



The Northern New Englander *Clinical Trials Network Newsletter*

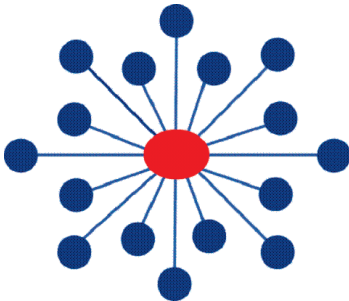
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Copersino on Research Utilization

Special Features:

- *Copersino on Research Utilization*
- *Journal Publications*
- *Levy's Corner*
- *CTPs in the News*



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News from the NNE Research Utilization Coordinator

Let me start by wishing everyone a happy and healthy New Year. Since I may not have had the opportunity to meet one or more of you, I'll briefly introduce myself. My name is Marc Copersino, and I am a psychologist working for Dr. Weiss in the addiction treatment program at McLean Hospital. When I started this position in October, I also assumed 2 roles in the Northern New England (NNE) Node of the Clinical Trials Network (CTN) as Training Director and Node Research Utilization Coordinator (NRUC). Whereas my first CTN-related role and corresponding responsibilities are self-explanatory, the second warrants some explanation.

The mission of the CTN is to develop, refine, and deliver new treatment options to patients in community treatment programs (CTPs) through the collaboration of scientists and practitioners. The NRUC is a role served by one person at each node in the CTN to facilitate fulfillment of one part of this mission, namely to support the dissemination of CTN-tested interventions within the CTN.

Research utilization is the term used to describe the incorporation of research evidence into clinical treatments; and the task of the NRUC is to foster this movement from innovation into practice.

Of course, successful implementation of research utilization activities requires the cooperative efforts of many people. In addition to the direct involvement of the NNE Node CTPs, there will also be collaboration at the national level with the Research Utilization Committee (RUC), and locally with the Addiction Technology Transfer Center of New England (ATTC-NE; head-quartered at the Brown University, Center for Alcohol and Addiction Studies). Whereas the NRUC is a nominated position, members of the RUC are elected by the NRUCs. In December, NRUCs were asked to nominate individuals from their respective nodes to stand for election for the 8-member RUC (4 CTP and 4 RRTC seats).

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Upcoming Meetings

- **CTN Steering Committee**
March 21-22, 2006
Dallas, TX (*tentative*)
- **NIDA Council, NIDA**
February 8, 2006
Rockville, MD
- **NNEN Executive Committee Face-to-Face**
February 27, 2006 from 10am-12pm
McLean Hospital—Belmont, MA

Journal Publications



Readability of Patient Handout Materials

Journal on Addiction Psychiatry, 14:339-345, 2005

In the recent article "Readability of Patient Handout Materials in a Nationwide Sample of Alcohol and Drug Abuse Treatment Programs," Mclean Hospital's own **Shelly Greenfield**, co-authoring with **Dawn Sugarman**, **Jessica Nargiso**, and **Roger Weiss**, evaluated the results of a study on the relationship between literacy rates and the ability of patients to read and comprehend medical literature intended for their use.

In this study, program-specific written materials intended for patient consumption were submitted by 52 consenting alcohol and drug treatment programs nationwide and assessed for grade level readability using the SMOG readability formula. These same programs also submitted a list of substance abuse literature given to patients which are published by an identified set of national organizations such as Alcoholics Anonymous, NIADD, NIDA, etc.

Greenfield et al. (2005) found that the average readability grade level of patient handout materials from these programs ranged from 10.59 to 13.24 when broken out by source of material. The overall average score, 11.84, was almost a full four grades higher than the 8th grade national average for reading level. Among other discussions, the authors observe that relying on these written materials as a treatment aid may diminish treatment effectiveness and options for lower literacy patients. ~

Copersino; Research Utilization

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I nominated Dr. Michael Levy from our node, who has a strong interest and commitment to quality improvement through the adoption of evidence-based practice.

Votes were subsequently cast, in which each NRUC selected four CTP representatives and four RRTC members to serve on the RUC from the list of nominees. The four CTP representatives and four RRTC members with the highest number of votes will serve on the RUC for a two or three year term depending on the grant renewal cycle.

Results of the voting are expected to be released soon by the CTN National Executive Committee Meeting (results will likely be made available before the NNE Newsletter goes out).

Research utilization will also be fostered at the local level through the NNE Node's relationship with the ATTC-NE. Dr. Susan Storti (Director) and Mr. Stephen J. Gumbley (Education Specialist) of the ATTC-NE have made available products developed through the National Institute on Drug Abuse (NIDA)/Substance Abuse and Mental Health Services Administration (SAMHSA)-ATTC Blending Initiative.

This collaborative initiative is closely linked to the CTN mission; and is designed to blend resources, information, and skills in order to encourage the use of current evidence-based treatment interventions by professionals in the drug

abuse treatment field. One product is the ATTC-NE Science to Service Lab, which uses Dr. Nancy Petry's contingency management fishbowl technique (a CTN-tested intervention) as a vehicle for practicing a Comprehensive Technology Transfer Model.

Almost fifty treatment agencies around New England have been involved in the project since 2003. A very interesting new product recently made available by the ATTC-NE is called "**S.M.A.R.T. Treatment Planning**." S.M.A.R.T. stands for Specific, Measurable, Attainable, Realistic, and Time-limited treatment planning; and it is a set of materials designed to make required Addiction Severity Index (ASI) data collection useful for counselors working in community-based treatment programs.

Another new product related to implementing buprenorphine detoxification treatment is due out some time in January.

These products are available to any CTPs in the NNE Node who are interested. Please feel free to contact me (mcopersino@mclean.harvard.edu) about these products, or about any other issues relevant to research utilization in our node. Also, please let me know if there is a particular issue or topic you would like covered or presented in future columns.

So, we have a lot to look forward to in the upcoming months and years as the CTN moves toward dissemination of research findings. Research utilization of CTN-tested interventions is the real payoff of all the CTN studies; and through the collaborative efforts of the NRUC, RUC, and ATTC-NE, the NNE Node can expect worthwhile rewards. ~

Protocol Updates

Active Protocols

CTN-0010: Treating Opioid Dependent Adolescents/Young Adults

Lead Node: Delaware Valley Node

Lead Investigator: George E. Woody, M.D.

This study compares two 3-month treatments for adolescents/young adults who are addicted to heroin. The researchers believe the use of a 3-month stabilization with buprenorphine/naloxone in combination with psychosocial therapy reduces participant heroin use, improves compliance with treatment, and improves overall adjustment more effectively than brief detoxification with buprenorphine.

The study is being conducted at Mercy Hospital's Recovery Center in Westbrook, Maine. Recruitment at the site started in January 2005.

As of December 28, 2005, the site reached its target goal of randomizing 30 participants into the study.

Research follow-up interviews will continue in 2006. ~



CTN-0017: HIV and HCV Intervention In Drug Treatment Settings

Lead Node: Rocky Mountain Region Node/Oregon Node

Lead Investigator: Robert Booth, Ph.D.

This study tests two strategies to reduce the risk of contracting HIV or HCV by reducing risk behaviors in patients undergoing drug detoxification by comparing two counseling modalities to standard care in drug detoxification settings. This study is being conducted within NNE at Stanley Street Treatment & Resources, Inc. (SSTAR) in Fall River, Massachusetts and North Kingstown, Rhode Island.

Recruitment began in December 2004 and concluded December 2005. SSTAR of North Kingstown randomized 101 participants and SSTAR of Fall River randomized 101 participants, meeting the targets for each site. Follow-up interviews will continue during the first 6 months of 2006.

CTN-0020: Job-Seekers Training for Patients with Drug Dependence

Lead Node: Mid-Atlantic Node

Lead Investigator: Dace Svikis, Ph.D.

This study examines the effectiveness of a 12-hour basic job-training program designed to give patients the skills they need to find and secure a job and set vocational goals and methods for locating employment.

The Job Seekers Workshop has exceeded enrollment targets at both NNE sites; 31 participants (target 30) at CAB Danvers, and 55 (target 52) at CAB Salem. CTN-0020's follow-up numbers are very strong and exceed national averages. ~

CTN-0029: Treating Smokers with Attention Deficit Hyperactivity Disorder (ADHD)

Lead Node: Northern New England Node

Lead Investigator: Timothy Wilens, M.D.

This randomized, two-group study compares the use of Osmotic-Release Methylphenidate (OROS-MPH) vs. placebo in the treatment of smokers who are diagnosable with attention deficit hyperactivity disorder (ADHD).

The primary objective of the study is to determine whether or not OROS-MPH increases the effectiveness of standard smoking treatment in obtaining prolonged abstinence for smokers with ADHD.

The CTN-0029 protocol is being conducted within NNE at the Pediatric Psychopharmacology Research Unit of Massachusetts General Hospital in Cambridge, Massachusetts.

Status

The site received endorsement from NIDA to begin pre-screening/screening subjects in November and recently completed the EMMES site initiation Quality Assurance visit on December 20, 2005. It is anticipated that the site will be endorsed by NIDA to begin randomization in early January. ~



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Protocol Updates

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New Protocols

CTN-0028: Treating ADHD in Adolescents with Substance Use Disorders

Lead Node: Rocky Mountain

Lead Investigator: Paula Riggs, M.D.

Co-Lead Investigator: Theresa Winhusen Ph.D.

Co-Lead Medical Investigator: Robert Davies, M.D.



This trial will evaluate use of Osmotic-Release Methylphenidate (OROS-MPH/Concerta) in treating adolescents who are diagnosable with ADHD and SUD (Substance Use Disorder). A total 300-participant study population will include adolescents 13-18 years old with ADHD (according to DSM-IV criteria) and at least one non-nicotine SUD (excluding opioid dependence).

Participants receive individual, manualized CBT (Cognitive Behavioral Therapy) and will also be randomly assigned to group receiving either OROS-MPH or a matching placebo. The CBT will focus on the treatment of the adolescent's substance use disorder.

Status

NNE's version of the Randomized Controlled Trial of Osmotic-Release Methylphenidate (OROS-MPH) for Attention Deficit Hyperactivity Disorder in Adolescents with Substance Use Disorders has received IRB approval for the initial versions, and will have submitted a third version at the time of this publication.

As one of the study's Wave 1 nodes, this site plans to initiate enrollment in mid-February at SSTAR. With the

exception of a still-to-be-hired medical clinician, all staff training is nearly complete.

CTN-0030: The Opioid Analgesic Dependence Treatment Study

Lead Node: Northern New England Node

Lead Investigator for Implementation: Roger Weiss, M.D.

Lead Investigator for Development: Walter Ling, M.D.

In this two-phase study, opioid analgesic dependent participants who wish to withdraw and abstain from opioid use will undergo (first phase) four weeks of treatment with buprenorphine, while receiving either "standard medical management" (SMM) or SMM plus twice weekly individual drug counseling (enhanced medical management, or EMM).

Participants who are successful in the first phase will be followed for eight weeks. Participants who fail in the first phase (or during follow-up) will be eligible for second-phase stabilization treatment with buprenorphine, plus randomly assigned SMM or EMM, followed by taper and follow-up.

The primary purpose of this study is to determine the benefit of individualized drug counseling over SMM in both short and long-term treatment paradigms.

Status

The CTN-0030 team is continuing to work towards study start-up. The CTN-0030 Operations Manual first draft has been completed, while minor revisions are made to the Case Report Forms. QA and Training plans are being developed.

The national protocol training will likely take place in late March 2006. Recruitment of participants across the three Wave 1 sites is still targeted for late April 2006.

The CTN-0030 development team wants to thank everyone who worked so hard to complete the Site Selection questionnaires and return them to apply for this study. The following three sites have been selected to participate in Wave 1:

- McLean Hospital in Belmont, MA (NNE Node)
- UCLA Les Kelley Family Health Center in Santa Monica, CA (PAC Node)
- Chestnut Ridge Hospital in Morgantown, PA (Tri-State Appalachian Node)

The second wave, consisting of an additional nine sites (yet to be selected), is scheduled for launch this fall (2006). ~



CONGRATULATIONS SSTAR!

Stanley Street Treatment and Resource, Inc. (SSTAR) was re-accredited by JCAHO earlier this month (January 2006). ~

Levy's Corner



Dr. Michael Levy is the Director of Clinical Treatment Services at CAB Health & Recovery Services, Inc. in Peabody, Massachusetts, and author of a syndicated column where he responds to reader's questions about

mental health conditions, resources, and problems. In this section of our newsletter, we attempt to synthesize Dr. Levy's columns contributions over the last quarter.

ADD/ADHD

A number of recent letters to Dr. Levy asked him about medications used to treat attention deficit disorders. Parents were concerned about whether certain stimulants predispose their children to addiction. Dr. Levy responds:

...there is no research that suggests that early exposure to a stimulant medication in childhood increases the chance of drug abuse in adulthood. In fact, there is evidence that treating attention deficit disorder with medication in adolescence may actually protect against later substance abuse problems.

Dr. Levy qualifies his response in the case of a parent whose teenager had "some drug problems" with the use of alcohol and marijuana, explaining that the extended-release nature of her son's prescribed medication would tend to forestall abuse. He also conveys that there is now a non-stimulant alternative for the treatment of ADHD (Strattera).

ALCOHOL ABUSE

Many readers wrote to Dr. Levy with questions about obtaining help with their own or a loved one's identified alcohol abuse.

One reader needed resources for a friend who had no insurance and sought longer term rehabilitation after detox. Dr. Levy suggested several resources:

- Medical Foundation HELP-line (MA) - 800.327.5050
- The Bureau of Substance Abuse Services (MA DPH)
- CAB Transitions (for men) - 978.851.8776
- CAB Ryan House (halfway house) - 781.598.1270

Other non-charge support services include AA and Smart Recovery.

Some family members sought ideas for getting loved ones to go to treatment or attend AA (Alcoholics Anonymous).

Dr. Levy suggested that sometimes, particularly when the use of drugs or alcohol is putting the person at severe risk, it may make sense to file a Section 35, which would ask the courts to mandate a 30-day commitment. However, other times, it may be best to compassionately talk with individuals and allow them to discover for themselves what they can achieve on their own and when they might require help. There are also self-help groups for friends and families of problem drinkers, such as Al-Anon, which can provide support and guidance.

MEDICATION INTERVENTIONS

A number of readers wrote in asking about various medications they had heard about that could help alleviate urges and/or stop use of a given substance. Dr. Levy discusses the following:

- **Revia (naltrexone):** Demonstrated in one study to double participants' rate of abstinence from **alcohol**.
- **Topamax (topiramate):** Used to treat **cocaine** addiction.
- **Antabuse (disulfiram):** Typically used to encourage abstinence from **alcohol**, now being researched as an adjunct to treatment for **cocaine** addiction.
- **Zyban (bupropion):** Used to help relieve symptoms of **nicotine** withdrawal. ~

CTPs In the News




UNODC Launches New Worldwide Strategy

United Nations Information Service, December 2005 – Stanley Street Treatment and Resources, Inc. of Fall River, MA and New Kingston, RI is one of two treatment centers chosen to represent the United States in Vienna Austria to join with participants from 19 other agencies from around the world developing the "International Network of Drug Treatment and Rehabilitation Centres." They will help develop a network of treatment centers that can deliver a variety of interventions in regions lacking such facilities over the next two years. ~




Clinical Tips

WHAT IS A STANDARD DRINK?

A standard drink is any drink that contains about 14 grams of pure alcohol (about 0.6 fluid ounces or 1.2 tablespoons). Below are standard drink equivalents as well as the number of standard drinks in different container sizes for each beverage. These are approximate, as different brands and types of beverages vary in their actual alcohol content.

STANDARD DRINK EQUIVALENTS	APPROXIMATE NUMBER OF STANDARD DRINKS IN:
BEER or COOLER	
 12 oz. ~5% alcohol	<ul style="list-style-type: none"> • 12 oz. = 1 • 16 oz. = 1.3 • 22 oz. = 2 • 40 oz. = 3.3
MALT LIQUOR	
 8–9 oz. ~7% alcohol	<ul style="list-style-type: none"> • 12 oz. = 1.5 • 16 oz. = 2 • 22 oz. = 2.5 • 40 oz. = 4.5
TABLE WINE	
 5 oz. ~12% alcohol	<ul style="list-style-type: none"> • a 750 mL (25 oz.) bottle = 5
80-proof SPIRITS (hard liquor)	
 1.5 oz. ~40% alcohol	<ul style="list-style-type: none"> • a mixed drink = 1 or more* • a pint (16 oz.) = 11 • a fifth (25 oz.) = 17 • 1.75 L (59 oz.) = 39 <p><small>*Note: Depending on factors such as the type of spirits and the recipe, one mixed drink can contain from one to three or more standard drinks.</small></p>

DRINKING PATTERNS

WHAT IS YOUR DRINKING PATTERN?	HOW COMMON IS THIS PATTERN?	HOW COMMON ARE ALCOHOL DISORDERS IN DRINKERS WITH THIS PATTERN?
Based on the following limits—number of drinks: On any DAY —Never more than 4 (men) or 3 (women) – and – In a typical WEEK —No more than 14 (men) or 7 (women)	Percentage of U.S. adults aged 18 or older*	Combined prevalence of alcohol abuse and dependence
Never exceed the daily or weekly limits (2 out of 3 people in this group abstain or drink fewer than 12 drinks a year)	 72%	less than 1 in 100
Exceed only the daily limit (More than 8 out of 10 in this group exceed the daily limit less than once a week)	 16%	1 in 5
Exceed both daily and weekly limits (8 out of 10 in this group exceed the daily limit once a week or more)	 10%	almost 1 in 2

*Not included in the chart, for simplicity, are the 2 percent of U.S. adults who exceed *only* the weekly limits. The combined prevalence of alcohol use disorders in this group is 8 percent.

Source: 2001–2002 National Epidemiologic Survey on Alcohol and Related Conditions (NESARC), a nationwide survey sponsored by the National Institute on Alcohol Abuse and Alcoholism of 43,093 U.S. adults aged 18 or older.

This section of the newsletter is intended to be a forum for CTN clinicians to share and benefit from each others' ideas, knowledge and experiences. If interested, please submit an article to Elena Loftus at: eloftus@mclean.harvard.edu.