



Clinical Trials Network

CTN Bulletin

July 24, 2008

Volume 08 – 13

Trial Progress – Over 9,000!



Trial enrollment is taken from the official Trial Progress Report prepared by the Data and Statistics Center (DCRI) each month. These enrollment numbers reflect information in the database through June 30, 2008.

Open Studies (5)

- CTN 0027 – Randomized 797
- CTN 0027A (Genetics) – Randomized 404
- CTN 0030 – Randomized 540
- CTN 0031 – Randomized 52
- CTN 0031A – Randomized 29
- **Total Randomized All Studies: 9,165**

CTN 0032 Update



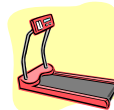
The HIV Rapid Testing & Counseling (CTN 0032) protocol is the first study to use a central IRB for study oversight. Seven of the twelve Community Treatment Programs (CTPs) have agreed to use the central IRB, Western IRB. The remaining five CTPs will continue to use their own local IRBs. EMMES will keep track of the multiple IRB processes.

An exciting ancillary study involving an economic evaluation of CTN 0032 is being undertaken in conjunction with the main study. The goal of the evaluation is to identify the additional resources that would be required to actually implement HIV testing using each of the three strategies being evaluated within the CTN 0032 trial. The economic evaluation team will be led by Bruce Schackman, Ph.D., Chief of the Division of Health Policy at Weill Cornell Medical College, and will include designated CTN 0032 protocol team members.

The Investigator's National Protocol Training will take place September 9-12, 2008, in Bethesda, Maryland. Invitation e-mails were sent out by Synergy Enterprises this week. For further information on the program content of the meeting, please contact Tim Matheson, Ph.D. at (415) 554-9064 or by e-mail at Tim.Matheson@sfdph.org. If you have any questions regarding the meeting logistics, please contact Beverly Hoefman. She can be reached at (240) 485-1700, ext. 116, or by e-mail (bhoefman@sei2003.com).

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 0037 Exercise for Drug Abuse Study



The "Exercise for Treatment of Substance Use Disorders Study" has been officially designated CTN 0037. The study development team is making good progress on a protocol that will be submitted to an independent Protocol Review Board in September. The team is led by Dr. Madhukar Trivedi, Co-PI of the Texas Node, and it includes members from seven Nodes, the two coordinating centers, NIDA, as well as several leading physical activity researchers. Please keep an eye out for future updates in the Bulletin!

Publications Committee (PC)



The Publications Committee reports that a manuscript entitled "Clinical Characteristics of Treatment Seeking Adolescents with Opioid versus Cannabis/Alcohol Use Disorders" has been accepted for publication in the journal *Drug and Alcohol Dependence*. This is an ancillary sub-study related to the CTN 0010 Buprenorphine/Adolescents protocol. It was conducted at the Mountain Manor site in the Mid-Atlantic Node. The authors are Geetha A. Subramaniam, M.D., Maxine A. Stitzer, Ph.D., George Woody, M.D., Marc J. Fishman, M.D., and Ken Kolodner, Sc.D. Congratulations to the study team!

A second paper, "[Community Program Therapist Adherence and Competence in Motivational Enhancement Therapy](#)" has been published in *Drug and Alcohol Dependence* by Steve Martino, Samuel A. Ball, Charla Nich, Tami L. Frankforter, and Kathleen M. Carroll. Congratulations! *An abstract of this paper is provided at the end of this newsletter.*

Sites to Remember

Here are some useful CTN and federal sites:

CTN Data Share – download public data sets, study information at www.ctndatashare.org.

CTN Dissemination Library – Open to the public <http://ctndisseminationlibrary.org>.

Federal Per Diem Rates and GSA Forms - <http://www.gsa.gov/Portal/gsa/ep/home.do?tabId=0>.

CRISP Data Base is a searchable database of federally funded research projects. <http://crisp.cit.nih.gov/>.

CTN brochures, directories, conference calls from Synergy Enterprises Inc. are available at CTNSupport@sei2003.com.

Lessons Learned in Secondary Data Analyses

Utilizing CTN Public Access Data



Thanks to the following CTNers for sharing their “lessons learned” in secondary data analyses: Audrey Brooks, Ph.D, Christina Meade, Ph.D., Jennifer Sharpe Potter, Ph.D., M.P.H., Yuliya Lokhnygina, Ph.D., Don Calsyn, Ph.D., Susan Tross, Ph.D., and Shelly Greenfield, M.D., M.P.H.

Several challenges were encountered in combining data sets across multiple CTN trials in the secondary data analysis project “Gender differences in the rates and correlates of HIV risk behaviors among drug abusers.” These included:

- Data discrepancies present in the data set required initial data cleaning prior to combining datasets and running analyses. A cross-tab conducted between questionnaires collecting the same data (the Demographic Form and ASI) revealed response discrepancies. For example, one participant was identified as male on one form and female on the other, or a participant married on one form was never married on the other. The decision was made to use the ASI data in most instances due to the rigorous interviewer training provided for the ASI.
- It was necessary to determine whether missing data on one form were available on the other to maximize the number of participants included in the analyses.
- Variation between data management centers in the CTN decentralized data management system in how skip out patterns were coded required recoding missing data and skip out patterns as needed.
- A determination of primary drug was also integral to our hypotheses. However, the necessary variable for this from the ASI (D14 – interviewer assessment of major drug problem) was never recorded in the original CRFs and thus was not in the public dataset. The workgroup reviewed data from the Demographic Form and ASI current use to develop an algorithm for assigning primary drug based on hypotheses predicting differences between primary opiate users, primary stimulant users, and combined opiate-stimulant users. A document describing the series of algorithms tested is available from Audrey Brooks at brooksj@email.arizona.edu.
- Lastly, in order to maintain the apriori approach to hypothesis development, no frequencies for the dependent variables were run until all hypotheses had been identified. However, once the frequencies were obtained, the target variables had lower frequencies than anticipated. Therefore, the dependent variables had to be redefined and analyses re-run to allow for sufficient power to detect any differences.

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



On July 1, the California-Arizona Node hosted a daylong conference titled “Historical Trauma: Healing Approaches in Native American Communities,” funded by a supplement from NIDA. The Native American Health Center, located in San Francisco and Oakland, worked with the CA-AZ Node to organize the event, which was sponsored by Walden House and Bay Area Addiction Research and Treatment (BAART). Nearly 170 participants attended from a number of states, including California, Oregon, Washington, Arizona, and New Mexico. The conference, which was held at the Presidio Officer’s Club in San Francisco, centered on the role of historical trauma in the treatment of substance use disorders.

Keynote speaker Maria Yellow Horse Brave Heart, Ph.D., Associate Professor of Social Work at Columbia University, spoke on “Historical Trauma and Unresolved Grief Theory and Intervention Research.” Other speakers and their topics included:

- Ethan Nebelkopf, Ph.D., Native American Health Center, Oakland – “Holistic System of Care for Native Americans in an Urban Environment,”
- Michele Maas, M.S.W., Native American Health Center, San Francisco – “Firewater and the Sword: Implications of Historical Trauma in Urban Native American Communities,”
- Karina L. Walters, Ph.D., M.S.W., William P. and Ruth Gerberding University Professor and Director of the Indigenous Wellness Research Institute at the University of Washington – “Historical Trauma and Indigenist Stress-Coping Processes: Preliminary Research Findings from the Honor Project Study,”
- Nelson Jim, M.F.T., of the San Francisco Department of Public Health – “Cultural and Traditional Healing Approaches for Urban Native Americans,”
- Theda New Breast, M.P.H., of New Breast Consultants in Babb, Montana – “The Four Generation Solution,” and
- Joseph P. Gone, Ph.D., Assistant Professor of Psychology, University of Michigan – “Re-Viewing Historical Trauma: Bridging Scientific Skepticism and Colloquial Claims.”

The conference was videotaped with the intent to post it on the Indian Health Services Web site. Once the video is on the Web site, a notice will be included in the CTN Bulletin. Thanks to all who participated in this event!

Florida Node News



On June 17, 2008, Dr José Szapocznik (Node PI), Chair of the Department of Epidemiology and Public Health and Director of the Center for Family

Studies at the University Of Miami Miller School Of Medicine, helped launch the White House Office of National Drug Control Policy's (ONDCP) national media campaign targeting Hispanic parents. During a radio media tour early Tuesday morning, Dr. Szapocznik conducted back-to-back radio interviews with, "CNN en Español", Caracol Radio in Florida, La Movidita in Chicago, and other Spanish language radio stations across the nation, addressing the research finding that Hispanic eighth graders have the highest rate of marijuana, cocaine, ecstasy, and heroin use than any other ethnic/age group in America. Due to this alarming statistic, and because research shows that media is a primary source of information about drugs for both parents and their children, Dr. Szapocznik, a national leader in drug abuse research with minority populations, discussed these issues on the popular morning radio shows.



Dr. Szapocznik conducted this media tour to promote the ONDCP's new advertising, including a redesigned Spanish-language website, www.LaAntiDroga.com, which targets Hispanic parents. Research demonstrates that they are often less acculturated than their teen children. Consequently, and because many of these parents are finding that parenting in this country is dramatically different than in their native country, the ONDCP media campaign is designed to alert these parents to high levels of pro drug influences their teens are exposed to and encourage them to face these tough issues by talking to their teens and opening up lines of communication within these families.

Dr. Szapocznik has been conducting drug abuse prevention and treatment with Hispanic families for over thirty years at the Center for Family Studies, one of the nation's foremost research programs on evidence-based family interventions with minority drug abusing adolescents, and a premier facility for training in this field. As Founding Chair and Chair since 1999 of the National Hispanic Science Network on Drug Abuse, Dr. Szapocznik leads this organization which addresses the conditions experienced by Hispanic populations in terms of drug abuse. Dr. Szapocznik also chaired the Minority Health Disparities workgroup of the National Advisory Council on Drug Abuse.

Clinical Coordinating Center (CCC) at EMMES

Training – Upcoming web seminars:



- IRB and Regulatory Documentation - August 4, 2008 at 1:00 pm (ET)
- HIPAA - September 10, 2008 at 2:00 pm (ET)
- Good Clinical Practice Overview - October 14, 2008 at 1:00 pm (ET)

Registrations and requests for seminars on CD are welcome via e-mail. Training ideas, requests, or comments are welcome and appreciated. All training related communications may be addressed to ctntraining@emmes.com. ***A list of available training resources is attached to this Bulletin.***

Regulatory Facts & Tidbits – *When IRB members cannot attend a convened meeting, may they send someone from their department to vote for them?*



No they may not. Alternates who are formally appointed and listed in the membership roster may substitute, but ad hoc substitutes are not permissible as members of an IRB. However, a member who is unable to be present at the convened meeting may participate by video-conference or conference telephone call, when the member has received a copy of the documents that are to be reviewed at the meeting. Such members may vote and be counted as part of the quorum. If allowed by IRB procedures, ad hoc substitutes may attend as consultants and gather information for the absent member, but they may not be counted toward the quorum or participate in either deliberation or voting with the board. The IRB may, of course, ask questions of this representative just as they could of any non-member consultant. Opinions of the absent members that are transmitted by mail, telephone, telefax or e-mail may be considered by the attending IRB members but may not be counted as votes or the quorum for convened meetings.

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.

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

CTSA Community Engagement Group Update

NIH supports a national consortium of medical research institutions funded through Clinical and Translational Science Awards (CTSAs). The institutions are working together to improve the way biomedical research is conducted. The consortium shares a common vision to reduce the time it takes for discoveries to become treatments for patients, and to engage communities in clinical research efforts. The following link (<http://caliber.ucpress.net/toc/jer/3/2>) will allow you to access the "Journal of Empirical Research on Human Research Ethics." The June issue has a series of articles on community-based participatory research that may be of interest to the CTN community.

Public Access Law Now Mandatory



The NIH voluntary Public Access Law became mandatory effective April 7, 2008. Investigators are now required to send to PubMed Central an electronic version of their final,

peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the date of publication. Specifically:

1. The Policy applies to all peer-reviewed articles that arise, in whole or in part, from direct costs funded by NIH, or from NIH staff, that are accepted for publication on or after April 7, 2008.
2. Institutions and investigators are responsible for ensuring that any publishing or copyright agreements fully comply with this Policy.
3. PubMed Central (PMC) is the NIH digital archive of full-text, peer-reviewed journal articles. Its content is publicly accessible (<http://www.pubmedcentral.nih.gov/>).
4. The final, peer-reviewed manuscript includes all graphics and supplemental materials that are associated with the article.
5. Beginning May 25, 2008, anyone submitting an application, proposal or progress report to the NIH must include the PMC or NIH Manuscript Submission reference number when citing applicable articles that arise from their NIH funded research.

For more information, click on this web site: [NIH Guide Notice for Public Access.](#)

Where to Get Information on the CTN



The NIDA CTN website includes information on the CTN Nodes, CTPs, and studies. For more information go to: <http://www.nida.nih.gov/CTN/Index.htm>.

CTN Data Share Web Site



Thirteen data sets from the CTN studies are now available on the CTN Data Share Web Site at: <http://www.ctndatashare.org>. Data are available for download in both SAS and ASCII formats. Each dataset is posted with corresponding study documentation, including the final study protocol, annotated CRF and data dictionary. Look next for data from CTN 0021, which should be posted in July 2008. So far, 116 requestors from five countries have downloaded 158 data sets.

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

Abstract:



Community program therapist adherence and competence in motivational enhancement therapy, Drug and Alcohol Dependence, 2008, vol 96, pages 37-48

Objective:

The extent to which clinicians in addiction treatment programs can implement empirically validated therapies with adequate fidelity that can be discriminated from standard counseling has rarely been evaluated. We evaluated the treatment adherence and competence of 35 therapists from five outpatient community programs who delivered either a three-session adaptation of motivational enhancement therapy (MET) or an equivalent number of drug counseling-as-usual sessions to 461 clients within a National Institute on Drug Abuse Clinical Trial Network multi-site effectiveness protocol. MET therapists were carefully prepared to implement MET using a combination of expert-led intensive workshop training followed by program-based clinical supervision. Independent rating of sessions demonstrated that the adherence and competence items were very reliable (mean interclass correlation coefficients for adherence = .89 and competence = .81) and converged to form two *a priori* defined skill factors conceptually related to motivational interviewing. Moreover, the factors discriminated between MET therapists and those who delivered drug counseling-as-usual sessions in predicted ways, and were significantly related to in-session change in client motivation and some client treatment outcomes (percent negative drug urine screens). These findings demonstrate the reliability and validity of evaluating motivational interviewing fidelity and suggest that the combination of expert-led workshops followed by program-based clinical supervision may be an effective method for disseminating motivational interviewing in community treatment programs.