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SEARCH

[NIDA Home](#) > [Publications](#) > [NIDA Notes](#) > [Vol. 21, No. 1](#) > [Research Findings](#)

## Study Finds Withdrawal No Easier With Ultrarapid Opiate Detox

Research Findings  
Vol. 21, No. 1 (October 2006)

**Three serious adverse events among 35 ultrarapid procedures were all related to unreported preexisting medical conditions.**

**BY LORI WHITTEN, *NIDA Notes* Staff Writer**

Heroin-addicted patients who undergo so-called ultrarapid, anesthesia-assisted detoxification suffer withdrawal symptoms as severe as those endured by patients in detoxification by traditional methods, according to a NIDA-funded clinical trial. Researchers Dr. Eric Collins and colleagues at the College of Physicians and Surgeons of Columbia University concluded that there is no compelling reason to use general anesthesia in the treatment of opiate dependence, especially as it presents particular safety concerns. The new findings corroborate those of three international studies.

The ultrarapid detox technique, developed about 15 years ago by clinicians who hoped to mitigate the discomfort of withdrawal and speed the initiation of relapse prevention therapy, relies on a general anesthetic to sedate the patient for several hours while an opiate blocker precipitates withdrawal. The method is not covered by insurance, which makes it difficult to determine how many patients have received anesthesia-assisted detox.

To compare anesthesia-assisted detox with other approaches, Dr. Collins and colleagues enrolled 106 people seeking heroin detox at Columbia University Medical Center's Clinical Research Center. The patients, aged 21 through 50, had abused heroin every day during the past month. All spent 3 days as Center inpatients during detox, then were scheduled for twice-weekly outpatient relapse prevention psychotherapy and naltrexone maintenance (50 mg/day) for 12 weeks.

The investigators randomly assigned the participants to one of three detox methods ([see chart](#)). The goal of each method was to minimize patients' discomfort during withdrawal. In the ultrarapid approach, physicians put patients under anesthesia for 4 to 6 hours while administering naltrexone, a medication that precipitates withdrawal by blocking opioid molecules from their receptors in the brain. In the second method, patients remained awake and took a single dose of buprenorphine, a medication that eases withdrawal symptoms by moderating and smoothing the rate of opioid clearance from the brain. In the third approach, patients also remained awake and received clonidine and other nonopioid medications as needed to counter symptoms for all 3 inpatient days. These medications were available to all groups as needed for the duration of the inpatient phase. Throughout detox, the researchers closely monitored patients for complications, assessed physical indications of withdrawal, and asked the participants to rate their subjective experiences.

**RESEARCHERS COMPARE THREE OPIATE DETOX METHODS** Investigators studied the safety profile and withdrawal symptom control of three

detoxification methods used in 106 patients at Columbia University Medical Center.					
	Inpatient treatment				Outpatient treatment
	Day 0	Day 1	Day 2	Day 3	Day 4 through week 12
Anesthesia-Assisted		Anesthesia 4-6 h → 2 h monitoring in post-anesthesia unit → naltrexone induction (50 mg)  Clonidine and nonopioid medications as needed for withdrawal symptoms	Begin naltrexone maintenance (50 mg/day) (continue through end of study)  Ancillary withdrawal medications continued	Discharge from inpatient treatment  Ancillary withdrawal medications continued	Twice-weekly psychotherapy  Naltrexone maintenance medication (50 mg/day)
Buprenorphine-Assisted	Buprenorphine (8 mg)	Clonidine and nonopioid medications as needed for withdrawal symptoms	Naltrexone induction (12.5 mg)  Ancillary withdrawal medications continued	Discharge from inpatient treatment  Naltrexone induction continues (25 mg)  Ancillary withdrawal medications continued	Twice-weekly psychotherapy  Naltrexone maintenance medication (50 mg/day)
Clonidine-Assisted		Clonidine and nonopioid medications as needed for withdrawal symptoms	Ancillary withdrawal medications continued	Ancillary withdrawal medications continued  Discharge from inpatient treatment	Twice-weekly psychotherapy  Begin 2-day naltrexone induction on day 7 (12.5 mg, then 25 mg), followed by naltrexone maintenance starting on day 9 (50 mg/day)

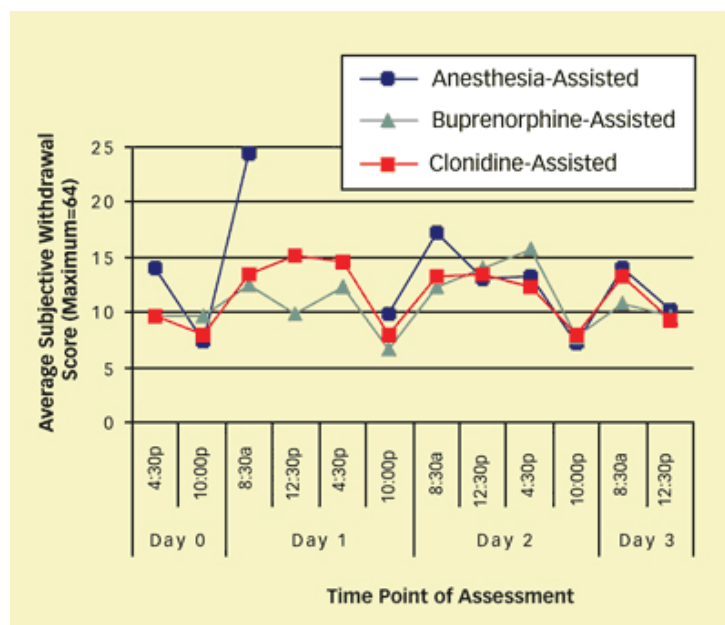
Once awakened from anesthesia, patients in the ultrarapid detox group demonstrated and reported symptoms of discomfort comparable to those experienced by participants receiving the buprenorphine- and clonidine-assisted methods ([see chart](#)). Three patients receiving the anesthesia-assisted method experienced serious adverse events—pulmonary and psychiatric complications as well as a metabolic complication of diabetes, all of which required hospitalization. The complications were related to preexisting medical conditions that the patients had failed to reveal when they were screened for admission into the study. No adverse events occurred with the other detox methods.

Treatment outcomes among the three groups were similar. Following detox, the researchers offered all the patients relapse prevention therapy consisting of outpatient counseling and naltrexone, which counteracts the pleasurable effects of subsequently administered opioids. More than 90 percent of the patients who received the anesthesia- and buprenorphine-assisted detox completed naltrexone induction; only 21 percent of those receiving clonidine completed induction. By the third week, more than half the patients in all three groups had dropped out of the study; only 18 percent remained in treatment the full 12 weeks. The percentages of patients submitting opiate-positive urine samples during outpatient treatment also were comparable, roughly 63 percent, across

the three detox methods.

### IN THREE DETOX METHODS, WITHDRAWAL SYMPTOM SEVERITY WAS SIMILAR

During a 72-hour inpatient detoxification stay, patients rated each of 16 withdrawal symptoms—for example, "I feel like vomiting," "I have cramps in my stomach," "I feel anxious," and "My eyes are tearing"—on a scale from 0 (not at all) to 4 (extremely). Symptom severity generally did not differ between heroin-addicted patients receiving anesthesia-, buprenorphine-, or clonidine-assisted methods. Researchers did not assess withdrawal symptoms for the anesthesia-assisted group during general anesthesia and the immediate recovery period.



### "NO ADVANTAGE"

"Although providers advertise anesthesia-assisted detox as a fast and painless method to kick opiate addiction, the evidence does not support those statements," says Dr. Collins. "Patients should consider the many risks associated with this approach, including fluid accumulation in the lungs, metabolic complications of diabetes, and a worsening of underlying bipolar illness, as well as other potentially serious adverse events," he says. Those with preexisting medical conditions—including some psychiatric disorders, elevated blood sugar, insulin-dependent diabetes, prior pneumonias, hepatitis, heart disease, and AIDS—are particularly at risk for anesthesia-related adverse events. "Careful screening is essential with the anesthesia-assisted method, because the thought of sleeping through withdrawal is so compelling that some patients may conceal their medical histories," says Dr. Collins.

"We now have several rigorous studies indicating that anesthesia-assisted detox—a costly and risky approach—offers no advantage over other methods," says Dr. Ivan Montoya of NIDA's Division of Pharmacotherapies and Medical Consequences of Drug Abuse. Dr. Montoya notes, "The low retention of patients in subsequent outpatient treatment in the present study, which is not unusual for the opiate-addicted population, highlights the need to engage people in long-term recovery after detoxification." Naltrexone can help motivated patients stay off opiates, but many do not stick to the regimen of daily tablets because of

the medication's side effects of anxiety and restlessness. Long-acting monthly injections of naltrexone, which are now available for alcoholism treatment, may work better for patients and show promise in NIDA-supported clinical trials.

Dr. Montoya also points out that with the current epidemic of prescription painkiller abuse, clinicians need more research on costeffective detox methods for these opiates (see "[2003 Survey Reveals Increase in Prescription Drug Abuse, Sharp Drop in Abuse of Hallucinogens \(archives\)](#)"). Some clinics are using buprenorphine for this purpose, and NIDA-funded investigators are studying various methods to improve prescription opiate detox and help patients engage in longer term treatment.

#### SOURCE

Collins, E.D., et al. Anesthesia-assisted vs buprenorphine- or clonidine-assisted heroin detoxification and naltrexone induction: A randomized trial. *Journal of the American Medical Association* 294(8):903-913, 2005. [[Abstract](#)]

### Volume 21, Number 1 (October 2006)

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[NIDA Home](#) > [Publications](#) > [NIDA Notes](#) > [Vol. 20, No. 2](#) > [Research Findings](#)

## Network Therapy Enhances Office-Based Buprenorphine Treatment Outcomes

Research Findings  
Vol. 20, No. 2 (August 2005)

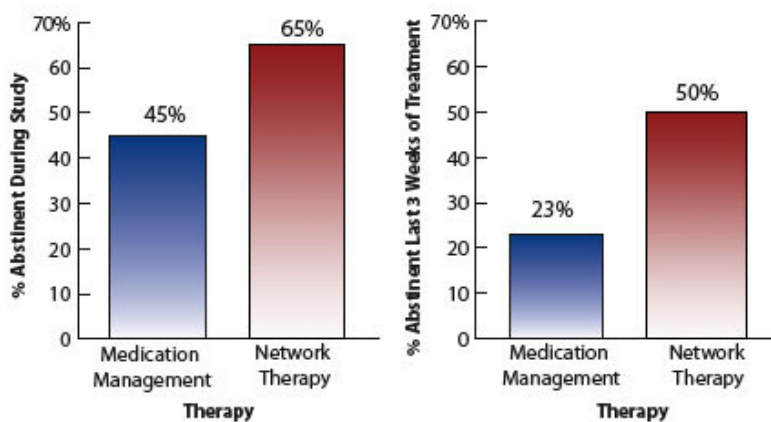
By Lori Whitten, *NIDA NOTES* Staff Writer

Network therapy—an office-based behavioral treatment that engages family and close friends in the recovery process—enhances abstinence among outpatients being treated with buprenorphine for opioid addiction. By the end of an 18-week NIDA-funded study, abstinence rates of patients who participated in network therapy (NT) were twice as high as those of a comparison group receiving standard medication management (MM) along with buprenorphine.

"NT transforms a few close relations from well-wishers to a team with skills to help patients achieve and maintain abstinence," says Dr. Marc Galanter, lead investigator of the study. In previous research, Dr. Galanter and his colleagues showed NT's promise as a therapy for cocaine addiction in both office- and community-based treatment settings; the new results in patients with opioid addiction add to the hopes that NT may offer a psychosocial adjunct to office-based buprenorphine treatment.

Dr. Galanter and colleagues at New York University Medical Center treated 66 heroin-addicted outpatients, aged 21 to 65, who reported abusing the drug for 12 years on average. Most (73 percent) had previous experience with addiction treatment, and about a third (30 percent) had tried methadone maintenance. Most lived with family or friends (77 percent) and were employed (67 percent). The investigators selected patients who could form a network—a few drug-free relatives or friends willing to help the patient achieve and maintain abstinence—and randomly assigned them to either MM or NT.

### Network Therapy Increases Abstinence Among Patients Taking Buprenorphine



*Among patients taking buprenorphine for heroin addiction, more of those who participated in network therapy attained abstinence during the 18-week study and throughout the last 3 weeks of treatment, compared with those who participated in medication management.*

All patients received a standard course of combined buprenorphine/naloxone tablets (16 mg/4 mg a day) taken under the tongue. Each patient also participated in two half-hour sessions per week of psychosocial treatment—either NT or MM—with a resident training in psychiatry. In MM, the therapist monitors the patient's response to the medication and encourages him or her to abstain from opioid abuse. The number of MM sessions and time investment are equivalent to those of NT, but the patient does not learn specific behavioral strategies for maintaining abstinence.

At the beginning of the study, patients chose people with whom they had an enduring relationship. Two people, on average, participated in each NT session with the patient. From the first NT session, therapists emphasized the primary guideline for this treatment approach: to focus on helping the patient achieve abstinence and to avoid discussions of relationship history, blaming, and emotional conflict. During sessions once a week, patients and their helpers communicated openly about events and people related to the patient's drug abuse and learned cognitive-behavioral techniques used widely in relapse prevention. As the supporters developed an understanding of relapse prevention, they helped the patient anticipate problem situations and develop recovery plans. They concentrated on creating an environment that helped the patient establish a drug-free residence, avoid substance-abusing peers, and stick to a medication regimen.

Although network members offer active support, patients in NT take full responsibility for their recovery. In weekly one-on-one sessions with a therapist, patients in the study strengthened the cognitive-behavioral skills they learned in network sessions, including monitoring of drug-abuse triggers, coping with craving, managing stress, and problem solving. Patients made and carried tools to assist them in recovery, such as cards to help them weigh drugs' attractions against the costs of abuse, written plans to deal with emergencies, and contact information for network members. The therapist encouraged patients to participate in 12-step programs, which can offer role models for abstinence and friendships with nonabusers. Throughout treatment, the researchers verified abstinence from illicit opioids with weekly urine tests.

Patients participating in MM and NT spent the same amount of time in therapy, 70 days on average, but more NT participants achieved abstinence by the end of treatment. Half receiving NT attained this goal, confirmed by opioid-free urine tests, during the last 3 weeks of treatment, compared with 23 percent of MM patients. More NT than MM patients produced opioid-free urine samples during the study (65 percent versus 45 percent). NT patients participated in 10 network sessions on average; those who attended more sessions sustained abstinence longer during the study. Whether the network comprised family or friends did not affect treatment outcomes.

*As the supporters developed an understanding of relapse prevention, they helped the patient anticipate problem situations and develop recovery plans.*

### **An Office-Based Approach**

"My colleagues and I designed NT principally for addiction treatment providers who do not have a large support team," Dr. Galanter says. "We find that those with psychotherapy experience learn the NT approach in about 10 training sessions with subsequent supervision." (See "[Network Therapy Expands Treatment Capabilities of Small Practice Providers](#)," *NIDA NOTES*, Vol. 18, No. 2)

"In this approach, a patient and therapist collaborate with a small group to achieve stable abstinence, weaving the contributions of each member and different treatment techniques into a supportive tapestry for a drug-free lifestyle. The network counteracts the environmental and social factors—for example, substance-abusing peers—that often compromise recovery," says Dr. Galanter. Although NT can help patients who have a few close associates willing to support their recovery, the therapy is probably not appropriate for homeless or mentally ill people or those who cannot achieve abstinence on their own for even 1 day.

Studies show that many heroin-addicted patients in treatment continue to abuse some form of opioids, with only about 20 percent of those on buprenorphine medication demonstrating opioid-negative urine tests at the end of 1 month of

*"The network counteracts the environmental and social*

treatment. Extending the therapy to 2 to 6 months increases the percentage of opioid-negative urine tests to 50 to 60 percent. Dr. Dorynne Czechowicz of NIDA's Division of Clinical Neuroscience, Development and Behavioral Treatment says, "It's impressive that NT therapy enhanced the results typically seen with short-term buprenorphine medication."

She emphasizes that the researchers should examine whether NT reduces abuse of other drugs among opioid-addicted patients, particularly cocaine, which puts people who are in recovery at high risk for opioid abuse relapse. She adds that investigators should also conduct longer-term studies to determine whether patients maintain these treatment gains and demonstrate NT's effectiveness in general medical practice.

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Dr. Galanter and his colleagues have posted a brief introduction to NT on the Internet (<http://www.med.nyu.edu/substanceabuse/manuals/nt/>). The American Psychiatric Association sells a training video on NT as an office-based addiction treatment; the video is appropriate for any mental health professional.

#### Source

- Galanter, M., et al. Network therapy: Decreased secondary opioid use during buprenorphine maintenance. *Journal of Substance Abuse Treatment* 26(4):313-318, 2004. [[Abstract](#)]

#### Volume 20, Number 2 (August 2005)

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Bulletin Board  
Vol. 20, No. 1 (August 2005)

## Institute of Medicine Report Recommends NIDA Research Agenda For New Addiction Therapies

By Patrick Zickler, *NIDA NOTES* Staff Writer

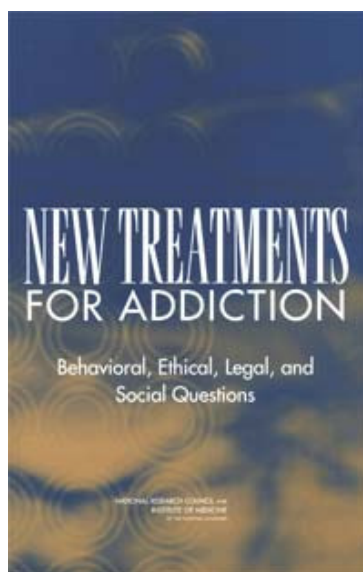
A mother asks a pediatrician to vaccinate her child against nicotine's pleasurable effects, practically eliminating the possibility that the child will become a smoker. A patient in treatment for heroin addiction receives an injection of sustained-release medication that will prevent her from feeling the drug's euphoric effects for a year. As current drug abuse research brings such scenarios closer to realization, NIDA has begun to study the broad implications of these and other new types of preventive treatment. These therapies underscore the need to balance therapeutic benefits and ethical considerations, particularly if the person receiving treatment—a minor child or a person involved in the criminal justice system, for example—is not the person who chooses it.

At NIDA's request, the National Research Council's Institute of Medicine (IOM) identified ethical, legal, and behavioral issues that must be considered in the development and application of active and passive immunotherapies and sustained-release medication. The Institute's 306-page report recommends a set of guiding principles as NIDA-supported research pursues the development of these potentially powerful new preventive interventions.

Immunotherapies destroy drug molecules before they reach the brain. Active immunotherapy involves a vaccine that stimulates the body's immune system to create antibodies against drugs in the same way that an inoculation creates antibodies against polio or measles virus. Passive immunotherapy involves periodic injections of antibodies rather than stimulation of the immune system; an example of this type of therapy is tetanus immune globulin, which contains antibodies to provide short-term protection for someone whose injury may have exposed them to soil-borne tetanus bacteria. Sustained-release therapies involve injection or implantation of long-acting formulations of medications that are released over a period of weeks or months to block the effect of drugs in the brain.

The IOM report identifies ways to meet the challenges these interventions are likely to pose for researchers, treatment providers, policymakers, parents, and the public. Because the treatments may have lifelong effects, IOM recommends long-term studies involving animals of different ages, as well as their offspring, before human studies are undertaken.

IOM also recommends studies that can be used to establish clear guidelines for use of the new therapies in circumstances that are inherently coercive or nonconsensual, such as in the criminal justice system, child welfare cases, or the protective immunization of minor children. What, for example, are the possible legal consequences of administering immunotherapy medications to children or adolescents? Competent adults have the right to decline medical treatment, but the





legal situation is more complicated when the patient is a minor and decisions made by others on his or her behalf may have a lifelong effect. Immunotherapies will leave long-lasting biological traces that can be detected in routine blood or urine tests. Such markers could label patients as drug abusers long after they have entered sustained recovery, which could discourage some from utilizing these treatments. In its report, IOM says the development of immunotherapy and sustained-release medications highlights the need to understand addiction as a chronic medical condition that requires long-term management, a partnership between primary medical care and addiction treatment, and integration of psychosocial services into the treatment environment. The IOM report recommends that NIDA support models that integrate the new pharmacotherapies with psychosocial services in addiction treatment and primary care settings that reduce the stigma of substance abuse treatment.

The full report, *New Treatments for Addiction: Behavioral, Ethical, Legal, and Social Questions*, is available online at [www.nap.edu/catalog/10876.html](http://www.nap.edu/catalog/10876.html).

### Volume 20, Number 1 (August 2005)

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