

**MAT TRAINING**

**PROVIDERS' CLINICAL SUPPORT SYSTEM**  
For Medication Assisted Treatment

# Pharmacotherapeutic Treatment of Nicotine and Alcohol Dependence

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- The American Academy of Addiction Psychiatry designates this enduring material for a maximum of (one) 1 *AMA PRA Category 1 Credit*<sup>™</sup>. Physicians should only claim credit commensurate with the extent of their participation in the activity.
  - Date of Release March 16, 2015
  - Date of Expiration March 16, 2018

# System Requirements

- In order to complete this online module you will need Adobe Reader. To install for free click the link below:
  - <http://get.adobe.com/reader/>

# Target Audience

- The overarching goal of PCSS-MAT is to make available the most effective medication-assisted treatments to serve patients in a variety of settings, including primary care, psychiatric care, and pain management settings.

# Educational Objectives

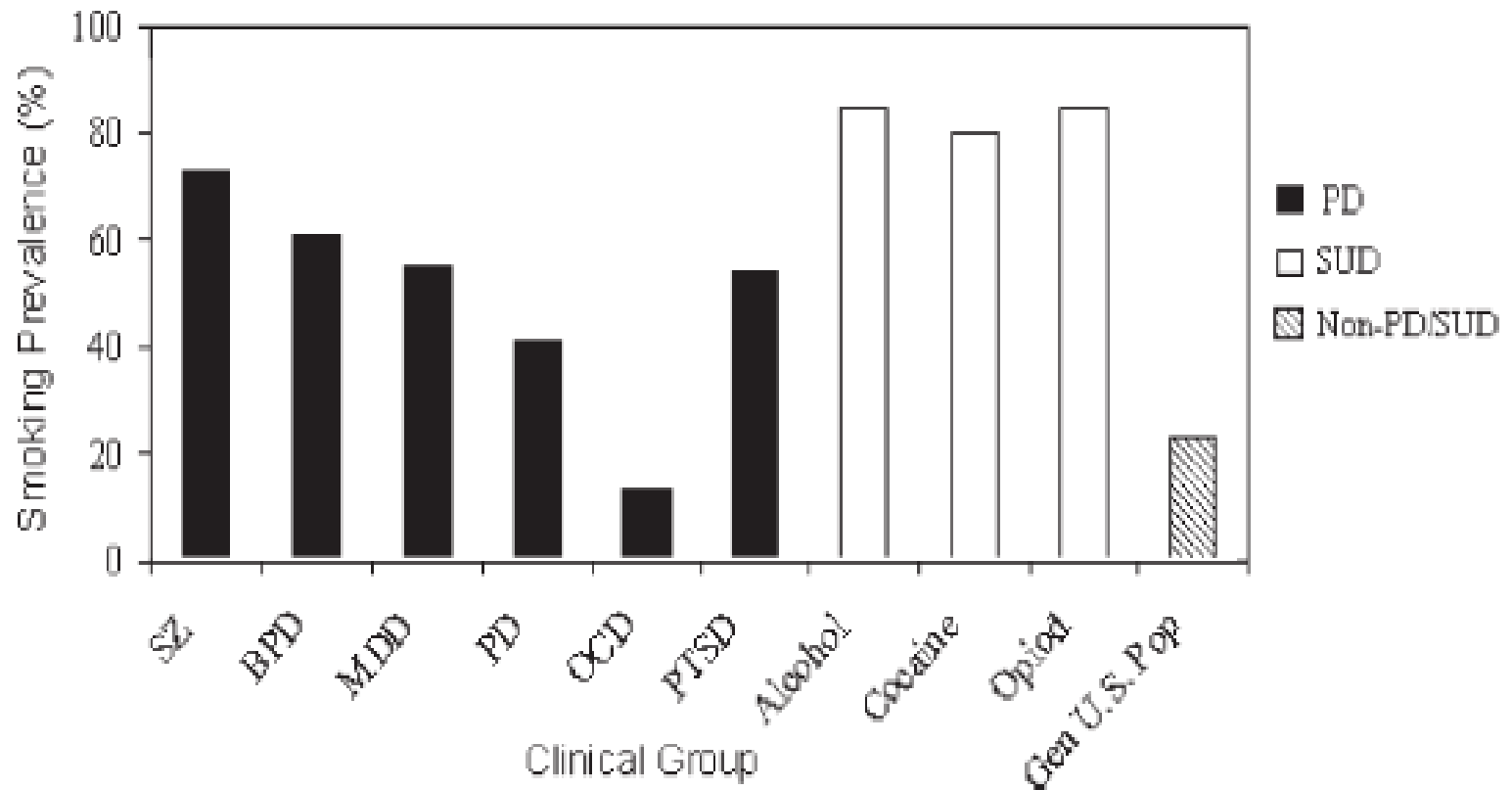
- At the conclusion of this activity participants should be able to:
  - Discuss pharmacotherapeutic treatment options for nicotine dependence
  - Discuss pharmacotherapeutic treatment options for alcohol dependence



# Outline

- Overview of treatment guidelines for nicotine dependence
- Review of specific medication options with prescribing information
- Overview of FDA-approved medications for the treatment of alcohol dependence
- Agents under investigation in the treatment of alcohol dependence
- Pharmacogenetics and the treatment of alcohol dependence

# Smoking and Psychiatric Illness



# Pre-mature Death

- About half of all smokers will die from the effects of smoking<sup>1</sup>
- On average, smokers die **10 to 14 years** earlier than non-smokers<sup>1,2</sup>
- The probability of dying in middle age increases threefold in smokers vs. non-smokers.<sup>1</sup>
- However, quitting at age 50 halves the mortality risk and quitting at 30 almost completely eliminates it.<sup>1</sup>

1. Doll et al., 2006  
2. MMWR, April 2002

# Clinical Practice Guideline Treating Tobacco Use and Dependence: 2008 Update

- Chronic disease requiring multiple interventions and quit attempts.
- Consistent ID smokers & current smoking status
- Use effective medication unless contraindicated NRT, Bupropion SR and Varenicline
- Both Counseling & med effective - combo more effective - use together.
- Telephone quit lines effective - ↑ access & use
- Use motivational therapy in smokers unwilling to make quit attempt - can ↑ future attempts

# “5 A’s” Model

1. **A**sk about tobacco use.
2. **A**dvice to quit.
3. **A**ssess willingness to quit.
4. **A**ssist in quit attempt.
5. **A**rrange follow-up.

# Meds vs. Counseling

- Combination of medication and counseling together is more effective than either alone
- Adding counseling to medication increases quit rates
- Two or more counseling sessions improve quit rates
- Adding meds to counseling also improves outcomes

# Nicotine Replacement Therapy

- Appropriate first-line medication
  - Nicotine gum (OTC) – low compliance
  - Nicotine inhaler (prescription) lowest compliance
  - Nicotine lozenge (OTC)
  - Nicotine nasal spray (prescription)
  - Nicotine patch (OTC) – highest compliance
- Efficacy: Increase success 1.5-2 fold compared to placebo, equally efficacious

# NRT

## Drug Interactions

- Smoking increases the metabolism of some other drugs and after successful smoking cessation drug levels may increase
  - Methadone and buprenorphine
  - Antipsychotic medications
  - Antidepressants
  - Some heart medications



# NRT General Precautions

- Common Adverse effects: Headache, dizziness, sleep disturbances, vivid dreams, nausea, vomiting, indigestion, local irritation at administration site.
- Rare: Irregular heart rhythms, rapid heart beat, palpitations, chest pain, BP changes.
  - Increased blood insulin levels & insulin resistance
  - Dizziness, lightheadedness, insomnia, & irritability 1-25%
- Contraindications: Hypersensitivity to nicotine Cardiovascular Disease
  - NRT not independent risk factor
  - Use with caution 1<sup>st</sup> 2 wks after a heart attack, heart rhythm irregularities, & chest pain

# Nicotine Patch

- 7mg/24h, 14mg/24h, 21mg/24h or 5mg/16h, 10mg/16h, 15mg/15/h
- Peak concentration: 6-12h with initial lag 1-2h
- Smoking > 10 cigarettes/d
  - Weeks 1-6 use one 21mg patch per day
  - Weeks 7-8 use one 14mg patch per day
  - Weeks 9-10 use one 7mg patch per day
- Smoking < 10 cigarettes/d
  - Weeks 1-6 use one 14mg patch per day
  - Weeks 7-8 use one 7 mg patch per day



# Nicotine Patch

- **Cost**
  - Nicotine patch 21mg/24h, 14mg/24h, & 7mg/24h for 14 patches \$27.99 (\$ from drugstore.com)
- **Administration Notes**
  - If have vivid dreams/sleep disturbances, remove at bedtime and reapply in the morning
  - If crave cigarettes on awakening wear for 24 h
- **Additional side effects**
  - Mild skin irritation, usually delayed
  - Moderate irritation in 36%
  - Severe reaction requiring discontinuation in 12%

# Nicotine Gum

- Dosage
  - Smokers <25 cigarettes a day use 2 mg gum
  - Smokers >25 cigarettes a day use 4 mg gum
- Use 1 piece every 1-2 hours for the 6 wks, then 1 pc. every 2-4 hours wks 7-9, then 1 pc. every 4-8 hours wks 10-12
- No more than 24 pieces in 24 hours
- Fixed schedule maybe more helpful than using ad lib



# Nicotine Gum

- Peak nicotine concentration 15-30 min
- Specific Adverse effects with gum- mechanical (sore jaw) & pharmacological (throat irritation, burning in mouth)
- Instructions: chew & “park” between cheek and gum for long periods
  - Avoid eating/drinking before, during, & after use.
  - Absorption ↓ by acidic environment (juice, soda, coffee)
- FDA Category C
- Cost: 4 mg box of 170 pieces \$49.99\*



\* Prices from drugstore.com

# Nicotine Lozenge

- 2 mg / 4 mg
- Heavy smokers (>25 cig/day) or 1<sup>st</sup> cigarette within 30 min of waking
- Light smokers (< 25 cig/day) use 2 mg
- Instructions
  - Weeks 1-6: 1 lozenge every 1-2 hours
  - Weeks 7-9: 1 lozenge every 2-4 hours
  - Weeks 10-12: 1 lozenge every 4-8 hours
- Maximum 5 lozenges/6h or 20 loz/24h



# Nicotine Lozenges

- Additional side effects: mild mucosal irritation, on 4 mg also increased h/a & coughing
- Avoid acidic beverages 15 min before and during use
- High dose lozenges may be more efficacious in highly dependent smokers
- Cost: Both 4mg & 2mg for box of 72 pieces \$37.59



Comes in flavors!

# Nicotine Inhaler





# Nicotine Inhaler

- 10 mg/cartridge delivers 4 mg of nicotine
- Peaks 15-20 min
- Nicotine vapor absorbed through mucosa
- Each cartridge provides about 20 minutes of active puffing
  - 80 deep draws or 300 shallow puffs
  - Therapeutic effect best by frequent continuous puffing for 20 minutes.
  - Ten puffs on inhaler = one puff of cigarette

# Nicotine Inhaler

- Usual Dose: 6-16 cartridges/day
  - Weeks 1-12, use 6-16 cartridges/day
  - Weeks 13-14 gradual taper
  - No optimal taper recommended
  - Max 16 cartridges/day
- Additional contraindication: hypersensitivity to menthol

# Nicotine Inhaler

- Additional Side effects: cough, throat irritation, rhinitis, bronchitis, relapse of asthma
- Acidic beverages interfere with absorption. Water only for 15 min before or during use
- May be particularly helpful for smokers with <20 cig/d and high behavioral dependence
- Cost: Inhaler and 168 cartridges \$189.76\*

# Nicotine Nasal Spray

- Nicotine content: 10 mg/mL
- Peak concentration: 4-15 minutes
- Venous concentration 2-12 ng/mL
- Most closely approximates the time course of plasma nicotine levels from smoking than other forms of NRT



# Nicotine Nasal Spray

- Dosage: One dose = 2 sprays (1 in each nostril)
  - 0.5 mg/spray or 1 mg/per dose
  - Weeks 1-8: 1-2 doses/h with at least 8 doses/d
  - Weeks 9-14: gradual taper
- Maximum dose: 5 doses/h or 40 doses/d
- Additional side effects: coughing, nasal irritation, exacerbation of asthma, transient changes in sense of smell & taste
- Higher abuse potential
- 10ml of spray 35.45\*



\*Langston Info Services

# Choice of NRT

- Equally efficacious
- Patch: GI, nasal & mouth irritation eliminated
- Patch: steady blood levels
- Spray most closely mimics smoking plasma nicotine levels
- Inhaler may assist with behavioral aspects

# Bupropion SR

- Precautions
  - Situations with increased risk of seizures.
  - Bipolar Disorder - Increased risk of manic/mixed episode with antidepressant treatment alone
  - Hepatic impairment
  - Renal impairment
- Seizure risk: on 300 mg/d incidence of 0.1%
  - In depression - predisposing factors were alcohol with possible alcohol abuse, history of head trauma

# Bupropion SR (Zyban, Wellbutrin SR)

- Appropriate first line treatment
- Action:
  - Weak inhibitor of norepinephrine reuptake
  - Weak inhibitor of dopamine reuptake
  - Noncompetitive inhibitor of NACh receptors
- Doubles odds of quitting
- Nearly 20 RCT relatively less withdrawal symptoms and craving compared to placebo
- Weight gain less during active treatment.



# Bupropion SR

- Dosage
  - 150 mg for 3 days then
  - 150 mg twice a day at least 8h apart.
  - Start treatment 1 week before quit date.
  - Continue treatment 7-12 weeks.
  - In presence of severe hepatic cirrhosis reduce dose to max of 150 mg every other day.
- If no progress by 7<sup>th</sup> week unlikely pt will quit.

# Bupropion SR

- Side Effects
  - 300 mg/d 8-12% discontinuation rates due to side effects
  - Most common tremor, rash, h/a, hives
  - Insomnia & dry mouth more likely than placebo
- Cost
  - Bupropion SR 150 mg # 60 \$75.99 (generic)

# Varenicline (Chantix)

- Appropriate first line treatment
- Action: nicotine partial agonist
  - Mimics nicotine → moderate & sustained dopamine release
  - Blocks subsequent nicotine dopamine release
- Triples odds of quitting compared to placebo
- Precautions
  - Significant renal disease or on dialysis - reduce dose
  - May experience impaired driving ability or operate heavy equipment

# Varenicline

- FDA Category C
- FDA Warning February 2008
  - Depressed mood, agitation, behavioral changes, suicidal ideation, & suicide reported during smoking cessation attempts with varenicline. Patients should tell providers about psychiatric history and clinicians should monitor for changes in mood / behavior.

# Treatment Comparison

<b>DRUG</b>	<b>Estimated Abstinence Rate</b>
Varenicline (Chantix) (2mg/day)	<b>33.2</b>
Varenicline (1mg/day)	<b>25.4</b>
Nicotine nasal spray	<b>26.7</b>
Nicotine patch (6-14 wks)	<b>23.4</b>
High dose nicotine patch (>24mg)	<b>26.5</b>
Long-term nicotine patch (>14wks)	<b>23.7</b>
Nicotine gum (6-14 wks)	<b>19.0</b>
Long-term nicotine gum (>14 wks)	<b>26.1</b>
Nicotine inhaler	<b>24.8</b>
Bupropion (Zyban)	<b>24.2</b>

# Electronic Cigarettes (e-cig)



- Battery-powered Vaporizer
- Delivers Nicotine
- Risk vs. Benefit Uncertain
  - ? initiate smoking
  - ? useful in cessation

# FDA-Approved Medications for Alcohol Dependence

Medication	Target
disulfiram (Antabuse®)	Aldehyde dehydrogenase 1949
naltrexone (Revia®, Depade®)	Opioid receptor 1994
acamprosate (Campral®)	Glutamate receptor 2004
Extended-release naltrexone (Vivitrol®)	Opioid receptor 2006

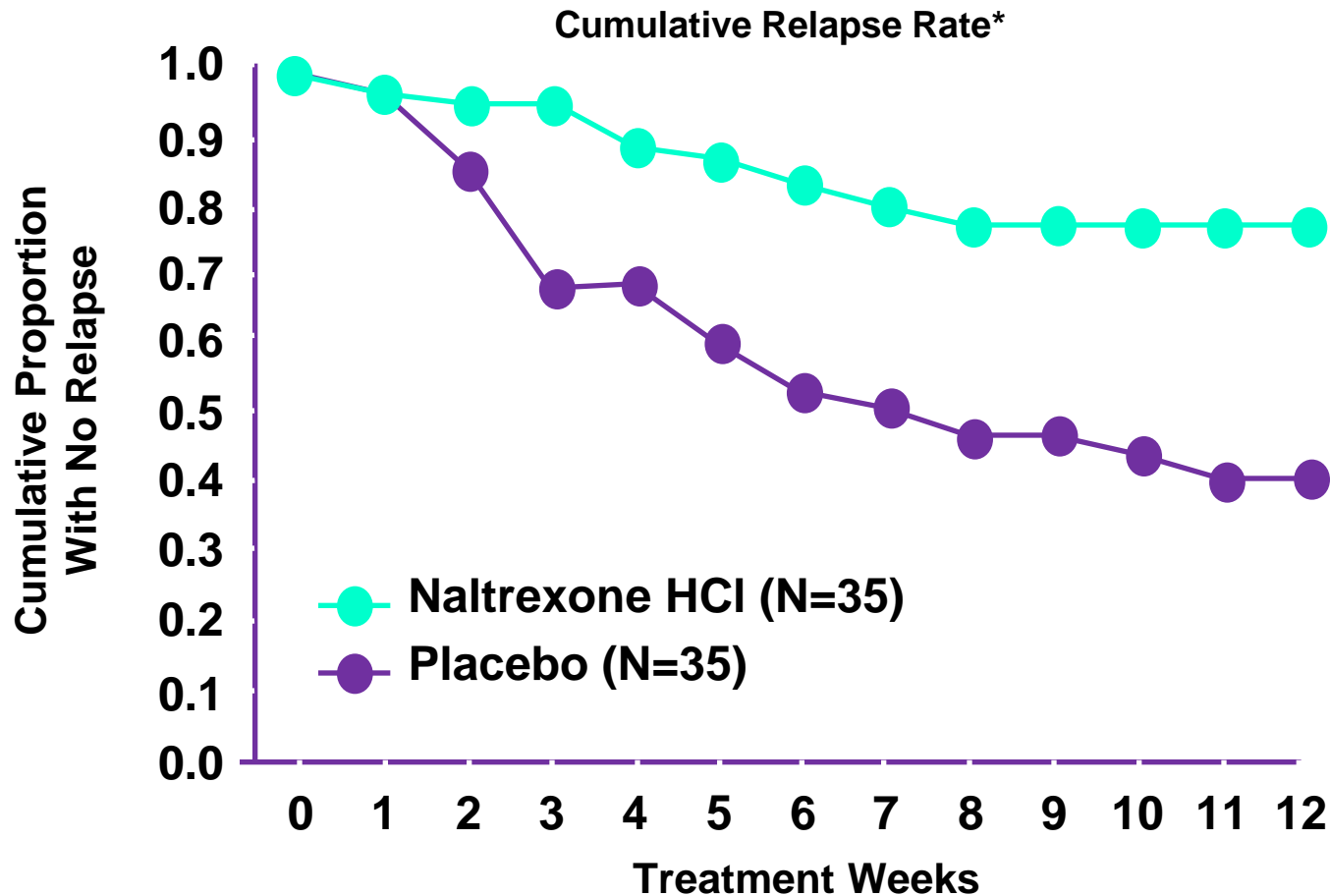


# Medications Tested in Alcohol Dependence

- Aversive agents (disulfiram)
- Serotonin reuptake inhibitors (fluoxetine, sertraline, citalopram)
- Serotonergic agents (ondansetron)
- Opiate antagonists (naltrexone, nalmefene)
- Acamprosate
- Anticonvulsants (topiramate, divalproex)
- Antipsychotics (quetiapine, olanzapine)

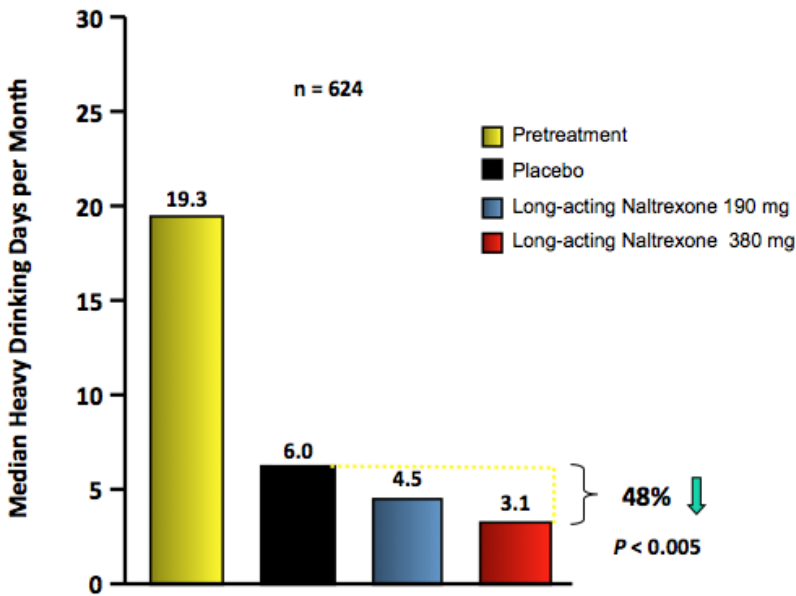


# Naltrexone in the Treatment of Alcohol Dependence: Primary Outcome



\*Time to first episode of heavy drinking;  $P < .01$

# Long-acting IM Naltrexone



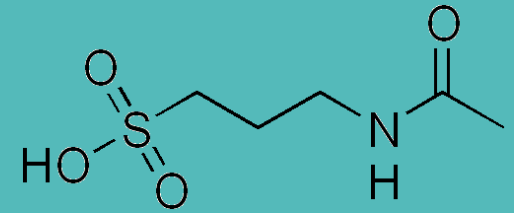
Heavy drinking defined as  $\geq 5$  drinks/day for men;  $\geq 4$  drinks/day for women; naltrexone 380 mg vs. placebo,  $P=.03$ ; naltrexone 190 mg vs. placebo,  $P=.07$

- **Primary Efficacy Measure, Event Rate Of Heavy Drinking:**
  - 380 mg group significantly better than placebo ( $p < 0.03$ )
  - ~48% reduction in median heavy drinking days
    - Baseline 19.3, Placebo 6.0, 380 mg 3.1
  - Benefits observed in both actively drinking and abstinent patients
- **Significant AEs**
  - Mild to moderate nausea (33%), fatigue (20%), decreased appetite
- **Well Tolerated / Favorable Liver Enzyme Profile**
- **AE Drop-outs**
  - 14% (380 mg ND), 7% (190 mg ND), 7% (placebo);  $P=0.01$
- **Injection Site Pain**
  - 380 mg vs. placebo (12% vs. 9%, respectively);  $P=0.04$

# Project COMBINE

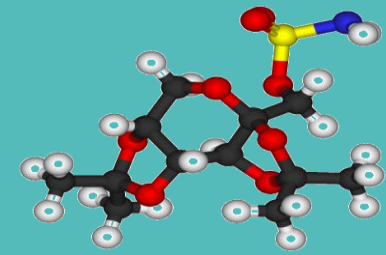
- 1,383 Recently abstinent alcoholics
- Naltrexone, acamprosate or combination
- Medical management, behavioral intervention or combination
- Naltrexone group had significant decrease in drinking outcomes
- No effect of acamprosate alone or in combination with naltrexone

# Acamprosate



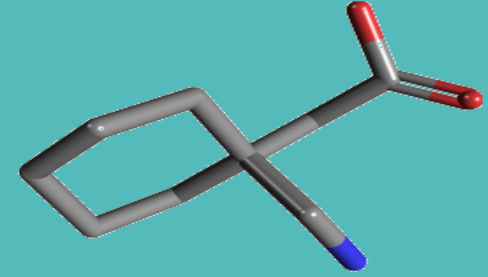
- Acamprosate is #1 selling alcohol medication in U.S.
- Acamprosate is not being actively marketed by Forest Pharmaceuticals in U.S.
- Recent meta-analysis of 22 acamprosate trials totaling 6,111 subjects (Mason and Lehert, *Alcohol Clin Exp Res* 36:497-508, 2012):
  - A significant effect across various treatment endpoints
  - Men and women respond equally to acamprosate

# Topiramate



- Targets: GABA, glutamate AMPA and kainate, L-type Ca channels, Na channels
- Approved for treating seizures and migraine
- 17-site trial with 371 alcohol dependent patients: efficacious in improving treatment outcome
- Side-effects: paresthesia, taste perversion, anorexia, difficulty with concentration

# Gabapentin



- Targets: GABA, glutamate
- Approved for treating seizures, pain
- Three independent, single-site studies demonstrate efficacy in improving drinking outcome in alcohol dependent subjects

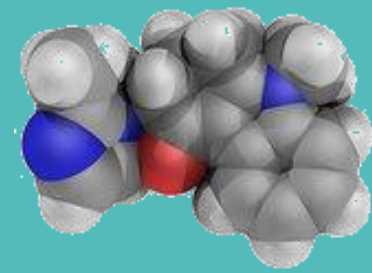
Mason et al., *Addict Biol* 14(1):73-83, 2009

Furieri & Nakamura-Palacios, *J Clin Psychiatry* 68(11):1691-1700, 2007

Karam-Hage & Brower, *Am J Psychiatry* 157(1):151, 2000

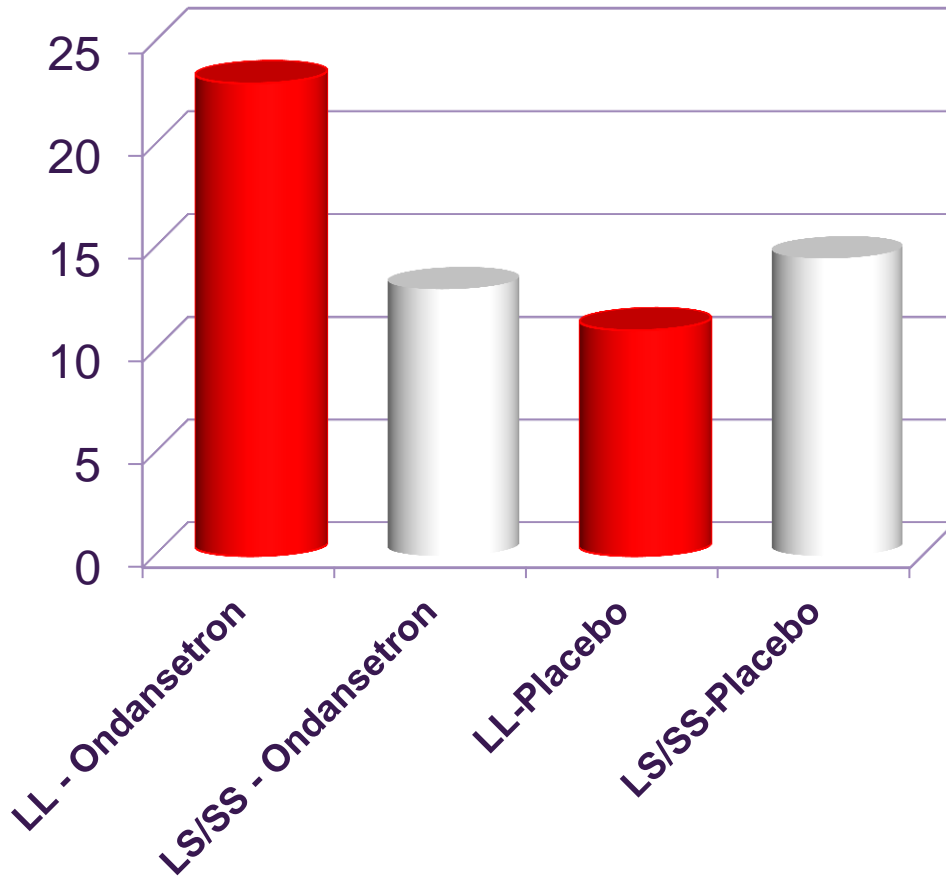
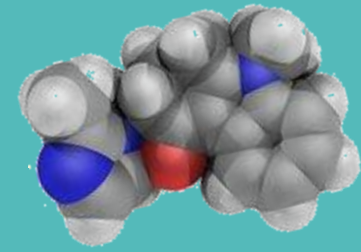


# Ondansetron



- Target: 5-HT<sub>3</sub> antagonist
- Approved for treating nausea and vomiting
- Single-site trial with 283 alcohol dependent patients: efficacious in improving treatment outcome with specific genotype
- Side-effects: Fatigue
- FDA Alert: Risk of developing prolongation of the QT interval
- Dosing: 8-24 mg/day for nausea versus .33 mg/day for alcohol

# Ondansetron

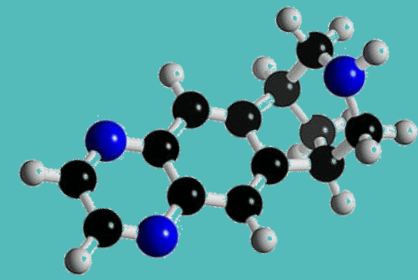


Two genetic variants of serotonin transporter gene

- 5-regulatory region with long form (L) that possesses 44 additional base pairs versus the short (S) form (LL versus LS/SS)
- Rs 1042173 (TT versus TG/GG) in the 3-untranslated region



# Varenicline



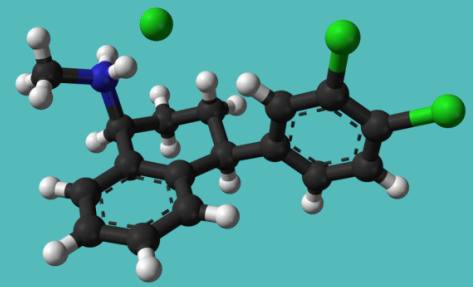
- Targets: nicotinic  $\alpha 4\beta 2$
- Approved for nicotine dependence
- Reduced drinking in human lab study and small clinical trial
- Results of a multi-site clinical trial of 200 alcohol-dependent smokers and nonsmokers pending

McKee et al., *Biol Psychiatry* 66:185-190, 2009

Mitchell et al., *Psychopharmacol* online, 2012



# Antidepressants (SSRIs)



## Depressed Alcoholics

- Antidepressants work well to reduce depression in depressed alcoholics. Impact on drinking is mixed
- SSRI (sertraline) in combination with naltrexone was most effective in improving drinking outcome in depressed alcoholics

# Sertraline and Alcohol

Prospective trial in 134 alcohol-dependent subjects

Early onset vs. late onset

LL vs. LS/SS variants of the serotonin transporter gene

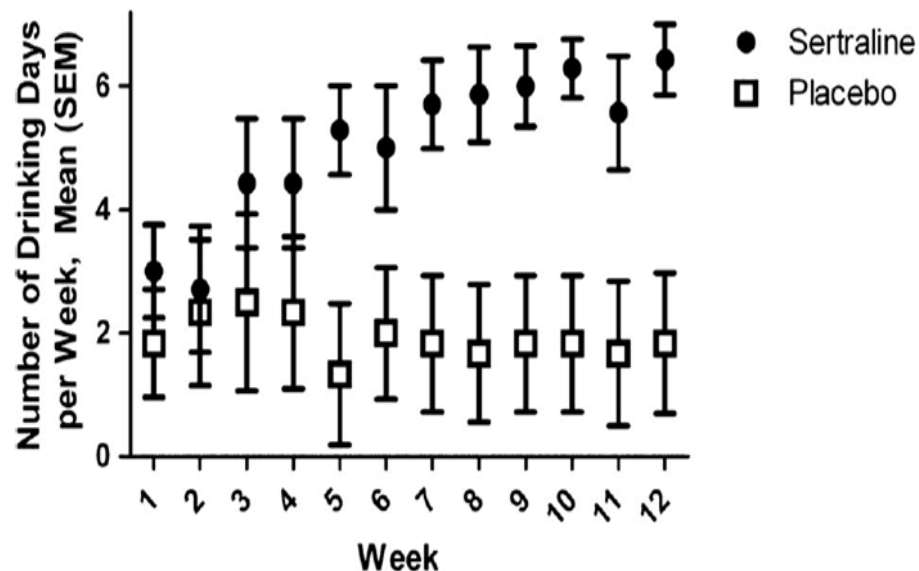
Treatment effect varied by onset of alcoholism and genotype

## Results

All LS/SS subjects (early and late onset) experienced no response to sertraline (75% of population)

LL subjects with early onset had increased consumption with sertraline

## L'L' Early Onset



Krantzler et al., 2011

# Positive Genetic Influences in Alcohol Pharmacotherapy

Medication	Genetic Variant	Outcome Moderated	Notable Studies
Topiramate	<i>GRIK1</i> (rs2832407)	Heavy drinking days (%); side effects	Kranzler et al., 2014 (2); Ray et al., 2009 (4)
Naltrexone	<i>OPRM1</i> (Asn40Asp), (rs1799971), <i>DRD4</i> VNTR	Heavy drinking days (%); abstinence rates; relapse to heavy drinking	Anton et al., 2008 (12); Kim et al., 2009 (13); Oslin et al., 2003 (14); Tidey et al., 2008 (15)
Ondansetron	LL/LS/SS (5-HTTLPR) (rs1042173), <i>SLC6A4</i> (5-HTTLPR)	Drinks per drinking day; days abstinent (%)	Johnson et al., 2011 (9)
Sertraline	5-HTTLPR triallelic <i>SLC6A4</i>	Heavy drinking days (%); drinking days (%)	Kranzler et al., 2011 (8)
Acamprosate	<i>GATA4</i> (rs1327367)	Relapse	Kiefer et al., 2011 (10)
Disulfiram	<i>DBH</i> (rs161115)	Adverse events	Mutschler et al., 2012 (11)

# Conclusions

- Across two decades, solid advances in medications development
- Many exciting possibilities

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# PCSS-MAT Mentoring Program

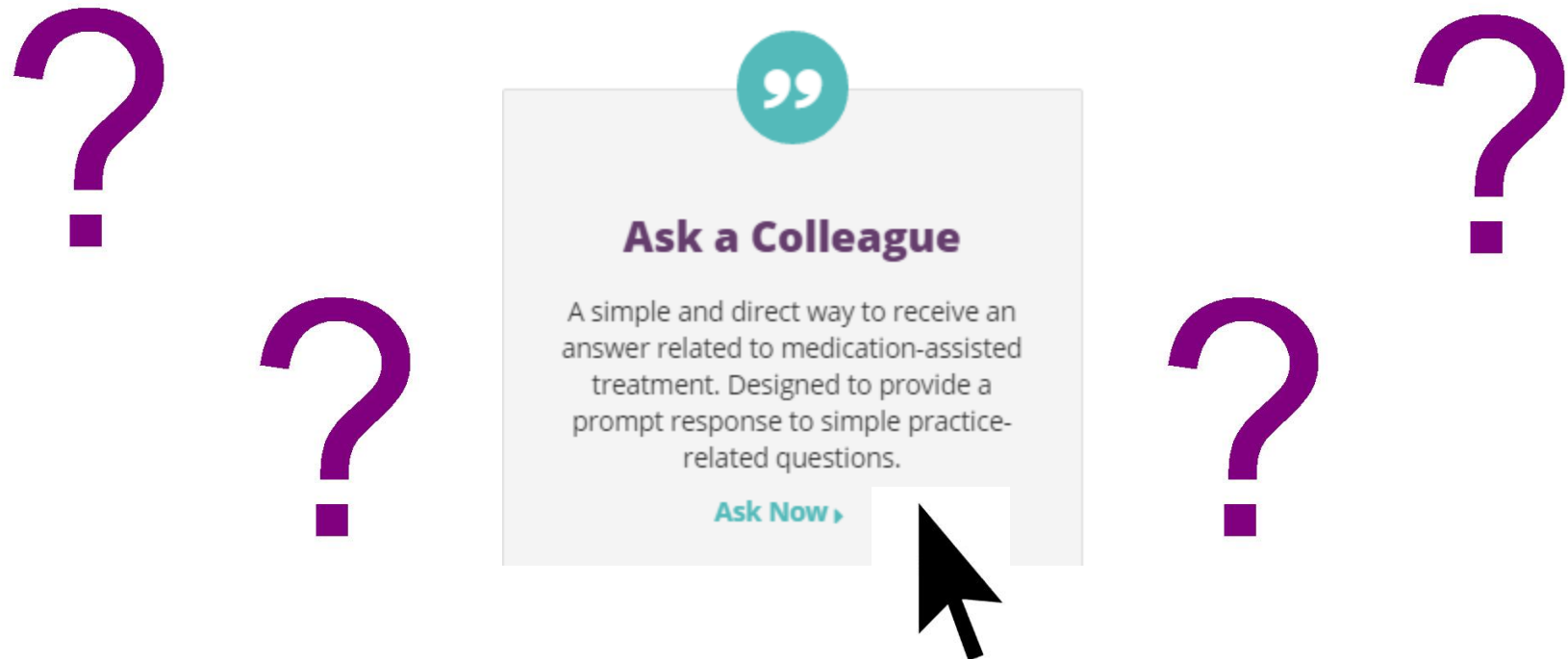
- PCSS-MAT Mentor Program is designed to offer general information to clinicians about evidence-based clinical practices in prescribing medications for opioid addiction.
- PCSS-MAT Mentors comprise a national network of trained providers with expertise in **medication-assisted treatment, addictions and clinical education.**
- Our 3-tiered mentoring approach allows every mentor/mentee relationship to be unique and catered to the specific needs of both parties.
- The mentoring program is available, at no cost to providers.

**For more information on requesting or becoming a mentor visit:**

**[pcssmat.org/mentoring](https://pcssmat.org/mentoring)**

# PCSS-MAT Listserv

Have a clinical question? Please click the box below!



The central graphic features a light gray rounded rectangle with a teal quote icon at the top center. Inside the box, the text reads: "Ask a Colleague", "A simple and direct way to receive an answer related to medication-assisted treatment. Designed to provide a prompt response to simple practice-related questions.", and a teal "Ask Now" button with a right-pointing arrow. A black mouse cursor is positioned over the button. Surrounding the box are four large purple question marks.

**Ask a Colleague**

A simple and direct way to receive an answer related to medication-assisted treatment. Designed to provide a prompt response to simple practice-related questions.

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PROVIDERS' CLINICAL SUPPORT SYSTEM

For Medication Assisted Treatment

**PCSSMAT** is a collaborative effort led by American Academy of Addiction Psychiatry (AAAP) in partnership with: American Osteopathic Academy of Addiction Medicine (AOAAM), American Psychiatric Association (APA) and American Society of Addiction Medicine (ASAM).

For More Information: [www.pcssmat.org](http://www.pcssmat.org)



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*Funding for this initiative was made possible (in part) by Providers' Clinical Support System for Medication Assisted Treatment (5U79TI024697) from SAMHSA. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services; nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government.*

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