

Dissemination of Nicotine and Cocaine Addiction Vaccines

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Claire Wilcox MD
Assistant Professor, Department of Psychiatry
University of New Mexico

How close are we to prime-time?

- Drug development
- More Phase II trials (dosing, efficacy)
- Phase III trials (effectiveness, multi-site)
- FDA approval process

Safety

QuickTime™ and a decompressor are needed to see this picture.

(Haney, 2009)

Safety

- Tachycardia:
 - Cocaine primarily increases heart rate by peripheral rather than central activation of the sympathetic nervous system.
 - Acute tolerance develops rapidly to the heart rate inducing effects of cocaine, which may mitigate the risk of negative cardiovascular consequences.
 - Needs to be studied more

(Haney, 2009)

Safety

- Do vaccines cause more cocaine use?
 - Concern that patients with elevated antibody might try and overcome the vaccine's effects by using larger amounts of cocaine
 - However no increase in cocaine-related adverse events (overdose, hospitalization)
 - Drug use decreased in the high AB group
 - Repeatedly warning participants, orally and in writing, of the potential dangers of attempting to surmount a blunted cocaine effect may be helpful.

(Hatsukami, 2005, Haney 2009k Martell 2009, Martell 2005)

Safety

QuickTime™ and a decompressor are needed to see this picture.

(Cornuz, 2006)

Safety

- Vaccine efficacy is not affected by cocaine or nicotine exposure, vaccination before abstinence initiation may be safe and efficacious.
- Vaccines relatively safe

(Cerny and Cerny 2009, Haney 2009, Martell 2009, Martell 2005, Orson 2008, Hatsukami 2005, Cornuz 2008, Hatsukami 2005)

Things to Work Out

- Need strategies to improve antibody production, such as manipulating the adjuvant or optimizing the frequency and inter-dose interval of vaccination
- Need to determine optimal antibody response (higher antibody levels = greater efficacy)
- Need to determine optimal dose
- Consider protocol to monitor antibody response to maximize efficacy given inter-individual variability?

(Haney 2009, Martell 2009, Cornuz 2008, Orson 2008, Hatsukami 2005)

Things to Work Out

- Need to determine timing of boosters.
- Quantity of drug ingested may affect vaccine efficacy (and ease of vaccine development).

(Cerny and Cerny 2009, Haney 2009, Martell 2009, Martell 2005, Orson 2008, Hatsukami 2005, Cornuz 2008)

Things to Work Out

- For which uses/in which populations will it work best?
 - Overdose treatment
 - Relapse prevention after abstinence
 - Criminal justice system patients
 - Prevention of fetal complications by drug abusing mothers
 - Drug abusing adolescents

Adherence Issues

- Patients must follow a vaccination schedule lasting about 2 months, and may need follow up boosters (Haney 2009, Martell 2009).
- Dropouts related to incarceration and housing loss related to cocaine use (Martell 2009).
- Financial incentives increase follow up for a Hep B vaccination schedule in cocaine dependent individuals (Stitzer 2009).

Adherence Issues

- Criminal justice system . . . would patients get boosters in jail? Consider involving criminal justice system; tag on to systems that provide methadone treatment in jails?
- Co-occurring substance use disorders and psychiatric disorders have lower follow-up rates (Weinstock, 2007).
- Disenfranchised populations (transportation, housing, financial) may have difficulty making appointments or paying for meds.

Patient Barriers to Addiction Pharmacotherapy

- Stigma
 - fear of failure
 - fear of being judged
- Lack of information
- Financial

(Roddy 2006)

Highest Intentions to Try Nicotine Vaccine

- Those who had tried to quit many times before
- Those who had tried different cessation methods
- Higher readiness to quit
- More positive attitudes towards vaccines

(Leader 2010)

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(Leader 2010)

Barriers to Implementation of Addiction Pharmacotherapy

- Slow uptake of new psychopharmacologic interventions in addiction treatment centers
- Decline in use of established medications in recent years
- Approx 20% of addiction treatment centers have adopted naltrexone for alcohol dependence; fewer (5-15%) have adopted buprenorphine for opioid dependence.

(Garner 2008, Abraham 2009)

Barriers to Implementation of Addiction Pharmacotherapy

- Program licensing requirements for medication administration
- Lack of program access to physicians
- Financial factors, lack of insurance coverage of medications
- Ideological factors (12 step orientation of field, recovering status of many providers)
- Diffusion of knowledge about EBP; provider attitudes

(Abraham, 2009)

Organizational Issues

- Roughly one quarter of all addiction treatment programs have no access to physicians.
- One third of addiction treatment programs retain a physician on a less than full-time, contractual basis.

(Ducharme 2006)

Predictors of Adoption of Addiction Pharmacotherapy

- Non-12 step > 12 step (organizational culture)
- Private centers > public centers; For profit > non-profit.
- Access to medical staff/physicians on staff
- Accredited > non-accredited (JCAHO, CARF)
- Availability of detox services
- Provision of prescription drugs
- Higher education level of leadership and counselors
- Provision of an employee handbook
- Participation in NIDA's CTN
- Trainings (for psychosocial interventions) for staff

(Garner 2008, Oser 2007,
Ducharme 2006)

Relevant Counselor Roles

- Recommendation of services: Play a vital role in identifying problems and introducing patients to medication-assisted therapies
- Provide advice and guidance
- Help patients navigate system: provide referrals to medical providers
- Offer ongoing support: encourage and monitor adherence for ongoing treatment

(Abraham, 2009)

Counselor Attitudes

- Counselors often lack information about the availability, effectiveness, and use of addiction medications: lack of information is a crucial barrier to recommendation of addiction pharmacotherapy.
- Counselors cite concerns about cost of medications.
- 86% of >2200 addiction counselors didn't know about the treatment efficacy of buprenorphine.

(Knudsen 2005, Knudsen 2007, Thomas 2008, Garner 2008, Abraham, 2009)

Counselor Attitudes Shaped by:

- Level of education
- Recovery status
- On the job exposure to patients receiving medications for substance dependence
- Receipt of specific training on use of pharmacotherapies
- Culture of organization in which they work

(Abraham 2009, Knudsen 2005, Knudsen 2007,
Thomas 2008, Garner 2008)

Predictors of Lack of Knowledge of Addiction Pharmacotherapy in Counselors

- Female counselors
- Shorter tenure in the treatment field
- Caucasian counselors
- 12-step orientation
- Lack of medication specific training
- Lack of use of the medication in the counselor's treatment program

(Abraham 2009, Knudsen 2005, Knudsen 2007, Thomas 2008, Garner 2008)

Counselor Attitudes

- Training of counselors changes their attitude toward naltrexone for alcohol dependence and buprenorphine for opiate dependence.
- CTN associated counselors are more likely to be more accepting of meds for addiction.

(Abraham 2009, Knudsen 2005, Knudsen 2007,
Thomas 2008, Garner 2008)

Physician Attitudes about Addiction Pharmacotherapy

- Express concerns about patients' compliance
- Express concerns about the cost of the medication
- Attitudes shaped by the philosophy of the organization in which they work
- Compared to counselors, physicians are more familiar with medications for addiction.

(Abraham 2009,
Garner 2008)

Improving Dissemination

- Education regarding pharmacotherapies targeting venues that are likely to reach program administrators and counselors
- Exposure to case studies of treatment providers who have successfully integrated medications into their practices
- Technical assistance to facilitate the adoption and implementation processes in specific clinics
- As treatment providers gain experience with clients who are increasingly motivated to achieve and maintain sobriety, relapse-prevention medications may be more likely viewed as consistent with an organization's philosophy.

(Ducharme 2006)

Collaborative Efforts

- NIDA's CTN and SAMHSA's Blending Initiative (identify important treatment findings, develop training curricula and dissemination plan) and CSAT's ATTC (Addiction Technology Transfer Center) have many trainings.
- Collaborations allow NIDA to ask important services research questions in the SAMHSA supported real-world services delivery settings in a cost effective manner.
- Blending conferences for researchers and clinicians to share ideas about technology development, transfer preparation, transfer implementation, transfer stabilization.

(Garner, 2008; Condon 2007)

Ethical Issues: Autonomy vs Beneficence

- Autonomy: Within bioethical contexts, it refers to the capacity of a rational individual to make an informed, un-coerced decision.
- Beneficence: The term beneficence refers to actions that promote the wellbeing of others. In the medical context, this means taking actions that serve the best interests of patients.

Ethical Issues: Autonomy vs Beneficence

- Adolescents
- Primary prevention in high risk populations
- Pregnancy
- Criminal Justice