



Evaluation of the Buprenorphine Waiver Program: Study Overview

Purpose

The key questions to be addressed by the Evaluation of the Buprenorphine Waiver are described in the Drug Addiction Treatment Act of 2000 (DATA). DATA establishes a program of waivers that permit qualified physicians to dispense or prescribe schedule III, IV, and V narcotic drugs or combinations of such drugs approved by the Food and Drug Administration (FDA) for the treatment of addiction to opiates. DATA also specifies that the Secretary of the Department of Health and Human Services (HHS), in conjunction with the Attorney General, may make determinations concerning whether:

- treatments provided under the Waiver have been *effective* forms of maintenance and detoxification treatment in clinical settings;
- the Waiver has significantly increased the *availability* of maintenance treatment and detoxification treatment; and
- such Waivers have *adverse consequences for the public health*.

In October, 2002, buprenorphine was approved by the FDA for maintenance or detoxification treatment of opiate addiction and thus became the first medication available for use under the Waiver program. Buprenorphine is available in two formulations, Subutex (a pure form of buprenorphine) and Suboxone (a combination of naloxone and buprenorphine). Based on their determinations concerning buprenorphine as prescribed and distributed under the Waiver program, the Secretary and Attorney General can decide whether the program should continue, and if so, whether standards should be changed or additional standards required.

The Evaluation of the Buprenorphine Waiver Program will elicit findings that can inform these determinations. The study is being conducted by the Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Treatment (SAMHSA/CSAT), Division of Pharmacologic Therapies (DPT), working in tandem with other agencies and stakeholders. The study will also collect information that could prove useful in the early identification of any significant problems with the Waiver (e.g., adverse consequences, diversion for illicit use) and that can help guide immediate intervention by policymakers, if needed.

In addition to collecting information needed for the determinations, the evaluation also addresses three related objectives. These are:

- (1) determining the impact of Waiver-based treatment on the existing treatment system;
- (2) providing information useful to guide and refine the processing/monitoring system being developed and maintained by CSAT/DPT; and

- (3) providing baseline data to inform future research and policy concerning the mainstreaming of addiction treatment, in SAMHSA's continuing effort to ensure that addiction issues are addressed by primary care providers as well as providers of behavioral treatment.

Evaluation Components

A new medication developed for the treatment of opiate addiction, buprenorphine has pharmacological properties that make it feasible and appropriate for use in clinics and office-based settings. The DATA Waiver has enabled its use in settings outside of highly regulated Opioid Treatment Programs (OTPs), which are few in number relative to the large number of persons known to be abusing opiates. The Waiver program has the potential to revolutionize the treatment of opioid addiction by increasing access to treatment for subgroups of clients who might not otherwise receive treatment. The evaluation will focus on the impact of the Waiver program on treatment availability for opiate addiction, the effectiveness of buprenorphine treatment provided under the Waiver, and any public health consequences resulting from the Waiver's implementation.

Treatment Availability. There is strong evidence from France and other countries to suggest that treatment of opioid addiction by physicians will greatly improve access to medication-assisted substance abuse treatment in the United States. However, many factors play a role in the availability of treatment, such as the willingness of providers to adopt it, payers to fund it, and policymakers to support it. Public demand will play a large role as well. All of these factors need to be considered in order for the evaluation to be complete.

Other aspects of availability to be examined will include whether the number of persons treated with detoxification and maintenance has increased as a result of the Waiver, and whether subpopulations treated with Buprenorphine differ from subpopulations treated with methadone/LAAM. The evaluation will also examine whether buprenorphine's availability increases the geographic distribution of treatment to regions where methadone treatment does not exist, and whether the number or distribution of opioid treatment programs changes as implementation of the Waiver program proceeds. For instance, an increase in the number of physicians who are prescribing buprenorphine, including those who are new to providing any medication-assisted treatment for opioid addiction, would suggest an increase in treatment availability, barring significant reductions in the number of OTPs.

Treatment Effectiveness. A number of studies and randomized clinical trials have shown that buprenorphine is an efficacious and safe maintenance agent for opioid addiction treatment. The present evaluation will not try to replicate these studies, but will evaluate the effectiveness of the medication as prescribed in multiple real-world settings, e.g. as specified by the Waiver program, in offices and clinics across the U.S.

To examine the effectiveness of buprenorphine treatment, the evaluation will assess a number of outcomes, including the patient's reported substance use, health status, satisfaction with treatment, and the length of time in treatment. Information will also be gathered about clinicians' perceptions of buprenorphine's effectiveness and their willingness to use medication to treat substance abuse disorders. Finally, data will be collected about other factors that may influence buprenorphine's effectiveness, e.g. prescription practices, adjunctive services, patient subpopulations being treated, and whether buprenorphine is used as a detoxification (medically supervised withdrawal) or maintenance agent. Buprenorphine treatment effectiveness will be benchmarked against findings from studies of methadone effectiveness.

Public Health Consequences. The evaluation of the buprenorphine Waiver program will also examine three key issues related to public health outcomes. First, evidence for the *abuse* of buprenorphine will be sought, and rate of abuse will be evaluated relative to the rates of abuse of other prescription drugs, including methadone. Second, the evaluation will search for evidence of *adverse medical consequences* of buprenorphine when it is taken as prescribed. Third, an assessment of the relationship between buprenorphine treatment and changes in patients' *high-risk or antisocial behaviors* will be made.

Data Sources

The evaluation will rely on both primary and secondary data. Primary data collection methods will include community forums, working groups, telephone interviews, a tracking study, and surveys of both physicians and patients. Secondary data sources will include administrative databases from CSAT as well as data being collected under other evaluation and surveillance efforts.

Community Forums. To identify general issues surrounding implementation of the Waiver program, we are collecting qualitative information through two large forums held at events with large and diverse groups of stakeholders. The first “Buprenorphine Forum” was held in Washington, DC, in April, 2003, in conjunction with the national conference of the American Association for the Treatment of Opioid Disorders (AATOD). After presenting information about the evaluation, we participated in an informal question and answer session, gathering comments reflecting the concerns of those who have traditionally provided methadone treatment for opioid addiction. A second, similar, forum will take place at a future conference or meeting of other stakeholders.

Telephone Interviews with Prescribing Physicians. In an effort to collect early data about how buprenorphine treatment is being implemented, semi-structured telephone interviews are conducted with nine prescribing physicians. These physicians are individuals whose primary experience with the drug has been gained in their regular practice, under the Waiver. They represent a diversity of respondents in terms of geography and experience. The interviews gather in-depth information about these physicians’ perceptions of buprenorphine’s effectiveness and availability, the clinical context in which it is typically prescribed, any adverse effects of the medication they may have observed, and whether the medication is seen as increasing the availability of treatment for opioid addiction.

Working Groups. Working groups, similar to focus groups, consist of informal discussions among nine individuals who are encouraged to express their diverse professional views. Their responses help shape survey design and analysis at various points in the study. Two working groups are planned. The first group will focus on *substance abuse treatment providers’* perceptions of the availability of treatment for opioid addiction, the effectiveness of buprenorphine in their treatment programs, adverse reactions, and any evidence of diversion. The second group brings *local public health and law enforcement professionals* together to discuss the impact of buprenorphine on their communities, the public health system, and drug-related criminal behavior.

Surveys. The evaluation utilizes data from two physician surveys conducted by mail and one longitudinal patient study conducted by telephone. The *Addiction Physician Survey* is sent to a sample of approximately 1,000 physician addiction specialists, including those who have and have not submitted a notification for a Waiver. The focus of this survey is specialists’ perceptions and acceptance of buprenorphine during the early days of the Waiver program. The *Waivered Physician Survey* is sent to a sample of approximately 1,800 physicians, all of whom have Waivers to prescribe buprenorphine, to learn more about physician experience treating with buprenorphine, once it has been available for at least one year. Longitudinal data from the *Patient Study* are collected by telephone interview from a cohort of about 400 buprenorphine patients to assess patient response to and satisfaction with buprenorphine therapy. Patients are recruited through a sample of prescribing physicians’ offices and will be interviewed at baseline, 30 days, and 6 months. The survey yields information about patient populations treated and the impact of the medication on a range of outcomes including substance use and drug abusing lifestyle. All surveys will obtain approval from the Office of Management and Budget before being fielded.

Payer/Provider Organization “Tracking Study.” This component of the evaluation examines trends related to reimbursement and organizational policies in the public and private sectors as they affect the dissemination of and adoption of buprenorphine as a treatment for opioid addiction. Qualitative data are collected from representatives of a variety of organizations who agree to be interviewed by telephone

periodically throughout a two year period. The group represents organizations from five important sectors: (1) Health Plans and Organized Systems of Care; (2) Public Payers; (3) Pharmaceutical Distributors; (4) Pharmaceutical Benefits Management Firms (PBMs); and (5) Pharmacies. Findings gathered over a two year period elucidate the extent to which organizational interest or reluctance to support or fund buprenorphine treatment may facilitate or challenge its availability.

Secondary Data Sources. The following additional sources will be used to track the availability of buprenorphine and its effects:

- *CSAT's Opioid Treatment Program (OTP) Certification and Accreditation Database.* Information from this database, maintained by SAMHSA/CSAT's Division of Pharmacologic Therapies (DPT), allows for the identification of the geographic distribution of programs providing opioid agonist therapy before and after the introduction of buprenorphine. Thus, this source assists in the examination of the effects of buprenorphine availability on the OTP system.
- *Buprenorphine Waiver Registration Database.* Also maintained by SAMHSA/CSAT's DPT, this is a list of physicians who have submitted a notification to use buprenorphine in the treatment of addiction to opiates under the Waiver program. This information, examined over time, establishes the geographic distribution of locations and rates at which buprenorphine becomes available.
- *Drug Abuse Warning Network (DAWN).* These data, available from SAMHSA's Office of Applied Studies (OAS), allow for the identification of medical consequences (related both to drug abuse and adverse reactions to medications taken as directed) by way of emergency department admissions.
- *Automation of Reports and Consolidated Orders System (ARCOS).* ARCOS, a database of the Drug Enforcement Administration (DEA), is an automated, comprehensive drug reporting system that monitors the flow of DEA-controlled substances from their point of manufacture through commercial distribution channels, to point of sale or distribution at the dispensing/retail level. ARCOS can be used to examine the geographic distribution of buprenorphine use and may help flag areas of potential diversion.
- *National Drug Intelligence Center (NDIC).* NDIC, established in 1993, is a component of the U.S. Department of Justice and a member of the intelligence community. Threat assessments, NDIC's primary products, provide policymakers and counterdrug executives with timely, predictive reports on the threat of drugs, drug-related violence, and drug-related financial crime in the United States. Consultation with NDIC staff provides early warning should buprenorphine diversion become a problem.
- *An Ethnographic Study of Heroin Injectors.* Dr. Jane Maxwell of the University of Texas at Austin is conducting structured interviews with heroin injectors as part of a National Institute on Drug Abuse study. She has agreed to include a few items related to abusers' knowledge of buprenorphine as a drug of abuse, including whether they have abused the drug, whether the drug is easy to buy or sell on the street, and whether it is perceived to be an attractive drug for abuse compared to heroin and methadone.

Additional Data Sources. The following sources will be consulted to provide contextual information and corroboration for evaluation findings:

- *Community Epidemiology Work Group (CEWG) of the National Institute on Drug Abuse (NIDA).* CEWG is a network comprised of researchers from major metropolitan areas of the United States and selected foreign countries, which meets semiannually to discuss the current epidemiology of drug abuse. The Work Group can provide valuable information stemming from ongoing community-level surveillance of drug abuse through the analysis of quantitative and qualitative research data. Informal discussions with CEWG and

some of its researchers, as well as the monitoring of semi-annual and special reports, provide context to other evaluation findings.

- *RADARS System.* The Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS™) System was established by Purdue Pharma to study the prevalence of abuse and diversion of certain controlled prescription medications. It is designed to obtain quantitative and qualitative information on the relative rates of abuse, addiction, and diversion of commonly prescribed prescription medications including buprenorphine. Three aspects of RADARS could be useful for confirming evaluation findings: a key informant network; links to law enforcement drug diversion units; and the Drug Evaluation Network System (DENS).
- *Reckitt Benckiser Post-Marketing Surveillance Study.* Coordination and informational discussions with Wayne State University, who is conducting this study, could provide additional information about whether the buprenorphine Waiver is associated with adverse events affecting public health and safety.
- *Consultation with the Food and Drug Administration (FDA).* FDA's Medwatch system, which receives reports from consumers and physicians, provides information concerning adverse reactions being reported by patients taking buprenorphine as prescribed for the treatment of opiate addiction. In addition, consultation with FDA analysts could provide the evaluation with additional data important to understanding availability of buprenorphine.

Summary

To summarize, SAMHSA/CSAT's Evaluation of the Buprenorphine Waiver Program is collecting data using a range of sources and methods, to provide information about (1) how the Waiver impacts the availability of detoxification and maintenance treatment, (2) whether buprenorphine is an effective form of detoxification and maintenance treatment, and (3) whether buprenorphine is associated with adverse public health consequences. Findings from SAMHSA/CSAT's study will be used by the Secretary, HHS, and Attorney General to make determinations concerning Buprenorphine as prescribed and distributed under the Waiver program, for instance, to decide whether the Waiver program should continue, and if so, whether standards should be changed or additional standards required. Information from this study will also help refine SAMHSA/CSAT's monitoring processes and will inform future research and policy concerning the "mainstreaming" of addiction treatment.

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