



Buprenorphine Research: Where are we today?

By Jerry Cunningham-Rathner, Project Director (jrathner@friendsresearch.org)

Over the past two decades, Walter Ling, the Director of ISAP, has been at the forefront of the research and development of buprenorphine as a treatment for opiate dependence.

Dr. Ling has been involved in virtually every phase of the process of obtaining Food and Drug Administration (FDA) approval for using buprenorphine to treat opiate dependence in the United States.

Dr. Ling began with early studies comparing buprenorphine to methadone, and then moved to studies of liquid versus tablet formulations, development of a combination product (buprenorphine/naloxone) to help prevent diversion and abuse, dose-ranging efficacy studies, and Phase III office-based studies. Most recently, he completed pivotal trials, in the National Institute on Drug Abuse (NIDA) Clinical Trials Network (CTN), comparing buprenorphine to clonidine for detoxification in inpatient and outpatient community-based treatment settings.

Both of these studies showed a clear advantage for buprenorphine over clonidine in both inpatient and outpatient settings, and because these trials were conducted in established community treatment programs with widely varying philosophical treatment strategies, the relative ease with which the programs implemented the research into their community settings proved that the research-to-practice initiative is a plausible strategy.

Most profoundly, however, these studies demonstrate how community settings, even those that were previously "drug-free" programs, have easily and readily adopted the use of buprenorphine pharmacotherapy, integrated with their own behavioral treatment strategies, as the new standard of care for the treatment of opiate dependence.

Although FDA approval of buprenorphine came in 2002, there still are outstanding research questions that must be addressed in order to optimize buprenorphine treatment. Some of these questions

(Please see ISAP's Buprenorphine Studies, Page 8)

Free copies of
**Clinical Guidelines
for the Use of
Buprenorphine in the
Treatment of Opioid Addiction
(A Treatment Improvement
Protocol: TIP 40)**

are available by calling (800) 729-6686,
and will soon be available on the Web at:
[www.ncbi.nlm.nih.gov/books/
bv.fcgi?rid=hstat5.part.22441](http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.part.22441)

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ISAP Submits Proposal to Continue as CTN Pacific Node Research & Training Center

www.uclaisap.org/ctn/index.html

By Albert Hasson, CTN Pacific Region Node Coordinator (alberthasson@earthlink.net)

ISAP recently submitted a proposal to the National Institute on Drug Abuse (NIDA) to continue as the Regional Research & Training Center for the Pacific Region Node of NIDA's Clinical Trials Network (CTN) for the next five years.

The mission of the CTN is to conduct multisite clinical trials of behavioral, pharmacological, and integrated behavioral and pharmacological treatment interventions across a broad range of community-based treatment settings and diverse patient populations.

The new submission proposes to add three new community treatment programs to the Pacific Region Node of the CTN—Phoenix House of California, Lake View Terrace, CA; Hina Mauka, Oahu, Hawai'i; and Van Ness Recovery House, Hollywood, CA.

The addition of these programs, together with our existing CTPs, Bay Area Addiction Research and Treatment, Inc., the Betty Ford Center, Matrix Institute, Haight Ashbury Free Clinics, Inc., and the Tarzana Treatment Center, would provide a tremendous amount of diversity to CTN's Pacific Region Node. We thank the existing CTPs and our potential new CTPs for their support in making this resubmission possible.

Staff Update

Catherine Domier rejoins ISAP to bolster the Pacific Region Node's quality assurance team of Sandy MacNicoll and Jessica Fradis. Ms. Domier has completed her coursework in the doctoral program in cognitive psychology at Claremont Graduate University and is currently working on her dissertation with Edythe London at the UCLA Laboratory for Neuroimaging Research. Welcome, Ms. Domier.

Protocol Update

CTN 0014 – The “Brief Strategic Family Therapy” project is about to begin recruiting subjects



Catherine Domier has joined the quality assurance team of the Pacific Region Node of the NIDA CTN.

at the Tarzana Treatment Center. Clinical and research staff from ISAP and the Tarzana Treatment Center will be traveling to the University of Miami to undergo four days of intensive protocol training. For more information on this protocol, please contact Ken Bachrach at (818) 654-3806.

CTN 0018 - Subject recruitment for the “Safer Sex for Men” project began at the Matrix Institute's Rancho Cucamonga site. This protocol offers gender-specific group therapy to men, with discussion focusing on avoiding communicable diseases and unsafe sexual contact while succeeding in recovery from substance abuse. For more information, contact Gina Richardson at ginx16@msn.com or (909) 989-9724.

CTN 0019 - Subject recruitment for the “Safer Sex for Women in Opioid Treatment Programs” began at the Bay Area Addiction Research and Treatment's La Puente site. This protocol offers gender-specific group therapy to women, with goals similar to those of the above protocol for men. For information, contact Allan Cohen at allanjcohen@aol.com or (213) 607-2010.

ISAP News by E-mail

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By Thomas Freese, PSATTC Director
(trefreese@ix.netcom.com)

The Pacific Southwest Addiction Technology Transfer Center (PSATTC) has spearheaded a major effort to disseminate information about buprenorphine as a treatment for opiate dependence through the National Institute on Drug Abuse

(NIDA)/Substance Abuse and Mental Health Services Administration (SAMHSA) "Blending Initiative."

This initiative encourages the use of evidence-based treatment interventions by professionals in the drug abuse treatment field.

Blending Teams, comprising staff from the Center for Substance Abuse Treatment's (CSAT) Addiction Technology Transfer Center (ATTC) and NIDA researchers, are charged with the dissemination of research results for implementation into practice.

Harnessing the skills, resources, and knowledge of these two federal agencies will facilitate moving key scientific findings into mainstream addiction treatment practice. The PSATTC chairs two of these blending teams related to buprenorphine:

Buprenorphine Awareness: A Training for Multidisciplinary Addiction Professionals

The goal of the first Blending Team was to create training materials designed to increase awareness about buprenorphine among non-physician practitioners. The materials include information designed to increase motivation for bringing buprenorphine to local communities and information about what to

expect when someone is treated with this medication.

Specific topics covered in the training include information about buprenorphine and how it works, identification of patients for whom buprenorphine treatment is appropriate, strategies for developing a coordinated system of

care across medical and psychosocial treatment systems, and information on treatment including induction onto the medication, maintenance, detoxification, and behavioral treatment strategies.

This package of materials will soon be released to the NIDA Clinical Trials Network (CTN) nodes and the

ATTC network.

Buprenorphine Taper

The second Blending Team being chaired by the PSATTC is charged with disseminating information on conducting an intervention to use buprenorphine to help people withdraw from opioids over a two-week period. This intervention was evaluated through the NIDA CTN.

These training materials will be geared primarily to physicians providing results from the research detailing the efficacy of this strategy and instruction on how to administer and manage patients during this taper protocol.

Additionally, training materials will be developed for psychosocial providers who provide behavioral treatment to patients receiving the buprenorphine taper.

<i>Blending Team Members</i>	
Buprenorphine Awareness	Buprenorphine Taper
Thomas Freese, Chair Pacific Southwest ATTC	Thomas Freese, Chair Pacific Southwest ATTC
Leslie Amass Friends Research Institute	Greg Brigham CTN Ohio Valley Node
Greg Brigham CTN Ohio Valley Node	Beth Finnerty Pacific Southwest ATTC
Glenda Clare Central East ATTC	Kay Gresham Morrison Southeast ATTC
Gail Dixon Southern Coast ATTC	Judy Harrer CTN Ohio Valley Node
Beth Finnerty Pacific Southwest ATTC	Dennis McCarty CTN Oregon Node
Eric Strain Johns Hopkins University	Susan Storti ATTC of New England

An online course for addiction counselors on buprenorphine treatment is available for \$20 at www.danyalearningcenter.org. Click on "Buprenorphine Treatment of Opioid Addiction: A Counselor's Guide."

Special Issue of *Prison Journal* Presents Treatment Outcomes in CA Prisons

www.uclaisap.org/CJS/index.htm

By Michael Prendergast, Principal Investigator
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Researchers at ISAP and at National Development and Research Institutes (NDRI), Inc., collaborated in producing a special issue of the *Prison Journal* (Volume 84, Issue 1, March 2004) reporting on outcomes of prison-based treatment programs in California.

The findings were based on evaluations conducted at 12 prisons in California over the past decade.

In an historical overview of correctional treatment in California, Michael Prendergast, of ISAP, and Harry Wexler, of NDRI, noted that since 1990 the treatment system for prisoners in California has become one of the largest in the nation.

Currently, the California Department of Corrections funds nearly 8,000 treatment slots at 36 programs in 19 prisons, as well as funding treatment in the community for those graduating from prison-based programs.

The findings from the special issue articles provide important information about the effectiveness of prison-based treatment and about factors that appear to be associated with success in this area, including the following:

- The more time that inmates participate in prison treatment, the more likely they are to enter aftercare and the less likely they are to be reincarcerated. Similarly, increased time in community aftercare treatment is associated with lower reincarceration rates.
- The length of time spent in aftercare, not the type of aftercare (residential or outpatient), predicts 12-month reincarceration.
- Although Hispanics are less likely than Whites and Blacks to participate in aftercare, they are also less likely to be reincarcerated, suggesting that Hispanics may rely more successfully on social and/or familial support sys-

tems than on aftercare following release from prison.

- Significantly fewer of the participants in the Amity treatment program at the R. J. Donovan Correctional Facility were returned to custody within five years after release to parole than were those in the no-treatment group (76% vs. 83%).
- The Amity participants who were returned to prison spent an average of six months longer on the street before their first reincarceration than did those in the no-treatment group.
- High-risk participants in the Amity prison program had significantly lower rates of reincarceration at three years compared with high-risk control subjects, but low-risk Amity participants did no better than low-risk controls. Both high-risk and low-risk participants benefited equally from community treatment.
- At 12 months following release, women who participated in the Forever Free Program at the California Institution for Women had fewer arrests, less drug use, and greater employment compared with women who did not receive treatment.
- A survey of client perceptions of correctional treatment found that even though inmates usually enter prison treatment involuntarily, most are positive about their treatment experience.

For more details, see:

Wexler, H.K., Prendergast, M.L., & Melnick, G. (Eds.). (2004). **Correctional drug treatment outcomes: Focus on California [Special issue]**. *Prison Journal*, 84(1).

Does Treatment Work for Alcohol and Drug Abuse/Dependence?



By Desirée Crèvecoeur, LACES Project Director
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Taxpayers want to know if the money spent on alcohol and drug treatment is a good investment.

It is no longer sufficient for treatment providers to say, "Give us treatment funding and we will provide successful treatment." It has now become necessary to demonstrate what kinds of treatment work for substance abuse treatment participants.

Treatment providers and policymakers in Los Angeles County anticipated this movement almost a decade ago.

Discussions began in the mid-1990s about building a countywide treatment outcomes monitoring system.

The actual design of this system began in 1999 via a partnership between treatment providers, the Los Angeles County Alcohol and Drug Program Administration (ADPA), and UCLA ISAP.

The resulting system, the Los Angeles County Evaluation System (LACES), is now one of the most advanced treatment outcomes monitoring systems in the United States.

The design of LACES significantly influenced the evolution of the California Outcomes Monitoring

System (CalOMS; see www.adp.ca.gov/CalOMS/CalOMSmmain.shtml for more information).

On Nov. 1, ADPA implemented a Web-based version of the revised Los Angeles County Participant Reporting System (LACPRS) admission and discharge questions, which reflect the new state and federal requirements (see box).

Revisions to the Los Angeles County Participant Reporting System (LACPRS) include:

- Questions requesting information on a diagnosis of communicable diseases such as tuberculosis and hepatitis C.
- Expanded employment categories, including "homemaker" and "student" as separate from the category of "Unemployed (Not seeking)."
- Additional questions concerning the treatment participants' mental health and child custody.
- Supplemental discharge categories to account for someone who was transferred regardless of their completion status in treatment (for example, someone who was in residential care and then was transferred to outpatient treatment).

For additional information, see the ADPA Web site at www.lapublichealth.org/adpa/.

Training occurred in September and October, with more than 700 staff members of county-funded treatment providers instructed in the use of the new system.

The LACPRS system shows the impact of drug and alcohol treatment on substance use rates as well as improvements in other aspects of the lives of treatment recipients.

The system balances the need to collect accurate and clinically meaningful information with the practical demands faced by treatment providers.

For questions concerning LACES, please contact De-

sirée Crèvecoeur at (310) 445-0874, ext. 314, or visit our Web site at www.laces-ucla.org.



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By Mary Hardy, Graduate Student Researcher
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In November 2000, 61% of California's electorate approved Proposition 36 (known as "Prop. 36"), mandating a large-scale criminal justice policy shift. Adults convicted of simple drug possession or drug-use offenses can now be sentenced to probation with drug treatment instead of either probation without treatment or incarceration.

Engaging and retaining clients in Prop. 36 programs has been challenging for the multiple agencies involved at the county level.

As part of the "Treatment System Impact and Outcomes of Proposition 36" (TSI) project, ISAP researchers are conducting an in-depth investigation of the retention efforts of five counties (see box for summary).

TSI, a five-year, multi-method study, funded by the National Institute on Drug Abuse, aims to understand the effect of Prop. 36 on local treatment delivery systems and on client outcomes in Kern, Riverside, Sacramento, San Diego, and San Francisco counties.

Yih-Ing Hser leads the project, which is guided by a steering committee composed of stakeholders from the five counties and other experts.

While drug use and recidivism rates are forthcoming, data on Prop. 36 clients' treatment completion

are available for first-year (2001-2002) admissions.

For outpatient programs, the modality in which a majority of clients are placed, treatment completion rates range from 21% to 35%. In national studies of drug treatment effectiveness,

completion rates range from 35% to 60% (for a detailed discussion of how first-year completion rates for Prop. 36 compare to other criminal justice treatment programs, see the *Evaluation of the Substance Abuse and Crime Prevention Act 2003 Report*, available at www.uclaisap.org).

Lengths of stay for discharged clients appear promising, ranging from 110 days to six months.

It is important to note that these data reflect retention rates at the

initial stage of the Prop. 36 program only. Second-year admission data, which are being analyzed now, will provide a more complete picture and allow researchers to assess midstream changes made by counties to improve retention.

For up-to-date information on ISAP's studies of Prop. 36, visit www.uclaisap.org/prop36/TSI/ and www.uclaisap.org/prop36/Prop36.htm.

Summary of TSI Counties' Prop. 36 Client Retention Strategies

- Designated Courts
 - Regular court reviews (or reviews shortly after sentencing)
 - Incentives for compliance (e.g., gift certificates, graduations)
 - Sanctions for noncompliance (e.g., court observation, relapse classes)
 - "Last chance" drug court for Prop. 36 failures
- Case Managers (e.g., California Association of Alcoholism and Drug Abuse Counselors [CAADAC] interns; alcohol & drug services counselors, public defender peer advocates)
- Shared Databases (e.g., criminal justice-alcohol and drug services; probation-treatment)
 - Service Co-location (e.g., assessment, case management, medical)
 - Out-Stationed Staff (alcohol & drug services assessors in court; probation officers and alcohol & drug services case managers at treatment)
 - Multidisciplinary Team Case Conferencing
 - Treatment Strategies
 - Reassessment
 - Denial management
 - Motivational interviewing
 - Relapse classes
 - Graduations
- Prop. 36 Alumni Meetings

ISAP's Buprenorphine Studies

(Continued from Page 1)

are being addressed in ongoing studies such as Dr. Ling's CTN study examining different taper schedules following stabilization on buprenorphine (7-day vs. 28-day taper off buprenorphine). This study is currently halfway toward its final goal of randomizing 480 participants and will be completed by late 2005.

Dr. Ling also has several buprenorphine studies in various stages of planning, development, and implementation. He has submitted a grant to examine how best to optimize buprenorphine treatment using various behavioral treatment strategies in conjunction with buprenorphine pharmacotherapy, he is leading the CTN development of a study to examine the effects of buprenorphine on liver function in hepatitis-positive individuals being maintained on buprenorphine, he is developing a study of the interaction of buprenorphine in HIV/AIDS-affected patients, and has just begun the development of a study examining buprenorphine use for the treatment of prescription opiate abusers.

Clearly, our ISAP director is a leader in developing, implementing, and refining the use of buprenorphine for the treatment of opiate dependence.

His national and international travels are helping to spread the word that not only is buprenorphine a safe and effective treatment for most opiate-dependent individuals, but that the research-to-practice initiative is a viable and effective means of disseminating results of quality research into community settings.

Through his efforts in coordination with the Addiction Technology Transfer Center (see related article on Page 3) and other groups and institutions, buprenorphine research results, guidelines for the proper use of the medication, and adjunct behavioral treatment strategies are being disseminated throughout the United States and wherever opiate addiction is a major issue.

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