



Study on Treating Opioid Dependence with Buprenorphine Implant Receives Wide Media Coverage

By Brian Perrochet, Principal Editor
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A multisite study has yielded promising results for treating opioid dependence with an implant that releases buprenorphine, receiving wide media coverage.

Findings from a Phase III randomized, placebo-controlled clinical trial of Probuphine (subcutaneous implant form of buprenorphine) treatment for opioid addiction were published Oct. 13, 2010, in the *Journal of the American Medical Association (JAMA)*. The lead author of the article was Walter Ling, M.D., Director of ISAP.

All the major news networks interviewed Dr. Ling regarding the publication of these important results, and the study was featured in *Reuters*, the *Los Angeles Times*, *BusinessWeek*, *Bloomberg News*, *U.S. News & World Report*, *HealthDay News*, *MedPage*, *Medscape Today*, *Canadian Press*, *HealthDay News*, and *Agence France-Presse*.

ISAP's Outpatient Clinical Research Center was one of the sites involved in the multisite, 163-patient trial, which showed that patients receiving the Probuphine implant had significantly less illicit opioid use, experienced fewer symptoms of withdrawal and craving, stayed in treatment longer, and had greater overall improvement when compared to placebo patients over the course of the 24-week study.

"The introduction of buprenorphine into clinical practice is arguably the most significant improvement in

the treatment of opioid addiction in the last decade," said Dr. Ling. "However, physicians excited with the clinical success of buprenorphine are also rightfully concerned about medication adherence and diversion—and potential for abuse—of the sublingual formulations of buprenorphine.



ISAP Director
Walter Ling, M.D.

"Probuphine does away with these concerns by eliminating the need for take-home doses. Additionally, by providing a sustained blood level of active medication, Probuphine helps diminish the daily fluctuation of the medication effects—and potentially side effects—and reduces the total exposure of buprenorphine over time."

Notable results of the publication, "Buprenorphine Implants for Treatment of Opioid Dependence: A Randomized Controlled Trial," include:

- Patients receiving Probuphine had a mean percentage of urine samples negative for illicit opioids across the full 24 weeks of 36.6%; those in the placebo group had a mean of 22.4%

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ISAP Launches Implementation Study to Improve Assessment, Case Planning Processes in Prisons

www.uclaisap.org/CJS

By Michael Prendergast, Principal Investigator
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On Aug. 17, 2010, Jerry Cartier, Meghan Lynch, and Michael Prendergast of UCLA ISAP met with correctional and treatment staff

at Coyote Ridge Corrections Center in Washington State to “kick off” ISAP’s part in the *Organizational Process Improvement Intervention (OPII)*.

The goal of OPII is to evaluate an implementation strategy to improve the organizational processes involving the assessment of offenders, the development of case plans, the transfer of this information to community-based treatment agencies, and the use of the case plan by community-based treatment agencies to provide services.

Airway Heights Corrections Center, another prison in Washington State, will serve as the comparison site to Coyote Ridge Corrections Center.

The OPII study is being conducted under the Criminal Justice Drug Abuse Treatment Studies (CJDATS) cooperative agreement, which is funded by the National Institute on Drug Abuse and comprises nine research centers around the country. All nine centers are conducting the same study in prisons in their area.

The implementation strategy of the study involves a local change team, consisting of prison correctional staff, prison treatment staff, and community treatment staff. An external facilitator (Jerry Cartier, for ISAP) assists and supports the change team in the process improvement activities.

Jerry also has weekly calls with the facilitators at the other eight participating research centers to ensure

fidelity to the model across sites. Meghan Lynch provides research support to the project, including taking notes at meetings, distributing study surveys to staff, rating case plans, and conducting interviews with staff.



Facilitators of the OPII project from around the country are (from top left) Thomas Litwicki and Michael Shafer, Arizona State University, Thomas Coyne, Temple University, Jerry Cartier, UCLA ISAP, and Martin La Barbera, Texas Christian University; (from middle left) Matthew Hiller, Temple University, Erin McNees, University of Kentucky, Phillip Barbour, Texas Christian University, Joe Stommel, National Development Research Institute, David Kressel, University of Delaware, Wendy Ulaszek, University of Connecticut/DMHMR, and Wayne Lehman, Texas Christian University; and (seated) Mary Clair, University of Rhode Island, and David Duffee, Arizona State University.

During the fall, members of the change team, Jerry, and Meghan conducted the needs assessment phase of the study, which will provide information for the development of a process improvement plan that focuses on specific goals and activities to improve the assessment and case-planning process at Coyote Ridge.

On Sept. 15, Meghan met with the change team to conduct a “walk-through” of the specific instruments and procedures involved in assessing offenders, preparing case plans, and forwarding case plans to community treatment programs.

Meaghan also rated a sample of assessments and case plans to determine their content and quality.

On Oct. 27, Jerry and Meghan again met with the change team at Coyote Ridge in order to review the results of the walk-through and the case-plan ratings. At the meeting, Jerry also conducted a “SWOT” focus group with the change team members. That is, they discussed strengths, weaknesses, opportunities, and threats involved in the current procedures by which assessment, case planning, and conveyance of the plans to community providers are accomplished.

An additional meeting was held in December to finalize the needs assessment report and to begin to develop the process improvement plan. The change team will implement the plan in the spring and summer of 2011.

CURB Study to Test Buprenorphine as a Treatment for Reducing Cocaine Use



Clinical Trials Network

www.uclaisap.org/ctn

By Albert Hasson, Project Director
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The newest National Institute on Drug Abuse (NIDA) Clinical Trials Network (CTN) protocol, *Cocaine Use Reduction with Buprenorphine (CURB)*, under the direction of UCLA ISAP Director and Principal Investigator Walter Ling with Co-Investigators Larissa Mooney, of UCLA ISAP, and Andrew Saxon, of the University of Washington, is nearing the end of the site selection process.

Continued widespread cocaine abuse has compelled efforts to develop effective treatment strategies. No medications are currently available to specifically treat cocaine dependence, although extensive research is striving to identify and test new medications.

A pharmacotherapy that has shown promise is buprenorphine, but it has not been adequately examined for its definitive efficacy in reducing cocaine use. However, recent pharmacotherapy research has rekindled interest in buprenorphine (a partial mu-opioid agonist and a kappa-opioid antagonist).

Buprenorphine's Efficacy among Concurrent Abusers of Opioids and Cocaine

Buprenorphine's effectiveness in reducing cocaine use has been documented for more than a decade, but these observations were restricted to opioid abusers in treatment who were also cocaine abusers.

To date, no experimental research has occurred in non-opioid-using cocaine abusers because of the fear of potentially eliciting opioid craving and habituation by exposing opioid-naïve individuals to buprenorphine.

Ivan Montoya and colleagues studied buprenorphine in patients who were abusers of opioids and cocaine (see articles in *Clinical Pharmacology & Therapeutics*, Vol. 75, Issue 1, 2004, and *Current Psychiatry Reports*, Vol. 10, Issue 5, 2008), finding that "sublingual buprenorphine solution at 16 mg daily is well

tolerated and effective in reducing concomitant opiate and cocaine use" (2004).

Buprenorphine Shows Promise in Treating Cocaine Use

The therapeutic effect of buprenorphine on cocaine use appears independent of that on opiate use, as noted in work by Gilberto Gerra (*Journal of Psychopharmacology*, Vol. 20, Issue 6, 2006) and by Richard Rothman (*Journal of Substance Abuse Treatment*, Vol. 18, Issue 3, 2000).

A recent review article by NIDA's David McCann observed that Gerra's work suggested that "buprenorphine is effective in reducing cocaine use even in the presence of naltrexone, the addition of which should alleviate concerns regarding physical dependence" (*Clinical Pharmacology & Therapeutics*, Vol. 83, Issue 4, 2008).

A three-arm, 8-week trial comparing the following three treatments: (a) 4 mg Suboxone (buprenorphine and naloxone) and Vivitrol (naltrexone), (b) 16 mg Suboxone and Vivitrol, and (c) placebo and Vivitrol in individuals meeting dependence criteria for cocaine and opioids is scheduled to begin recruitment in 10 to 12 community treatment programs in the CTN.

Participants will be inducted onto Vivitrol and then provided with either 4 mg or 16 mg Suboxone or placebo on a daily basis for 8 weeks. A total of 300 participants, 100 in each arm, will be recruited over the course of the two-year trial.

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From Saudi Arabia...

Mohammed Abdul Jabbaar Bardi, M.D., of Saudi Arabia, began a year as a visiting scholar at UCLA in September 2010.

Dr. Bardi is Senior Registrar in the Psychiatry Department at Riyadh Military Hospital in Saudi Arabia and is on the Arab Board of Medical Specialties in Psychiatry.

He is interested in developing a subspecialty in addiction. While at UCLA, he has been attending several lectures and workshops on addiction psychiatry and research, neuroscience research, autism, and telemedicine.



Mohammed Abdul Jabbaar Bardi, visiting scholar from Saudi Arabia.

From Iraq...

ISAP was one of several U.S. host sites that welcomed scholars from Iraq last fall as part of a partnership between the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) and Iraq's Ministry of Health.

Drs. Nesif Jasim Mhaimed Al-Hemiary and Mushtaq Talib Hashim, Psychiatrists from Baghdad University Teaching Hospital, and Iman Ali Hussein Al-Nasrawi and Jinan Abdulameer Mansoor Al-Shakeri, Psychiatric Nurses from the same hospital, visited ISAP for two weeks in October.

These scholars were part of a second cohort of Iraqi mental health professionals to visit the United States; the first cohort visited in 2008.

The goal of the visits was to have the Iraqi teams observe and learn mental health and substance abuse interventions for possible implementation in Iraq. While here, the teams had access to professional staff, observed clinical and evaluation services, and received assistance in program planning and implementation.

From Egypt...

Maha Wasfi Mobasher, Ph.D., Professor of Psychiatry and Lecturer at Cairo University Faculty of Medicine, visited ISAP from August to November 2010 as the first participant in that university's collaboration with UCLA.

Dr. Mobasher, who works in addiction treatment, oversees a women's recovery home and is a pioneer in women's psychiatric treatment in Egypt.

While here, Dr. Mobasher gave a presentation on "Spirituality in Relation to Addiction Recovery" and participated in trainings on medication treatments for substance abuse, cognitive behavioral therapy, motivational interviewing, the Matrix model, contingency management, and mindfulness.

Three other scholars from Cairo University visited ISAP Nov. 1–12: Dr. Momtaz Abdel Wahab and Dr. Tarek Gawad, Professors of Psychiatry, and Dr. Azza El-Bakry, Professor of Child Psychiatry.



From left: Fawzy I. Fawzy, Professor and Executive Vice Chair of the UCLA Department of Psychiatry & Biobehavioral Sciences, Dr. Maha Wasfi Mobasher, visiting scholar from Cairo University, and Richard A. Rawson, ISAP Associate Director.

ISAP Hosts NIDA INVEST/CTN Fellows from Australia and Brazil

ISAP welcomes two National Institute on Drug Abuse INVEST/CTN Fellows this year, Suzanne Nielsen, Ph.D., from Australia, and Andrea Domanico, Ph.D., from Brazil. INVEST/CTN Fellowships are awarded to non-U.S. scientists to work with a mentor from one of the 16 Clinical Trials Network (CTN) Regional Research and Training Centers.

Dr. Nielsen, who began her one-year fellowship with ISAP in June 2010, is from Turning Point Alcohol and Drug Centre in Melbourne. She received her Ph.D. from Monash University, Victorian College of Pharmacy, where she completed her dissertation on "Concurrent Opioid and Benzodiazepine Use and the Safety of Opioid Substitution Pharmacotherapies."

Dr. Nielsen has been working with her mentor, ISAP Director Walter Ling, on the CTN protocol *Cocaine Use Reduction with Buprenorphine* (see Page 3). She has also conducted secondary analysis on data from the *Prescription Opiate Addiction Treatment Study*.



Suzanne Nielson, from Australia, and Andrea Domanico, from Brazil, are NIDA INVEST/CTN Fellows at ISAP this year.

Dr. Domanico received her Doctor of Philosophy in Social Sciences from the Bahia Federal University, Salvador, Brazil, in 2006 and recently completed a Humphrey Fellowship at the Johns Hopkins Bloomberg School of Public Health.

Dr. Domanico has 20 years of clinical experience in HIV prevention and harm reduction with crack cocaine users in Sao Paulo, Brazil, and will use this experience to assist Dr. Ling in the development and implementation of the *Cocaine Use Reduction with Buprenorphine* protocol. Dr. Domanico began her six-month fellowship with ISAP in August 2010.

As noted on the NIDA International Program Web site, "The INVEST/CTN Drug Abuse Research Fellowship combines postdoctoral research training in the United States with professional development activities and grant-writing guidance to form a unique program for drug abuse scientists."

ISAP Postdoctoral Scholar Awarded Canada's Bisby Fellowship

Congratulations to Bohdan Nosyk, Ph.D., who was chosen by the Canadian Institutes of Health Research (CIHR) in August 2010 to receive a Bisby Fellowship for his work on advancing longitudinal drug abuse research.

The Bisby Fellowships honor Dr. Mark Bisby, who played an important role in Canada's health research community from 1997 until his retirement in June 2006. He was Vice President of Research at CIHR and Director of the Programs Branch at CIHR's predecessor, the Medical Research Council of Canada.

As noted by the CIHR, Bisby Fellowships are intended to "enable recipients to assert themselves as thought leaders on the national and international research stage through engagement in national or international

conferences, workshops or meetings related to the award recipient's research."

Dr. Nosyk, who received his doctorate from the University of British Columbia, is a postdoctoral scholar at ISAP this year working with Associate Director M. Douglas Anglin, Principal Investigator Yih-Ing Hser, and other ISAP investigators on various research interests.



Bohdan Nosyk, ISAP postdoctoral scholar from Canada and 2010 Bisby Fellowship awardee.

ISAP to Evaluate SAMHSA-Funded Treatment Project for Homeless with Co-occurring Disorders

www.uclaisap.org/evaluation

By Anne Bellows, Project Director
(abellows@mednet.ucla.edu), and Christine E. Grella,
Professor and ISAP Associate Director

The Evaluation Services unit at UCLA ISAP has received a new contract to evaluate a five-year project that was recently funded by the Substance Abuse and Mental Health Services Administration (SAMHSA). The project, *Homeless Co-occurring Treatment Program* (HCOTP), run by Special Service for Groups, Inc., of Los Angeles, is part of SAMHSA's Homeless Treatment Program. The evaluation will be directed by Christine Grella, Professor-in-Residence at UCLA and Associate Director at ISAP.

Los Angeles has one of the largest homeless populations in the United States. Considerable research has documented high rates of mental health and substance use problems among homeless individuals, with estimates that approximately one-fifth of the homeless population has co-occurring disorders (COD).

Moreover, recent housing trends that reduce availability of public housing and the rise in unemployment have compounded the problem of homelessness in Los Angeles County. Cutbacks in publicly funded treatment services have led to further barriers to the accessibility of services.

Project Goals

The HCOTP project will address three interrelated problems among its participants: co-occurring disorders, lack of stable housing, and limited self-sufficiency and social supports.

The goals of the project are to increase motivation for recovery, reduce psychiatric symptoms, and increase social support and social functioning among participants. To achieve these goals, the project will implement several evidence-based practices; these include motivational interviewing, outpatient treatment using the Matrix Model, individual and group counseling, intensive case management services, wrap-around support services, and peer-led recovery support services.

HCOTP will assist at least 38 homeless individu-

als with COD per year over the five-year project. It is hoped that the treatment program will help reduce homelessness among individuals with COD and promote their ongoing recovery.

ISAP's Evaluation Services

UCLA ISAP regularly serves as the evaluator for grantees who have received funds from SAMHSA for program improvement or expansion. The ISAP team measures their progress toward recruitment, retention, and the implementation of the project as well as their progress in meeting project goals and objectives.

ISAP performs both process and outcome evaluations using data from various sources. These sources include the Government Performance and Results Act (GPRA) tool, which is an interview that gathers data regarding nine domains of a participant's life and functioning (including alcohol and drug use, crime and criminal justice status, mental and physical health problems, family and living conditions, social connectedness), as well as other project-specific assessments that target the unique goals of the project.

ISAP also conducts interviews with project staff and other stakeholders, focus groups with project participants, and observations of program activities, in order to describe the implementation process and lessons learned that may assist other providers in implementing similar projects.

Buprenorphine Implant

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- Nearly 66% of patients receiving Probuphine completed the study vs. the 31% who received placebo implants
- Probuphine patients experienced fewer clinician-rated and patient-rated withdrawal symptoms
- Probuphine patients reported lower ratings of craving
- The most common adverse events were minor implant site reactions, which were consistent across the Probuphine and placebo groups.

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