart shows the percentage of patients who requested NRT and the subsequent smoking status at 1 week post-discharge.
Expert System and Counseling Completion

- Computer-counseling completion
  - 96% on unit
  - 59% 3-months
  - 55% 6-months

- Extended CBT counseling engagement
  - 23% any session
  - Mean = 3.4 sessions completed
Abstinence over time by Condition

UC vs. Brief/Extended: Odds Ratio = 1.66, p = .048
Brief vs. Extended NS
QUIT OVER TIME by DIAGNOSIS

Baseline 3 mo 6 mo 12 mo 18 mo

Unipolar Dep Bipolar Dep Psychosis Other

21.3% 20.0% 19.4% 15.6%
## 3092 SERIOUS ADVERSE EVENTS

<table>
<thead>
<tr>
<th></th>
<th>Usual Care (n=132)</th>
<th>Brief Treatment (n=416)</th>
<th>Extended Treatment (n=408)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total SAEs</strong></td>
<td>506</td>
<td>1179</td>
<td>1407</td>
</tr>
<tr>
<td><strong>Proportion</strong></td>
<td>78%</td>
<td>74%</td>
<td>76%</td>
</tr>
<tr>
<td><strong>Mean SAE</strong></td>
<td>3.78</td>
<td>2.85</td>
<td>3.45</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>30 total AEs (excluding SAE)</th>
<th>253 total AEs</th>
<th>227 total AEs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Proportion</strong></td>
<td>13%</td>
<td>29%</td>
<td>31%</td>
</tr>
<tr>
<td><strong>Mean AE</strong></td>
<td>.22</td>
<td>.61</td>
<td>.56</td>
</tr>
</tbody>
</table>

*Note: SAE includes death (n=29), life-threatening event, hospitalization, or ED treatment

**Note: AEs are non-life-threatening reported events related (e.g. nausea) and unrelated (e.g., broken bone) to NRT use

*aIncludes one participant with 43 SAEs, one with 41, one with 27, one with 26, one with 21 SAEs

*bIncludes two participants with 22 SAEs and one with 20 SAEs

*cIncludes one participant with 47 SAEs, one with 37, two with 30, one with 28, two with 23, and two with 22 SAEs

**SAEs were unrelated to quitting smoking or to treatment condition**
CONCLUSIONS

- Tobacco treatment during psychiatric hospitalization and continued 3 months post-discharge significantly increased abstinence relative to usual care.
- More extended interventions out to 6 months did not increase abstinence further.
- Patients used combination NRT during hospitalization and post-discharge.
- Abstinence rates did not differ by psychiatric diagnosis.
- Serious adverse events were common and unrelated to treatment condition or quitting smoking.
TREATING TOBACCO DEPENDENCE in DEPRESSED SMOKERS

322 depressed smokers recruited from four outpatient psychiatry clinics

Stepped Care Intervention
Stage-based expert system counseling
Nicotine patch
6 session individual counseling

Brief Contact Control

Hall et al., 2006. Am J Public Health
ABSTINENCE RATES by TREATMENT CONDITION

Likelihood of quitting was unrelated to baseline depression severity

* p < 0.05 for group comparison
DEPRESSION & QUITTING SMOKING

- No increase in suicidality
  - Quit: 0% vs Smoking: 1-4%
- No increase in hospitalization
  - Quit: 0-1% vs. Smoking: 2-3%
- Comparable improvement in emotional problems
- No difference in use of THC, stimulants, opiates
- Less alcohol use among those who quit smoking

Prochaska et al., 2008, Am J Public Health
REPLICATION of TREATMENT EFFECTS

Comparison of TTM-Tailored Trials
12 to 18-mo abstinence rates

<table>
<thead>
<tr>
<th>Category</th>
<th>Treatment</th>
<th>Control</th>
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<tbody>
<tr>
<td>GENERAL POP</td>
<td>20.40%</td>
<td>16%</td>
</tr>
<tr>
<td>DEPRESSED OUTPT</td>
<td>24.60%</td>
<td>19.10%</td>
</tr>
<tr>
<td>INSURED INPT PSYCH</td>
<td>26.20%</td>
<td>16.70%</td>
</tr>
<tr>
<td>PUBLIC INPT PSYCH</td>
<td>20%</td>
<td>7.70%</td>
</tr>
<tr>
<td>INSURED INPT PSYCH-2</td>
<td>19%</td>
<td>13%</td>
</tr>
</tbody>
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INTEGRATING TOBACCO TREATMENT within PTSD SERVICES

- RCT with 66 clients from VA Medical Center
- Integrated care (IC)
  - Manualized treatment delivered by PTSD clinician and case manager (3-hr training)
  - Behavioral counseling 1x a week for 5 weeks + 1 follow-up
  - Bupropion, nicotine patch, gum, spray
- Usual care (UC): referral to VA quit smoking clinic

McFall et al. (2005) Am J Psychiatry
INTEGRATING TOBACCO TREATMENT within PTSD SERVICES

- Cessation Medication Use
  - Integrated Intervention: 94%
  - Usual Care: 64%

- Counseling Sessions Attended
  - Integrated Intervention: M=5.5
  - Usual Care: M=2.6

- At all assessments, the odds of abstinence were 5 times greater for integrated care vs. usual care

McFall et al. (2005) Am J Psychiatry
INTEGRATING TOBACCO TREATMENT within PTSD SERVICES

- Multi-site RCT with 943 clients from 10 VA Medical Centers, train-the-trainer model
- Integrated care (IC) vs. Usual care (UC)
- Cessation outcomes: **2-fold increase in quitting**
  - 18-mo 7 day PPA: IC 18.2% vs. UC 10.8%
- Strongest predictor of tx effect: # of counseling sessions received
- Quitting had no detriment on PTSD symptoms
- IC = $1,286 and UC = $551, for $32,257 per QALY

McFall et al. (2010) JAMA; Barnett et al. (2015) NTR
VARENICLINE USE in SMOKERS with DEPRESSION

- 525 adults smokers stably treated or past depression
- Significant treatment effects at all time points
- NS difference in suicidal ideation or worsening
- Most frequent AE: Nausea in 27%
- 2 deaths in varenicline group during non-tx phase

Anthenelli et al. (2013) Arch Intern Med
VARENICLINE USE in SMOKERS with SCHIZOPHRENIA

- 12wk open label trial, N=112 stable outpatients
  - 28-day continuous abstinence = 34%
  - Improved psychiatric, depressive & NW sx
    Pachas et al. 2012 J Dual Diag

- 12 wk RCT
  N=127 stable outpatients
  Varenicline was well tolerated
  no evidence of sx exacerbation
  Williams et al. (2012) J Clin Psychiatry
VARENICLINE for RELAPSE PREVENTION in SCHIZOPHRENIA & BIPOLAR

- N = 87 participants
- 2+ wks cont abst @ wk 12 of open treatment
- Randomized to CBT with varenicline vs. placebo from wks 12-52
- Followed to wk 76
- Significant all time pts

Evins et al. (2014) JAMA
2 META-ANALYSES of BUPROPRION FOR QUITTING SMOKING in PERSONS with SCHIZOPHRENIA

- 6 RCTs, N = 260 total (19 – 59)
- EOT: RR = 2.57 (95% CI 1.35, 4.88)
- 6 mo FU: RR = 2.78 (95% CI 1.02, 7.58)
- Gen Pop: RR = 1.69 (95% CI 1.53, 1.85)


Bupropion for quitting smoking found to be well tolerated in patients with schizophrenia who are stabilized on an adequate antipsychotic regime.
FDA BOXED WARNING S

- On July 1, 2009, varenicline and bupropion received Boxed Warnings concerning the risk of serious neuropsychiatric symptoms:
  - Patients should be advised to stop taking varenicline or bupropion and to contact a health-care provider immediately if they experience agitation, depressed mood, and any changes in behavior that are not typical of nicotine withdrawal, or if they experience suicidal thoughts or behavior.
Cochrane Network Meta-Analysis: Serious Adverse Events

- **21 Bupropion studies (n=7859):**
  - Event rates for any SAE: 2.5% for bupropion, 2.2% for placebo
  - Neuropsych event rate: 0.8% (B) and 0.9% (P)
  - No excess of neuropsychiatric (RR 0.88; 95% CI 0.31 to 2.50)

- **14 Varenicline trials (n=6333):**
  - Event rates for any SAE: 2.1% for varenicline, 2.0% for placebo
  - Neuropsych event rate: 0.15% (V) and 0.21% (P)
  - No excess of neuropsychiatric (RR 0.53; 95% CI 0.17 to 1.67)

Cahill et al., 2013 Cochrane Review
Cochrane Review: Varenicline Safety (Cahill et al 2016)

“Early reports of possible links to suicidal ideation and behavior have not been confirmed by current research”

- Cochrane Review 2016

<table>
<thead>
<tr>
<th></th>
<th>Nausea</th>
<th>Insomnia</th>
<th>Abnormal Dreams</th>
<th>Headache</th>
<th>Depression</th>
<th>Suicidal Ideation</th>
<th>Severe AE’s</th>
<th>Neuro-psychiatric SAE’s</th>
<th>Cardiac SAE’s, incl. Death</th>
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</thead>
<tbody>
<tr>
<td># studies</td>
<td>32</td>
<td>29</td>
<td>26</td>
<td>25</td>
<td>36</td>
<td>24</td>
<td>29</td>
<td>23</td>
<td>21</td>
</tr>
<tr>
<td># participants</td>
<td>14,963</td>
<td>14,447</td>
<td>13,682</td>
<td>13,835</td>
<td>16,189</td>
<td>11,193</td>
<td>15,370</td>
<td>8,955</td>
<td>8,597</td>
</tr>
</tbody>
</table>
39 trials, N=10,761 participants

Relative to placebo, no increased risk of:
- Suicide or attempted suicide: OR=1.67 (.33, 8.57)
- Suicidal ideation: OR=0.58 (.28, 1.20)
- Depression: OR=0.96 (0.75, 1.22)
- Irritability: OR=0.98 (.81, 1.17)
- Aggression: OR=0.91 (.52, 1.59)
- Death: OR=1.05 (.47, 2.38)

Increased risk of sleep disorders (1.63, 1.29-2.07), insomnia (1.56, 1.36-1.78), abnormal dreams (2.39, 2.05, 2.77), and fatigue (1.28, 1.06-1.55)

Decreased risk of anxiety (0.75, .61-.93)
<table>
<thead>
<tr>
<th>Study</th>
<th>No of events/total Treatment</th>
<th>Odds ratio (95% CI)</th>
<th>Weight (%)</th>
<th>Odds ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jorenby 2006</td>
<td>0/343</td>
<td>-0.00 (-0.01 to 0.01)</td>
<td>15</td>
<td>-0.00 (-0.01 to 0.01)</td>
</tr>
<tr>
<td>Hughes 2011</td>
<td>0/107</td>
<td>-0.01 (-0.03 to 0.02)</td>
<td>5</td>
<td>-0.01 (-0.03 to 0.02)</td>
</tr>
<tr>
<td>Zhao 2011</td>
<td>0/14</td>
<td>0.00 (-0.15 to 0.15)</td>
<td>1</td>
<td>0.00 (-0.15 to 0.15)</td>
</tr>
<tr>
<td>Brandon 2011</td>
<td>0/46</td>
<td>0.00 (-0.04 to 0.04)</td>
<td>2</td>
<td>0.00 (-0.04 to 0.04)</td>
</tr>
<tr>
<td>Ebbert 2011</td>
<td>0/38</td>
<td>0.00 (-0.05 to 0.05)</td>
<td>2</td>
<td>0.00 (-0.05 to 0.05)</td>
</tr>
<tr>
<td>Steinberg 2011</td>
<td>0/40</td>
<td>0.00 (-0.05 to 0.05)</td>
<td>2</td>
<td>0.00 (-0.05 to 0.05)</td>
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<tr>
<td>Bolliger 2011</td>
<td>2/390</td>
<td>0.01 (-0.01 to 0.02)</td>
<td>11</td>
<td>0.01 (-0.01 to 0.02)</td>
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<tr>
<td>Tashkin 2011</td>
<td>0/248</td>
<td>0.00 (-0.01 to 0.01)</td>
<td>11</td>
<td>0.00 (-0.01 to 0.01)</td>
</tr>
<tr>
<td>Williams 2012</td>
<td>5/84</td>
<td>-0.01 (-0.10 to 0.08)</td>
<td>2</td>
<td>-0.01 (-0.10 to 0.08)</td>
</tr>
<tr>
<td>Rennard 2012</td>
<td>1/486</td>
<td>-0.01 (-0.03 to 0.01)</td>
<td>10</td>
<td>-0.01 (-0.03 to 0.01)</td>
</tr>
<tr>
<td>Mitchell 2012</td>
<td>0/33</td>
<td>-0.03 (-0.12 to 0.05)</td>
<td>1</td>
<td>-0.03 (-0.12 to 0.05)</td>
</tr>
<tr>
<td>Wong 2012</td>
<td>0/151</td>
<td>0.00 (-0.01 to 0.01)</td>
<td>6</td>
<td>0.00 (-0.01 to 0.01)</td>
</tr>
<tr>
<td>McClure 2013</td>
<td>0/41</td>
<td>0.00 (-0.05 to 0.05)</td>
<td>2</td>
<td>0.00 (-0.05 to 0.05)</td>
</tr>
<tr>
<td>Stein 2013</td>
<td>1/111</td>
<td>0.01 (-0.04 to 0.05)</td>
<td>2</td>
<td>0.01 (-0.04 to 0.05)</td>
</tr>
<tr>
<td>Cinciripini 2013</td>
<td>0/86</td>
<td>-0.01 (-0.04 to 0.02)</td>
<td>4</td>
<td>-0.01 (-0.04 to 0.02)</td>
</tr>
<tr>
<td>Meszaros 2013</td>
<td>2/5</td>
<td>0.00 (-0.61 to 0.61)</td>
<td>&lt;1</td>
<td>0.00 (-0.61 to 0.61)</td>
</tr>
<tr>
<td>Anthenelli 2013</td>
<td>0/256</td>
<td>-0.01 (-0.03 to 0.00)</td>
<td>11</td>
<td>-0.01 (-0.03 to 0.00)</td>
</tr>
<tr>
<td>Evins 2014</td>
<td>2/40</td>
<td>0.01 (-0.08 to 0.10)</td>
<td>2</td>
<td>0.01 (-0.08 to 0.10)</td>
</tr>
<tr>
<td>Chengappa 2014</td>
<td>2/31</td>
<td>0.03 (-0.08 to 0.14)</td>
<td>1</td>
<td>0.03 (-0.08 to 0.14)</td>
</tr>
<tr>
<td>Gonzales 2014</td>
<td>0/249</td>
<td>0.00 (-0.01 to 0.01)</td>
<td>10</td>
<td>0.00 (-0.01 to 0.01)</td>
</tr>
</tbody>
</table>

Overall: $I^2=0\%$, $P=0.995$ 15/2799 18/2191

Fig 3 | Forest plot of risk of suicidal ideation events (Mantel-Haenszel risk difference) associated with varenicline use in 20 placebo controlled randomised trials
## Observational Studies of Varenicline & NPS

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample</th>
<th>Outcome</th>
<th>Adj. HR*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meyer 2013 Addiction</td>
<td>35,800 US MHS 2006-2007</td>
<td>NPS hospital. (prim diag) 30 days</td>
<td>1.14 (0.56, 2.34)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NPS hospital. (any diag) 30 days</td>
<td>0.79 (0.50, 1.24)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NPS outpt visits</td>
<td>0.71 (0.60, 0.84)</td>
</tr>
<tr>
<td>Thomas 2013 BMJ</td>
<td>112,805 UK NHS 2006-2011</td>
<td>Fatal/nonfatal self-harm 90 days</td>
<td>0.88 (0.52, 1.49)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Initiated antidepressant 90 days</td>
<td>0.75 (0.65, 0.87)</td>
</tr>
<tr>
<td>Kotz 2015 Lancet Resp Med</td>
<td>158,209 UK NHS 2007-2012</td>
<td>Depression</td>
<td>0.65 (0.61, 0.68)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fatal/nonfatal self-harm 6 mo</td>
<td>0.60 (0.48, 0.76)</td>
</tr>
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<td>0.15 – 2.00 all NS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NPS outpt visit in 30 days</td>
<td>Signif for Schiz only</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>1.27 (1.07, 1.51)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>+5 visits per 100 yrs tx</td>
</tr>
<tr>
<td>Molero 2015 BMJ</td>
<td>69,757 Sweden (self-controlled) 2006-2009</td>
<td>Hospital or outpt specialist psychoses, mood, or anxiety</td>
<td>1.18 (1.05, 1.31)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fatal/nonfatal self-harm</td>
<td>(Specific to mood or</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>anxiety tx in Psych-HX)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1.00 (0.72, 1.37)</td>
</tr>
<tr>
<td>Pastemak 2013 Addiction</td>
<td>77,726 Denmark 2007-2010</td>
<td>NPS ER visit or hosp. in 30 days (vs. bupropion)</td>
<td>0.85 (0.55, 1.30)</td>
</tr>
</tbody>
</table>

*All analyses used statistical adjustment to control for confounds, effect is a hazard ratio
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<td>Signif for Schiz only</td>
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<td><strong>1.18 (1.05, 1.31)</strong></td>
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<tr>
<td></td>
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</tr>
<tr>
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<td></td>
<td></td>
<td><strong>1.00 (0.72, 1.37)</strong></td>
</tr>
<tr>
<td>Pastemak 2013 Addiction</td>
<td>77,726 Denmark 2007-2010</td>
<td>NPS ER visit or hosp. in 30 days (vs. bupropion)</td>
<td>0.85 (0.55, 1.30)</td>
</tr>
</tbody>
</table>

*All analyses used statistical adjustment to control for confounds, effect is a hazard ratio*
## Observational Studies of Varenicline & NPS

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample</th>
<th>Outcome</th>
<th>Adj. HR*</th>
</tr>
</thead>
<tbody>
<tr>
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<td>35,800 US MHS 2006-2007</td>
<td>NPS hospital. (prim diag) 30 days</td>
<td>1.14 (0.56, 2.34)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NPS hospital. (any diag) 30 days</td>
<td>0.79 (0.50, 1.24)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NPS outpt visits</td>
<td>0.71 (0.60, 0.84)</td>
</tr>
<tr>
<td>Thomas 2013 BMJ</td>
<td>112,805 UK NHS 2006-2011</td>
<td>Fatal/nonfatal self-harm 90 days</td>
<td>0.88 (0.52, 1.49)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Initiated antidepressant 90 days</td>
<td>0.75 (0.65, 0.87)</td>
</tr>
<tr>
<td>Kotz 2015 Lancet Resp Med</td>
<td>158,209 UK NHS 2007-2012</td>
<td>Depression</td>
<td>0.65 (0.61, 0.68)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fatal/nonfatal self-harm 6 mo</td>
<td>0.60 (0.48, 0.76)</td>
</tr>
<tr>
<td>Cunningham 2016 Addiction</td>
<td>15,255 US VA 2006-2007</td>
<td>NPS hospital. (prim diag) 30 days</td>
<td>0.15 – 2.00 all NS</td>
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<td></td>
<td></td>
<td>NPS outpt visit in 30 days</td>
<td>Signif for Schiz only</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>1.27 (1.07, 1.51)</td>
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<td>+5 visits per 100 yrs tx</td>
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## Fatal/Non-Fatal Self-Harm

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Author</th>
<th>Varenicline # Events/Sample Size</th>
<th>Comparator # Events/Sample Size</th>
<th>Hazard Ratio</th>
<th>95% CI</th>
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</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Lower Limit</td>
</tr>
<tr>
<td>Suicide attempt</td>
<td>Cunningham</td>
<td>0 / 11,774</td>
<td>0 / 23,548</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Suicide</td>
<td>Thomas</td>
<td>2 / 30,352</td>
<td>6 / 78,407</td>
<td>NA</td>
<td>NA</td>
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<tr>
<td>Fatal Or Non Fatal Self Harm</td>
<td>Thomas</td>
<td>19 / 30,352</td>
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<td>0.88</td>
<td>0.52</td>
</tr>
<tr>
<td></td>
<td>Kotz</td>
<td>119 / 51,450</td>
<td>540 / 106,759</td>
<td>0.56</td>
<td>0.46</td>
</tr>
<tr>
<td></td>
<td>Molero</td>
<td>657 / 69,757</td>
<td>NA</td>
<td>1.00</td>
<td>0.72</td>
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Efficacy & Neuropsychiatric Safety in those with Psychotic, Anxiety & Mood Disorders: EAGLES Trial (N=8144, n=4116 psych+)

Continuous Abstinence Week 9-12 by Treatment Group

Primary NPS Composite Safety Endpoint by Treatment Group

Adapted from AE Evins (2016) Poster presented at the Society for Research on Nicotine and Tobacco; Chicago IL
SUMMARY: TOBACCO TREATMENT in SMOKERS with MENTAL ILLNESS

- Support for currently available interventions
  - Treatments matched to motivation
  - NRT, bupropion, varenicline
- Tobacco treatment does not appear to harm mental health recovery
- Integration into mental health treatment settings increases receipt of care and abstinence rates
- Treating tobacco is highly cost-effective
Tobacco & Mental Illness: A Health Disparity Issue

**AGENDA**

- Prevalence
- Morbidity & Mortality
- Status Quo
- Treatment Efficacy & Safety
- Policy Efforts
PRICE SENSITIVITY

- Smoking by individuals with substance abuse or mental disorders was significantly sensitive to cigarette prices:
  - 10% increase in price → 18% decline in smoking

- Limitations:
  - Cross-sectional (cannot prove causation)
  - Quantity of use not available
  - Data from 2001 to 2002

Ong et al. (2010) AJ PH
Smoking Bans in Restaurants & Bars

- Statewide smoking bans in restaurants and bars associated with quitting smoking:
  - 6% decline among men with alcohol use disorders
  - 10% decline among women with anxiety disorders
  - No effect for smokers with mood disorders

Smith, Young-Wolff, et al. (2014) NTR
SMOKING BANS

- At a population level, comprehensive smoking bans in the home and workplace are associated with a significantly reduced risk of developing major depression.

Bandiera et al. (2010) Annals Behavioral Medicine
AFFORDABLE CARE ACT

- ACA mandates access to tobacco treatment
- >30 health care organizations have called for barrier-free access to all evidence-based FDA-approved cessation therapies and counseling
- Massachusetts saved >$3 for every $1 spent on cessation services for state Medicaid program beneficiaries

Richard et al. (2012) Plos ONE
PSYCHIATRY RX for CHANGE

http://rxforchange.ucsf.edu
A national effort to increase surveillance, research, and treatment is needed.

Williams et al. (2013) AJ PH

THINK GLOBALLY, ACT LOCALLY
ADDRESSING MYTHS & BARRIERS

• Individuals with mental illness are just as motivated to quit smoking as the general population.

• Tobacco use is a leading cause of death for those with mental illness & smoking adversely impacts treatment.

• Treatments are available, including the quitline.

• Smokers with mental illness can quit and without harm to their mental health recovery.

• MH providers are interested in training to treat tobacco dependence and training improves practice & systems.

Prochaska (2011) NEJM Perspective
MH EX-SMOKERS’ CESSATION ADVICE

“Smoking not only destroys your health, it creates an addiction, which can complicate emotional stability.”

“There is likely to be physical agitation. Walk or do something to “spend” your energy.”

“I never realized until I quit that the nicotine was what made me anxious and the addiction kept me feeling like it was the only way to cope.”

“Discover why smoking calms you and then find something that will come close to that effect, in a good way.”

“A routine benefits a person with mental illness who wants to quit smoking.”

“Keep a quit journal.”

“Avoid alcohol at all costs.”

“Don’t think of it as losing a friend, think of it as gaining your freedom.”

“Stay away from negative people and fellow smokers until you feel stronger.”
MAKE a COMMITMENT...

Address tobacco use with all patients.

At a minimum, commit to incorporating brief tobacco interventions as part of routine patient care:

Ask, Advise, and Refer.

Become an advocate for smoke-free hospitals and clinics, agencies, workplaces, and public places.
Acknowledgements

- Sharon Hall, PhD
- Neal Benowitz, MD
- Kevin Delucchi, PhD
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- Stephen Hall, MD
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- Romina Kim
- Kathleen Gali
- Anne Michalek
- Danielle Pandika
- Rachel Schuck
- Nicole Anzai
- Amardeep Sekhon
- Susan Iyican
- Christina Wa
CONTACT INFORMATION:

Email: JPro@Stanford.edu
Ph: 650-724-3608
Website: rxforchange.ucsf.edu
A tobacco-free agency is a treatment setting that has policies, training, assessments, and services in place to protect clients and staff from secondhand smoke exposure and smoking cues and is aimed at supporting client and staff efforts to quit smoking and live life tobacco-free. Successful agency attention to tobacco control requires:

1. Written policy **banning tobacco** (and e-cigarettes) from agency setting
2. Written policy requiring **zero evidence** of tobacco use for staff at work
3. **Training of staff** in the treatment of tobacco dependence
4. Availability of **cessation treatment for staff** who smoke
5. **Assessment** of client tobacco use (and e-cigarettes) with documentation
6. **Tobacco treatment planning** for all smokers to include FDA-approved cessation **pharmacotherapy**, such as NRT and **cessation support**
7. **Referrals** for cessation treatment, such as the state quitline
AGENCY READINESS

In your opinion, has your agency done what it can to be a tobacco-free agency?

- No, and it does not intend to within the next 6 months.
- No, but it intends to within the next 6 months.
- No, but it intends to within the next 30 days.
- Yes, it has, but for less than 6 months.
- Yes, it has for more than 6 months.
STAFF READINESS

Given your role at the agency, have you done what you can to get involved in making your agency tobacco-free?

- No, and I do not intend to within the next 6 months.
- No, but I intend to within the next 6 months.
- No, but I intend to within the next 30 days.
- Yes, I have, but for less than 6 months.
- Yes, I have for more than 6 months.
Prochaska’s Stages of Change: Processes & Activities that Can Be Promoted at Each Stage of Change

Pre-contemplation
- Consciousness Raising: Public education using mass media, small groups.
- Dramatic Relief: Taking action to decrease anxiety and other negative emotions through role playing, grieving, testimonies, simulations, and other group activities.
- Environmental Re-evaluation: Learning how one's actions affect one's self/others through guided discussions with family members, testimonies, story telling.

Contemplation
- Self-Reevaluation: Re-evaluation of self-image through group activities:
  - values clarification exercises
  - contact and discussions with role models
  - guided imagery (where people imagine themselves in the new situation [e.g., committed to abstinence])

Preparation
- Self-and Social Liberation: Belief that one can change and commit to change, and creating social conditions for change by:
  - Changing community norms to favor change
  - Drawing attention to those who have made commitments
  - Organizing events for public commitments

Action
- Using and fostering social support and caring relationships through peer groups
- Contingency management: Reinforcing positive steps towards desired behaviors (e.g., commitments), giving group praise and recognition

Maintenance
- Continue positive reinforcement & social support through:
  - continuance of support groups
  - institutionalization (e.g., through local organizations) of rewards and recognition for keeping commitments.
- Stimulus Control: Removing triggers for unhealthy behaviors, Role-playing to substitute prompts for healthy behaviors.
- Maintain self-efficacy: Maintain confidence to resist temptations through regular discussions, accountability system.

Use of Mass Media, Motivational Interviewing techniques, and Other Methods
Skill Building, Social Support through Small Groups, and Other Methods
TREATING TOBACCO with YOUTH in ADDICTIONS TREATMENT

- Randomized, controlled trial of 54 youth age 13-18 in outpatient substance abuse treatment
- 6-session Smoking Reduction and Cessation (SRC) vs. waitlist control
- More teens in the SRC group reported cessation attempts and abstinence at all time points (3 mo FU significant)
- Tobacco cessation intervention appeared to enhance substance abuse treatment outcomes

(Myers & Brown, 2005; Myers & Prochaska, 2008)
TREATING TOBACCO with YOUTH in INPATIENT PSYCHIATRY

- Randomized trial of motivational interviewing (MI) vs. brief advice for smoking cessation
  - Two 45-min sessions and offered 8 weeks NRT
- 191 youth age 13-17 from inpatient psychiatry
- No advantage of MI in smoking outcomes
- MI more likely to increase self-efficacy and intention to change in those with low intention

Brown et al. (2003) Tobacco Control
SPARK STUDY: RCT

Recruited from 17 MH settings in SF Bay Area, 110 screened
- 47 ineligible: lifetime cigarettes < 100, age > 25, lack of contact information, plans to relocate out of area, not in MH treatment
- 3 declined

N = 60 randomized

usual care
3-mo (94%)
6-mo (87%)
12-mo (90%)

intervention
3-mo (93%)
6-mo (89%)
12-mo (86%)

received up to $160 in study incentives

Prochaska et al. (2015) NTR
### Sample Descriptives

<table>
<thead>
<tr>
<th></th>
<th>Boys</th>
<th>Girls</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n = 29</td>
<td>n = 31</td>
</tr>
<tr>
<td>Age (years)</td>
<td>19.7 (3.0)</td>
<td>19.3 (2.9)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>41.4%</td>
<td>38.7%</td>
</tr>
<tr>
<td>Hispanic</td>
<td>24.1%</td>
<td>9.7%</td>
</tr>
<tr>
<td>African American</td>
<td>6.9%</td>
<td>9.7%</td>
</tr>
<tr>
<td>Asian American</td>
<td>10.3%</td>
<td>3.2%</td>
</tr>
<tr>
<td>Multiracial/other</td>
<td>17.3%</td>
<td>38.7%</td>
</tr>
<tr>
<td>Education (years)</td>
<td>11.2 (3.1)</td>
<td>11.9 (2.1)</td>
</tr>
<tr>
<td>Past month # days with mental health visits</td>
<td>8.5 (8.9)</td>
<td>8.5 (8.0)</td>
</tr>
<tr>
<td>Lifetime psychiatric hospitalization</td>
<td>51.7%</td>
<td>71.0%</td>
</tr>
<tr>
<td>Trauma exposed</td>
<td>58.6%</td>
<td>67.7%</td>
</tr>
<tr>
<td>Depression/internalizing scale z-score</td>
<td>-0.23 (.96)</td>
<td>0.21 (.96)</td>
</tr>
<tr>
<td>Hears or sees things others do not</td>
<td>13.8%</td>
<td>27.6%</td>
</tr>
<tr>
<td>Past month substance use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol</td>
<td>58.6%</td>
<td>58.1%</td>
</tr>
<tr>
<td>Marijuana</td>
<td>51.7%</td>
<td>32.3%</td>
</tr>
<tr>
<td>Other illicit drug</td>
<td>17.2%</td>
<td>25.8%</td>
</tr>
<tr>
<td>Past 30 days treated for alcohol or drugs</td>
<td>6.9%</td>
<td>16.7%</td>
</tr>
<tr>
<td>History of drug overdose</td>
<td>13.8%</td>
<td>35.5%</td>
</tr>
<tr>
<td>Smoking Characteristics</td>
<td>Boys</td>
<td>Girls</td>
</tr>
<tr>
<td>-------------------------</td>
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</tr>
<tr>
<td></td>
<td>( n = 29 )</td>
<td>( n = 31 )</td>
</tr>
<tr>
<td>Age first tried smoking</td>
<td>12.9 (3.2)</td>
<td>13.7 (2.6)</td>
</tr>
<tr>
<td>Years smoking regularly (years)</td>
<td>4.0 (2.6)</td>
<td>3.1 (1.7)</td>
</tr>
<tr>
<td>Daily smoker</td>
<td>51.7%</td>
<td>48.4%</td>
</tr>
<tr>
<td>Cigarettes/day</td>
<td>8.2 (5.7)</td>
<td>6.2 (5.8)</td>
</tr>
<tr>
<td>$ spent past month on tobacco (median, IQR)</td>
<td>$30 (10, 60)</td>
<td>$25 (10, 64)</td>
</tr>
<tr>
<td>Use of tobacco products other than cigarettes*</td>
<td>62.1%</td>
<td>19.4%</td>
</tr>
<tr>
<td>Smoke within 30 min of waking</td>
<td>34.5%</td>
<td>41.9%</td>
</tr>
<tr>
<td>Smoking stage of change</td>
<td>55.2%</td>
<td>48.4%</td>
</tr>
<tr>
<td>Precontemplation</td>
<td>27.6%</td>
<td>45.2%</td>
</tr>
<tr>
<td>Contemplation</td>
<td>17.2%</td>
<td>6.5%</td>
</tr>
<tr>
<td>Preparation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Past year 24-hr quit attempt</td>
<td>48.3%</td>
<td>60.0%</td>
</tr>
<tr>
<td>Thoughts about abstinence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Desire to quit</td>
<td>5.8 (2.5)</td>
<td>4.5 (2.7)</td>
</tr>
<tr>
<td>Perceived success with quitting</td>
<td>4.9 (2.8)</td>
<td>4.3 (2.4)</td>
</tr>
<tr>
<td>Anticipated difficulty staying quit</td>
<td>6.9 (2.9)</td>
<td>6.5 (2.3)</td>
</tr>
<tr>
<td>No goal to quit</td>
<td>27.6%</td>
<td>19.4%</td>
</tr>
<tr>
<td>Parent smokes</td>
<td>48.3%</td>
<td>44.8%</td>
</tr>
<tr>
<td>Home is smoke-free</td>
<td>41.4%</td>
<td>58.1%</td>
</tr>
<tr>
<td>3 or more of 5 closest friends smoke*</td>
<td>75.9%</td>
<td>48.4%</td>
</tr>
</tbody>
</table>

*Note. IQR, interquartile range.*

\(^{*}p \leq .05\) for test of difference by gender.
RESULTS

- 47% reduced cigarettes/day from baseline
  - 20% reduced cpd by 50%+
- 80% made a 24-hr quit attempt
- Abstinence at 3, 6, 12-mo fu
  - 11%, 13%, 17% (missing = missing)
  - 10%, 12%, 15% (missing = smoking)
- No difference by treatment group
  - all p-values > 0.300
**PREDICTORS of 12-MO ABSTINENCE**

- **Gender**: AOR = 8.9, 95% CI = 1.8, 44.4
- **Heaviness of smoking**: AOR = 4.5, 95% CI = 1.0, 21.0
- **Condition** (p = .477), use of other tobacco products (p = .722), # close friends who smoke (p = .086), hearing voices (p = .760), depression/internalizing symptoms (p = .655), trauma exposure (p = .693), and residing at home (p = .933) all NS
- Entry did not influence strength of associations of gender and heaviness of smoking with abstinence

*Median split at 7+ cpd vs. < 7 cpd*
Results, missing=smoking
CONCLUSIONS

- Adolescent/young adult smokers with mental illness complex group to engage and treat for tobacco use
  - Particularly heavier smokers and boys

- Girls and lighter smokers quit with minimal support
  - All 9 girls who were quit at 12 mo were residing at home with parents, supportive parenting effect
Meta-analysis of 19 trials
- 12 in treatment; 7 in recovery

Findings: Tobacco Cessation
- In Treatment Studies: Post treatment abstinence rates were intervention=12% vs. control=3%
- In Recovery Studies: Post treatment abstinence rates were intervention=38% vs. control=22%
- No significant effect for tobacco cessation at long-term follow-up (> 6 months)

Prochaska, Delucchi & Hall (2004) JCCP
SMOKING CESSATION RATES

Post–Treatment Long-term FU

18 studies 15 studies

7 day PPA

Comparison Intervention

In Treatment In Recovery
Post–Treatment 18 studies

28% 38%

In Treatment In Recovery
Long-term FU 15 studies

6% 7% 15% 20%
Does quitting smoking cause relapse to alcohol and illicit drugs?

- At ≥ 6 months follow-up, tobacco treatment with individuals in addictions treatment was associated with a 25% increased abstinence from alcohol and illicit drugs (Prochaska et al., 2004).

- Caveat: One well-done study (N=499) of concurrent versus delayed treatment reported (Joseph et al., 2004):
  - Comparable smoking abstinence rates at 18 months (12.4% versus 13.7%)
  - Lower 6-month prolonged alcohol abstinence rates among those offered concurrent compared to delayed tobacco cessation treatment; NS at 12 and 18-months.
Drug Abuse Treatment Settings

- Prospective study, N=649
- At 12-month follow-up, 13% of the 395 baseline smokers reported quitting smoking and 12% of the 254 baseline nonsmokers reported starting/relapsing to smoking

Kohn et al. (2003) Drug Alc Dep
TOBACCO BANS in DRUG TREATMENT PROGRAMS

- National survey of drug treatment programs
  - 2006-08: 897 surveyed, 86% screened for tobacco use, 42% provided treatment
  - 2009-2010 follow-up: problems with discontinuing services:
    - Staff disinterest, inadequate staff skills, time demands, and having a less medically-oriented treatment approach
- 2008 NY State mandated addiction tx facilities ban tobacco & offer cessation treatment
  - Increased screening & cessation treatment practices

National Survey 2006-08

- No formal prog, 58%
- Med only, 25%
- Med + Counsel, 11%
- Counsel only, 5%
HOSPITAL SMOKING BAN &
TEEN ADDICTION TREATMENT

- Chart review
- Sole adolescent hospital-based addictions tx
  program in northern two thirds of British Columbia, Canada
- Mar 2001-Dec 2005, partial to full to partial ban
- Total smoking ban no effect on adolescent smokers:
  - Seeking treatment at the facility
  - Completing treatment

Callaghan et al. (2007) J Subst Ab Tx