

The Northern New Englander

Clinical Trials Network Newsletter



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Northern New England Node International Activities:

Host to a NIDA CTN INVEST in 2008/2009



During the past year, the Northern New England Node hosted Dr. Amit Chakrabarti, as a research fellow from India. Amit's fellowship was funded through the INVEST/CTN program. INVEST fellows work for one year in the United States with a research mentor with the goal of developing a longer-term international collaboration. Fellows conduct research within the scope of CTN research priorities and participate in professional development activities, including active participation in NIDA CTN Steering Committee meetings and also receive training and guidance in the National Institutes of Health (NIH) grant-writing process. Amit has been working under the mentorship of Dr. Roger Weiss (PI: CTN Northern New England Node). In this addition of the newsletter, we profile Dr. Chakrabarti's background, experiences, and plans for the future through a Question & Answer format.



Can you describe your professional background and qualifications?

Amit: I am a physician and psychopharmacologist by training. I received my MBBS in 1987 from Medical College, Calcutta, which happens to be the oldest medical school in Asia (est. 1835). Next, I received a MD in medical pharmacology with a specialization in psychopharmacology in 1994 from Banaras Hindu University, regarded as the largest single campus university in Asia. In India, MBBS is the basic medical degree after four and a half years of training, after which people can choose to specialize in particular fields by fulfilling a 3-year residency resulting in a MD. I also had training in drug abuse epidemiology, prevention, and treatment through the NIDA-supported Humphrey program in 2002/03 at Johns Hopkins University.

How did you become involved in addictions research?

Amit: I started my career as a psychopharmacologist, but within a few years realized that I wanted to understand medicine in more detail beyond the confines of a laboratory setting. Substance abuse is closely linked with psychopharmacology and also is an important public health issue. Hence, I made the move to addictions research also enabled, in part, through the fellowship at Johns Hopkins.

How did you hear about the NIDA INVEST fellowship?

Amit: The INVEST/CTN program was launched in 2007 at the annual CPDD conference in Quebec. I found the INVEST/CTN program appealing because it provides a training opportunity in clinical trials in community settings with support from academic research centers. I am interested in the pharmacotherapy of opioid dependence and the CTN work done in the Northern New England Node was a natural fit.

What lessons from your experience as an INVEST fellow do you hope to apply when you return to India?

Amit: I am planning to apply for a couple of grants through the India Council of Medical Research once I return—one grant will focus on opioid analgesics and dependence and the other on a Phase II trial of buprenorphine/naloxone. I have a couple of job offers in India upon my return. I believe my experience and training through the NIDA INVEST fellowship and the Northern New England Node's Regional Research and Training Center will enable me to successfully obtain funding for my research interests. I am also confident that the contacts I have made during the fellowship period will provide a platform for collaborative efforts in the future.

What are some of the salient differences between the substance abuse treatment delivery systems in the U.S. and India?

Amit: The treatment delivery system in the U.S. is more organized, marked by clearly defined levels of care, more so compared to India. Efforts are needed in India to evaluate the effectiveness of our existing treatment system.

Is there any advice you would offer others in considering fellowships in foreign countries?

Amit: My recommendation is to be pragmatic. It is important to set realistic and achievable goals and do some research about the characteristics of the host country and institution. As a fellow, a good rule of thumb to consider is that every aspect learned may not be directly reproducible or necessary in his/her home country. The important thing is to consider ways of translating the knowledge in the particular socio-cultural context of your home country.

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Fall 2009	



Site News

Protocol Updates

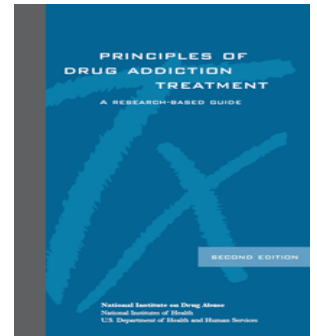


The NIDA-CTN-0030 (POATS) trial is nearing completion, with study database lock projected for September 7, 2009. The McLean Hospital site randomized 85 participants into the trial. Overall, 653 participants were randomized into Phase 1 and 360 participants were randomized into Phase 2 across 10 sites.

Progress also continues with the follow-up extension to the POATS trial. The extension study will examine long-term outcomes for individuals dependent on opioid analgesics and extends the follow-up period by three years from study randomization. All sites have begun contacting participants for the project. The first assessment was completed on March 17, 2009. As of June 22, 62 telephone assessments (49 month-18 & 13 month-30) have been completed by the lead node staff at McLean Hospital.

Principles of Drug Addiction Treatment: A Research Based Guide (2nd Edition)

The National Institute on Drug Abuse (NIDA) recently released the newly revised 2nd Edition of the *Principles of Drug Addiction Treatment: A Research Based Guide*. The publication (NIH Publication No. 09-4180) is available in PDF format at: <http://www.nida.nih.gov/PODAT/PODATIndex.html> or it can be ordered through NIDA DRUGPUBS at 1-877-NIDA-NIH. This publication was first printed in October 1999 and subsequently reprinted in July 2000 and February 2008. The guide provides research-based information about addiction, drug treatment, and recovery for new patients undergoing treatment for addiction and for their friends and families. The guide outlines 13 principles of effective treatment for substance use disorders.



Northern New England Node Dissemination Activities Update

Monika Kolodziej and Roger D. Weiss facilitated a presentation entitled, “*Researchers and practitioners working in partnership to strengthen service delivery*” at the Massachusetts Dept. of Public Health Bureau of Substance Abuses Services & AdCare Educational Institute conference “Innovations in Addictions: Research to Recovery” on May 4, 2009 at the Boston Park Plaza Hotel. The presentation provided an overview of the extensive means through which researchers and practitioners are partnering to make a difference—from 1) the broad systemic testing of promising practices to 2) individual researcher-program partnerships, focused on important practice issues. The presentation also included: a) an overview of the NIDA Clinical Trials Network (CTN): its purpose and accomplishments to date; b) the CTN Northern New England Node: regional partnerships leading to innovative treatment practices; and c) the AdCare Hospital research program: development of research endeavors in a clinical setting, partnership with the CTN, and implementation of specific studies to inform clinical services, e.g., the Patient Feedback Survey and a study of craving assessment and management.

Lisa Najavits, Ph.D. was the guest speaker at a VA Substance Abuse Seminar that was co-sponsored by the NIDA CA-AZ Node on May 13, 2009. She shared her thoughts and perceptions regarding the dissemination of the “Seeking Safety” treatment in the context of the NIDA Clinical Trials Network CTN-0015 protocol, “Women’s Treatment for Trauma and Substance Use Disorders.”



The **Northern New England Node** has been actively involved in the [NIDA/SAMHSA Blending Initiatives](#). From March through May, trainings for *Promoting Awareness of Motivational Incentives* (PAMI) were held for staff at SSTAR, AdCare, CAB, McLean, and the BPHC Bureau of Addictions Prevention, Treatment, and Recovery Support Services. Another PAMI training is scheduled for the staff at Mercy Hospital in July. In addition to the PAMI trainings, 5 clinical staff from the node will be attending a *Buprenorphine Training of Trainers* in Warwick, RI on July 14–15, 2009 and also host a one-and-a-half a *Motivational Interviewing Assessment: Supervisory Tools for Enhancing Proficiency* (MIA:STEP) on August 26–27, 2009. More details about the MIA:STEP training will be forthcoming.



Levy's Corner

Dr. Michael Levy is the Director of Clinical Treatment Services at CAB Health & Recovery Services, Inc. in Peabody, MA. He is the 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 have reprinted letters from the column.

I have been meaning to write you for some time and am finally getting around to it. I have finally realized that I am addicted to pain killers. I have been prescribed these drugs for many years for migraines and other medical issues and for about the last two years, I see that I use them too much and I want to get off of them. I also know that my family is concerned about me, too, as I have been taking more pills than I should. I have tried to stop myself, but can't seem to do it. I am not sure what to do, but I know I need some help and really want to get off of these things. What would you recommend? Thank you so much.

Always, the first step is admitting to yourself that you have a problem, and that is a big and courageous step. Most people who are addicted to pain killer type of medication, in order to stop, need to get medically detoxified in an inpatient program. That is, stopping this medication on your own can be very difficult to do, as you have realized. Consequently, my recommendation would be for you to enter an inpatient detoxification program so that you can safely and comfortably

I have been taking Suboxone for almost 4 months and I am thinking of getting off of it. I am wondering if you have any recommendations about how long the detox should be? I have heard that it should be stretched out over months, but I am wondering if I can do it more quickly. I really want to see if I can just get off of it, but I don't want to do anything stupid.

You ask a great question. The first thing I must say is that I am not a physician and do not and cannot prescribe Suboxone, although I am quite familiar with Suboxone treatment. The second thing I must say is that you should discuss the process of detoxification with the person who is prescribing Suboxone for you. With those two caveats, let me share with one study that has looked at this issue.

There is a very well designed study that was recently published that compared a 7-day taper using Suboxone to a 28-day taper. This was a randomized controlled trial that took place across a number of different treatment sites across the country. Clients who struggled with opiate dependence were initially stabilized on a dose of Suboxone and after one month, were tapered. Clients were randomly assigned to either receive a taper from Suboxone over the course of 7 days and the other group was tapered over a period of 28 days. Essentially, the researchers found that

free your body from this medication. In terms of where to go, if you have health insurance, I would contact them directly, explain to them that you need to be detoxified from the medication you are taking, and they should be able to inform you what you need to do and where you can go. They will tell you if someone first needs to evaluate you prior to your going to a program, or rather, if you can go directly to a program. They will also let you know what programs they are contracted with and where you can go to be detoxified. If you do not have health insurance, CAB Health & Recovery Services has some funds available for people who do not have health insurance, and they can be contacted at (978) 777-2121.

I should also say that a detoxification from pain killers, or narcotic analgesics, generally lasts about 6 days. During this time, decreasing amounts of medication will be given to you in a gradual way so that the detoxification is comfortable and safe. During this time, staff will be available to meet with you individually to develop an aftercare plan, which are treatment recommendations for you after you are discharged. There will also be a variety of groups to attend while going through this process to help you to better understand your problem and help you to remain drug-free after you are discharged.

there were no differences in treatment outcome and no reported significant differences in the discomfort of the withdrawal process. The researchers concluded that a detoxification could be as well accomplished over one week as compared to one month. Obviously, even a 1 month taper is a relatively short period of time and there needs to be additional studies that look at tapers for even longer periods of time. In addition, in this study, participants were only on Suboxone for one month, which is another variable to consider. Based on this study, it appears that a long taper is not necessarily better than a short taper. However, with that being said, people need to do what feels comfortable for them. If a person is afraid of a short taper, then it may need to be somewhat longer as it may not work. On the other hand, if a person wants to be detoxified more quickly, it is not necessarily contraindicated. And finally, it is clear that more research is needed about this important issue.

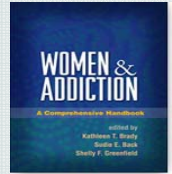
And I want to say one more thing. I do not know whether in addition to taking Suboxone, you are also involved in any other kind of psychosocial treatment, whether this consists of self-help meetings or seeing a therapist. If you are involved in other treatment, I would encourage you to continue with that. And if you are not, I would strongly encourage you to connect with something. No longer being on Suboxone may present some challenges for you and you should have some solid support.



NNE Node Publications/Presentations

PUBLICATIONS:

"*Women and Addiction: A Comprehensive Handbook*" Edited by Kathleen T. Brady, Sudie E. Back, and **Shelly F. Greenfield** April 2009, The Guilford Press, 622 Pages Size: 7" x 10" ISBN 978-1-60623-107-4



PRESENTATIONS:

Connery, Hilary Smith "*When more is better: Buprenorphine treatment for young adults with opioid dependence*" (summary of main outcome findings from the NIDA-CTN 0010 study) . McLean Hospital Alcohol and Drug Abuse Treatment Program Brown Bag lunch seminar. March 18, 2009. Belmont, MA.

Chakrabarti, Amit. A presentation of recent data on drug use and treatment demand in India as well as results of secondary analyses of NIDA-CTN 0010 looking at predictors of buprenorphine-naloxone dosing. NIDA CTN Steering Committee Meeting. Bethesda, MD. March 26, 2009.

Weiss, Roger D. "*Using research to improve drug abuse treatment: The National Institute on Drug Abuse Clinical Trials Network*". International Meeting of the All-Party Parliamentary Group on Drug Misuse in London, England. May 13, 2009

Upcoming Events/Conferences

A.) 22nd Annual Cape Cod Symposium on Addictive Disorders, **September 10—13, 2009**

<http://www.ccsad.com/agenda.html>

B.) October 2009 NIDA CTN Steering Committee Meeting, **October 20—22, 2009 • Bethesda, MD**

<http://www.sei2003.com/NIDA/CTN/Meetings/1025024/Index.htm>

C.) 2009 Addiction Health Services Research (AHSR) conference, **October 28—30, 2009 • San Francisco, CA**

<http://www.ucsfcmec.com/blast2010/MPS10005.htm>.

Announcements

On June 1st, the NIH/NIDA, released RFA-DA-10-009 "The National Drug Abuse Treatment Clinical Trials Network." This Funding Opportunity Announcement (FOA) is the sixth solicitation for participation in the CTN. It is intended for both new applications and competing continuation (renewal) applications. For details, click on:

<http://grants.nih.gov/grants/guide/rfa-files/RFA-DA-10-009.html>

NIDA's Services Research Branch released a funding announcement (PA-09-105: "**Building System Capacity for Implementing Evidence-Based Practices in Substance Abuse Treatment and Prevention**") (R34) on March 16, 2009 seeking implementation research by and for community-based organizations. Applicants are encouraged to form partnerships with other service providers, funders, and/or researchers and to design and test alternative approaches for implementing an evidence-based treatment, prevention, or business practice. Such studies might include tests of implementation strategies around the CTN Blending products, treatment approaches for which CTN protocols demonstrated evidence of effectiveness, or other non-CTN related practices. For more details, click on: <http://grants.nih.gov/grants/guide/pa-files/PA-09-105.html>