

The SAMHSA Evaluation of the Impact of the DATA Waiver Program

Summary Report

FINAL

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The SAMHSA Evaluation of the Impact of the DATA Waiver Program Final Summary Report

1. INTRODUCTION

In 2000, Congress passed the Drug Abuse Treatment Act (DATA 2000) to address the growing gap between the persons needing treatment for opioid dependence and the treatment available. DATA created a program of waivers from existing regulations for qualified physicians, permitting them to dispense and prescribe certain opioid medications approved for use in treating opioid dependence from a range of medical settings. DATA also outlined physician qualifications and set a 30 patient limit on individual and group practice as a condition for obtaining and maintaining a Waiver. It also specified that the Secretary of the Department of Health and Human Services (HHS), in conjunction with the Attorney General, could make determinations concerning whether:

Treatments provided under the Waiver Program were effective;

The Waiver Program had significantly increased the availability of maintenance treatment and detoxification treatment; and

Such Waivers had adverse consequences for the public health.

In October 2002, buprenorphine was approved by the Food and Drug Administration (FDA) for maintenance or detoxification (detox) treatment of opioid 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 Waiver Program should continue, and if so, whether standards should be changed or additional standards required.

1.1 Purpose

This evaluation was conducted by Westat on behalf of the Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Treatment (SAMHSA/CSAT), working in tandem with numerous other agencies and stakeholders. The Evaluation of the Impact of the DATA Waiver Program was designed primarily to provide information that could inform the determinations specified in DATA. The key objectives of the Evaluation involve assessing:

- (1) The impact of the Waiver Program on the availability of medication assisted treatment (MAT);
- (2) The effectiveness of treatment provided under the Waiver Program; and
- (3) Evidence for consequences affecting public health, including diversion and adverse reactions.

Secondary objectives of the Evaluation were to assess the impact of Waiver-based treatment on the existing treatment system, to identify any early, significant problems with the Waiver Program (*e.g.*, adverse consequences, diversion for abuse), to provide useful information to guide data systems being developed and maintained by CSAT, and to provide baseline data to inform future research and policy.

1.2 Data Sources

The Evaluation involved analysis of both primary and secondary data. Primary data collection methods included a forum, telephone interviews, a tracking study, and surveys of physicians and patients. Secondary data sources included administrative databases from CSAT as well as data being collected under other evaluation and surveillance efforts. In this section, we briefly describe each data source.

1.2.1 Primary Data Sources

Community Forum. The "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, project staff participated in an informal question and answer session, gathering comments

reflecting the concerns of those who have traditionally provided methadone treatment for opioid addiction.

Telephone Interviews With Prescribing Physicians. In an effort to collect early data about how buprenorphine treatment was being implemented, semi-structured telephone interviews were conducted with nine prescribing physicians. These physicians were individuals whose primary experience with the drug was gained in their regular practice under the Waiver Program. The interviews gathered 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 observed by the physicians, and whether the medication seemed to the respondents to be increasing the availability of treatment for opioid addiction.

Reimbursement and Availability Tracking Study. This component of the Evaluation examined trends related to reimbursement and organizational policies in the public and private sectors as they affected the dissemination and adoption of buprenorphine as a treatment for opioid dependence. Qualitative data were collected from 10 to 12 representatives of a variety of organizations who agreed to be interviewed by telephone in fall 2003, spring 2004, fall 2004, and spring 2005. Participants represented organizations from five important sectors of the healthcare environment: (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 2-year period elucidate the extent to which organizational interest or reluctance to support or fund buprenorphine treatment may facilitate or challenge its availability.

Addiction Physician Survey. The Evaluation used data from two physician surveys conducted by mail. The first survey, the Addiction Physician Survey, involved mailing surveys to 959 addiction medicine specialists sampled from American Academy of Addiction Psychiatrists (AAAP), the American Society for Addiction Medicine (ASAM), and the American Osteopathic Academy of Addiction Medicine (AOAAM) mailing lists. The survey was fielded in September 2003, with responses received through December 2003. The response rate was 80 percent.

Waivered Physician Survey. This survey was sent to a sample of 1,837 of the 3,498 waivered physicians in CSAT's Buprenorphine Waiver Notification System (BWNS). The sample was drawn in September 2004, and the survey was fielded from January through March of 2005. The response rate was 86 percent.

Longitudinal Patient Study. Longitudinal data from the Patient Study were collected by telephone interview from a cohort of about 433 buprenorphine patients to assess patient response to and satisfaction with buprenorphine treatment. Patients were recruited through a sample of 132 waived physicians' offices or clinics, and were interviewed at treatment initiation and 30 days and 6 months later. The survey yielded information about patient populations treated and the impact of the medication on a range of outcomes including employment, continued substance use, and high-risk behaviors.

1.2.2 Secondary Data Sources

The following secondary data sources were used to track the availability of buprenorphine and its effects.

CSAT's OTP Accreditation Database. Information from this database, maintained by SAMHSA/CSAT, allowed for the identification of the geographic distribution of programs providing opioid agonist therapy over time. This source thus assisted in assessing the effects of buprenorphine availability on the opioid treatment program (OTP) system, commonly referred to as methadone clinics.

Buprenorphine Waiver Notification System (BWNS). The BWNS is a database maintained by SAMHSA/CSAT. It contains a list of all physicians who submitted a notification of qualifications to prescribe under the Waiver Program as well as whether the qualifications were verified or not. This information, examined over time, establishes the geographic distribution of locations and rates at which buprenorphine treatment became available.

Drug Abuse Warning Network (DAWN). The Drug Abuse Warning Network (DAWN), a SAMHSA/Office of Applied Studies (OAS) project, is a surveillance system that monitors drug-related visits to hospital emergency departments (EDs) and drug-related deaths investigated by medical examiners and coroners. DAWN data allow for the identification of medical consequences (related both to drug abuse and adverse reactions to medications taken as directed) by way of ED (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 was used to examine the geographic distribution of buprenorphine shipments as compared to methadone shipments to OTPs from 2003 to 2004.

National Survey of Substance Abuse Treatment Services (N-SSATS). N-SSATS, an annual survey administered by SAMHSA's Drug and Alcohol Information System (DASIS), collects information from substance abuse treatment centers listed in the Inventory of Substance Abuse Treatment Services (I-SAT). This master list of all organized substance abuse treatment centers is maintained by SAMHSA. Each site is sent a yearly survey intended to collect data on the location, characteristics, services offered, and utilization rates of each center. In 2003, the survey included a question about whether buprenorphine treatment was offered at the site. N-SSATS provided information about the number and geographic distribution of substance abuse treatment centers providing buprenorphine treatment as well as trends in the number of centers providing methadone treatment over time.

Treatment Episode Data Set (TEDS). TEDS, a data system supported by SAMHSA's OAS, provides information on the demographic and substance abuse characteristics of the approximately 1.9 million admissions to facilities reporting to individual state administrative systems. The coverage for TEDS varies by state, with some states excluding admissions from private facilities providing methadone. Nevertheless, TEDS is the best data source available for understanding the overall characteristics of patients admitted for methadone treatment on a national level. The Evaluation reports on trends in the number and characteristics of patients treated for opioid dependence in the TEDS sites providing methadone treatment.

2. EFFECTIVENESS OF BUPRENORPHINE PRESCRIBED UNDER THE DATA WAIVER PROGRAM

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 does not replicate these studies, but reports on outcomes related to the effectiveness of the medication as prescribed in a range of clinical sites across the United States providing treatment under the Waiver Program.

Outcomes investigated during the Evaluation included patients' reported substance use, satisfaction with treatment, and retention in treatment. Information was also gathered on physicians' perceptions of buprenorphine's effectiveness and their willingness to use medication to treat substance abuse disorders. Finally, data were collected about factors that may have influenced buprenorphine's effectiveness such as prescription practices, adjunctive services, patient subpopulations being treated, and whether buprenorphine is used as a detoxification (medically supervised withdrawal or short-term treatment) or maintenance agent. Outcomes from buprenorphine treatment were also benchmarked against findings from effectiveness studies of methadone and buprenorphine. The key questions investigated include the following:

What is the effectiveness of buprenorphine prescribed under the Waiver Program?

Do patients show improvements over the 6 month study period as indicated by high levels of drug abstinence, treatment retention, and employment and low rates of criminal activity?

Are patients satisfied with treatment?

Is there evidence for buprenorphine's effectiveness under the Waiver Program compared to methadone treatment and buprenorphine clinical trials?

The data in Figure 1 are from the Waivered Physician Survey conducted in 2005. Waivered physicians with experience providing buprenorphine treatment under the Waiver Program generally favored longer-term buprenorphine treatment. Physicians were asked, "Overall, how would you rate the effectiveness of buprenorphine treatment... (a) ...completed within 7 days? (b) ...completed within 8-30 days? (c) ...involving treatment for at least 1 month?" Almost three-quarters (74%) indicated buprenorphine treatment of 1 month or longer was very effective (and 96% said it was very or somewhat effective). In contrast, fewer waivered physicians indicated that buprenorphine treatment of 1 week or less (32%) or 8-30 days (40%)

was very effective. It is noteworthy that 12 to 15 percent of physicians did not answer or indicated that they did not know the effectiveness of buprenorphine treatment provided for less than 1 month.

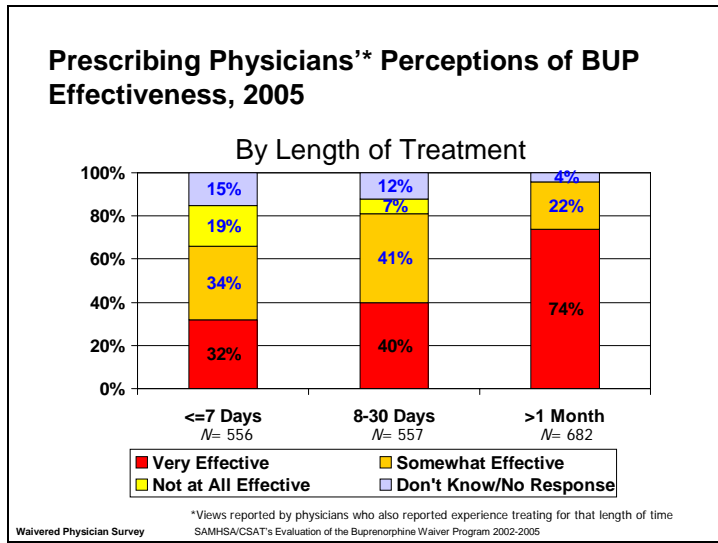


Figure 1. Prescribing physicians' perceptions of buprenorphine effectiveness, 2005

Figure 2 shows patients' reports of abstinence from drugs over the previous 30 days.

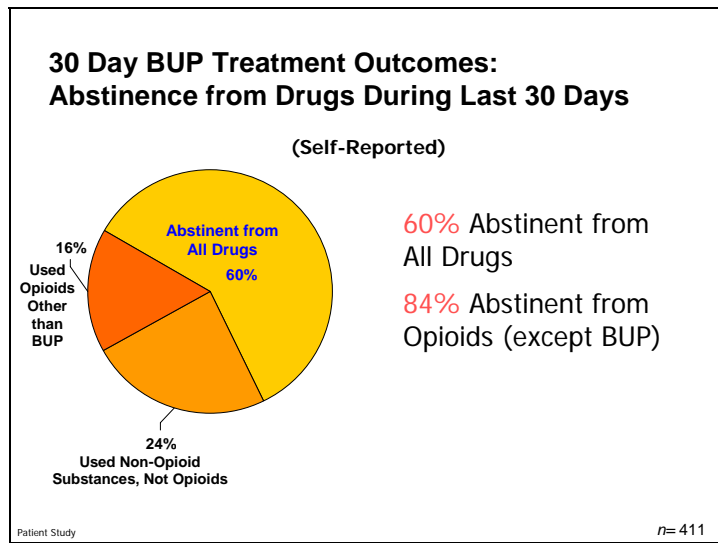


Figure 2. Thirty day buprenorphine treatment outcomes: Abstinence from drugs during last 30 days

Patient Study respondents were asked: "In the past 30 days, how many days have you used... [heroin] or [nonprescription or "street" methadone] or [other opiates/narcotic

analgesics such as *OxyContin*[®], *oxycodone*, *Percodan*[®], or *Percocet*[®]]?” At 30 day followup, the majority (84%) of buprenorphine patients reported abstinence from all abused opioids during the past 30 days. Sixty percent reported that they had been free of all drugs for the previous 30 days, and 46% denied any drug or alcohol use during the previous 30 days.

Figure 3 shows that at 6 month followup, the majority (81%) of buprenorphine patients reported abstinence from all abused opioids during the past 30 days. Fifty-nine percent said they had been free of all drugs for the previous 30 days, and just under half (45%) denied any drug or alcohol use during the past 30 days. These abstinence rates at 6 month followup were relatively robust, as they remained similar to those reported at 30 day followup.

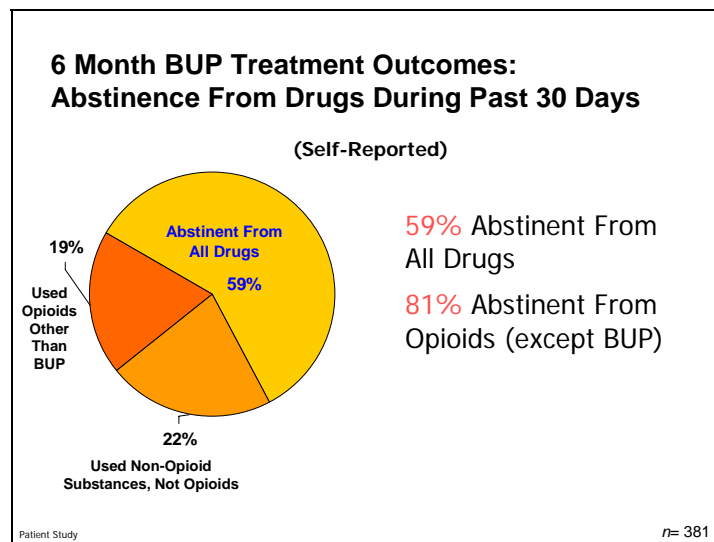


Figure 3. Six month buprenorphine treatment outcomes: Abstinence from drugs during past 30 days

It should be noted that outcomes from the Patient Study are based exclusively on patient self-report, with no independent validation using biological samples or other methods. It is possible that some patients may have underreported drug and alcohol use to the anonymous telephone interviewers. However, patients were assured their responses would never be identified or reported to their treating physicians or to anyone else.

Figure 4 compares the self-reported opioid abstinence rates at 30 days and 6 months for respondents who reported at baseline habitually abusing heroin only, opioids available by prescription (i.e., opioid painkillers or narcotic analgesics), and both kinds of opioids. The analyses were restricted to 381 persons responding to the interview at both 30 days and 6 month

followup. Abstinence in this context means 0 days of use of opioids other than buprenorphine reported over the last 30 days.

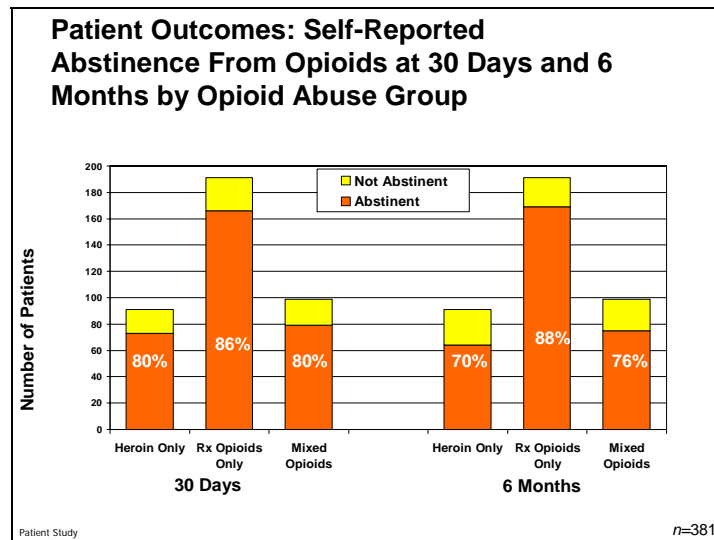


Figure 4. Patient outcomes: Self-reported abstinence from opioids at 30 days and 6 months by opioid abuse group

Thirty days after initiation of buprenorphine treatment, the abstinence rates for the three groups were similar, at about 80 percent. At 6 months, however, abstinence rates for persons initially abusing primarily heroin and heroin and prescription opioids were significantly lower than the rate for persons abusing prescription opioids only (where statistical significance was determined by a chi-square analysis with a *p* less than .01). Notably, the abstinence rate for the prescription opioid only group remained at about the same level as it had been at 30 days, while the abstinence rate of the other two groups involving heroin decreased.

Figure 5 shows that 91 percent of all buprenorphine patients in the Patient Study reported that they had completed or were still in treatment at the 30 day followup (80% were still in treatment, while about 11% overall had completed treatment). The chart shows retention rates with respondents categorized according to which opioid they had habitually abused prior to treatment. There were no statistically significant differences between the groups, as measured by a chi-square test. In the heroin only group, 76 percent were still in treatment and 13 percent had completed treatment; in the prescription opioids only group, 81 percent were in treatment and 12 percent had completed treatment; and for the mixed opioids group, 85 percent were still in treatment while 5 percent had completed treatment.

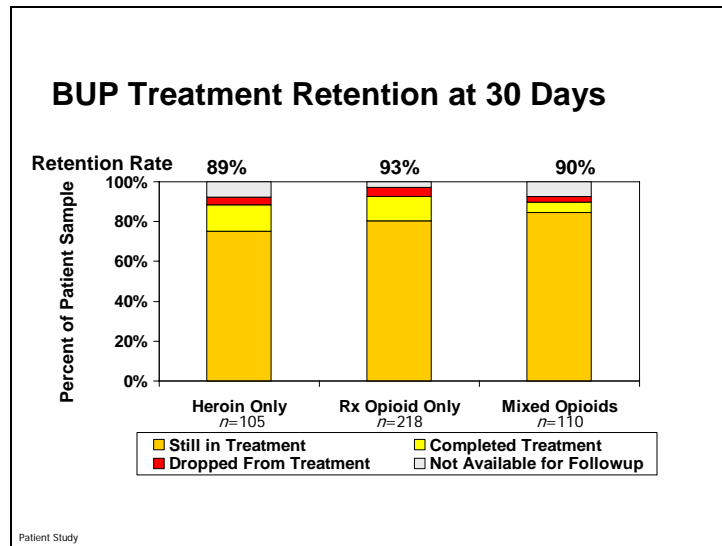


Figure 5. Buprenorphine treatment retention at 30 days

The retention rate displayed in Figure 5 includes those patients who completed treatment with those who were still in treatment. (That is, the retention rate is defined as: $\text{Retention rate} = \frac{[\text{Still in treatment} + \text{Completed treatment}]}{[\text{Still in treatment} + \text{Completed treatment} + \text{Dropped from treatment} + \text{Not available for followup}]}$). This is a conservative estimate of retention, as some patients who did not provide information at 30 days may have completed treatment successfully, but were not counted in the numerator of the retention rate.

Figure 6 shows that 60 percent of all buprenorphine patients in the Patient Study were still in treatment at 6 month followup and an additional 15 percent reported that they had completed treatment. The bar chart shows retention rates with respondents categorized according to which opioid they habitually abused prior to treatment. There were no statistically significant differences between the groups. In the heroin-only group, 58 percent were still in treatment and 13 percent had completed treatment; in the prescription opioids only group 60 percent were still in treatment and 17 percent had completed treatment; and in the mixed opioid group 62 percent were still in treatment while 12 percent had completed treatment.

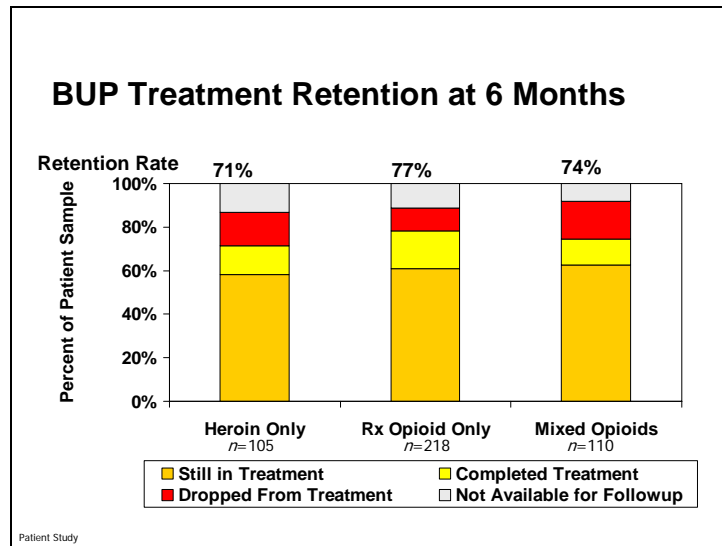


Figure 6. Buprenorphine treatment retention at 6 months

Figure 7 attempts to provide benchmark data for the comparison of treatment outcomes for opioid-dependent patients participating in the Patient Study with outcomes from other studies of MAT for opioid dependence. There is, however, evidence that the characteristics of patients recruited into the Patient Study were quite different from the characteristics of patients treated in most MAT studies. Therefore, as shown in Figure 7, the outcomes of a subgroup of the Patient Study respondents who were habitually abusing heroin prior to treatment are compared to the outcomes of published studies in an attempt to match the populations most frequently studied in benchmark studies of methadone and buprenorphine. The benchmark comparisons are derived from the review of methadone and buprenorphine outcome literature detailed in the Evaluation Final Report.

For a variety of reasons explained in the Evaluation Final Report, comparing outcomes from the Patient Study to available benchmarks is problematic. Specifically, study populations, dosages, followup intervals, and other factors differ considerably among the studies from which the benchmarks were extracted. Nonetheless, it is apparent that the outcomes obtained in the Patient Study are at least as good as those typically found for methadone or buprenorphine in recent studies.

Benchmarks for Patients Primarily Using Heroin

Outcome at 6 Months	Patient Study (Primary Heroin User Group)	Methadone Benchmarks	BUP Trials Benchmarks
Retention in Treatment	67%*	53-63%	39-55%
Abstinence	70%	73%	N.A.
30 Day Illicit Opioid Use	1.2 days	3.1-6.9 days	5.1-6.2 days

* An additional 14% reported that they had "Completed Treatment" within 6 months.

Figure 7. Benchmarks for patients primarily using heroin

At 6 month followup, almost all buprenorphine patients in the Patient Study reported high satisfaction with buprenorphine as a medication-based treatment for their opioid dependence (see Figure 8). Ninety-nine percent described buprenorphine as helpful—95 percent as extremely or very helpful. Similarly, 97 percent of buprenorphine patients indicated they would recommend buprenorphine treatment to an opioid-dependent friend. These high satisfaction ratings showed little change from 30 day followup.

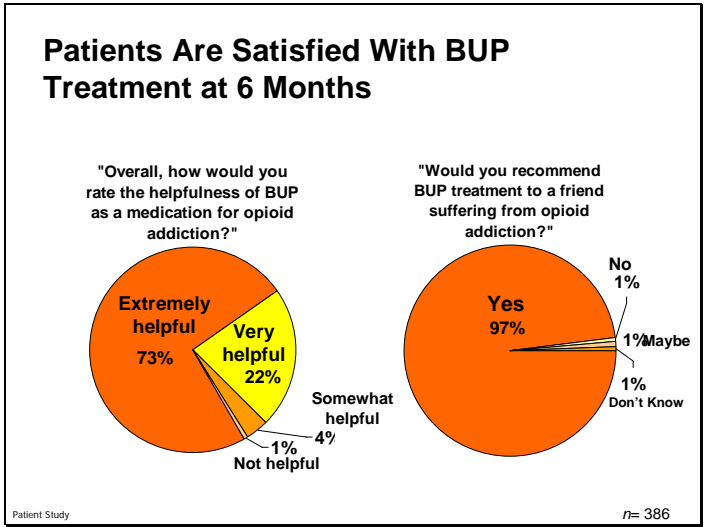


Figure 8. Patients are satisfied with buprenorphine treatment at 6 months

Figure 9 shows that 6 months after initiation of buprenorphine treatment, patients reported very slight improvements in full- and part-time employment and a small decrease in the

percentage unemployed. The finding is noteworthy since it means that most of the sample that was employed at baseline was able to remain employed while receiving buprenorphine treatment. In contrast, patients receiving other forms of treatment can find it difficult to maintain employment, especially if the treatment is residential or involves daily dosing at an OTP.

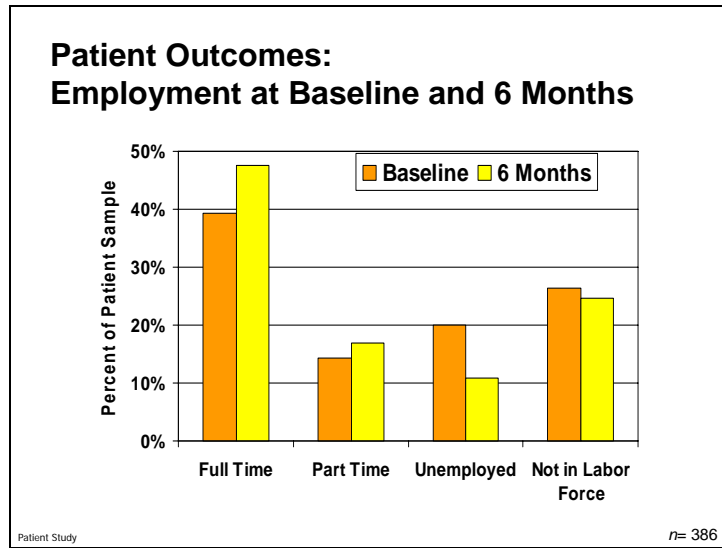


Figure 9. Patient outcomes: Employment at baseline and 6 months

Importantly, at the 6 month followup 10 percent of patients had started or returned to an educational program. These individuals are characterized as “not in the labor force,” but should be recognized as having a positive outcome. Definitions for the different employment categories are derived from those used by the Department of Labor. Working Full-time is defined as working for pay for 35 or more hours per week in one or more jobs, including self-employment. Working Part-time is defined as working less than 35 hours per week or being employed, but not currently working due to illness, leave, furlough, strike, or having a seasonal job. Unemployed is defined as being unemployed or laid off and looking for work. Not in the labor force is defined as being a full-time homemaker, in school only, retired, disabled for work, receiving worker’s compensation/SSI, being a caretaker for parents, incarcerated, or unemployed and *not* looking for work.

Figure 10 shows patients’ self-reported street acquisition of drugs before and after commencing buprenorphine treatment. Patients were asked, “In the past 30 days, how many days did you get drugs ‘on the street’?” Dramatic decreases in obtaining drugs from the street were noted from baseline to 30 days and 6 month followup. Only two-thirds of the sample reported street acquisition of drugs at baseline. Those persons who did report obtaining drugs on the street

at baseline, on average, reported acquiring them almost half of the days during the month prior to beginning buprenorphine treatment. In contrast, reports of street acquisition were practically nonexistent at 30 day followup. Even at 6 month followup, rates had dropped 87 percent from baseline; 80 percent of patients denied obtaining any drugs from the street in the prior 30 days.

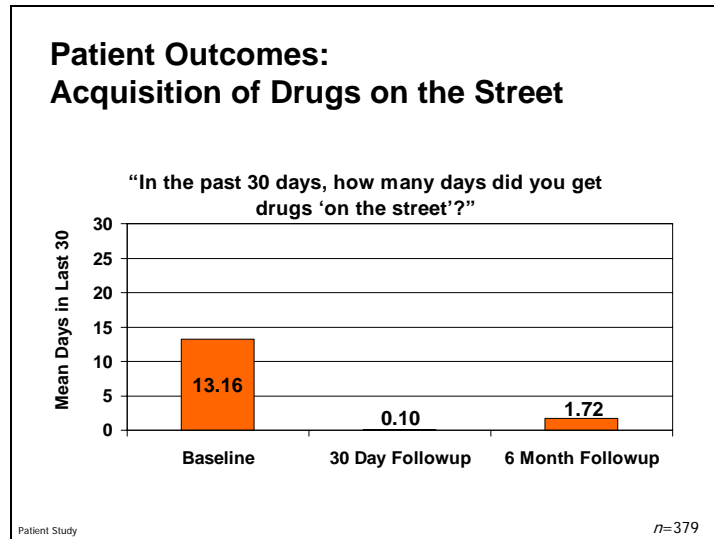


Figure 10. Patient outcomes: Acquisition of drugs on the street

Importantly, we do not know if these drugs were actually “bought” or *how* the drugs were acquired “on the street”. Potentially, some may have been acquired via barter for sex or other goods/services, stolen, or obtained from peers, and so forth.

Figure 11 shows the percentage of patients who reported acquiring drugs on the street before and after treatment with buprenorphine. Respondents were asked: “In the last 30 days were you involved in any of the following illegal activities... bought drugs or traded/bartered for drugs (not including legal prescriptions)?” At baseline about two thirds of the sample (250 persons) reported acquiring drugs on the street. Almost one-third (32%) of respondents indicated they did not get drugs on the street *any* of the past 30 days. At the 30 day followup, only 17 patients (4%) indicated they had obtained drugs from the street since starting treatment. Only two said they had done so on more than 3 of the past 30 days.

At 6 month followup, 80 percent reported acquiring drugs on the street for *none* of the past 30 days. Of those who did acquire drugs on the street, 64 percent did so 5 or fewer of the past 30 days, 3 percent 21 or more days, and 2 percent did so daily. It is possible that some of the

prescription opioid-dependent patients obtain opioids by prescription, over the Internet, or have some other source.

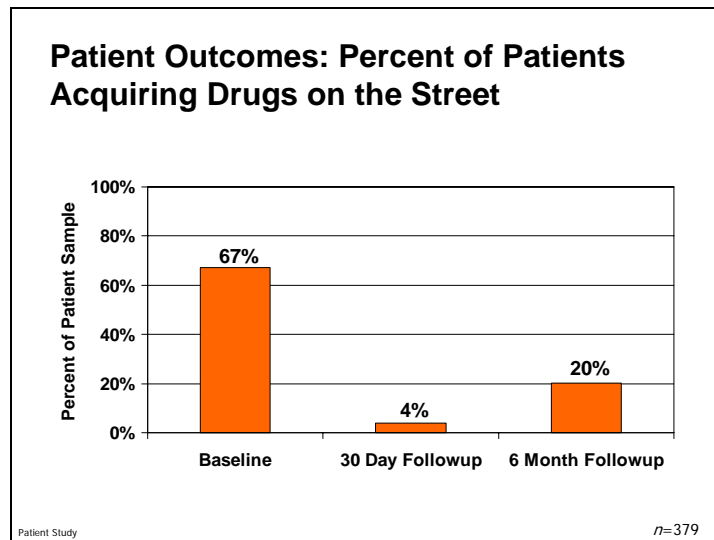


Figure 11. Patient outcomes: Percent of patients acquiring drugs on the street

Figure 12 shows that patient-reported criminal activity decreased dramatically in the period following buprenorphine treatment—particularly for drug-related activities.

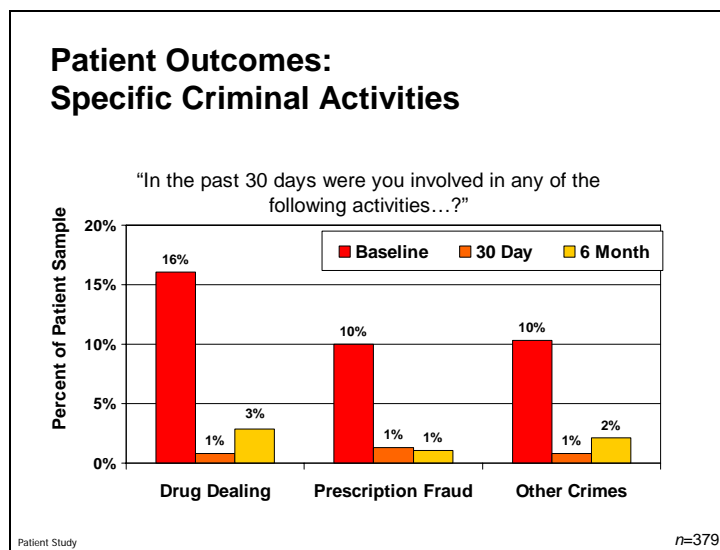


Figure 12. Patient outcomes: Specific criminal activities

Respondents were asked: “In the last 30 days were you involved in any of the following illegal activities: Sold or traded illegal drugs? Obtained prescription drugs illegally (stole prescription pad, forged or changed a prescription, sold drugs prescribed to you)? Property

crime (robbery, shoplifting, stealing car), or violence (armed robbery, assault, rape, or murder)?” Specifically, marked improvements were noted in the following behaviors:

Dealing or selling drugs decreased 82 percent over the study period, with 16 percent of patients reporting such activities at baseline, dropping to 3 percent at 6 month followup. This decrease was even more dramatic during the first 30 days of treatment, but the longer 6 month outcomes suggest a more stable outcome.

Prescription fraud—that is, obtaining prescription drugs illegally (through stealing prescription pads, forging or changing a prescription, seeking drugs from multiple physicians or pharmacies)—decreased 89 percent from 10 percent of patients reporting such activities at baseline to 1 percent at 6 month followup.

Other criminal activities decreased 79 percent, from 10 percent at baseline to 2 percent at 6 month followup, with even greater short-term (30-day) improvements. Other criminal activities include property crime (such as robbery, shoplifting, and stealing cars), fraud (such as forging checks, credit card fraud, identity theft, and scams), and violent crimes (such as armed robbery, assault, rape, and murder).

Summary on Effectiveness

Evaluation findings regarding the effectiveness of buprenorphine treatment for opioid dependence provided under the Waiver Program can be summarized as follows:

1. Most prescribing physicians perceived buprenorphine to be effective, particularly for treatment of longer duration.
2. Positive treatment outcomes were observed among patients treated in a range of actual clinical practice settings.
3. Outcomes are consistent with and comparable to the results of numerous clinical trials that have found buprenorphine to be effective in research contexts. In addition, in this study, buprenorphine treatment appeared to be somewhat more effective for patients who were dependent on prescription opioids than for those primarily dependent on heroin.

3. AVAILABILITY OF MEDICATION ASSISTED TREATMENT (MAT)

There is strong evidence from France and other countries, where buprenorphine treatment for opioid dependence has been available since the mid to late 1990s, to suggest buprenorphine treatment as provided under the Waiver Program would significantly 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, patients to seek it, payers to fund it, and policymakers to support it.

The Evaluation examined three main subject areas to assess whether medication-assisted treatment (MAT) availability actually increased after the implementation of the Waiver Program: (1) the number and characteristics of physicians providing treatment under the Waiver Program; (2) the geographic availability of MAT; and (3) the characteristics of patients treated under the Waiver Program. The Evaluation also gathered information on physicians', patients', and payers' attitudes toward buprenorphine treatment as provided under the Waiver Program, and examined what factors restricted the dissemination of buprenorphine treatment. Following are the key questions that the Evaluation attempted to answer about treatment availability.

Does the Waiver Program:

Increase the number and types of physicians providing MAT for opioid addiction?

Increase the number of treatment locations and geographic accessibility?

Impact the number of OTPs?

Increase access to treatment for specific subpopulations?

Figure 13 is based on three data sources: (1) the Waivered Physician Survey, (2) the Addiction Physician Survey, and (3) the BWNS. It shows the number of waived physicians over time, along with their prescribing rates. Nearly 1,000 physicians had obtained a Waiver prior to FDA approval of buprenorphine in October 2002. By fall 2003, the number of physicians who had obtained a Waiver had nearly doubled. However, estimates from the Addiction Physician Survey indicated that at that time, only about half of waived physicians were actually prescribing buprenorphine. By the time the Waivered Physician Survey was fielded in early 2005, the number of waived physicians had grown to well over 4,000, and the rate of prescribing had increased to 67 percent of waived physicians.

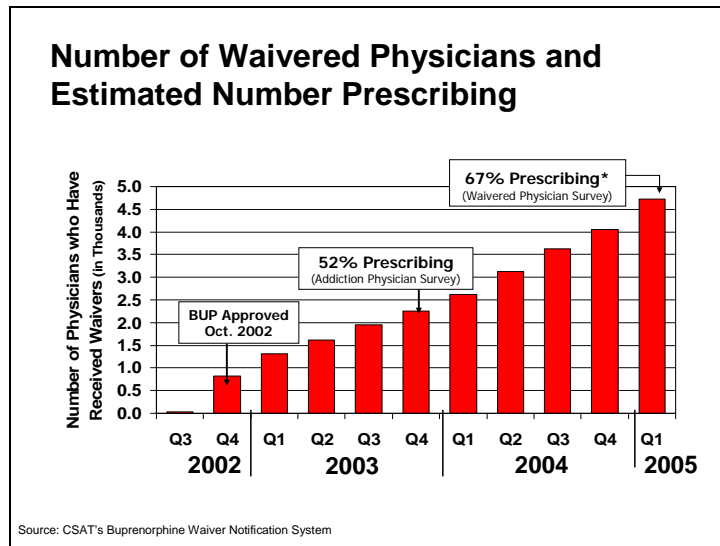


Figure 13. Number of waived physicians and estimated number prescribing

These findings suggest that the diffusion of buprenorphine treatment under the Waiver Program is dependent upon two key factors: (1) increasing the total number of waived physicians, and (2) increasing the proportion of waived physicians who are prescribing. In the following sections, we identify factors related to obtaining a Waiver and challenges to prescribing faced by physicians who are already waived.

The question of whether the Waiver Program allows MAT to be provided by a broader range of physicians is addressed by Figure 14, which is based on data from the Waivered Physician Survey conducted in early 2005. A high number (39%) of waived physicians reported more than one primary specialty. Addiction medicine and addiction psychiatry were the specialties most often reported in combination with other specialties (i.e., they were rarely reported as the physician's sole specialty); these two addiction specialties made up 44 percent of waived physicians at the time of the survey. Importantly, *more than half* of waived physicians did *not* report a specialty in addiction medicine or addiction psychiatry. The finding is noteworthy in that treatment of opioid dependence by physicians who are not addiction specialists could indicate that efforts to expand substance abuse treatment from specialty care into primary care are starting to bear fruit. The finding also raises the question of how a patient receiving buprenorphine treatment from a physician without a specialty in addiction gains access to appropriate counseling resources.

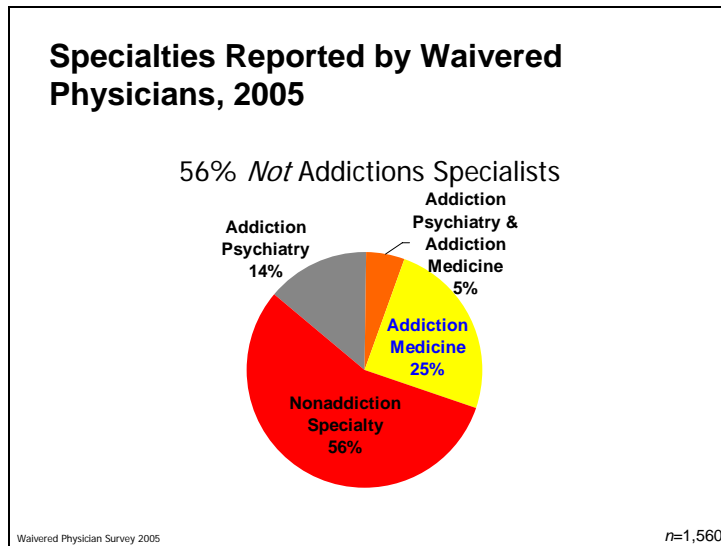


Figure 14. Specialties reported by waivered physicians, 2005

Figure 15 presents data from N-SSATS 2002 and 2003 and the BWNS showing increases in the number of sites providing MAT across the United States. With the introduction of the DATA Waiver Program, the total number of sites in which MAT was available for opioid addiction increased from 1,080 to 2,564 during the first 14 months of the Waiver Program. (At the time this was written, 2005 data were not yet available from these sources. Considering the fact that the number of waivered physicians has more than doubled from 2003 to 2005, it is likely that additional increases would have been noted.) Thus, the Waiver Program appears to have more than doubled the number of sites at which it is possible to obtain MAT for opioid addiction. The increase in the number of sites providing MAT associated with the introduction of buprenorphine occurred in all Census regions. There was no apparent decrease in the number of OTPs in any region over the same time period.

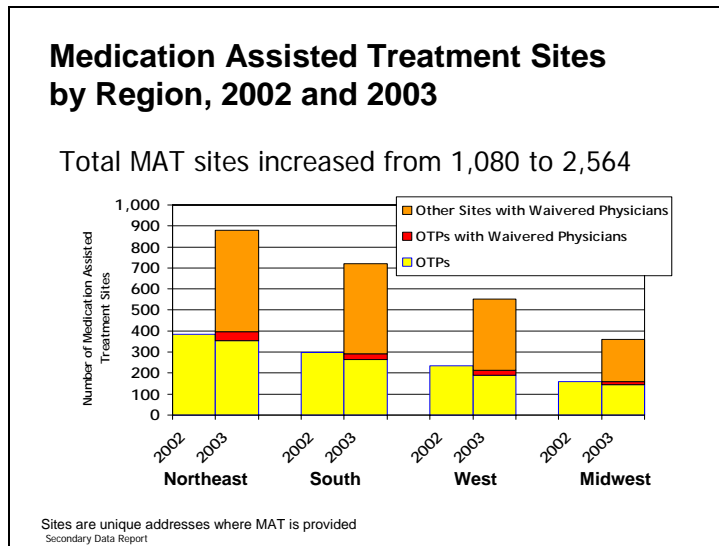


Figure 15. Medication assisted treatment sites by region, 2002 and 2003

Figure 16, based on data from N-SSATS 2002 and 2003, the BWNS, and the Census, shows that the modest increases in MAT treatment *capacity* (treatment “slots” per 100,000 population) that occurred between 2002 and 2003 were attributable to the new buprenorphine sites.

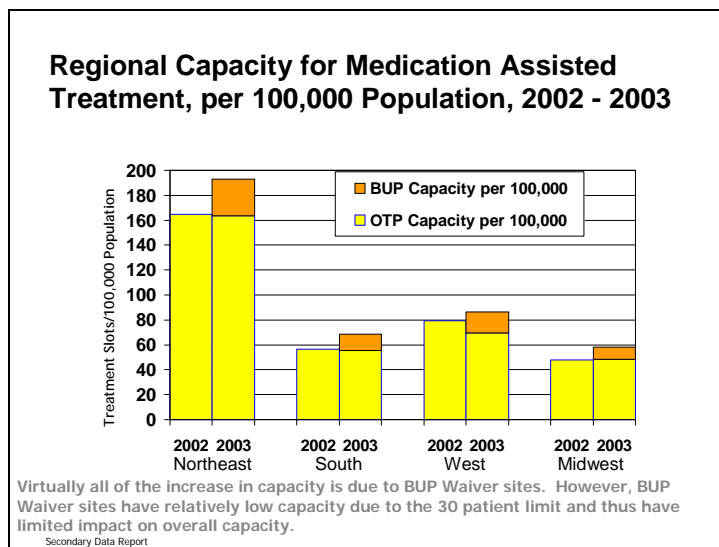


Figure 16. Regional capacity for medication assisted treatment, per 100,000 population 2002-2003

In 2002, persons with opioid dependence could receive MAT only with methadone or levo-alpha-acetyl-methadol (LAAM)¹ provided through highly regulated OTPs. Though

¹ In early 2004, LAAM was discontinued as a MAT due to associated cardiac disturbances.

treatment with methadone remains somewhat controversial in the United States, the clinical and empirical literature generally holds that methadone treatment, the most common form of MAT, is the most effective form of treatment for opioid dependence. The map in Figure 17, based on N-SSATS data, shows that in 2002 opioid-dependent persons in Idaho, Mississippi, Montana, North Dakota, South Dakota, and Wyoming had no access to methadone treatment within their states. Moreover, in many other states, OTPs were concentrated in just a few urban areas. Thus, the geographic availability of MAT for opioid dependence was limited prior to the approval of buprenorphine in October 2002. Buprenorphine was the first medication to be approved for use under the DATA Waiver Program.

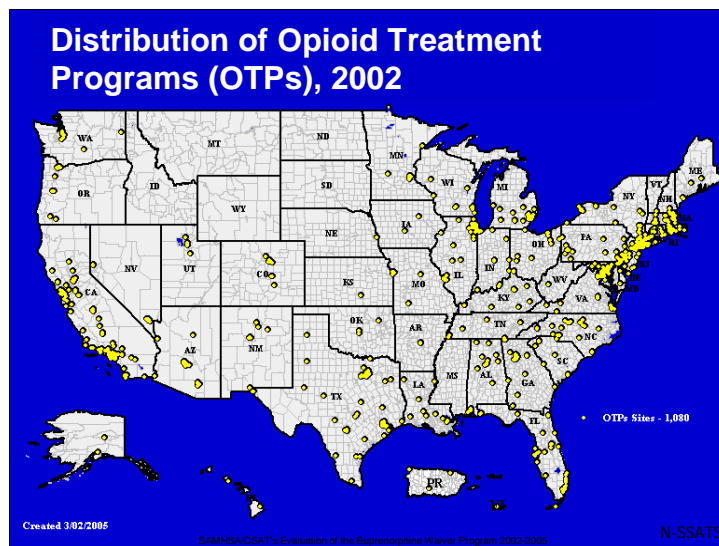


Figure 17. Distribution of opioid treatment programs (OTPs), 2002

The map in Figure 18 shows that buprenorphine treatment sites extended coverage to some previously underserved rural areas in addition to adding capacity to some of the areas already covered by OTPs.

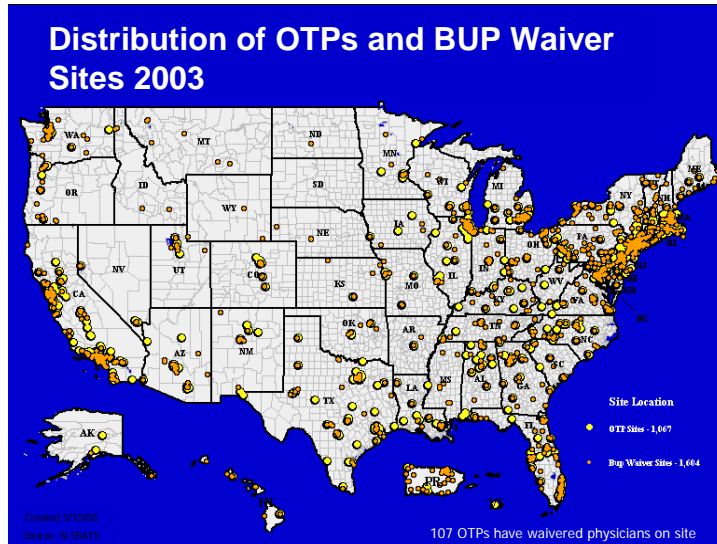


Figure 18. Distribution of OTPs and buprenorphine waiver sites 2003

To address the question of whether the Waiver Program has had an impact on the availability of methadone treatment through OTPs, Figure 19 presents shipment data from the DEA’s ARCOS. Overall, there was no statistically significant relationship between increasing shipments of buprenorphine and shipments of methadone, though there was a slight decline in methadone shipments during the latter part of 2004.

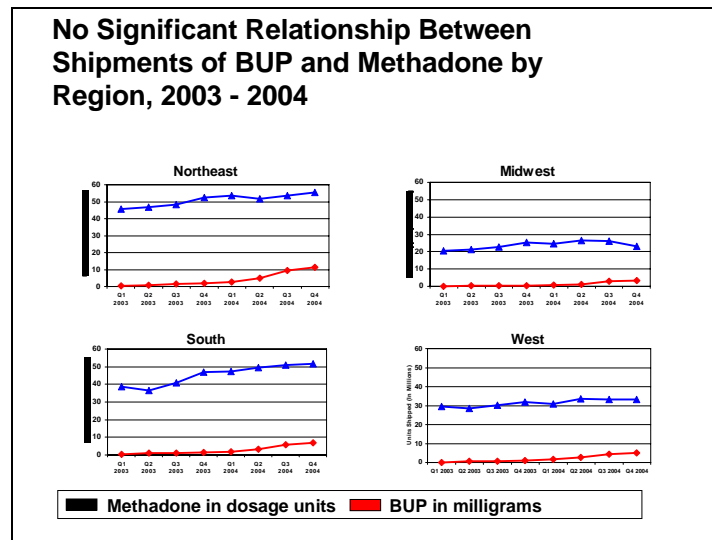


Figure 19. No significant relationship between shipments of buprenorphine and methadone by region, 2003-2004

Regional data provide an important perspective on the relationship between shipments of methadone to OTPs and shipments of buprenorphine. In the Midwest, methadone

shipments declined during the last half of 2004. In fact, the decline in shipments to the Midwest is the source of the decline in total methadone shipments, since shipments in the other regions were steady or increased slightly. If buprenorphine were the cause of the decline in the Midwest, it would be expected that the rate of growth of buprenorphine in the Midwest would exceed growth rates of the three regions that did not display such a marked decline. However, this is not the case. The rate of growth of buprenorphine in the Midwest during the last quarter of 2004 actually lagged behind that of the other three regions. This implies that perhaps some common factor in the demand for treatment for opioid abuse affected shipments for both medications in the Midwest. For example, a shift in the pattern of drug abuse in the Midwest from opioids to methamphetamine around this period could have produced such a change in shipments of medications for treatment of opioid abuse.

Additional statistical analysis of the trends by all 50 states and three territories from the third quarter of 2004 to the fourth quarter of 2004 found, in fact, that increases in the total amount of buprenorphine shipped from the third quarter to the fourth quarter were positively and significantly associated with the amount of methadone shipped in the fourth quarter and that changes in shipments of buprenorphine were *positively* correlated with changes in shipments of methadone. That is, there were increased shipments for both medications during this period, even though there was a downturn of shipments in the Midwest. Thus, there is no evidence from ARCOS data for a negative impact of buprenorphine treatment on the use of methadone for treatment.

Further evidence concerning increased treatment availability and the potential impact of buprenorphine treatment on the OTP system of methadone treatment is presented in Figure 20.

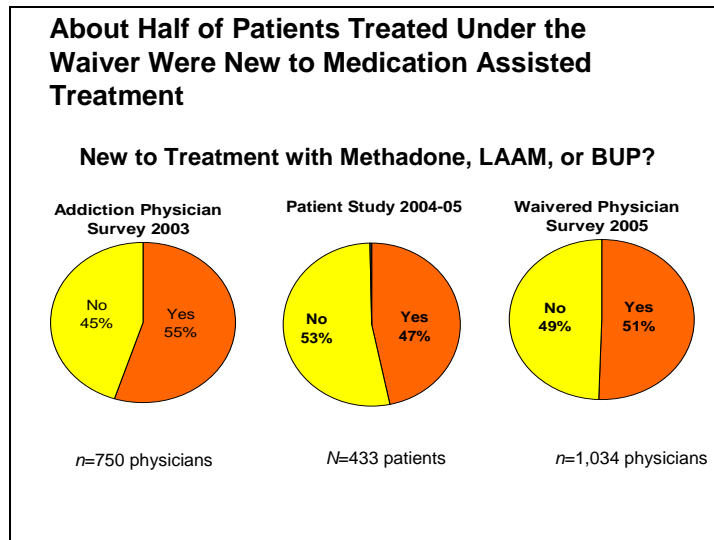


Figure 20. About half of patients treated under the Waiver were new to medication assisted treatment

This figure contains data from three sources: (1) the Addiction Physician Survey, (2) the Patient Study, and (3) the Waivered Physician Survey. Similar results from these three sources, over time, support the robustness or reliability of this finding. It shows that about half of patients treated with buprenorphine under the Waiver Program had never before been treated with methadone, LAAM, or buprenorphine. This indicates that the Waiver Program has increased the availability of treatment by reaching a considerable number of patients new to MAT. Of note is that item wording differed slightly between the surveys.²

During the first few years of the Waiver Program, it appears that relatively few patients treated were transitioning from methadone maintenance to buprenorphine treatment. (An increase in the number of patients transitioning from methadone to buprenorphine over time

² The *Addiction Physician Survey* asked, “Approximately what percentage of the patients you have treated with buprenorphine since FDA approval in October 2002 have, in their lifetime, never before had medication assisted treatment for opioid addiction (e.g., methadone, LAAM, or buprenorphine)?” The total percentage was based on the percentage for each physician weighted by the number of patients inducted, producing an estimate that 55 percent of the patients responding physicians treated were new to MAT. The *Patient Study* asked, “Have you received methadone/LAAM for your drug/alcohol problems? How many times have you started buprenorphine treatment in the past?” Forty-seven percent of the sample reported “0” to both questions. The *Waivered Physician Survey* asked, “At the time your patients were inducted onto buprenorphine, about how many had never before received MAT for opioid addiction (e.g., methadone, LAAM, or buprenorphine)?” It was estimated that 51% of their patients were new to MAT, using the proportion reported by each physician weighted by the number of patients the physician had inducted. (The term “inducted” rather than “treated” was used because of the increasingly prevalent practice of transferring patients from specialists who provided induction to physicians providing maintenance treatment. Describing the characteristics of inducted patients was an attempt to prevent double counting by the two physicians.)

might suggest a possible impact on the OTP system.) The apparent increase over time shown in Figure 21 is within the expected error of the instruments, which involve (1) different forms of the question,³ and (2) reliance on physician memory for estimates of the number of patients treated and the proportion of patients making such a transition.

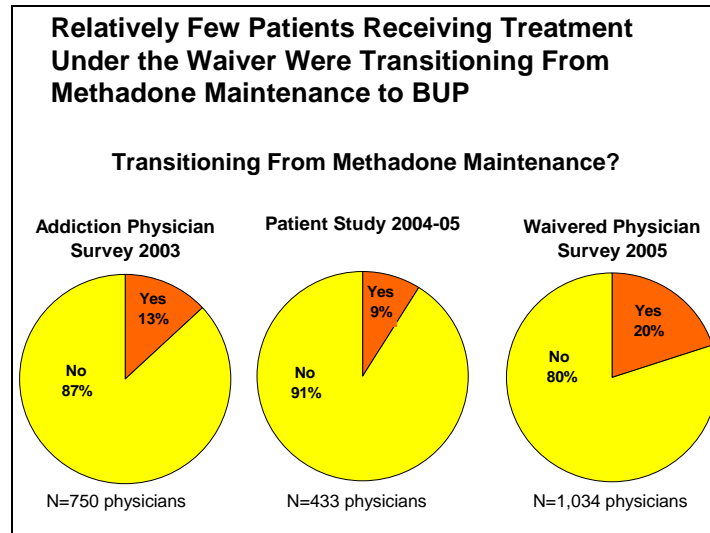


Figure 21. Relatively few patients receiving treatment under the Waiver were transitioning from methadone maintenance to buprenorphine

Findings suggest that, at least early in the Waiver Program, the patient population treated with buprenorphine was different than that treated in most OTPs. Figure 22 shows demographic differences between opioid-dependent buprenorphine patients in the Patient Study and methadone patients treated in OTPs reporting to TEDS in 2003, which represent 96,659 admissions involving methadone treatment. In comparison to patients admitted for methadone treatment in facilities reporting to TEDS, persons in the Patient Study were more likely to be employed, white, and better educated, and were slightly more likely to be female. These demographic differences may be related to barriers to treatment availability. For example, almost one-half of the Patient Study sample paid for physician visits out-of-pocket, and the cost of

³ The *Addiction Physician Survey* asked, “For approximately what percent of your buprenorphine patients have you managed the transition from methadone/LAAM maintenance to buprenorphine?” The total percentage was based on the percentage for each physician weighted by the number of patients treated. The *Patient Study* asked respondents to “Please think about the day you started on buprenorphine treatment this time. Were you receiving other treatment for your drug use just before your doctor prescribed buprenorphine for you? If yes, were you receiving methadone (or LAAM) maintenance?” The *Waivered Physician Survey* asked, “In general, at the time your patients were inducted onto buprenorphine, about how many were transitioning from methadone maintenance to buprenorphine?” The total percentage was based on the proportion reported by each physician translated into percentages, and weighted by the number of patients inducted.

treatment was reported by physicians to be a major challenge to providing buprenorphine treatment. In addition, the different patient characteristics may also be related to the high proportion of buprenorphine patients dependent on prescription opioids only; relatively few such patients were treated in TEDS sites in 2003.

However, it is important to understand the limitations of TEDS data when interpreting these findings. The coverage for TEDS varies by state, with some states excluding admissions from private facilities providing methadone. However, TEDS is the best data source available for understanding the overall characteristics of patients admitted for methadone treatment on a national level. Since private treatment centers are not represented in TEDS in some states, the TEDS data may be weighted more heavily toward patients of lower socioeconomic status and racial/ethnic minority patients than the actual population treated in all methadone clinics. Nevertheless, the wide disparities shown in figure 22 suggest that buprenorphine treatment as first provided under the Waiver Program was reaching a patient population that was more likely to be white, educated, and employed.

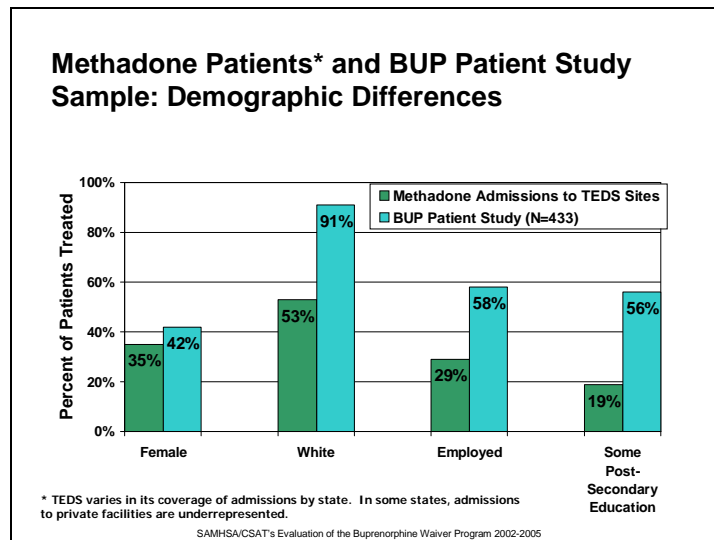


Figure 22. Patients treated under the Waiver Program differed from those treated in OTPs

Figure 23 displays data indicating that buprenorphine treatment provided under the Waiver Program may be capturing the opioid-dependent subgroup that is at present the most common in the general population but has been underrepresented in methadone clinics receiving public funding.

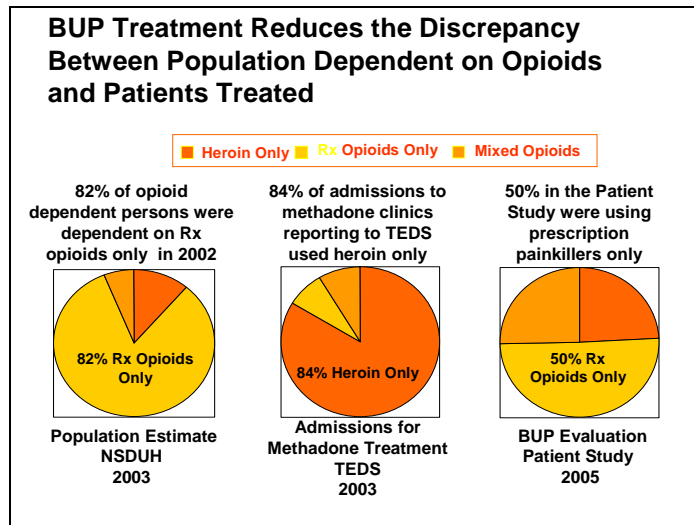


Figure 23. Buprenorphine treatment reduces the discrepancy between population dependent on opioids and patients treated

Population estimates suggest that most opioid-dependent individuals (82%) were dependent on prescription opioids alone. However, those dependent on prescription opioids alone make up less than 10 percent of public treatment admissions in contrast with half (50%) of people treated with buprenorphine in the Patient Study.

The 2003 estimates of opioid dependence come from the National Survey of Drug Use and Health (NSDUH), a household survey providing drug use prevalence rates among the general population. In 2003, the most recent year for which data are available, the vast majority (82%) of the 1,019,004 persons estimated to be dependent on opioids were dependent on prescription opioids, not heroin. A relatively small proportion of persons reported dependence on heroin only (11%), and 7 percent were dependent on both heroin and prescription opioids.

Similarly TEDS 2003 data indicate that admissions for methadone treatment in OTP facilities reporting to the national TEDS overwhelmingly involved heroin only, not prescription opioids. Eighty-four percent of 94,690 admissions for methadone treatment (where the opioid of abuse was known) were using heroin only. Although data collection in some states is restricted to those facilities receiving public funding for treatment, TEDS provides the best estimate of the characteristics of patients admitted for substance abuse treatment in the United States. Although TEDS is probably biased toward patients receiving treatment from the public sector, most facilities receive public funding, so it is clear that most methadone treatment in 2003 was oriented toward heroin, not prescription opioids. Under the Evaluation of the Impact of the DATA Waiver Program, data were collected on 433 patients entering buprenorphine treatment at sites recruited

from a national sample of waived physicians. As shown in Figure 23, 50 percent of the sample patients were dependent on prescription opioids only prior to treatment, while 25 percent were dependent on heroin only. The findings suggest that, though they made up a high proportion of the opioid-dependent population, persons dependent on prescription opioids were treated less often in OTPs than persons dependent on heroin, at least in 2003. In contrast, buprenorphine treatment provided under the Waiver Program in 2004-5 seemed to involve a high proportion of persons dependent on prescription opioids.

Summary on Treatment Availability

Evaluation findings regarding the impact of the Waiver Program on the availability of treatment for opioid dependence can be summarized as follows:

1. Many waived physicians were not addiction specialists; the range in terms of the types of physicians providing treatment for opioid addiction appears to have increased, and shows desired expansion into the general practice/primary care realm of care as well.
2. Geographic availability of MAT increased from 2002 to 2003, following the introduction of the Waiver Program.
3. There is no evidence for an immediate decrease in methadone availability in response to buprenorphine introduction.
4. The overall capacity for treating opioid dependence increased minimally.
5. Buprenorphine treatment provided under the Waiver Program appeared to reach a patient population not typically treated in OTPs.

Two additional factors may serve to increase treatment capacity. Firstly, though capacity increased minimally between 2002 and 2003, recent (August 2005) changes in the law that formerly limited entire medical practices to 30 patients allow individual physician, whether in a group or individual practice, to treat 30 patients at any given time. This means that medical groups, substance abuse treatment clinics, and hospitals with more than one waived physician can now greatly increase their treatment capacity. Secondly, many Evaluation analyses are based on data collected within a year of buprenorphine becoming available. The number of waived physicians has more than doubled from 2003 to 2005. Greater increases in MAT capacity attributable to buprenorphine treatment provided under the Waiver Program may be expected as the medication becomes more widely known and accepted.

4. PUBLIC HEALTH CONSEQUENCES

The Evaluation of the Impact of the DATA Waiver Program examined three key issues related to public health outcomes. The first involves the abuse of buprenorphine, where abuse was evaluated relative to the rates of abuse of other prescription drugs, including methadone. The second involves adverse medical reactions to buprenorphine when taken as prescribed. The third involves the impact of treatment on risky behaviors such as needle sharing and multiple sexual partners.

Figure 24 is based on data from the Patient Study. It displays information about the ease with which buprenorphine patients, at 30 day followup, believed they could purchase diverted buprenorphine on the street. Patients were asked, “Compared to OxyContin® or methadone, how easy or hard do you think it is to buy or sell buprenorphine on the street?” Patient responses were similar when buprenorphine was compared with OxyContin® and with methadone. Fewer than 5 percent of patients found buprenorphine easier to buy or sell. Rates remained stable from baseline through 30 day and 6 month followups.

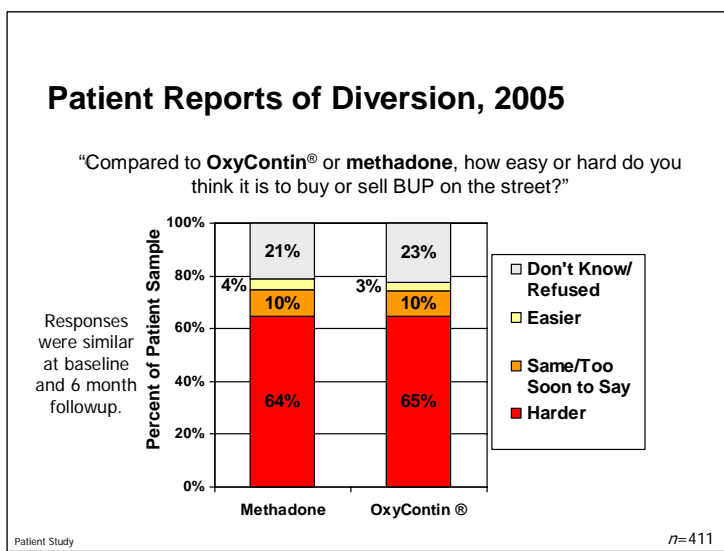


Figure 24. Patient reports of diversion, 2005

More than half of the sample indicated buprenorphine was *harder* to buy or sell than OxyContin® (65%) or methadone (64%). However, 10 percent (for each comparison) said one could buy or sell buprenorphine as easily as the comparison drug or that it was too soon to say as

buprenorphine was not yet available enough. Almost one-quarter said they did not know (23% for OxyContin®, 21% for methadone). It is also worth noting that many buprenorphine patients dependent on prescription opioids only may never have obtained drugs on the street, and so may not be reliable informants on this subject.

ED visits attributable to drug use and abuse are one important indicator of adverse public health consequences of a medication. Figure 25 presents raw data from DAWN indicating that in 2004, buprenorphine was rarely involved in ED visits. These data are unweighted and have not been published by DAWN; they were obtained by special request from the OAS at SAMHSA. Buprenorphine-related ED visits in 2004 were not only very rare, but they appeared to be most frequently related to adverse reactions, rather than abuse. (The second most common category, "seeking detox" refers to visits for medical evaluations required by local substance abuse treatment programs prior to admission for detox treatment).

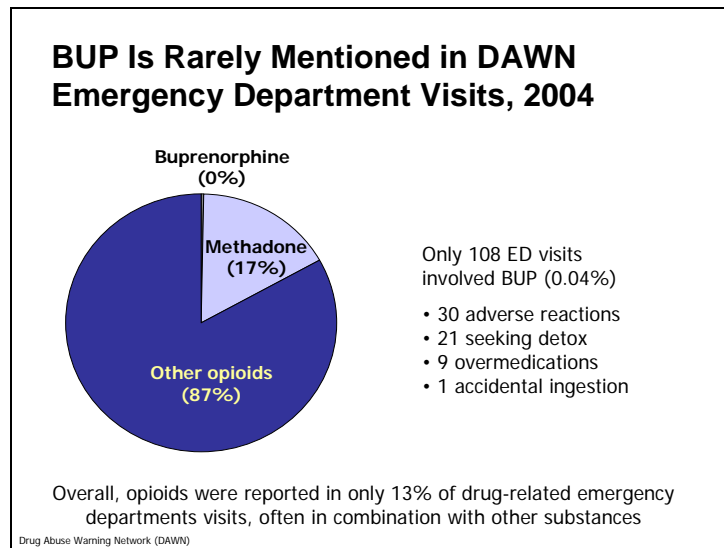


Figure 25. Buprenorphine was rarely mentioned in DAWN emergency department visits, 2004

Only 0.04 percent of opioid-related ED visits in 2004 involved buprenorphine. In contrast, methadone (from the street and from valid prescriptions) was involved in 17 percent of opioid-related ED visits in 2004. The rest of the opioid-related ED visits involved other opioids or narcotic analgesics (*e.g.*, hydrocodone, oxycodone, and codeine) and heroin. This being said, it should be noted that opioids were reported in only 13 percent of all drug-related ED visits in 2004, and buprenorphine was involved in less than .1 percent of those opioid-related visits.

In interpreting these data, it is important to note that opioids (and other drugs) are often reported to DAWN in combination with other substances, which in some cases could be the primary substance "responsible" for causing the ED visit. In other words, it may be buprenorphine in combination with another drug that may be driving adverse reactions, and it may be an addiction to multiple drugs including buprenorphine that may be driving a request for detoxification. In addition, the data presented in Figure 25 represent unweighted data for 2004 from DAWN, which collects data from a national sample of EDs in the United States. Publicly released DAWN data are typically weighted to provide national estimates (i.e., estimates of the actual number of ED visits in the nation), so the numbers reported may not appear directly comparable to weighted estimates that will be released in the future. In spite of these caveats, it is clear that there were no indications from DAWN in 2004 that the abuse of buprenorphine was becoming a significant public health problem.

Figure 26 is based on data from the Waivered Physician Survey, 2005. It shows that “severe adverse reactions to the medication (i.e., reactions that were life-threatening or that required...intervention to prevent permanent impairment or disability)” were rare. Only 0.5 percent of physicians reported severe adverse reactions in any patients. Specific reactions reported included: withdrawal (103 unweighted cases, 58 physicians), 12 allergic reactions ([5 were rash only] 7 physicians), 9 respiratory depressions (5 physicians), 9 drug interactions—6 benzos, 1 alcohol, 1 anesthesia, 1 over-the-counter inhaler (1) (5 physicians), 2 liver problems (2 physicians), and 2 renal insufficiency (or aggravation of it) (2 physicians). Thirteen physicians, reporting 80 reactions, did not specify type.

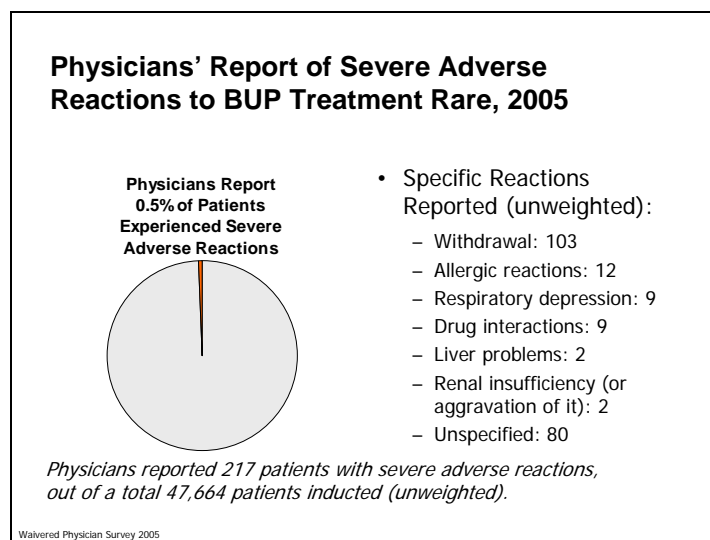


Figure 26. Physicians' report of severe adverse reactions to buprenorphine treatment rare, 2005

Figure 27 displays the percentage of patients in the Patient Study who reported engaging in risky behaviors before and after treatment with buprenorphine. In general, behaviors that place patients at risk for HIV and hepatitis C transmission occurred relatively infrequently in this patient population, relative to other opioid-dependent treatment seekers. Nonetheless, reductions were noted in needle sharing and multiple sex partners over the study period. Reports of these risky behaviors were virtually nonexistent at the 6 month followup, a statistically significant decrease.

Respondents were asked, “How many different sexual partners have you had in the past 30 days?” Their reports of sex practices remained stable over the study period and were relatively low risk. Few patients reported having more than one sex partner in the past 30 days. However, of those with more than one sex partner at baseline and 30 days, 34 percent and 50 percent reported always using condoms. Therefore, for a significant percentage, more than one sex partner did not represent a risk factor. Other opioid treatment studies have shown that risky sexual behaviors decreased after treatment, related to a decreased need for bartering sex for drugs, and related to improved personal judgment. The low initial level of risky sexual behavior in the Patient Study sample demonstrates again that the sample is different from samples studied in most MAT research.

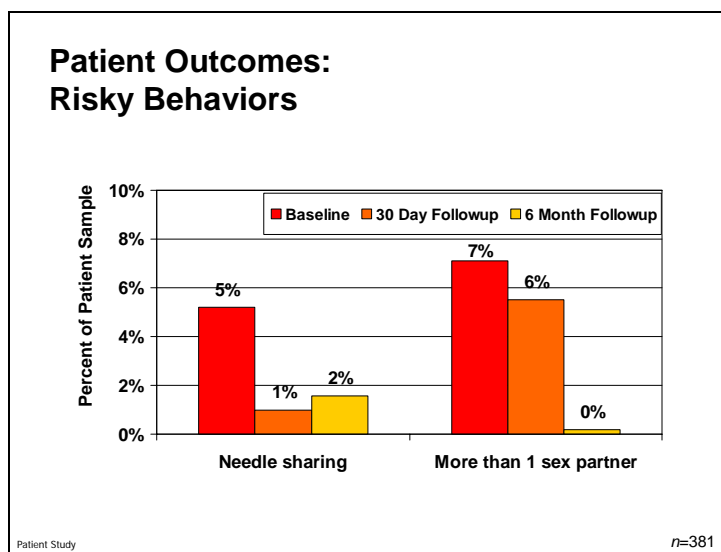


Figure 27. Patient outcomes: Risky behaviors

Summary of Public Health Consequences

To summarize, during the first 3 years of the Waiver Program, the Evaluation found no evidence for serious negative health consequences. There was no indication that there was significant diversion of buprenorphine. Furthermore, severe adverse reactions were rare. Finally, there was evidence that treatment provided under the Waiver Program had positive consequences for public health, in that treatment was associated with decreases in high-risk health behaviors.

5. SUMMARY OF EVALUATION FINDINGS

In 2000, Congress passed DATA 2000, reducing restrictive regulations and creating an opportunity to increase the availability of effective treatment for the growing problem of opioid dependence. The purpose of the Evaluation of the Impact of the DATA Waiver Program was to provide data to inform the determinations described in the legislation, to identify early on any problems associated with the dissemination of treatment under the Waiver Program, and to inform future research and policy. Conducted on behalf of SAMHSA's CSAT, this study has been the largest and most comprehensive evaluation of buprenorphine treatment to date, providing information about treatment sites, treating physicians, patients treated, treatment effectiveness, and adverse consequences, including public health consequences, associated with treatment. In this section, we summarize findings, discuss their relevance to policy and the field of addiction medicine, and suggest areas needing further investigation.

5.1 Evidence for the Effectiveness of Buprenorphine Treatment Under the Waiver Program

Buprenorphine treatment provided under the Waiver Program has demonstrated its effectiveness in actual clinical practice settings. Patient outcomes at 6 months after starting buprenorphine treatment are promising and include substantial improvements in drug abstinence, slight increases in employment, reduced criminal activity (illegal drug acquisition, drug dealing, and other crimes), and reduced high-risk behaviors. Waivered physicians with experience prescribing buprenorphine treatment under the Waiver Program reported that they find it to be an effective treatment for opioid dependence and that patients are satisfied, particularly those patients with longer treatment regimens. Patients echo this satisfaction with the medication and the treatment. Although Evaluation findings are difficult to compare to other treatment outcome studies because of major differences in client characteristics (primarily socioeconomic status and other demographic differences), the outcomes achieved with buprenorphine treatment under the Waiver Program are comparable to those observed in earlier clinical trials of buprenorphine.

Buprenorphine patients whose addiction was limited to prescription opioids tended to have better outcomes than those whose addiction also involved heroin. Persons previously dependent on prescription opioids only were more likely to report abstinence from opioids at 6 months than persons whose addiction involved heroin. Importantly, though persons dependent on

prescription opioids only did better than persons whose addiction involved heroin, the latter did show significant reductions in drug use as well as moderate levels of treatment retention.

One factor related to the effectiveness of buprenorphine treatment provided under the Waiver Program is the high treatment retention rate observed in the sample of patients followed in this Evaluation. Specifically, the 6 month buprenorphine treatment retention rate of 60 percent (excluding the 15% who completed buprenorphine treatment before that time) matches or exceeds those typically reported for methadone or buprenorphine trials. These rates are particularly impressive given the high proportion of treatment-naïve patients in the sample, in that patients new to MAT tend to show lower treatment retention rates than those who received treatment previously.

One reason for the relatively high patient retention rates may be the fact that this patient sample was atypical relative to public sector OTP clients on whom many outcome studies are based. That is, these buprenorphine patients were, on average, of relatively high socioeconomic status, with a college level education and employment, and they exhibited fairly low levels of criminal and high-risk behaviors. Their ability to seek out and engage physicians providing a new treatment (buprenorphine) may indicate a higher-than-average level of motivation and skill than patients receiving more widely accepted treatment. It is also possible that patients who were treated initially with buprenorphine were of higher socioeconomic status because they could afford treatment. It is likely that buprenorphine patients will remain a relatively select subpopulation of opioid-dependent persons if access issues involving cost and reimbursement remain unchanged.

Finally, it is possible that self-selection may have played a role in obtaining the study sample, since the patients who participated selected themselves for inclusion in the study by initiating study involvement by telephoning the study center. A non-response analysis showed only a slight gender bias (females being more likely to call in to participate) but did not assess for socioeconomic status levels. It is unclear whether the study design selected for more highly motivated persons with higher socioeconomic status or not, since it could be argued that persons with lower income were more likely to need study incentive money and people who view themselves in a more prominent role in society might be less inclined to participate due to confidentiality concerns. In addition, it is possible that sites agreeing to participate in the Patient Study were different than those that refused to participate, although these differences could not be ascertained under the scope of this project.

5.2 Evidence for the Increased Availability of Medication Assisted Treatment for Opioid Dependence

This study provides strong evidence that in the 3 years since approval by the FDA in October 2002, buprenorphine treatment provided under the Waiver Program has steadily increased access to and the availability of MAT for opioid dependence. Under the Waiver Program, the number of geographic areas in which MAT is available has increased. The program accomplished this by (1) providing MAT access to patient populations infrequently served by OTPs; (2) permitting qualified physicians with no previous experience treating addictions or providing MAT to prescribe buprenorphine for opioid addiction; (3) moving MAT from a restricted OTP-based system to a range of clinical settings and to some previously underserved rural areas, including five states that previously had no MAT sites. Data from 2004 and 2005 suggest that buprenorphine treatment attracted a patient population that was new to treatment and/or primarily dependent on prescription opioids. The OTP system has treated these patients much less frequently than heroin-addicted patients. As existing barriers to the dissemination of treatment are addressed (*e.g.*, cost, the 30 patient limit, and others), it appears that the use of buprenorphine can grow to reach its full potential for increasing access to treatment for opioid dependence.

Treatment availability has been expanded not only by providing treatment in a variety of non-OTP settings, but also by diversifying the types of settings in which treatment is provided. First, the Waiver Program has involved physicians who work in primary care settings and have access to the general adult population—including patients who might not otherwise identify themselves or seek treatment for opioid dependence. Second, while the use of buprenorphine in individual physician practices and medical clinics was expected and encouraged, the use of buprenorphine in substance abuse treatment clinics is a promising and somewhat unexpected development. These clinics of varying sizes specialize in the treatment of addictions, but are unaffiliated with a hospital and do not operate as OTPs. Evaluation findings revealed that these organizations are treating a significant number of patients with buprenorphine. Some clinics that may have previously sent opioid-dependent patients to other facilities for detox prior to substance abuse treatment may now provide buprenorphine detox in-house, with the potential of greatly increasing treatment retention.⁴ Maintenance treatment provided from such

⁴ Amass L, Ling W, Freese TE et al. Bringing Buprenorphine-Naloxone Detoxification to Community Treatment Providers: The NIDA Clinical Trials Network Field Experience. *Am J Addict* 2004; 13 (Supplement 1): S42-S66.

clinics would be highly advantageous because of the proximity of counseling and other supportive services.

To some extent, buprenorphine treatment provided under the Waiver Program has also attracted a new patient population, including many patients with no prior opioid dependence treatment experience and patients dependent primarily on prescription opioids—a population which has grown substantially in the last few years. In fact, though the prevalence of prescription opioid dependence far exceeds that of heroin dependence, the bulk of public sector OTP treatment admissions for opioid dependence involve heroin. Indeed, were the large estimated number of prescription opioid-dependent individuals to present for treatment now, the available substance abuse treatment capacity would be inadequate to meet the need. Evaluation findings suggest that buprenorphine could partially fill the gap between need and available treatment, particularly if barriers related to third party funding (both private and public) are addressed.

Analyses of patient characteristics, site locations, and shipments of buprenorphine and methadone suggest that, at least at the time of the Evaluation, the OTP treatment system was working in parallel to the system of sites (waivered physicians) providing treatment under the Waiver Program. Also, there is no evidence that increases in treatment availability related to the Waiver Program were offset by decreases in the number of sites providing methadone treatment. However, because of multiple factors affecting the OTP system, including an accreditation process, possible shifts in the popularity of heroin, and even perhaps the potential for growing use of buprenorphine within OTP settings, it seems impossible to ascertain with certainty what kind of impact the Waiver Program has on the OTP system, now or in the future.

Treatment Challenges. The dissemination of buprenorphine treatment as provided under the Waiver Program has encountered a number of barriers, like any other new medical treatment. While many of these are transient, we have identified three that appear to be more enduring: (1) the 30 patient limit, (2) limited third-party reimbursement, and (3) high medication/treatment costs. The 30 patient limit on the number of patients who may be treated by an individual practice has been one of the most controversial components of the Waiver Program. (The limit originally imposed by DATA 2000 was recently revised to apply only to individual, not group practices.) Many physicians have been very vocal about its deleterious effects, and it is clear that it does provide an upper limit for potential treatment capacity. However, it is also clear that it is not the only barrier to treatment. In fact, only a small percentage of physicians were actually at or near the limit, and a significant percentage of physicians who are qualified to prescribe were not providing treatment at all. The high cost of buprenorphine treatment and

limited third-party and public coverage appear to limit both patient demand as well as physician willingness to provide treatment. Many patients currently receiving buprenorphine treatment are paying out-of-pocket, though it is unknown how many did this out of the desire to ensure confidentiality, rather than to compensate for lack of insurance coverage for the treatment.

A few additional challenges were associated with reduced prescribing or even hesitation to initiate prescribing among waived physicians. Some waived physicians reported being limited by the lack of a sufficient number of patients or appropriate referrals (possibly related to cost), difficult initial treatment setup and logistics, and patients' resistance to counseling as a component of treatment. A number of nonwaived physicians cited common challenges to obtaining a Waiver, including lack of appropriate training or experience, concerns about recordkeeping and potential audits by the DEA, and a scarcity of appropriate concomitant counseling resources in their areas. Physicians' willingness to provide buprenorphine treatment and counselors' willingness to support these patients are expected to increase as buprenorphine treatment becomes more widely known and accepted.

5.3 Public Health Consequences Related to the Waiver Program

The Evaluation produced little evidence of negative public health consequences attributable to the Waiver Program. Indeed, serious adverse reactions and diversion were rarely reported by patients or by treating physicians. High-risk client behaviors, such as needle sharing and multiple sexual partners, were rare and virtually disappeared at followup.

Little Evidence of Diversion. There was little evidence reported by patients or physicians in this study for the diversion of buprenorphine, but additional sources of information are needed to confirm this finding. Both buprenorphine patients and waived physicians providing buprenorphine treatment under the Waiver Program reported little knowledge of anyone diverting buprenorphine medication. Anecdotal evidence from post-marketing assessment of buprenorphine⁵ and an Internet scan of drug users' sites suggest that the small amount of buprenorphine that is reportedly diverted is used for self-medicating or trial buprenorphine use with a view to the experimenter entering treatment, rather than for its actual abuse potential. This is a potential concern in that it might reflect a response to waiting lists in areas affected by the 30 patient limit or other factors limiting access to treatment. Since evidence for diversion is so

⁵ Schuster CR. Results from the Wayne State University post-marketing assessment of buprenorphine. 2005 Jun; Orlando, FL: College for Problems of Drug Dependence; 2005.

minimal, another study would be needed to truly determine why any level of diversion was occurring. Diversion may however have been mitigated by availability of the formulation of buprenorphine with naloxone (Suboxone®).

Serious Adverse Reactions Rare. Serious adverse reactions were rarely reported by patients or treating physicians. When reported, most reactions seemed to involve withdrawal symptoms possibly caused by either (1) cautious physicians initially undermedicating patients with buprenorphine, at least during the initial induction phase, or (2) precipitated withdrawal because patients still had too much of the abused opioid in their system at the initiation of buprenorphine treatment. (Clinical guidelines recommend that buprenorphine treatment be initiated when the patient is in mild withdrawal. Because buprenorphine displaces other opioids from brain receptors, but provides less stimulation of those receptors, the introduction of buprenorphine in the presence of other opioids can precipitate withdrawal symptoms.) Precipitated withdrawal can be particularly challenging for physicians to prevent because (a) patients, fearing the discomfort of withdrawal symptoms, can tend to overestimate the time since their last opioid use or over report the level of distress from opioid withdrawal, and (b) early opioid withdrawal has few clear, objective signs for physicians to note reliably. It should be noted that physicians more experienced in the treatment of opioid addiction might see withdrawal symptoms as a clinical management issue, rather than an adverse reaction related to the medication itself. Excluding reactions that seem to be related to withdrawal, the adverse reaction rate is even lower than the low rate reported.

Evidence of Decreased Risky Behaviors. Though the baseline incidence of high-risk client behaviors was quite low, patients reported decreasing their risky behaviors even further following treatment at the 30 day and 6 month followup points. In particular, patient reports of needle sharing and multiple sex partners were almost nonexistent at 6 month followup.

5.4 Implications for Policy

The Waiver Program appears to be achieving its policy objectives of increasing the availability of safe, effective MAT for opioid dependence and for drawing both new clients and new practitioners into the fold, somewhat decreasing the treatment gap. Two challenges faced by the DATA Waiver Program are particularly relevant to policy objectives: (1) the (recently revised) 30 patient limit, and (2) the cost of obtaining buprenorphine treatment. By definition, the 30 patient limit restricts provider capacity to treat patients with buprenorphine. Both the 30 patient group and individual physician limits received considerable attention from study

respondents, many of whom voiced concerns that they may be creating negative consequences for treatment access and dissemination. (Comments provided by physicians about the 30 patient limit may be found in Appendix A.) The 30 patient limit on group practices was removed in August 2005, after data collection for the Evaluation had been completed. This will greatly increase the number of patients that could be treated at a single site with multiple waived physicians. In addition, larger medical groups and health management organizations (HMOs) may now be more interested in providing buprenorphine treatment under the Waiver Program. However, in the months immediately following this modification, there has been no particular rise in the number of waiver notifications submitted. Notably, even with this change, the consequences of the 30 patient limit for individual practices remain, so that there continues to be an upper limit for capacity improvements related to the Waiver Program.

Evaluation findings suggest that the remaining policy limiting individual physicians to 30 buprenorphine patients at one time may have had a direct although unintended effect on clinical practice—particularly on physicians in individual practice and physicians whose preference is to provide maintenance treatment. One of the reasons for the creation of the limit was to prevent a single physician from prescribing buprenorphine to large numbers of patients for short-term treatment (detox). The Clinical Guidelines recommend against short-term treatment except under unusual circumstances⁶; its short duration does not typically provide adequate treatment time for thorough patient care and relapse prevention. Ironically (judging from physicians’ responses to open-ended survey items), the 30 patient limit may have perversely shifted current practice from longer-term treatment (maintenance) toward short-term treatment. Indeed, from a triage perspective, continuing to provide buprenorphine maintenance for more stable, higher-functioning patients can be viewed as unnecessarily tying up valuable treatment slots that might be needed far more desperately by other persons that are actively using but seeking treatment. Physicians report sometimes discontinuing buprenorphine treatment for a patient who is not clinically ready but is more likely to succeed in drug-free treatment in order to admit to treatment a treatment-seeking active user who otherwise would continue participating in risky behaviors related to active opioid abuse. Some physicians in our surveys commented that they refused to prescribe for maintenance because of the 30 patient limit.

Concerns about the high cost of buprenorphine treatment also remain to be addressed. Patients, physicians, and public sector purchasers alike consistently noted high cost—

⁶ Center for Substance Abuse Treatment. Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. Treatment Improvement Protocol (TIP) Series 40 [DHHS Publication No (SMA) 04-3939]. 2004. Rockville, MD.

of the medication and office visits and procedures—as posing a significant barrier to obtaining and continuing buprenorphine treatment. There is concern that the low level of substance dependence benefits and coverage for buprenorphine medication and care, particularly in the public sector, may disproportionately limit access to buprenorphine treatment to those opioid-dependent persons who can pay out-of-pocket. A formal cost effectiveness study and better estimates based on detailed, site-specific treatment and medication costs are needed to address payers’ concerns related to reluctance to encourage benefit redesign, coverage, or use of the new treatment. Credible information about reductions in overall medical costs after successful treatment would be compelling information to provide to public and private payers to give them an incentive to reimburse for buprenorphine treatment. In addition, perhaps government and provider pressure, group purchasing strategies and financial incentives could be used to reduce medication and therapy costs.

6. CONCLUSION

Buprenorphine treatment under the Waiver Program appears to be clinically effective and also well accepted by patients. The DATA Waiver Program appears to have increased the availability of MAT for opioid dependence. Treatment provided under the Waiver Program has been demonstrated to be safe and effective as prescribed in actual clinical settings. Undesirable effects, whether involving diversion or adverse clinical events or public health consequences, have been minimal. Longer-term studies are necessary to determine the relative cost-effectiveness of buprenorphine treatment. Buprenorphine treatment provided under the Waiver Program has demonstrated the potential to increase significantly the availability of effective treatment for opioid-dependent persons, including the growing number dependent on prescription opioids and also for those patients who may be dependent on heroin for whom methadone might not be the most appropriate option. However, the 30 patient limit on individual physician practices as well as continuing cost and reimbursement issues appear to have a dampening effect on fully realizing the potential for this new treatment to improve access and thereby to increase overall treatment capacity for opioid dependence. The results of this Evaluation indicate that continued dissemination of buprenorphine and efforts to increase access to this treatment option appear to be desirable but the future rate of dissemination will depend upon the extent to which strategies that address these and other challenges are successfully deployed.

APPENDIX A: VERBATIM COMMENTS FROM PHYSICIANS REGARDING THE 30-PATIENT LIMIT

Commonly Used Abbreviations:

Rx= prescribe
Tx=treatment
MD= medical doctor
ASAM= American Society of Addiction Medicine
APA= American Psychiatric Association
HHS= Health and Human Services
Pt= patient
Psych= psychiatric
Doc= doctor
ABPN= American Board of Psychiatry and Neurology
HMO= health management organization
Meth= methadone
Approx= approximately
MD= medical doctor
SSRIs= selective serotonin reuptake inhibitor
w/draw= withdrawal
CAQ= Certificate of Added Qualification

Physicians say it limits access.

- I am 1 of 2 prescribers in an area population of 250,000-i need to be able to rx more than 30 patients at a time!
- The lack of adequate prescribing physicians & the 30 patient limit are restricting access to care to the point of being unethical.
- I could help many more patients if you would increase 30 limit rule. This is my biggest obstacle with this fantastic aid for those whom I treat with addiction.
- Must raise the number of patients. It is unethical to tell the parent to go to the drug dealer because they limit me at #30. It is inhuman to tell the court who want to release from jail the inmates if I accept to take them in the Suboxone program because I am limited to 30 patients to keep them in jail. The tax program must pay \$72,000. Addiction is a disease, like no other, more than coronaries, more than hypertension, more than mental illness. As Justice Kennedy put it "addiction destroys the fabric of our democracy" family, society, moral values are the prime victims.
- The thirty patient limit is catastrophic, limiting access to care & limiting the skill & experience of prescribers.
- Since I am geographically remote with no accessible methadone clinics, I estimate that the need will soon exceed the 30 patient limit. My initial feeling is that this drug will salvage a large number of addicted patients from iv drug use, huge expenditures and theft.
- The 30 patient limit per physician has been a major problem limiting treatment. I constantly have a waiting list of 15-20. So do all the other waived physicians in the area. This limit has to be removed to provide better access to care.

- The 30 patient limits are preventing many patients from receiving the care they deserve.
- I work in a group practice in a psychiatric hospital all of our 30 buprenorphine slots are constantly full and a small number of our doctors usually manage these patients. We try to do the induction phase then transfer them out to community based primary care providers. We have a number of adolescents in our community who are addicted to OxyContin and would benefit from this treatment but we are so limited in the number of patients we can serve.
- What can we do to get more doctors to prescribe/to get a higher # patients in rural areas like this where few prescribers are available? Please help!
- Buprenorphine is very effective in my practice. There are not enough physicians in our community who prescribe buprenorphine-limit of 30 should be doubled to 60 patient limit.
- I am receiving 5 to 10 calls each day from patients & clinics seeking tx with buprenorphine-if the 30 patient limit was lifted, I could easily handle 30 to 50 more patients-they are a pleasure to treat & observe their profoundly positive response!
- The patient demand for this medication is increasing monthly. SAMHSA should raise the ceiling limit to at least 40-45 patients per MD.
- Would like to see the 30 pt limit lifted-there is such a need.
- I hope these comments are passed on to Dr. Clark. We have 20,000 opiate addicts in <my region>. I estimate 13,000 would benefit from buprenorphine maintenance therapy. It will take almost 500 doctors prescribing at their maximum level of 30 patients (unless two or more of them are in 1 group) to provide the service. The drug is astoundingly effective as a pathway to recovery. The only way to make a significant impact is to allow some doctors (ASAM & APA added qualification certified?) to treat an unlimited number of patients. It is a crime & unethical to continue to deny access to so many patients. We all know the HHS secretary can lift or change the limits by regulation, implying it will take an "act of Congress" is just a smoke screen. Can you in good conscience not open up access to this life-saving treatment to thousands?
- Buprenorphine is a revolution in addiction treatment. The biggest problem is the 30 patient limit. If this could be changed many more patients could be helped.
- Practicing in <my state>, buprenorphine has been a godsend as no methadone programs exist. However, we have only a small number of physicians with the waiver. Those that do, are primarily associated with addiction treatment programs and all of us are near or at 30 pt. limit. In rural settings with primary care physicians being in short supply there is no interest or incentive to pursue the waiver. Without success, I have tried to recruit new docs. Please consider removing the 30 patient limit for addiction medicine specialists working within established inpatient and outpatient programs. The need in my area far exceeds my available slots. We have received up to 4 calls per day requesting consideration for Suboxone. Thanks.
- Access-we have been at 30 for months with only a 1 or 2 pt per month attrition rate. We need more space! The demand is huge, just from people who can use the internet. We work with vulnerable populations (HIV, homeless, non-English speaking, chronic psych) and the referrals keep pouring in. Ask Congress to let us treat this people.
- The 30 patient limit is a real problem. I am in a 12 doctor group-3 of our docs are licensed for buprenorphine-there is only one other in the entire county of 520,000+ people. We have a long waiting list.
- Consider strategies to relax the 30-patient limit. This is seriously limiting access to treatment for needy patients.

- The limitation of 30 patients per physician has resulted in prevention of buprenorphine treatment for many Vermonters. I am the only clinician in <my state> who is certified to provide buprenorphine who has not reached the limit of 30 patients per practice.
- The biggest problem is trying to find other physicians to be prescribers and I could recruit some of my partners, but we're still limited to 30 in the practice as a whole. I'm concerned about 2-3 months from now when I'll have the 30 filled.
- Both the addiction clinic at [the] medical center where I refer my patients for induction and our private practice group are at our 30 patient limit with a considerable waiting list. Everything possible should be done to remove this restriction.
- I feel that many patients will be served if the 30 patient limit is lifted. I have at least 30-60 patients on my waiting list.

Physicians say it is difficult to administer.

- I have received numerous telephone inquiries concerning my availability to treat opiate-addicted patients. I have not yet begun to do so. The limitation on the number of patients entering such a practice requires multiple changes in the way my practice would function: only 30 patients at a time is not enough to justify the changes one would have to make in ones practice arrangements.
- As I indicated, the biggest problem with the way the BUP treatment is set up now is the 30 patient restriction and I would welcome a change in that policy.
- Buprenorphine is an excellent drug for the treatment if opioid dependence. It will not reach its full potential until it is used as intended by primary care physician. The 30 pt limit will limit the use and therefore the acceptance of the drug. At this rate it will take 10-15 years to gain widespread use/acceptance of this drug.
- At this point 30 cap/institution is a big problem, because puts too much pressure on providers to select, and consumers who are fearful they will lose forever their "spot"-their chance. 30 cap/institution is absurd-and cap for providers could be a bit higher to accommodate returnees.
- In addition to the more obvious problems associated with the 30 pt. limit is this: if I were to be suddenly unable to provide more due to both disability, loss of licensure, etc., it would be extremely difficult for any 30 pts. to find other qualified providers. There should be some providers for exception to the limit in such situations.

Physicians say it is too restrictive for group practices.

- Buprenorphine is easy to use, unfortunately the 30 pts limit for the group (6 or more doctors in our clinic) restricts its use & our clinical experience we could have otherwise.
- There should be no limit to the number of patients treatable by a physician who is otherwise authorized to prescribe bup under DATA 2000. I turn away 3-5 unique patients calling every day, because my billing in a 650+ physician group practice is limited to a fraction of the entire group's 30 patient total. I'm a bup trainer but can't train colleagues ethically, as my 3 addiction specialty (ASAM certified and ABPN CAQ holders) colleagues and I must divide up the 30 spots among us.
- I work at a university. Because we have never been able to figure out what defines a "group practice" at our university, I am essentially the sole buprenorphine provider. We have not set up a specific clinic for this medication. There are two other faculty members who would like some experience so I have passed on some of the allotted 30 to them. We

have not yet allowed residents or our addiction fellows to rx this drug because keeping track of everyone's numbers would get unwieldy. As a result, although many of our residents & fellows have completed the training, none of them have actually applied for a waiver.

- The buprenorphine program has been wonderful for a select group of patients. Most importantly the 30 pt. rule per practice should be liberalized to 30 per provider (maybe a larger cap on the practice).
- Our community has a significant drug (opioid) abuse problem. Our buprenorphine program has had a significant impact. Many young adults have been saved and given another chance at life...The 30 pt limit needs to be lifted! It's hampering our multi-specialty group. 6 of our physicians have waivers & experience & we only can treat 30 pts between us! Our waiting list has always been too long. People have died of overdose/?suicide who were on our waiting list!! Our government is entirely nuts considering my large hospital to be subject to the same 30 pt limit as a group practice.
- The main limitation is the 30 pt limit "per group". I work for <a large HMO> and look forward to the revision in the legal wording.
- This drug, along with the ability to legally prescribe it, has been a godsend in treating the substantial portion of patients in my addiction medicine practice who are opioid dependent. It would seem a logical step, from my perspective as a member of an academic based addiction medicine team, to relax the 30 patient limit, at least for addiction medicine training programs. I can't personally take care of the large # of people in my community who need help with opioid dependence, but neither can I hire additional practitioners with a 30 patient limit! In my role as medical director of the local community- level treatment center I often have to turn patients away because of the administration's fear of the 30 patient limit.
- 30 patient limit is a joke; I will not be able to rx any more patients until this is changed (all practitioners considered 1 group).
- I would like to start prescribing buprenorphine-but the 30 pt limit is a problem for the large psychiatric group of whom I am one of 4 primary care specialists.
- Suboxone has been amazingly effective for a number of my addicted patients. I am severely limited in practice number because one of the doctors who shares my practice tax id# is in charge of an opiate addiction program. I use 2-4 of the 30 open slots & he uses 26+ of the slots. They need to redefine "practice" by something other than tax id when setting caps.
- Until the 30 patient limit is changed it will be very difficult for me to use buprenorphine. Being in a group of approximately 3,500 physicians, it is impossible to assure that we do not exceed the legal limit. Maintenance is not even an option that can be considered under this limit in a medical group of this size.
- I work for...a large staff model HMO. The northern Calif. region has 3-4 million patients. We are limited to 30 patients that we can treat. As a result, I have not used buprenorphine...a large HMO needs to have more latitude in treating patients (no 30 patient limit).
- The 30 limit should not apply to those of us of are addictionists and work in rehab programs!
- The lack of 30 pt waiver for HMO has effectively prohibited use in our territory care setting.
- I work in an integrated health system in a 250 physician multispecialty group, of which 20 are psychiatrists. Because of the 30 pt rule, this entire group (which provides 90% of the psychiatric care for 2 counties of about 500,000 population) can only treat 30 patients. The nearest meth clinic is 45 minutes away. We would treat hundreds of patients if we

- could. The current system is really a cruel joke, offering in theory but denying in practice effective treatment for a very difficult problem.
- I am a member of a group of approx 20 adult psychiatrist- that means a total cap of 30 patients for maintenance buprenorphine which is a drop in the bucket. Therefore referral for maintenance buprenorphine in my area is impossible!
 - The 30 patient per practice rule is very frustrating-many people could be helped by this med. I am part of a big health system & one MD is rx for thousands of patients.
 - My current job is at a large HMO, and due to the 30 patient limit, our entire region (northern California) is only able to service a small number of clients, as we are all under one tax id#. Buprenorphine, from my experience with it, is safe, effective, and when Suboxone is used, not easily abusable. I hope, if the 30 patient limit is rescinded to be able to treat patients again with buprenorphine. Thank you.
 - Need to get rid of the 30 cap for "groups"!

Physicians are forced to change treatment practices

- I have just started (6 weeks) treating patients for long-term maintenance. So far, I have been taking fairly stable patients following induction. I already have 15 patients and will quickly be up to the 30 patient limit. I see this as a major problem in treating opioid dependant patients with long term maintenance planned. I am also the director of addiction medicine a medical center. I will be hindered in starting the Suboxone maintenance program unless this 30-patient limit is abolished. I truly hope that the 30 patient limit is done away with, as there are so many opioid addicts who qualify for Suboxone maintenance.
- The 30 day cap is killing me, can't maintain except of label for pain which stuns me. Some people as you know must be maintained but 15 cases for myself and partner won't cut it! No room to carry the numbers!
- I give prescription on discharge for about a week and would like the patient to be able to continue maintenance buprenorphine if possible, but there are not many physicians in the area to do so because of the 30-patient limit. I feel the 30-patient limit should be voided so that more patients get the benefit of buprenorphine.
- I am medical director for a 93 head addictions hospital which uses buprenorphine exclusively for opiate detox. Because of the "30 limit" our hands are tied as far as maintaining an extended opiate treatment program (which would be more effective). We therefore try to refer our patients after inpatient detox and rehab for practical taper by other physicians. However, the limited number of physicians using buprenorphine makes this impossible.
- Bup is proving to be a very effective ambulatory detox method for this population in a moderately controlled environment.-I am very much in support of the increased pt. limit. I am going to start maintenance treatment and don't want to be limited by the number in detox.
- My success rate is dropping because I have reached my limit of 30 and now can only do detox for about 10 days! I could have in excess of 200 patients at one time! (all on buprenorphine). Patients find buprenorphine superior to methadone for so many reasons. Please find a way to lift the 30 max limit. I don't know any surgeons who limit appendectomies at 30! You are doing an incredibly important service. Thank you. Buprenorphine is to my opioid addicts what SSRI's are to my depressed patients.
- The '30 patient limit' makes it virtually impossible to treat patients for a period of time necessary for me to acquire the necessary tools of recovery-can remain clinically viable.

For a physician whose practice is limited to treat clinically dependent persons, and faced with a dilemma-discharge patients with physician (in this case it would be one with no specialty training in addiction medicine) or place people in need of treatment on a waiting list. I believe it is a disservice to both. I feel that the '30 patient limit' should be lifted for those certified in addiction medicine.

- We need to raise the 30 patient limit. Patients stay on this medicine longer than you think. It's impossible to know one's total # of patients at any given time as some patients stop and some don't follow up on a regular basis.
- In our area long term detox and maintenance difficult (impossible) to find possibly due to the economics of the 30 patient cap.
- The 30 pt restriction is counterproductive- as you get closer to that number it becomes distracting for treatment. I strongly feel that should be lifted.
- I think buprenorphine is an excellent agent for treating opiate dependence & w/draw. The 30 pt limit has adversely affected patient care in my area because I no longer can offer maintenance therapy thus resulting in high relapse rate. I have had almost no diversion (diversion seen was to treat w/draw & not to get high) and no addiction to buprenorphine. The 30 pt limit needs to be eliminated at least for physicians certified in addiction medicine. The limit is definitely adversely affecting patient care. The government is committing malpractice with limit. The health value of buprenorphine greatly outweighs the risks of diversion.
- We think that bupe is an important tool in a treatment strategy but, limited by the 30 pt limit, we are very careful about who we offer it to. I would like to see no limit on patients treated with these medications.

Physicians say it is not necessary.

- I would like to see the 30 patient ceiling lifted-I'm not sure what purpose it serves.
- The restriction limiting each provider to 30 pts is unrealistic.
- The buprenorphine/naloxone sublingual treatment of opiate dependence is very effective in arresting active addiction to heroin or prescription opiates. Prescribing Suboxone have been very satisfying because my patients lives are dramatically improved. Their suffering and the suffering of their families is promptly placed in remission. Few other physicians in my area are willing to prescribe. Concern about having addicts come to their private office are often the reason given, but I have had no problems what so ever. Please advocate, using the data from this survey, for legislation to change the limit from 30 per practice/institution to 30 per physician. The only doctors I have been able to convince of the great value to prescribing Suboxone have been my partners in the practice who see how easily it can be done within a private practice setting and how well the patients do. This valuable, life saving treatment can be safely expanded by lifting the ban on more than 30 patients per practice.
- The 30 patient limit needs to be eliminated. This is a political limit.
- The limit of 30 patients is fine for general medicine practice but inappropriate for the practice of addiction medicine.
- Need to end the 30 patient limit. Until buprenorphine is treated like any other rx with no additional constraints placed on doctors, both doctors & patients will continue to stigmatize this area of medical care.
- I believe that the 30-patient limit is unduly restrictive, especially as my work encompasses both outpatient treatment of opioid-addicted patients and inpatient

detoxification. I believe that the safety profile of the drug is excellent and merits a lifting of the restriction.

- How many physicians support the 30-patient limit?
- I was told that buprenorphine was limited by congress to prevent "pill mills" and diversion, with the ready availability of opiates online now, how is this a justifiable expense? I recommend we stop all limitations and all physicians, with or without waiver, prescribe as much as is wanted or needed. Risk reduction should be the key words here.
- The patient limit must be withdrawn as soon as possible. It is akin to placing limits on cardiac or diabetic patients. When are we truly going to acknowledge this problem as a disease and let those of us who practice addiction medicine full time do what we are trained for? It is unconscionable to turn patients away because of some bureaucratic limits. Unlimited numbers are the only option. Do it now!!
- 30 patient limit is ridiculous for providers with interest and expertise with this population.
- Need to consider higher cap for ASAM certified or CAQ addiction psychiatrists.