



Clinical Trials Network

CTN Bulletin

May 15, 2008

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CTN 0028 Study Hits Target N=300!



The CTN 0028 Adolescent ADHD/SUD trial randomized its 300th participant on May 6, 2008, achieving the targeted national enrollment. CTN 0028 is the largest combined pharmacotherapy/

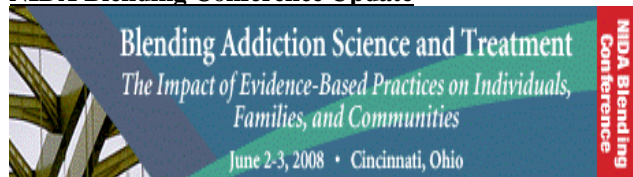
behavioral intervention study ever conducted in adolescents with co-occurring psychiatric and substance use disorders. The study's successful recruitment, excellent safety record, and high treatment retention and completion rates are a strong demonstration of CTN's ability to address important research gaps in adolescents with co-occurring disorders.

The 0028 Lead Team congratulates the participating sites for this outstanding achievement.

CTN 0028 CTP Honor Roll:

- Stanley Street Treatment and Resources Inc. (SSTAR) Northern New England Node
- Synergy Outpatient Program ARTS, University of Colorado
- Lexington Richland Alcohol and Drug Council (LRADAC), Southern Consortium Node
- Gateway Community Services, Florida Node
- MHMR of Tarrant County, Texas Node
- Operation PAR, Florida Node
- Crittenton, Ohio Valley Node
- Mountain Manor Baltimore, Mid-Atlantic Node
- Addiction Medicine Services, Appalachian Tri-State Node
- St Luke's Roosevelt, Child and Family Institute, Long Island Node
- Rehab After Work, Delaware Valley Node

NIDA Blending Conference Update



Don't miss out on this state-of-the-art conference highlighting the science of addiction treatment, *Blending Science and Treatment: The Impact of Evidence-Based Practices on Individuals, Families and Communities*, June 2-3, 2008 in Cincinnati, Ohio. Nearly 1,200 attendees have signed up for this conference!

For additional information go to

www.NIDABlendingConference.info

Steering Committee (SC) Meeting

The NIDA CTN Steering Committee Meeting will be held June 4-5, 2008 at the Hyatt Regency, Cincinnati, Ohio. To register for the Steering Committee meetings, please visit the following link:

www.sei2003.com/NIDA/CTN/Meetings/

Please see information about other activities at the SC Meeting below in this Bulletin.

Share Your Knowledge Workshop in Cincinnati



CTN CTPers and PIs will join together for the second half of their scheduled caucus meetings in Cincinnati to promote the involvement of more people in publishing opportunities. The opening sessions of the

Steering Committee Meeting will be caucus meetings held from 6:30 to 8:30 pm on June 3rd. The PIs will join the CTP Caucus already in session at 7:30 p.m. and at that time, the Publications Committee of the CTN will sponsor a workshop titled "Share Your Knowledge by Publishing and Presenting." The workshop is open to all and will promote publishing opportunities among CTP members through linkages to experienced hands in the Nodes and other community sites. Get involved and attend this workshop! Contact Steven Sparenborg at 301-496-4844 or sparenborgs@nida.nih.gov for further information.

What is Protocol CTN 0033?

Protocol 0033: Methamphetamine and Other Drug (MOD) Use among American Indians is a new project. The protocol team (aka the "MOD Squad") will meet on June 4, 2008, 4:30-6:30 p.m., on the first evening of the SC meetings.

Ohio Valley Evening Event at the SC



Please join the Ohio Valley Node for an evening of good food, conversation, and lively bluegrass music on Wednesday, June 4th, from 7-10:00 p.m. The event will take place at Arnold's Bar and

Grill, located seven blocks from the hotel. Arnold's is a historic Cincinnati establishment serving primarily Italian food. The cost of the buffet dinner (soft drinks and vegetarian choices included) is \$30, including entertainment. To make your reservation, please contact Matthew Elmore at 513-487-7807 or e-mail at Matthew.Elmore@mdru.uc.edu Since space is limited, only the first 75 reservations can be accommodated.

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.

CTN 0032



The HIV Rapid Testing and Counseling (CTN 0032) protocol team is conducting site selection visits. A total of 16 treatment units from 15 CTPs are still potentially eligible to participate in the study. Site visits will end by May 30. Sites will be notified of selection decisions on a rolling basis. While site selection activities are underway, the Investigative Team, various work groups and collaborators continue to develop the manual of operations, intervention materials and training materials. Protocol training dates are being considered for the fall.

Publications Committee (PC)



The Publications Committee reminds CTNers who are giving oral or poster presentations at the upcoming College on Problems of Drug Dependence (CPDD) in June, or at any other meetings, to send those presentations to the PC (jblaine@nida.nih.gov) for review well in advance of the meeting. There are usually a large number of CTN presentations at CPDD and the PC hopes to avoid a last minute rush. PC review helps make CTN presentations better and clearer by identifying areas where the audience may not follow what the authors intend to communicate, and sometimes by identifying areas where CTN authors have not thought or articulated clearly what their study methods and results really show. PC review requires about 2 weeks. Please submit early. Thanks to those who have already sent your presentations!

Pacific Northwest Node – Award



Beth Dannhardt, Director of Triumph Treatment Services in Yakima, Washington, and the alternate CTP representative for the Pacific Northwest Node, has been selected as the recipient of the 2007 Nichols Leadership Award. The Nichols Leadership

Award is presented annually by Residence XII, a specialty chemical dependence treatment program for women and families in Kirkland, Washington, and one of the Pacific Northwest Node's CTPs, to an individual, or group, who has consistently demonstrated community leadership to better meet the needs of chemically dependent women and their families. Triumph Treatment Services operates the oldest gender-specific chemical dependency treatment program for women and their children in the state of Washington. Beth will be honored with a reception and award presentation at Residence XII on May 30th. Congratulations, Beth!

News from the California-Arizona (CA-AZ) Node



The CA-AZ Node looks forward to welcoming two students who will be spending 10 weeks at the Node, funded by Summer Research with NIDA 2008. One student is a senior at California State University, Dominguez Hills and is pursuing a major in biology and human services and a minor in health science, and the other is a junior at Howard University, pursuing a major in psychology. The two students will be working with Dr. Carmen Masson on a CTN pilot project to examine access to HIV and Hepatitis C screening and treatment among ethnic minority drug users. Drug users in and out of drug abuse treatment will be recruited from prevention and treatment settings. The students will also participate in the UCSF Summer Research Training Program, which hosts up to 50 students from multiple disciplines every summer. Students participate in seminars, presentations, journal groups, and social events throughout the summer, as well as a final poster session. The Node is delighted to have an opportunity to provide these accomplished students with an introduction to clinical research.

Texas News Tidbits

Lois Jordan is the owner and director of Solutions



Outpatient Services, a Texas CTP. Ms. Jordan has written an article, "The Invisible Golden Ghetto" to be published in Recovery Today Online.

The article discusses the difficulties of treating patients who grew up in the midst of wealth. To access the article, go to <http://www.recoverytoday.net/>

Texas CTP partners presented a talk on May 7 at the Louisiana State treatment conference. "Integrated Services in Texas: A Provider Perspective" was given by Doug Denton, the Executive Director of Homeward Bound, Inc. at the 3rd Annual Leadership Summit offered by the state of Louisiana. Homeward Bound, Inc., a Texas CTP partner, offers chemical dependence treatment for the indigent population and those referred by the criminal justice system, local hospitals and private practitioners.

Topics for CTN Articles in NIDA Notes

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

Federal Offices Closed



The CCTN office and NIDA will be closed on Monday, May 26, 2008, for the Memorial Day holiday observance.

Oregon/Hawaii Node



In celebration of National Public Health Week (April 7-13), once again the Oregon/Hawaii Node participated in a poster session sponsored by the Oregon Health Sciences University (OHSU)

Department of Public Health and Preventive Medicine. Node personnel shared information about the CTN, the Node, and protocols that are currently being implemented. Members of the OHSU campus, as well as the public, were among those in attendance.

On May 6, 2008 Dr. Todd Korthuis of the Oregon/Hawaii Node hosted a Summit Meeting of Treatment, Policy and Community Leaders titled “Opiate Abuse in Oregon: The Epidemic, Community Response and Challenges for the Future.” Dr. Korthuis described his study, “Portland Integrates Care of Opioid Dependent HIV/AIDS Patient (PICODAP).” The keynote speaker was Patrick O’Connor, M.D. M.P.H., Chief, Section of General Internal Medicine, Yale University School of Medicine. Dr. O’Connor addressed “Treatment Options and How They Work.” Other speakers from the Oregon/Hawaii Node included Dennis McCarty, Ph.D., OHSU who presented “Policy Challenges to Addressing Opiate Addiction,” John Gardin, II, Ph.D., Director of Behavioral Health and Research at ADAPT, Inc. who described the CTN 0030 POATS study currently taking place at ADAPT, and Tim Hartnett, M.S.W., M.H.A., Executive Director of CODA, who discussed “A Vision for the Future.” In addition, there were speakers from multiple fields of interest, a Client Panel “Personal Story: Three Perspectives on Opiate Addiction and Recovery,” and more than 100 attendees.

Reminder – NIH Public Access Policy



The Public Access Policy ensures that the public has access to the published results of NIH funded research by requiring scientists to submit papers that arise from NIH funds to the archive PubMed Central. As of **April 7, 2008**, all final peer-reviewed manuscripts arising from NIH funds must be submitted to PubMed Central upon acceptance for publication. And as of **May 25, 2008**, NIH applications, proposals, and progress reports must include the PubMed Central reference number when citing a paper that falls under the policy and is authored or co-authored by the investigator, or arose from the investigator’s NIH award. More information including a list of frequently asked questions and answers is available on the website at <http://publicaccess.nih.gov>

Visit the CTN Dissemination Library:
<http://ctndisseminationlibrary.org>.

Novel Computer Tool Can Help Treat Drug Abuse

NIDA Researchers Say Computer-Based Training Enhances Traditional Counseling

For years, the only concept of drug abuse counseling was for patients to meet face-to-face with a therapist. Scientists are now convinced we can add a computer to that picture. The first randomized controlled trial that combined a computer learning program with traditional counseling showed a longer period of abstinence from drugs than for those patients who had the counseling alone. The study, conducted by researchers from the Yale University School of Medicine, was published May 1 in the American Journal of Psychiatry, and was funded by the National Institute on Drug Abuse (NIDA).

Some patients undergoing face-to-face counseling were asked to also use a multimedia computer program teaching the principles of cognitive-behavioral therapy (CBT). When used for drug abuse treatment, CBT helps patients recognize the situations in which they are most likely to use drugs, avoid those situations when appropriate, and cope more effectively with a range of problems and behaviors associated with substance abuse.

Those who were randomized to the computer program were led through six modules in a range of formats, including movies of actors demonstrating coping skills in realistic situations and opportunities for patients to review and practice the new skills. The modules covered several core concepts, including understanding and changing patterns of substance abuse, coping with craving, refusing offers of drugs and alcohol, problem-solving skills, identifying and changing thoughts about drugs and alcohol, and improving decision-making skills.

During the study period, participants’ self-reports of illegal drug use were verified through urine toxicology screens that were obtained at every assessment visit. Those who used the computer-based program submitted significantly fewer drug-positive urine specimens and tended to have longer periods of abstinence during treatment compared to patients who only met with a counselor.

With this computerized approach, treatment can be tailored to the needs of the individual, selecting specific topics, modifying speed of presentation and repetition of modules as necessary. The research team plans to use the program for more refined studies of the individual CBT components as well as to determine whether or not it could be effective when delivered alone, rather than as an adjunct to standard treatment.

NIDA Teams with Scholastic to Create Award at Intel International Science and Engineering Fair



This year, for the first time, three students will receive awards for exemplary projects in Addiction Science at the Intel International Science and Engineering Fair (ISEF), the world's largest science competition for high school students. The Addiction Science

award is co-sponsored by the National Institute on Drug Abuse (NIDA), and Scholastic, the global children's publishing, education and media company.

Every year, nearly 1500 students from more than 40 countries compete in the ISEF competition, which is coordinated by the Society for Science & the Public. This year the 59th annual Intel ISEF will be held in Atlanta beginning May 11. NIDA scientists will participate as judges and the winners of the Addiction Science Awards will be announced at the awards ceremony on May 15; winners will receive cash awards.

Addiction science projects can involve a variety of scientific disciplines, including biology, neurology, psychology and medicine. Addiction scientists research the role of genetics and what makes people vulnerable to addiction, as well as the structure and function of the brain and how it is changed by drug use. They also study the behaviors that can lead to addiction; strategies that can prevent it; counseling and medication to treat it; and how our health system can get the best treatments to those who need it.

Scholastic will co-sponsor the award as part of its ongoing collaboration with NIDA. Scholastic provides age-appropriate educational information on substance abuse and the effects that drugs have on the brain for select Scholastic classroom magazines, including Science World and Super Science.

The nonprofit organization Society for Science & the Public partners with Intel—along with dozens of other corporate, academic, government and science-focused sponsors— to provide support and awards for the Intel ISEF each year. This is the first series of awards given exclusively for projects that advance addiction science. NIDA has developed a special section on its Web site to help science fair entrants understand the criteria for the awards, which includes other resources on addiction science at <http://www.drugabuse.gov/sciencefair/>

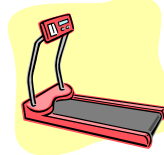
CTN 0012 Paper Selected for Editor's Choice



The Infections and Substance Abuse Study (NIDA CTN 0012) paper that appeared April 1st in the American Journal of Public Health's First Look online publication is in the May issue of

AJPH. The paper is entitled "States and Substance Abuse Treatment Programs: Funding and Guidelines for Infection-Related Services." Authors are: Steven Kritz, MD, Lawrence S. Brown Jr, MD, MPH, R. Jeffrey Goldsmith, MD, Edmund J. Bini, MD, MPH, Jim Robinson, MEd, Donald Alderson, MS, Patricia Novo, MPA, and John Rotrosen, MD. The paper was also highlighted in the Editor's Choice page, Viral Hepatitis Prevention – New Challenges, New Directions. The paper examines how state funding and guidelines affect substance abuse treatment programs that provide infection-related services.

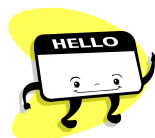
Exercise for Drug Abuse Concept Update



The exercise concept team would like to thank all of the CTPs that completed the survey of residential treatment programs. An impressive total of 65 surveys were submitted.

The project is moving into the protocol development phase, and the study team is expanding to include additional CTP and RRTC members.

New CCTN Staff Member



NIDA's CCTN office welcomes Dr. Udi Ghitza, who has joined the team as a Health Scientist Administrator. His background is in neuropsychology, and he has done work on animal models of drug abuse, as well as clinical studies

of behavioral and pharmacological therapies. Dr. Ghitza's interests have spanned both behavioral-neuroscience and clinical trials research. In behavioral neuroscience research, he has used a rat relapse model to examine the cellular and neuroanatomical mechanisms underlying relapse to drug- and high-fat food-seeking behavior. In clinical trials research, he has evaluated behavioral and pharmacological treatments for cocaine and heroin abuse. He has a degree in biological psychology from Rutgers University, and has worked at the Intramural Program of the National Institute on Drug Abuse with Dr. Kenzie Preston. In the CCTN, Udi will be part of Dr. Harold Perl's Behavioral and Social Science Team. His e-mail is ghitzau@nida.nih.gov.

Clinical Coordinating Center (CCC) at EMMES

Welcome New Team Member!



Please join the CCC in welcoming their new project director, Eve Jelstrom, CRNA, MBA. Eve comes with over 16 years of experience in the clinical research and

pharmaceutical industry. We know that Eve will be a great addition to the team. Eve and Robert Lindblad will be happy to take any inquiries that were previously directed to Michele Straus or Jacqueline Mazza, who departed in early April. Eve can be reached at 301-251-1161, ejelstrom@emmes.com.

Site Supply FYI



The supply system within the CTN is set up for a site to have at least 3 weeks supply of any article or study drug but not exceeding 2 months supply on hand at any one time.

Ideally a site will order a one-month supply each month to stay within these thresholds. All orders should be placed through ctnsupport@emmes.com instead of addressing emails to any individual to ensure that coverage to fill the order is always available.

Training – The ASI Booster training was held on May 1.

The response was terrific; about 50 registrants were in attendance from 10 of the 16 nodes. The CCC would like to thank Sabrina Poole and Ron Jackson for making the booster possible. A recording of the ASI booster is available through Liz Buttrey at ctntraining@emmes.com.

The next training opportunity is Timeline Follow Back on May 15 at 1pm ET. Send your registrations to ctntraining@emmes.com. Site Management Overview will be held on June 12. We currently have 30 registrants but are happy to include you, so please submit your registrations! A complete listing of 2008 training is also available on Livelink under CCC Training. If you have any questions or comments please contact Liz Buttrey at ebuttrey@emmes.com or ctntraining@emmes.com.

Who to contact at the CCC

- Robert Lindblad, M.D., Principal Investigator and Medical Monitor
- Regulatory submissions should be directed to the protocol specialist assigned to the protocol
- Eve Jelstrom, Project Director and CTN-0032
- Liz Buttrey for matters related to training
- Amanda Moore, Protocols CTN-0029 and CTN-0031
- Maria Campanella, Safety Monitor and Protocols CTN-0028 and CTN-0030
- Jack Chally, Protocols CTN-0027 and CTN-0032
- Rajesh Venugopal, Regulatory Specialist

- Natasha Arocho, Administrative Coordinator
- ctnsupport@emmes.com for laboratory and/or medication supplies
- ctnsafety@emmes.com for safety related issues/adverse event follow-up
- ctntraining@emmes.com for training related topics

Other CCC related questions and topics- Robert Lindblad at 301-251-1161, rlindblad@emmes.com

What is CRISP?



CRISP (Computer Retrieval of Information on Scientific Projects) is a searchable database of federally funded research projects. The database, maintained by the National Institutes of Health (NIH), includes projects funded

by NIH, the Substance Abuse and Mental Health Services Administration, the Health Resources and Services Administration, the Food and Drug Administration, the Centers for Disease Control and Prevention, the Agency for Health Care Research and Quality, and the Office of the Assistant Secretary of Health. This site is open to the general public. Users can search for scientific concepts, emerging trends, awards by investigators, institutions, etc. To access this database go to <http://crisp.cit.nih.gov>.

Data and Statistics Center (DSC) at DCRI

Data Share Update

Look for the de-identified data sets for CTN 0003 and CTN 0013 to be added to Data Share this month. Data sets for CTN 0021 (Spanish MET) will be posted next, approximately in July. The data sets for the HIV protocols (CTN 0017, CTN 0018, and CTN 0019) will be posted over the following months, followed by CTN 0020, CTN 0015, and CTN 0010. Data is made available on the data share site 18 months after data lock or after acceptance of the primary results publication, whichever occurs first. There are no requirements to access the CTN data. The site is at



<http://www.ctndatashare.org/>

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.

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

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