

# NIAA Research Findings

Summary: National Institute on Alcohol Abuse and Alcoholism (NIAAA) Research Findings – Orientation to Naltrexone and the Integration of Medication into State Treatment Systems.

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The following material is a summary of the “National Institute on Alcohol Abuse and Alcoholism (NIAAA) Research Findings – Orientation to Naltrexone and the Integration of Medication into State Treatment Systems.” This presentation took place on Saturday, June 2<sup>nd</sup> from **9:00 a.m. – 12:30 p.m.** in LaSalle Ballroom “C” at the Intercontinental Hotel in New Orleans, Louisiana, as part of the NASADAD Annual Meeting, 2001.

Introduction: Kelly Green Kahn, MPA, NIAAA

Presenters: Robert Swift, Ph.D., NIAAA

Cindy Parks Thomas, Ph.D., NIAAA

Panel Members: Arthur Evans (CT), Maria Canfield (NV), Ray Stephens (AR)

Moderator: Ken Stark (WA)

Ken Stark introduced the panel members and explained the structure of the session, which would include a question and answer period following the presentations and reactions from panel members.

Kelly Green-Kahn, Public Liaison Officer for NIAAA began the session. Ms. Green-Kahn reviewed many of NIAAA’s current research-to-practice initiatives. These included the Subcommittee on College Drinking, the NIH Director’s Council on Public Representatives, the Alcohol Abuse Research Centers, the Public Education Campaign on Fetal Alcohol Syndrome, National Alcohol Screening Day, the Leadership Initiative to Keep Children Alcohol Free, curriculum development and other academic initiatives, and a multitude of symposiums, conferences, and workshops (please visit the NIAAA Web site for more information on these and other initiatives). She urged the session attendees to utilize the resources and information that NIAAA has assembled.

After responding to several questions from the attendees, Ken Stark introduced the first speaker, Robert Swift, M.D., Ph.D. Dr. Swift is Associate Professor of Psychiatry and Human Behavior at Brown University, Associate Chief of Staff for Research Education at the Providence VA Medical Center, and the Associate Director of the Brown University Center for Alcohol and Addiction Studies.

Dr. Swift began by commenting on the need to bring the results of research, including new technologies and new treatment approaches to the awareness of those who may need treatment

and to the general population. He reviewed the most current data available (1997) concerning the impact of alcohol abuse on the individual and society, in terms of the benefits of treatment. He noted that there is a lifetime prevalence of heavy drinking among 13-15% of the general population, and that in any given year about 7.4 percent of the population are suffering from alcoholism. There are about one million individuals who are engaged in some form of treatment for addiction to a substance, and that addiction usually involves alcohol. He noted annual costs to the U.S. economy of hundreds of billions of dollars due to major health care costs related to accidents and disease, including heart disease, diabetes, and cirrhosis.

Dr. Swift cited treatment as an effective method for dealing with the costs to society for alcohol abuse and addiction. He noted barriers to treatment intervention including the patient's denial of the problem and inadequate treatment resources, and discussed the need to improve the overall system. He identified the use of pharmacotherapy as part of that process of improvement, along with the continued use of tried and true measures such as cognitive behavioral therapies, family therapies, and use of self-help groups.

Dr. Swift explained that pharmacotherapy in the treatment of alcoholism improves treatment outcomes, and lengthens periods of abstinence. As we increase and expand our understanding of how the brain functions, and fully appreciate the systemic devastation that alcohol wreaks on the human body, we can see the value of using whatever tools that can be employed to improve the effectiveness of treatment.

Medications are used effectively in the treatment of other types of drug dependencies. Methadone and naltrexone have been used effectively in the treatment of opiate addiction, and buprenorphine will soon be available for the same purpose. Nicotine-dependence medications have played a major role in smoking-cessation programs. Medications are also used in treating those who are dual-diagnosed (those who have a mental health disorder and are also addicted to one or more substances). Dr. Swift discussed an important barrier to the incorporation of medications in treatment for alcoholism, which is the marginalization of treatment in the health care industry. He noted the need to "medicalize" treatment, and bring it into the mainstream of health care.

There is medication that causes an adverse reaction to alcohol by interfering with the metabolism of alcohol (disulfiram), which is most effective in reducing alcohol consumption in mature treatment populations. Alcohol abuse can also be reduced in the dual-diagnosed population when psychiatric symptoms are treated. Researchers still need to develop medications that address the protracted withdrawal from alcoholism.

But some of the most promising medications for the treatment of alcohol addiction involve those that act on neuroreceptors for opiate peptides. Dr. Swift summarized several studies that indicate that individuals prone to alcoholism lack certain naturally occurring opiate peptides, that opiate agonists increase alcohol consumption, and that opiate antagonists decrease consumption. There are medications currently on the market that reduce the craving for alcohol and the urge to drink by acting on the brain's opiate receptors (naloxone, naltrexone, and a new one called nalmathine). They have been proven to be effective in reducing alcohol consumption because they strongly

decrease the urge to drink, and also decrease the subjective stimulation and pleasure from alcohol.

Dr. Swift cited studies that indicate alcohol addiction treatment that supports the utilization of opiate antagonists and other medications is more effective than addiction treatment that does not include this component. He noted that it is also better to combine psychosocial treatment than to simply administer the medication alone.

A second class of medications that are also effective in reducing alcohol consumption involve the brain's glutamate receptors. Glutamic acid, a major neurotransmitter, has an excitatory effect on these receptors. Alcohol inhibits this effect. Over time, the receptor compensates by becoming supersensitive to excitation. Removing alcohol causes the brain to be overexcited. A medication developed in Europe called acamprosate has a regulatory effect on this receptor. Clinical trials conducted show that acamprosate reduces alcohol consumption and improves abstinence rates. It may also stabilize some of the persistent neurobiological abnormalities seen in prolonged withdrawal from alcohol.

Dr. Swift discussed the NIAAA study, COMBINE, which is a large trial designed to explore the efficacy of combined medication and psychotherapy, utilizing either naltrexone or acamprosate. The study will evaluate the use of these medications in conjunction with either moderate or minimal intensity behavioral intervention, and compare the results with those who receive moderate behavioral intervention and a placebo instead of the medication. At the conclusion of his remarks, he fielded several questions from the floor regarding this study, and gave attendees a toll free number to call for more information: 1-866

Ken Stark introduced Cindy Parks Thomas, Ph.D., Senior Research Associate at Brandeis University, Schneider Institute for Health Policy. Dr. Parks is the director of the NIAAA research project "Adoption of Naltrexone by Clinical Providers." Dr. Clark identified issues related to integrating the use of medications such as Naltrexone into alcoholism treatment models, and also discussed the findings of this study.

Naltrexone was approved for alcoholism treatment in conjunction with counseling in late 1994. The approval was timed to coincide with a strong publicity campaign, and its use was advocated by the medical establishment and by federal agencies such as SAMHSA. Despite this, clinical providers did not accept it, and it never achieved widespread use. Dr. Thomas touched on barriers related to the diffusion of naltrexone, citing issues concerning relative safety of using medications as opposed to other treatment approaches, overall effectiveness, cost/benefit ratios, complexity of the mechanism that makes the drug "work," consistency with current treatment approaches, and resources available to support its use. She noted that the channels used to publicize it bypassed clinicians and State AOD treatment systems, the effort did not take into consideration changes in the funding environment, physicians are frequently not available in treatment facilities, and clients are usually not insured and lack prescription coverage. In addition, naltrexone was not marketed to the general population as other drugs that are used to treat allergies or depression are marketed.

But there were still many unanswered questions concerning the relative failure of naltrexone to achieve widespread use. The NIAAA study was designed to answer as many of those questions as possible. The States who participated in the study included Tennessee, Massachusetts, and Rhode Island. The survey took into consideration demographics, professional training, treatment setting clients, and asked for indicators such as whether or not the treatment professional recommended the use of naltrexone, and also examined the reasons for the specific indicators.

The study revealed very low rates (about 50% who said they prescribed it at least occasionally) of prescribing naltrexone by the physicians in the study group, who are addiction specialists. Over 50% of counselors never recommended it, and most of the counselors who did recommend it did so only occasionally. Physicians and counselors “in recovery” were highly unlikely to prescribe or to recommend naltrexone.

The study revealed that Medicaid is an important factor in the provision of naltrexone, as is the endorsement of the organization that supports the provision of treatment. The most important barriers to the use of naltrexone identified by treatment professionals were cost, and lack of knowledge about the use of the medication in the treatment of alcoholism. A third barrier to its use concerned the predictability of outcomes, and when it is most appropriate to recommend its use. The study concluded that not enough information about naltrexone is reaching clinicians.

Dr. Thomas noted the need for State AOD Agencies to take a stronger role in the integration of naltrexone in the treatment system. The States need to identify sources of funding, such as Medicaid and the Veterans Administration, for the use of naltrexone in treatment, and need to play a stronger role in disseminating the information to the clinical staff, with a clear program for promoting acceptance among providers.

Ken Stark introduced the panel members Arthur Evans (CT), Maria Canfield (NV), and Ray Stephens (AR). Maria Canfield began her remarks by describing the Nevada system as a “social model treatment system.” Nevada contracts with local community based organizations and sometimes with government providers through the mental health system. Access to physician services is not usually possible within this system. Ms. Canfield identified this lack of access to addiction focused medical care as a primary barrier. She discussed the composition of the treatment population, which are at least 70% poly-substance abusers. She also discussed the current nature of the work force, which is still largely lacking in formal training, and schooled in the 12-Step model of addiction treatment. Ms. Canfield identified barriers that exist due to the structure of the public health care delivery system, which is non-managed care, and then touched on the stigma associated with addiction. This last issue makes it almost impossible to market Naltrexone in the same way that other medications are marketed.

Ray Stephens echoed many of these Nevada-identified issues for the State of Arkansas, which has a similarly organized treatment system, lack of access to physicians, lack of Medicaid funding, a conservative workforce, and lack of resources to pay for mediation on the part of the clients. In both States, the workforce standards have recently been raised, but it will take time for the workforce to meet those standards. Using naltrexone would require workforce training, physician access, funding for the medication, monitoring for proper use and effectiveness, and

other cost-related issues that make selling the use of Naltrexone to providers and the State legislature difficult.

Arthur Evans noted his experience both as a clinician and as an administrator in describing the obstacles to the integration of Naltrexone with the treatment system. The Connecticut system uses a managed care model and is currently focusing on measuring and improving continuity of care, readmission and access. An analysis of the data they are developing indicates that a key issue is implementation of system-wide procedures that improve access to appropriate treatment. Mr. Evans noted the need to move from identifying barriers to identifying cost-effective procedures for using naltrexone in a system that is not set up to use medication. This may involve changing the current infrastructure so that access to medical care is possible, as well as addressing attitudes and work force competency. In addition, the nature of current funding streams demands that State Agencies interact to determine how medical care bills will be paid.

The moderator, Ken Stark, also contributed to the panel discussion by describing his experience with attempting to integrate the use of naltrexone in the Washington State treatment system. The Washington State AOD Agency worked with the State's Medicaid agency to include naltrexone in the formulary and provided clients with a 30-day supply of the medication and required it as an adjunct to treatment, with the support of providers and others. Mr. Stark noted that the use of naltrexone had still not really caught on despite State AOD Agency and provider support. He attributed this to the cost involved, including the cost of medical resources such as physician appointments, medical tests, and the cost of the medication itself. The population that most State AOD Agencies serve is not eligible for Medicaid, but even when they are, dealing with the gap in resources is the main obstacle to integrating naltrexone with treatment in Washington State. This is especially an issue when Medicaid services are delivered under a managed care system.