



CTN 0030 POATS



As of July 7, 2008, 547 participants have been randomized into Phase 1 of the Prescription Opiate Addiction Treatment Study (POATS). Now that summer has arrived, a number of staffing transitions are taking place across participating sites. We want to thank those staff members who have contributed to the success of the POATS study in recent years and are now leaving for other opportunities. To accommodate the needs of the sites and new staff members, the Lead Node is holding a 2-hour webcast booster training on Friday August 1st from 12:30 – 2:30 p.m. EDT to review study operations. Details for the training session will be distributed to the research staff via e-mail in the near future. Please mark your calendars!

SC and EC Elections



Congratulations to Jim Sorensen (California/Arizona Node PI) and Greg Brigham (Ohio Valley Node CTP Director) on their second term as Chair and Co-Chair of the CTN Steering Committee (SC). Half of the members on the Executive Committee (EC) are up for re-election this month. The newly elected members will be announced in the August CTN Bulletin.

CTN 0032 Update



Multi-site calls for HIV Rapid Testing & Counseling Study (CTN 0032) continue to be held bi-weekly on Tuesdays at 3:00 PM EDT. While the Investigative Team, work groups and collaborators continue to develop the manual of operations, intervention materials and training materials, the sites are gearing up for IRB submission and pre-training. The majority of sites have reported that they have a good understanding of their local and state regulations concerning HIV testing. Additionally, the majority of study personnel who have already been hired have completed training in the protection of human research subjects.

The initial CTN 0032 protocol and first site-specific protocol were reviewed by the central IRB, Western IRB, on July 3, 2008, and the study team is awaiting formal feedback. After receiving approval, subsequent site-specific protocols will be submitted and reviewed on a rolling basis.

CTN is a program of the National Institute on Drug Abuse, part of the National Institutes of Health within the Department of Health and Human Services.



Grants Tidbit Corner – New Grants

The following grant opportunities may be of interest to researchers in the CTN:

Pilot Clinical Trials of Pharmacotherapies for Substance Related Disorders (R01) (RFA-DA-09-005)

<http://grants.nih.gov/grants/guide/rfa-files/RFA-DA-09-005.html>

Criminal Justice Drug Abuse Treatment Studies 2 (CJ-DATS 2) (U01) (RFA-DA-09-006)

<http://grants.nih.gov/grants/guide/rfa-files/RFA-DA-09-006.html>

Improving Effectiveness of Smoking Cessation Interventions and Programs in Low Income Adult Populations (R01) (RFA-CA-08-022)

<http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-08-022.html>

Improving Effectiveness of Smoking Cessation Interventions and Programs in Low Income Adult Populations (R21) (RFA-CA-08-023)

<http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-08-023.html>

Medications Development for Polydrug Addiction Treatment (R01) (PAS-08-186)

<http://grants.nih.gov/grants/guide/pa-files/PAS-08-186.html>

Medications Development for Polydrug Addiction Treatment (R21) (PAS-08-187)

<http://grants.nih.gov/grants/guide/pa-files/PAS-08-187.html>

Exploratory Collaborations with National Centers for Biomedical Computing (R21) (PAR-08-183)

<http://grants.nih.gov/grants/guide/pa-files/PAR-08-183.html>

Collaborations with National Centers for Biomedical Computing (R01) (PAR-08-184)

<http://grants.nih.gov/grants/guide/pa-files/PAR-08-184.html>

Request for Information



NIDA needs to keep track of the grants that use CTN as a platform. Please send the information to Quandra Scudder at: ScudderQ@nida.nih.gov. Thanks!

The NIDA Networking Project (NNP)



The NIDA Networking Project (NNP) is expanding. Read about the newest updates below:

Cocaine/Alcohol Addiction

Pharmacotherapies

This Medication Development Center (MDC) trial tested the efficacy of disulfiram, naltrexone and their combination in 208 patients for co-occurring cocaine and alcohol dependence. [Read more...](#)

'Treatment As Usual?'

Scientists analyzed the Treatment As Usual (TAU) arm of two CTN treatment effectiveness trials to see what constitutes standard treatment practice in these comparison sites. [Read more...](#)

Program Reduces Stress in Foster Care Children

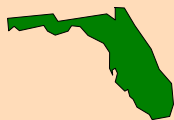
Scientists from the OSLC Transdisciplinary Prevention Research Center (TPRC) found that a therapeutic family intervention prevented the development of atypical cortisol levels—a biological measure of stress—in foster care preschoolers. [Read more...](#)

FY 2009 RFAs Posted

Two 2009 RFAs are posted on NIDA's website for the newest Genes Environment & Health Initiative (GEHI) [RFA-DA-09-003 \(R21\)](#), [RFA-DA-09-004 \(R03\)](#), and on medications development for cannabis-related disorders [RFA-DA-09-001 \(R01\)](#)

For more information, please contact Susan David at 301-435-0640 or davids2@nida.nih.gov.

Florida Node News



It is with regret that the Florida Node announces the departure of José Cassul from the University of Miami Center for Family Studies. For nearly five years, José has served as the Quality

Assurance Director for the Center. In this role, he also served as the Lead Quality Assurance Monitor for the national clinical trial of Brief Strategic Family Therapy™ (BSFT™) for the Treatment of Adolescent Drug Abuse (CTN 0014). He has earned the respect and recognition of the Clinical Trials Network as a consultant in matters of Good Clinical Practices, and trial implementation.

Dr. Elizabeth Alonso has been promoted to the position of Quality Assurance Director for the Center for Family Studies. Dr. Alonso received her doctorate in Counseling Psychology from the University of Miami. During the past four years, she has been an essential team member of the BSFT™ study, where she excelled in a number of roles, including the development of training and operation procedures, national training and oversight of all Florida sites. Her leadership was fundamental to bringing this complex psychotherapy research study to Puerto Rico as a participating site, thus creating a model for clinical trial implementation for Spanish-speaking only participants living in a fully Hispanic context.

Delaware Valley Node News



Dr. George Woody (Delaware Valley Node PI) was one of several NIDA grantees who participated in a meeting on collaborative research with investigators from the university and substance abuse treatment programs in Reykjavík, Iceland, July 1-3. The researchers learned that Iceland has a population of about 300,000, two-thirds of whom live in Reykjavík. It is a democracy that gained independence from Denmark in 1944. Children must learn Icelandic, Danish and German by the time they finish school. Norwegian Vikings first settled Iceland in the year 857, and the language is relatively unchanged from that time due to the country's isolation. The average temperature in Reykjavík during the winter is a little higher than New York since the climate in the southern part of the country is modified by the Gulf Stream. The island is volcanic with geothermal energy and little need for oil, has water that does not need chemical purification, and boasts many waterfalls and other interesting things to see.

The main substance abuse problem in Iceland is alcoholism, but a significant number of patients have amphetamine dependence, often injecting, and others have marijuana and benzodiazepine abuse or dependence. There is little cocaine and no heroin; however, they have a small number of patients with prescription opioid abuse and dependence. This problem began several years ago and its rise was checked when codeine was made available only by prescription, and a nationwide prescription monitoring program was begun.

The treatment system is well organized, staffed and funded. All patients begin with an 8-10 day hospital stay where they are detoxified and stabilized; about a third go on to a 28-30 day residential treatment and the rest to IOP (Intensive OutPatient) treatment. There are a number of program choices: a women's specialty inpatient program, buprenorphine and methadone programs (total of about 60 patients), an adolescent program, and a longer-term residential program for patients with multiple relapses (the "Viking" program.) Treatment is provided essentially on demand, though waiting lists of 10-30 days develop at times. They estimate that 50% of the target population has been treated, and employers readily send their employees to treatment and return them to work with positive expectations about treatment response. There are many AA meetings, a national consensus that addiction is a disease and that treatment works, and less stigma about the problem than occurs in many other settings. *Thanks George for sharing this information!*

Publications Committee (PC)



The Publications Committee thanks and congratulates all the study teams and authors who presented reports of CTN work at various recent national meetings.

The June College on Problems of Drug Dependence (CPDD) meeting in San Juan, Puerto Rico, was the venue with the largest number of CTN presentations. The PC was kept busy right up to the last minute in reviewing and approving presentations for CPDD. Other recent meetings with CTN presentations include the American Psychiatric Association in May and the Research Society on Alcoholism in June. Presenters are encouraged to make their presentations available through the CTN Dissemination Library. Contact the librarians for details: info@ctndisseminationlibrary.org.

Another paper from CTN 0008 (CTN Baseline Study) has been accepted for publication. *Understanding attitudes toward use of medication in substance abuse treatment: A multilevel approach*, by Fitzgerald, J.P. & McCarty, D., Psychological Services, is in press. The paper is abstracted from John Fitzgerald's dissertation in Systems Science/Social Psychology at Portland State University. Psychological Services is an American Psychological Association journal (Division 18) that focuses on psychological services within public service (government) settings. The editor invited the submission after John's dissertation won the 2007 Patrick DeLeon award from APA's Division 55 (American Society for the Advancement of Pharmacotherapy) for the best graduate student paper on pharmacotherapy.

A second paper has been published – *Infrequent Illicit Methadone Use Among Stimulant-Using Patients in Methadone Maintenance Treatment Programs: A National Drug Abuse Treatment Clinical Trials Network Study*, by Li-Tzy Wu, Dan G. Blazer, Maxine L. Stitzer, Ashwin A. Patkar, and Jack D. Blaine in: *American Journal on Addictions*, Volume 17, Issue 4 July 2008, pages 304 – 311.

A third paper is in press – *Using a standardized patient walk-through to improve implementation of clinical trials*, by H.E. Fussell, L. E. Kunkel, C.S. Lewy, B.H. McFarland, and D. McCarty; *Journal of Substance Abuse Treatment* March 2008. This paper describes experiences using an actor trained to mimic a substance abuser seeking treatment and “walked” through study intake processes.

Abstracts of these three published papers are provided at the end of this newsletter.

Oregon/Hawaii Node Reports on CTN 0031C



Data collection for the CTN 0031C Health Services Research (HSR) ancillary study is complete. The supplemental study was designed to assess the organizational factors associated with CTP implementation of the CTN 0031 STAGE-12 (Stimulant Abusers Group to Engage in 12 Step) protocol. The project included visits to all 10 sites participating in STAGE-12 for qualitative and quantitative data collection. The HSR team thanks all of the sites for their hospitality and their efforts in getting the data collected in a timely fashion!

The Science of Eliminating Health Disparities



Join the NIH Institutes, Centers, Offices, and their many partners engaged in research on minority health and health disparities on December 16-18, 2008, at the Gaylord National Resort and Convention Center, National Harbor, Maryland. The conference will:

- Highlight the research progress of the NIH on health issues among racial/ethnic minority and medically underserved populations
- Increase awareness and understanding of disparities in health
- Showcase best-practice models in research, capacity-building, outreach, and integrated strategies to eliminate health disparities
- Identify strengths and gaps in health disparities research
- Network and dialogue with the nation's leading experts on minority health and health disparities

You may register online for this free summit:
www.ncmhd.nih.gov

This event is sponsored by: National Center on Minority Health and Health Disparities (NCMHD).

Topics for CTN Articles in NIDA Notes

Please forward ideas for CTN related articles to Jeff Selzer (Long Island Node) at selzer@lij.edu.

More Delaware Valley Node News



Long time CTN member and CTP Director Sue Gordon and her husband report that they are stunned and very happy to announce the arrival of their first grandchild: Darcy Rose Bernstein was born July 9. Mom and baby are fine. Congratulations!

Clinical Coordinating Center (CCC) at EMMES

Regulatory Facts & Tidbits – 32. 21 CFR 56.115(a) (1)



requires that the IRB maintain copies of "research proposals reviewed." Is the "research proposal" the same as the formal study protocol that the investigator receives from the research sponsor?

Yes it is. The IRB should receive and review all research activities [21 CFR 56.109(a)]. The documents reviewed should include the complete documents received from the clinical investigator, such as the protocol, the investigator's brochure, a sample consent document and any advertising intended to be seen or heard by prospective study subjects. Some IRBs also require the investigator to submit an institutionally-developed protocol summary form. A copy of all documentation reviewed is to be maintained for at least three years after completion of the research at that institution [21 CFR 56.115(b)]. However, when the IRB makes changes, such as in the wording of the informed consent document, only the final approved copy needs to be retained in the IRB records.

Training – The CCC is happy to report that the Adverse and Serious Adverse Event web seminar on July 8 was attended by 44 CTN members from eight Nodes. An online training evaluation survey was introduced as part of their ongoing training improvement; they appreciate the feedback submitted thus far. The next seminar is scheduled on July 24 at 2 p.m.

ET and will cover Informed Consent. The following session will address IRB and Regulatory Documentation on August 4. All sessions will be via webinar format. Registrations and requests for seminars on CD are welcome via e-mail. Training ideas, requests, or comments are welcome and appreciated. Training related communications may be addressed to ctntraining@emmes.com.

Other CCC related questions and topics- Bob Lindblad at 301-251-1161, rlindblad@emmes.com, ctnsupport@emmes.com for laboratory and/or medication supplies, and ctnsafety@emmes.com for safety related issues/adverse event follow-up.

NIDA Project Officer – Steve Sparenborg at (301) 496-4844, sparenborgs@nida.nih.gov.

Data and Statistics Center (DSC) at DCRI



The DSC would like to remind all users of the web-based systems for clinical trials, InForm and CRIS, that you should **NOT** use the internet browser "back button" while using these systems.

Using the "back button" can cause an array of problems for the systems and the user. The only internet browser icon approved for use with either InForm or CRIS is the "Print" icon. We recommend using the "full screen" view when using InForm and CRIS to reduce the chance of error.

Additionally, the DSC has been alerted that there have been incidents of extended wait time for the pages to load when using the InForm Signature Panel to sign participant casebooks. We will need your help to identify and resolve the problem. Since not all sites are experiencing this issue, the DSC needs to assess this while it is actually happening. If you experience this problem, please do the following:

- Contact the Helpdesk **WHILE** you are signing casebooks and experiencing the problem. You may contact the Helpdesk at 1-888-372-7743.

Please note: 40 seconds is the expected time it should take a page on the signature panel to load. If it is taking longer, we need to hear from you! In the interim, try applying the filter at the top of the page to 'unsigned' casebooks. This may help to speed-up the loading process. We value your time and want to make the process of signing participant casebooks as efficient as possible.

Who to Contact:

You may contact the Site Support Help Desk at 1-888-DSC-SSHD (1-888-372-7743) from 8:00 a.m. to 8:00 p.m. Monday through Friday or send an e-mail to: nidadsc-help@mc.duke.edu.

Data Management Lead:

Lori Poole, B.A., Phone (919) 668-8238
lori.poole@dcric.duke.edu

Lead Statistician:

Jeff Leimberger, Ph.D., Phone (919) 668-8758
leimb001@dcric.duke.edu

NIDA Project Officer, Carol Cushing, at:
ccushing@nida.nih.gov, telephone (301) 443-9815.

Training Reminder



From the CTN Bulletin January 27, 2006

A. Common Assessment Battery:

The Common Assessment Battery (CAB) is optional for future studies. If a protocol intends to measure a particular construct that is captured by a CAB instrument, it is strongly urged that the CAB instrument be considered over non-CAB assessments.

B. Training:

1. RRTCs (Nodes) are responsible for providing training to staff in protocol and CAB measures. The Node PI is responsible for assuring that all appropriate members of the CTP team and RRTC are trained and competent to conduct study procedures.
2. The TSC Training Plans for CAB measures are no longer required. Each Node is responsible for setting their own criteria to determine that a staff member can be an interviewer and/or a trainer on any specific measure or intervention, unless specified in a protocol. The CCC (Clinical Coordinating Center) will have standardized training sessions and opportunities available for interviewers and trainers on the following measures: GCP, Biological Measures Handling, Demographics, and CTN versions of CIDI, ASI and RBS. These trainings are available to the Node staff if needed.
3. CTN-wide certification and re-certification of training in core measures is no longer required. The Node PI is responsible to ensure and monitor the competency of his/her staff.
4. There is no requirement for central certification or tracking of training. The training tracking system database has been discontinued and will not be developed or supported by the CCC or DSC. The Node PI will attest to the training and competency of his/her staff and be able to demonstrate the competency as necessary.

Updates for this Bulletin should be sent to Carol Cushing at: ccushing@nida.nih.gov

Abstracts:



Understanding attitudes towards use of medication in substance abuse treatment: A multilevel approach by Fitzgerald, J.P. & McCarty, D., Psychological Services, in

press.

Objective:

Individual and organizational variables influence attitudes towards use of naltrexone, methadone, and buprenorphine for the treatment of alcohol and drug disorders. Prior research has not considered both sets of influences simultaneously. Hierarchical linear modeling tested the contribution of individual and organizational variables using data from the National Drug Abuse Treatment Clinical Trials Network treatment unit and

workforce surveys (n = 2,269 staff nested within 247 treatment units). Individual-level variables consistently had more influence on attitudes, but a unique blend of variables existed for each medication. One predictor, *support for psychiatric medications*, influenced attitudes across all medications. Staff attitudes towards addiction medications varied significantly between treatment units. Implications for increasing the appropriate use of addiction medications are discussed.



Infrequent Illicit Methadone Use Among Stimulant-Using Patients in Methadone Maintenance Treatment Programs: A National Drug Abuse Treatment Clinical

Trials Network Study, by L.Wu et al.

Objective:

We sought to determine the prevalence, patterns, and correlates of past-month illicit methadone use and history of regular illicit use among stimulant-using methadone maintenance treatment patients. We obtained self-reported information on illicit methadone use from 383 participants recruited from six community-based methadone maintenance programs. Overall, 1.6% of participants reported illicit use in the past month, and 4.7% reported a history of regular use. Younger age and history of outpatient psychological treatment were associated with increased odds of past-month illicit use. Illicit methadone use among patients in maintenance programs is infrequent; however, a number of factors may increase risk of illicit use.



Using a standardized patient walk-through to improve implementation of clinical trials, by H.E. Fussell et al.

Objective:

This report describes a standardized patient (SP) walk-through to facilitate implementation of a clinical trial within the National Drug Abuse Treatment Clinical Trials Network (CTN). SPs are actors trained to portray a set of symptoms consistently across interactions with multiple clinicians. The Oregon/Hawaii Node of the CTN employed one SP to pilot participant screening processes in a study testing a combined pharmacological and behavioral therapy for women and men dependent on prescription opioid analgesics. The SP mimicked an individual seeking treatment and “walked” through study intake processes. Findings such as study staff members’ inadequacy in describing issues of patient confidentiality and problems explaining the Health Insurance Portability and Accountability Act led to modifications to the clinical implementation of the study. Research coordinators and the staff found the use of an SP to be highly effective. The node is now making routine use of SPs in the implementation of CTN protocols.