



Enhancing Treatment in a Drug Court Setting: An Evaluation of San Diego County's Pilot Vivitrol Project

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ENHANCING TREATMENT IN A DRUG COURT SETTING: AN EVALUATION OF SAN DIEGO COUNTY'S PILOT VIVITROL PROJECT

INTRODUCTIONS

In 2012, the North County Drug Court began a pilot project administering Vivitrol to drug court clients with a primary opiate addiction. Vivitrol is an extended-release injectable formulation of naltrexone that was approved in 2006 by the U.S. Food and Drug Administration (USFDA) for the treatment of alcohol dependence and in 2010 for the treatment of opiate dependence (USFDA, 2010). The County of San Diego Health and Human Services Agency (HHSA) contracted with the San Diego Association of Governments' (SANDAG) Criminal Justice Research Division to conduct a two-year evaluation of the Vivitrol Pilot Project to determine if the program was implemented as planned and if the expected outcomes were achieved. This is the fourth and final evaluation report and provides the findings from data collected between August 2012 and June 2014.

BACKGROUND

Opioid addiction, including heroin and prescription pain killers such as OxyContin and Vicodin, is an ongoing concern in the United States, directly afflicting over two million people who were dependent on or have abused pain relievers or heroin (SAMHSA, 2011). The National Institute of Drug Addiction (NIDA) notes that over four million Americans aged 12 and older have reported trying heroin, with around one in four becoming addicted (NIDA, 2013). Although the actual number of heroin users is small in comparison to other illicit drugs (e.g., marijuana), the numbers indicate an uptick in use, mostly driven by young users (18 to 25 years old). The National Survey on Drug Use and Health (NSDUH) reported an increase in first time users from 2006 (90,000) to 2013

Key Findings of Vivitrol Pilot Project

This report constitutes a two-year evaluation of the North County Vivitrol Pilot Project. It is one of the first studies to look at the longer term impacts of Vivitrol among opioid dependents. While the evaluation was limited by small sample size and available comparison group, the findings support further exploration of intramuscular injections of Vivitrol to support engagement and retention in drug treatment among individuals involved in the criminal justice system. Some key findings included:

- Regardless of the number of shots received, program clients generally reported that Vivitrol helped to control their cravings and supported their recovery.
- Program clients who completed the prescribed six or more doses of Vivitrol experienced decreased desire to use, did not relapse, and did not reoffend during the study period (a total of 18 months).
- While positive outcomes were realized for those clients who received the full dosage amount, only around one quarter (26%) received six or more shots.
- Older clients (36 years old on average) whose primary method of heroin administration was injection were more likely to receive six or more doses than those who were younger and reported other primary modes of use.
- Program stakeholders surveyed recommended that the Vivitrol project continue because of the success of the clients they witnessed during the pilot project including decreased cravings and greater focus on treatment.

(156,000) (SAMHSA, 2013). Exemplifying this trend and public health concern was the identification of heroin by over half of Community of Epidemiology Work Group (CEWG)¹ members as being one of the most important drug abuse issues impacting their communities (NIDA, 2013).

Contributing to this growing issue is the increase in the illicit use of prescription pain relievers. According to the NSDUH, several measures indicate a growing trend in the misuse of prescription pain relievers, including increased initiation rates (.04 in 2002 to .06 in 2010 of the general population), a two-fold increase from 2002 to 2010 in the receipt of specialty treatment for nonmedical pain reliever misuse (199,000 to 409,000, respectively), and an increase in emergency department visits for narcotic pain relievers (145,000 in 2004 to 306,000 in 2008) (SAMHSA, 2011).

The actual use of heroin is lower in San Diego compared to other regions in the United States (e.g., 5% compared to 25% in Chicago in 2002)², however, San Diego is experiencing the same trend of increased opioid use. For example the most recent Substance Abuse Monitoring (SAM) data from SANDAG showed a two-fold increase in arrestees who tested positive for opiates between 2002 (5%) and 2012 (10%) and the number of adult arrestees who reported ever trying heroin increased from 17 percent in 2002 to 26 percent in 2012. Furthermore, the illicit use of prescription drugs could be fueling this trend, with about one-quarter of those who have used heroin reporting using prescription opioids prior to their heroin use, of which 63

percent said they had started using heroin as a substitute for the prescription opioids (Burke, 2013).

While the personal costs of addiction are beyond quantification, the economic cost is in the billions and well documented (NIDA, 2008). The overall cost of prescription opioid abuse in the U.S. has been estimated at \$53 billion, with heroin addiction costing over \$26 million including health care, criminal justice, and loss of productivity costs (Mark, Woody, Juday, & Kleber, 2001). These costs do not take into account the impact to the friends and families of those addicted.

The rising use of opioids and associated costs gains a new sense of urgency when examined within the context of the fundamental changes in the California correctional system. Intent on reducing the state's prison overpopulation, the passage of Assembly Bill 109 (AB 109) and Senate Bill 678 (SB 678) have altered how certain felons are processed and held accountable in the California criminal justice system. These offenders, who once would have been sentenced to prison and/or parole, now find themselves serving their time locally. This influx of offenders greater calls for a under local supervision range of service options, not only because of the longer detainment time, but also because of greater needs of the population, many of whom struggle with addiction. As such, finding effective treatment to prevent relapse and recidivism has never been so pressing to the local jurisdictions. The use of Vivitrol by the courts as one option to help prevent recidivism among opioid dependent offenders is being explored by several drug courts throughout the nation and having a better understanding of its effectiveness is more important than ever (Ballantyne, 2014; Byers, 2014; Lane, 2014).

As with other anti-dependent medication, Vivitrol is to be used in conjunction with psycho-social treatments (e.g., outpatient or

¹ Established in 1976, CEWG is a network of researchers from major metropolitan areas of the United States whose primary purpose is to provide ongoing community-level surveillance of drug abuse through analysis of quantitative and qualitative research data.

² These data are based on male arrestees in both San Diego and Chicago detention facilities gathered as a part of the Arrestee Drug Abuse Monitoring (ADAM) and Substance Abuse Monitoring (SAM) programs.

inpatient treatment). However, unlike other effective pharmaceuticals, such as methadone or buprenorphine, which require daily doses, Vivitrol is administered monthly via injection and is not a controlled substance. The benefits of these two differences are the increased opportunity for compliance because of the extended release associated with Vivitrol which decreases the opportunity for non-compliance (i.e., by missing a dose) and the decreased risk of addiction on the treatment medication (AATOD, 2013). Unlike the numerous studies on the effectiveness of Vivitrol among alcohol dependents (Crevecoeur-MacPhail, et al., 2005 Garbutt, et al.; Pettinati, et al., 2010), the study of Vivitrol effectiveness with opioid dependents, while sound, is minimal. The clinical trial study that launched its USFDA approval for opioid addiction was a double blind placebo randomized control study conducted in Russia involving 250 dependent individuals. The six-month dosage study found positive results as measured by monthly urine tests, Urge to Use scales, and retention in the study (Krupitsky, et al., 2011).

While the initial trial study indicated positive results, it did not measure the long-term impacts of Vivitrol nor did its sample focus on use within a controlled setting such as the criminal justice system. The use of Vivitrol as an opioid relapse preventative tool is still new and not without its challenges. In addition to a need for further long-term research on its effectiveness, the injections are expensive (approximate \$1,000 per month) and require that an individual be detoxed from his/her opiate use prior to receiving the injections (Vivmont, 2011).

Even with these challenges, Vivitrol is being seen as a hopeful addition to the prevention and treatment tool box for the growing opiate problem in the U.S. These initial positive results, along with the devastating impact associated with opioid addiction, and the changing criminal justice climate, are

driving the momentum to test the water of Vivitrol use among the offender population.

In the San Diego region, the North County Drug Court was the first entity to start using Vivitrol as a treatment option for those processed in their drug court. Given the newness of Vivitrol, the court and the County of San Diego's Health and Human Services Agency (HHSA) wanted to evaluate the effectiveness of its use and established a pilot study to do so. With the majority of funds directed toward treatment, the evaluation took on more of a "formative" design with the intention to document the outcomes in order to refine and replicate future implementation and also inform a more rigorous evaluation if the opportunity arose. This report summarizes the findings from this pilot period and provides stakeholders and others with a local perspective on what has been successful and what can be improved upon if the use of Vivitrol is continued or replicated in other courts.

METHODOLOGY

Research Design

This pilot study was intended to provide local providers and decision makers with information on both the process and impact of Vivitrol on a small sample of clients. The scope and design of the evaluation for this project was influenced by the availability of a valid comparison group and funding. A pre-post, quasi-experimental design utilizing a non-equivalent comparison group was employed. A sample of convenience was used to select both the Vivitrol and comparison groups. The population pool was comprised of individuals who were enrolled in drug court during the time of the sample selections (August 2012 to June 2013). The size and methodological limitations of the evaluation prohibit generalizing the results and was never intended to do so; however, the results are valuable in informing local decision makers on the next steps in this movement

towards utilizing Vivitrol within criminal justice settings.

Sample Selection

The original design called for ten individuals sentenced to North County Drug Court who met eligibility criteria and volunteered to participate in the Vivitrol pilot study. Eligibility was determined by a multi-disciplinary team comprised of the judge, treatment staff from a local community-based organization (i.e., Mental Health Systems, Inc.), the District Attorney, and the Public Defender. To be eligible for the project, individuals had to be opiate dependent and had detoxed from opioid use. Individuals who were pregnant, currently taking opiate-based medications, or had severe liver disease were not eligible to receive Vivitrol. If deemed eligible for the project, the individual was approached by the judge about participating in the study. Participation was voluntary and all the individuals who were offered the program agreed to participate. After agreeing to participate, individuals met with a SANDAG research staff who explained the study and had him/her sign an informed consent. Clients then underwent a medical screening by a certified medical professional contracted through MHS.

A total of 19 individuals from North County Drug Court who were opioid dependent consented to be enrolled in the Vivitrol pilot program and received at least one injection (Table 1). This number was greater than the ten originally anticipated due to clients dropping out after one or two Vivitrol injections (rather than the anticipated four to six injections).

Because random assignment was not feasible, a comparison group was established by engaging clients from the South Bay and East County Drug Courts who also were opioid dependent, but who would not receive Vivitrol. Drug court staff at each of the

facilities identified possible comparison group members, approached them about the participation in the study, and if they agreed SANDAG staff met with the individual to administer the informed consent. All but one of the individuals offered the study chose to participate.

Table 1
CONSENTS CONDUCTED BY MONTH AND SITE

	Comparison Clients		
	Vivitrol Clients	South Bay	East County
August 2012	10	0	0
September 2012	3	0	0
October 2012	0	5	12
November 2012	2	0	0
February 2013	1	0	0
May 2013	2	0	0
June 2013	1	0	0
TOTAL	19	5	12

NOTES: No clients were entered into the study after June 2013 to ensure that there was time to track 12-month follow-up data on each client.
SOURCE: SANDAG, 2014

To ensure the full protection of study clients, all data collection forms and study protocol were submitted to and received approval by an Institutional Review Board (IRB).

Research Questions

Specific research questions answered as part of this research included:

- What were the characteristics of clients who agreed to participate in the project (e.g., gender, age, race, drug use history, criminal history, mental health history, etc.)? If any clients refused to participate, what were their characteristics?

- What was the medication compliance rate for Vivitrol?
 - What side effects of Vivitrol were reported by clients?
 - How did treatment compliance (including drug tests results and other measures of success for drug treatment and drug court) vary for the Vivitrol and comparison groups?
 - How did the recidivism rates for the Vivitrol and comparison groups vary during the course of drug court participation?
 - What were the program partners' perspectives on the challenges and successes of the pilot project?
- **Urge to Use Scale:** The Urge to Use assessment is a five-question instrument that was administered weekly to both the Vivitrol and comparison groups to rate their craving for opiates over the previous week. Possible scores on the scale ranged from 0 to 28, with a higher score demonstrating a stronger urge to use and more time spent thinking about using during the past week.
 - **Client Intake Information:** Data collected during client intake by program staff were shared with SANDAG for research purposes. These data included demographic information, drug use history, criminal history, employment and education status, gang activity, and family relationships. Client intake information was received for all 36 Vivitrol and comparison group clients and is presented throughout this report.
 - **Compliance Rates:** Data regarding compliance with drug court conditions, including drug test results, were also compiled for both groups. This information was transferred to SANDAG on a weekly basis and was reliably received for both groups.
 - **Medical Monthly Survey:** This instrument was completed monthly by program staff for each Vivitrol client and documented the completion of data collection instruments, changes in cravings, injection side effects, and perceived benefits and concerns related to the use of Vivitrol.
 - **Program Staff Survey:** SANDAG created a brief opinion survey to garner feedback from staff who participated in the Vivitrol pilot project. The purpose was to document successes and lessons learned.

Data Collection

To answer the process and impact evaluation research questions, data were collected for both the Vivitrol and comparison groups by program and research staff at intake, up to 18-months after program enrollment,³ as well as on a weekly and monthly basis. The five primary sources of data compiled during the course of the evaluation included:

- **Criminal Activity:** Criminal history and recidivism data were collected for both Vivitrol and comparison group clients 12 months prior to study enrollment, and 6-, 12-, and 18-months post consent. Criminal history for the 12 months prior to program enrollment, including the instant offense leading to drug court admission, were collected and documented for all 36 clients.

³ Drug court clients are mandated to complete a 12-month drug treatment program followed by six months of aftercare.

STUDY GROUP CHARACTERISTICS

What were the characteristics of clients who agreed to participate in the project? If any clients refused to participate, what were their characteristics?

Between August 10, 2012 and June 30, 2013, 21 individuals were approached to be in the Vivitrol group and all consented to receive Vivitrol and participate in the research. However, two of these individuals dropped out prior to receiving their initial dosage (i.e., one client did not pass the initial mouth swab that determines intoxication level and the other absconded). The comparison group was comprised of individuals ordered to attend drug courts in either South Bay or East County. A total of 18 individuals were approached and 17 consented to be part of the comparison group (5 from South Bay and 12 from East County). One individual from East County refused to participate because he did not have time to go through the consent process.

Once the comparison group was selected the two groups were analyzed to identify differences and similarities between groups. The two groups did not differ significantly on demographic characteristics, but there were slightly more males (53% and 71%, respectively) and clients who identified as White (90% and 71%, respectively) in the Vivitrol group compared to the comparison group. Clients in both groups were around 30 years old (mean age 30.53 and 33.76 years old, respectively). Nearly three-quarters had never been married (72% and 80%, respectively) and around two in five had dependent children (44% and 38%, respectively). Around two-thirds had a high school diploma or GED, and between one-quarter (25%) and over one-third were employed (38%) (Table 2).

Table 2
VIVITROL AND COMPARISON GROUP CHARACTERISTICS

	Vivitrol Clients	Comparison Clients
Males	53%	71%
Age	30.53 (<u>SD</u> = 9.34)	33.76 (<u>SD</u> = 11.13)
White	90%	71%
Completed H.S./GED*	65%	64%
Never Married	72%	80%
Dependent Children	44%	38%
Employed	25%	38%
TOTAL	17-19	14-17

*The three courts administered different intake forms so it is unclear how many clients received a high school diploma versus a GED.

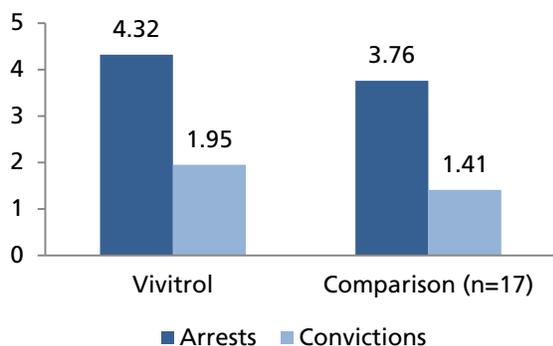
NOTE: Cases with missing information not included.

SOURCE: SANDAG, 2014

The groups were similar in regard to criminal history, with individuals having around four arrests on average (4.32, SD = 2.47 Vivitrol; and 3.76, SD = 1.60 comparison) and an average of one (1.41, SD = 1.06 comparison) to two convictions (1.95, SD = 1.72 Vivitrol) 12 months prior to enrollment (Figure 1). With the exception of one comparison individual, clients had a most recent prior highest conviction for a felony-level offense. As for type of conviction, a similar proportion of Vivitrol clients had a prior property offense (47%) or drug offense (53%), whereas most of the comparison group's highest conviction charge was for a drug crime (71%), followed by a property crime (21%), or for an "other misdemeanor (7%)" (not shown)⁴.

⁴ Significance was not able to be determined because of the small sample size.

Figure 1
VIVITROL AND COMPARISON CLIENTS
HAD SIMILAR CRIMINAL HISTORIES



SOURCE: SANDAG, 2014

In regard to substance abuse history, a similar amount of individuals in both groups reported having injected drugs in their life (89% and 88%, respectively), including doing so in the past year (83% and 80%, respectively). Most of the clients also reported having received prior treatment for their drug addiction (89% and 79%, respectively) (not shown).

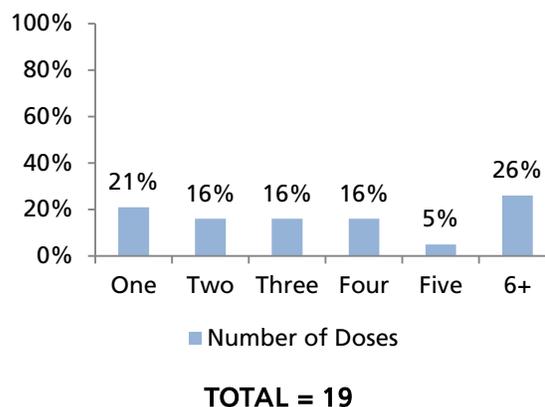
While all clients involved in the study had a diagnosis of opioid dependence (a criterion for eligibility into the program), there was a significant difference between the two groups in their primary drug of choice. Opioids was the primary drug for nearly the entire Vivitrol group (94%)⁵ compared to just over one half of the comparison group (56%). The remaining comparison clients listed methamphetamine (31%) and marijuana (13%) as their primary drug of choice (not shown). In addition, all (100%) of the Vivitrol clients were poly-substance users as were 81 percent of the comparison group.

⁵ The other Vivitrol client selected barbiturates as his/her primary and opioids as his/her secondary choice.

What was the medication compliance rate of Vivitrol clients?

Of the 19 individuals in the Vivitrol group, only five (26%) received six or more injections (ultimately determined to be full dosage⁶) and 74 percent received five or less (not shown). Figure 2 shows the number of monthly injections received by clients. Specifically, 21 percent only received one dose of Vivitrol, 16 percent each received two, three, or four doses, and 5 percent received five. The five clients who did receive the minimum six doses (referred to later as “medication compliant”) received between six and 12 doses.

Figure 2
NUMBER OF VIVITROL DOSES RECEIVED
BY CLIENTS



SOURCE: SANDAG, 2014

Given that Vivitrol was administered monthly, the number of doses administered also represents the months a client was compliant with Vivitrol. For example, one in five (21%) clients stopped the medication after one month, another 16 percent ended after 60 days, and so on.

⁶ Originally, full dosage was defined as four injections, but because of early client turnover, additional funds were available to extend the offering to six injections and eventually 12-months for those clients that requested it.

The reasons provided for discontinuing use of Vivitrol was documented by program staff when the client exited. As Table 3 shows, most clients voluntarily stopped receiving the injections. The reasons clients gave for voluntarily withdrawing from the program included feeling like s/he didn't need it anymore to stay clean, entering a residential treatment facility, and graduating drug court and not wanting to continue. Three clients also stopped because of the side effects (stopped after 2, 3, or 5 doses) they attributed to Vivitrol and three were terminated from drug court for non-compliance including absconding.

Table 3
REASONS FOR STOPPING VIVITROL INJECTIONS BEFORE RECEIVING THE MINIMUM SIX DOSES

Reason for Stopping	Percent of Clients
Terminated From Drug Court	21%
Side Effects	21%
Entered Residential Treatment	14%
Didn't Need It	29%
Completed Drug Court	14%
TOTAL	14

SOURCE: SANDAG, 2014

To better understand possible factors related to retention (i.e., receipt of the prescribed six doses), further analysis was conducted to explore the characteristics of the medication compliant and non-compliant Vivitrol groups. Results revealed that the medication compliant group was older on average than the non-compliant group (38.80 years and to 27.57 years, respectively), more likely to have completed high school/some college (80% and 58%, respectively), and more likely to report injecting heroin as their primary method of administration (100% and 60%, respectively) (Table 4). There were no differences with respect to gender or race. These findings suggest that those clients who remained engaged in the Vivitrol study entered with a greater level of motivation to

change, if age (as a proxy for years of use) and method of administration are indicators of severity of addiction at intake.

Table 4
CLIENT DEMOGRAPHICS BY DOSAGES RECEIVED

	Medication Compliant (6+ doses)	Medication Non-Compliant (<6 doses)
Average Age	38.80 (SD = 8.29)	27.57 (SD = 8.04)
High School or Some College	80%	58%
IV Primary Use Method	100%	60%
TOTAL	5	12-14

NOTE: Cases with missing information not included.
SOURCE: SANDAG, 2014

Anecdotally, clients were asked during their monthly injections why or why not they planned to come back for their next shot. Of the 15 individuals who provided responses over the course of the pilot, 53 percent said they planned to come back because they noticed a decrease in cravings and felt it was working. Other comments were because there was a comfort in knowing they could not get high even if they took the drug and it was helping them stay sober (2 each). Two clients reported that they would not be returning because they felt the Vivitrol had worked and they could do it on their own. Worth noting is that none of these clients received the full six doses (not shown). The following quotes illustrate these reasons:

- "Because I like the fact that even if I wanted to use I can't."
- "It has almost completely stopped the cravings."
- "I feel like I'm ready to do this on my own and am very grateful for this opportunity to receive the help."

What side effects of Vivitrol were reported by clients?

One of the questions the project wanted to answer was the type of side effects, if any, the clients might have experienced while taking Vivitrol. Information regarding side effects of the drug was captured when clients visited the Physician Assistant (PA) for their monthly shot or by program staff when someone exited the program. A total of five individuals (26%) reported some type of side effect while taking Vivitrol, including nausea, sleep disruption, and medical complications and two of these noted the side effects as the reason for ceasing to participate in the project. The dosage that each of these clients received varied with two receiving two doses, and one each receiving one, three, or five doses (not shown).

"I feel comforted knowing I can't use heroin while I'm on it [Vivitrol] because I won't get high and that is my first thought that counteracts any cravings." (Vivitrol client's response on the medical monthly report)

OUTCOME RESULTS

How did treatment compliance vary for the Vivitrol and comparison groups?

In alignment with the drug trial research previously described, similar indicators were used to measure the success of Vivitrol among

"It is taking the cravings away but I am not a fan of the side effects; nausea, sleeplessness, and this last shot, I had a twitch in my leg." (Vivitrol client's response on the medical monthly report)

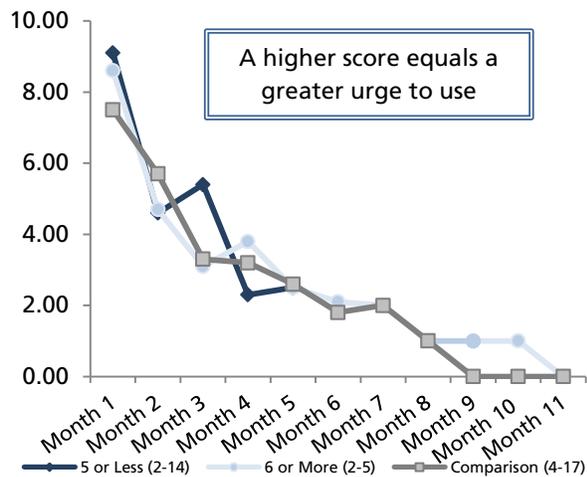
study clients. These measures included the desire to use (i.e., Urge to Use assessment), relapse (i.e., positive drug test), and criminal activity (i.e., new arrest and/or conviction 6-, 12-, and 18-months post consent).

Urge to Use

The primary purpose of Vivitrol is to decrease an individual's craving for opiates and prevent relapse. To measure the desire to use, clients in both groups were asked to complete a weekly Urge to Use assessment, with a higher score indicating a greater desire to use. The comparison group completed an average of 25 ($SD = 23.37$) Urge to Use assessments, whereas the Vivitrol clients who had received 6 or more doses completed 33 assessments ($SD = 10.31$) on average, and those who received less than six doses only completed an average of ten ($SD = 6.56$).

Comparisons were made between study groups and within the Vivitrol group because of the difference in dosages received. Figure 3 illustrates the average scores on the Urge to Use Scale over the first eleven months of the study. No statistical comparisons could be conducted between the Vivitrol and comparison groups due to constraints in the small sample size. At the start of the study, the initial Urge to Use score was considerably lower for the comparison group (8.76, $SD = 7.59$) compared to the Vivitrol group (15.95, $SD = 7.02$); however, opioid cravings decreased for both groups over time.

Figure 3
URGE TO USE OPIATE SCORES DECREASED
OVER TIME



NOTES: Cases with missing information not included. Scores were calculated by summing the 4 weekly scores and calculating the average score for the month. SOURCE: SANDAG, 2014

SANDAG staff worked with the project partners to determine why the comparison group’s Urge to Use scores were lower at intake than the Vivitrol group’s scores. Some of the possible explanations for the discrepancies in scores included:

- **Opiates Not a Primary Drug of Choice:** Nearly half (44%) of the comparison group reported a drug other than opiates as a primary drug of choice, suggesting that this proportion of the comparison group may not be as dependent on opiates as the Vivitrol group.
- **Use of Suboxone:** Almost one-quarter (24%) of the comparison group was arrested and sentenced to jail for illegal use of Suboxone, a drug also used to treat opiate dependence. The use of Suboxone most likely resulted in reduced opiates cravings, which also could have contributed to the lower Urge to Use assessment among the comparison group (not shown).

Urinalysis

Depending on the phase of drug court the client is in, the number of urinalysis tests given weekly can vary, with fewer tests administered the longer the individual remains in drug court. Between August 2012 and March 2014, SANDAG staff received an average of 39 test results per client for the Vivitrol group (range 0 to 87, SD = 28.37) and 54 for the comparison group (range 0 to 133, SD = 39.73) (not shown). These ranges also varied depending on how long the individual had been participating in the study or whether the individual had been removed from the study (e.g., absconded or entered residential treatment).

Data were available for 19 Vivitrol clients, 5 of whom received a minimum of six doses of Vivitrol, and 14 comparison clients. Because of the small sample size, tests of significance were not possible; however, fewer individuals in the Vivitrol group had a positive urinalysis test than the comparison group. In fact, none (0%) of the clients who received six or more Vivitrol doses tested positive compared to almost one-quarter (21%) of clients who received 5 or fewer doses, and over three-quarters (79%) of the comparison group (Table 5).

Table 5
DRUG TEST FOR THE MEDICATION
NON-COMPLIANT, COMPLIANT VIVITROL
GROUPS AND THE COMPARISON GROUP

	Non-Compliant (<6 doses)	Compliant (6+ doses)	Comparison
Positive Any Drug	21%	0%	79%
Positive Opiate	14%	0%	36%
TOTAL	14	5	17

SOURCE: SANDAG 2014

The fact that fewer Vivitrol clients tested positive and that four comparison clients who did not test positive but had been identified by program staff as having used Suboxone (known to reduce cravings for opiate/heroin use), may be indicators that Vivitrol is having a positive effect on Vivitrol client success (not shown). These findings also emphasize the value of completing the full dosage and suggest examination of strategies to increase retention.

How did the recidivism rates for the Vivitrol and comparison groups vary during the course of drug court participation?

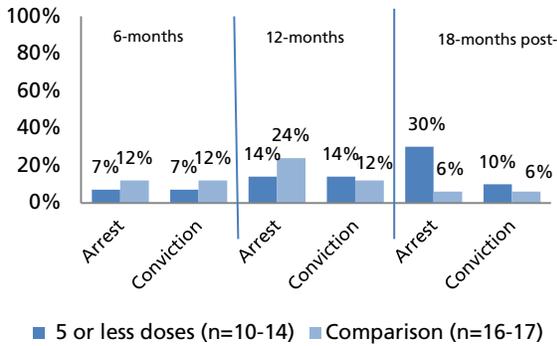
To measure recidivism rates for both groups, data on arrests and convictions were collected during program participation (6-months after consent to the study), up to 12-months after consent and then 18-months post-consent. Again, tests of significance were not possible due to the small sample size; however, analysis showed that those who received six or more doses of Vivitrol (compliant) had no new arrests or convictions in each time period. Although this is only five individuals, the result is important because of the lack of long-term research on Vivitrol use for opioid dependence.

As Figure 4 shows, those clients who were medically non-compliant (5 doses or fewer), as well as those in the comparison group, did have arrests and/or convictions for a new charge during and post-consent. Specifically, seven percent who were medically non-compliant had a new arrest within six-months of consenting to the program, 14 percent had an arrest at 12-months post-consent, and 30 percent of those out of custody⁷ had a new arrest 18-months post-consent. Similar results were found with the comparison group for the first two time periods, with 12 percent having a new arrest within 6-months of consenting and 24 percent being rearrested 12-months post-consent. However, the comparison group had only six percent rearrested within 18-months post-consent.

As with the arrest data, the non-compliant group had a similar number of convictions as the comparison group at both 6- (12% each) and 12-months post-consent (14% and 12%, respectively). Although the non-compliant group had more arrests at 18-months, they had the same number of individuals convicted as the comparison group. Again, the small sample size does not allow for any correlations to be made, but this preliminary information does suggest the value of receiving at least six doses of Vivitrol (Figure 4).

⁷ If an individual was detained during the reporting period, they were considered not included in the denominator because of their incarceration.

Figure 4
ARREST AND CONVICTION DATA FOR
MEDICALLY NON-COMPLIANT VIVITROL
AND COMPARISON GROUPS



NOTE: The range in sample size represents the number of clients who were not already detained during the period.
 SOURCE: SANDAG 2014

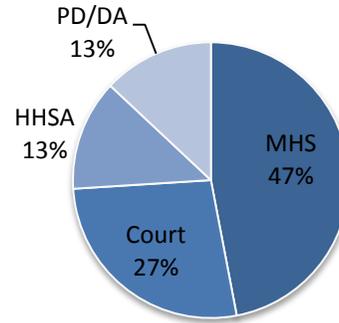
What were the program partners’ perspectives on the challenges and successes of the pilot project?

In an effort to hear from the program partners about their perspectives on the challenges and successes of the pilot project, a short survey was sent to them at the end of the project (May 2014). Almost all of the partners responded (15 out of 16), representing the courts, Public Defender, District

“All agencies worked together in a collaborative effort with good communication and cooperation. The pilot project was administered in the context of highly supervised and well-organized program with support from reps from different arenas of the criminal justice system.”
 (Partner survey respondent)

Attorney, and the treatment partners (Figure 5). Of these 15 respondents, 67 percent worked directly with the Vivitrol clients (not shown).

Figure 5
AGENCIES REPRESENTED IN PROGRAM
PARTNERS’ SURVEY



TOTAL = 15

SOURCE: SANDAG Vivitrol Program Partner Survey, 2014

All (100%) of the respondents felt that the project was implemented well (80% “very well” and 20% “well”) and noted that the top three reasons contributing to this success were the collaboration across agencies (n=7), the medical team’s dedication and support of clients (n=5), and the support received by leadership at both HHS and the court (n=4) (not shown). Also mentioned as being helpful were the quality of Vivitrol, having the pilot project be fully funded, the client investment in the process, and use of the Urge to Use assessment (one each) (not shown).

“I feel the shots should have been given while the clients were still in custody, to the extent possible.”
 (Partner survey respondent)

In an effort to improve the program moving forward, respondents were asked to list three things that could have been done differently, and eight individuals provided suggestions (and seven did not), such as expanding the project to increase the number of clients and courts and providing the first Vivitrol shot prior to release from jail (3 each), followed by

improving the evaluation design by developing it at the beginning and having a more equivalent comparison group (2 each) (not shown). Other suggestions included having a more flexible schedule for the clients, ensuring clients know where to go for relapse prevention after program completion, soliciting more feedback from clients, and offering Vivitrol for a year (1 each) (not shown).

Program partners were also asked to share the lessons learned from their experience with the pilot project. The primary lesson that emerged from their comments was the increased or new confidence in the effectiveness of Vivitrol (5), followed by the need to engage clients in treatment and supervision, and the administration of Vivitrol (4 each). This awareness is consistent with the literature on Vivitrol that explicitly states that the drug's use is most effective within the context of other modes of addiction treatment (i.e., counseling, outpatient). Several quotes from the program partners elaborate on these themes:

- *"This [Vivitrol] has contributed to the success of clients that had otherwise not been able to stay clean."*
- *"That the younger population we 'thought' would benefit the most was incorrect and the 'older' population of addicts excelled."*
- *"The medical provider can make or break the project. Find someone who believes in recovery to administer the shots."*
- *"We learned the value of administering the drug as early as possible after the decision is made to give the client the drug. Clients who have access to caring and supportive staff in the context of close and consistent supervision will do better with this drug."*

When asked if they would recommend continuing the Vivitrol project in San Diego,

all respondents (100%) reported affirmatively.

Elaborating on reasons why they felt this way, the answers fell into two categories



"I truly believe that lives are being saved by using this intervention" (Partner survey respondent)

echoing earlier responses: the perceived success with the clients, and the desire to expand the use to other clients and courts. The following quotes illustrate these points.

- *"The shot gives patients time to collect tools of recovery instead of focusing on cravings and drugs."*
- *"I would recommend that Vivitrol be made available in as many inpatient and outpatient programs as possible."*
- *"We have long needed a medical assisted treatment that is not opioid based to help combat the serious situation we are facing with regard to opiate users."*

SUMMARY

The use of anti-addiction pharmaceuticals is an ever evolving field. The recent approval by the USFDA of intermuscular injection of naltrexone, known as Vivitrol, for opiate addiction has grabbed the attention of drug courts around the nation. In search of effective methods to support relapse prevention, drug courts are turning to Vivitrol in conjunction with traditional psycho-social treatment to reduce non-compliance among opioid dependent offenders. In 2012, the North County Drug Court launched a two-year pilot project to administer Vivitrol to drug court clients with a primary heroin/opiate addiction. To measure success, SANDAG was contracted to conduct a small quasi-experimental design study with a Vivitrol and matched comparison group. This report covers the period of August 2012 through June 2014 and includes 36 study

clients; 19 Vivitrol and 17 comparison group clients.

Analyses of demographics, prior criminal history, and drug use showed that the two study groups were similar on most characteristics, with the exception of primary drug use, as evidenced by a greater proportion of Vivitrol clients reporting opioids as their primary drug of choice and comparison group clients reporting a lower urge to use score on their initial assessment.

Further analysis showed that the Vivitrol clients who remained medically compliant (i.e., received 6 or more doses) in the study were more likely to use drugs intravenously and were older, on average, than those who received less than six doses. These results also suggest that those who remained in the program may have had a longer history of abuse and were better prepared to work towards sobriety and follow through with receiving medical treatment to remain drug-free.



“The project increased my confidence level in the product itself. We saw how well it worked and how much it helped the clients.” (Partner survey respondent)

Examination of outcome data between these two Vivitrol populations and the comparison group found that those clients who received a minimum of six doses demonstrated positive outcomes on all the main indicators of success. That is, they had no new arrests or convictions at 6-, 12-, and 18-months post-consent, had decreased urge to use scores, and had no positive drug tests 12-months post-consent. These results while encouraging, were tempered by a low compliance rate, with only about one-quarter of the Vivitrol group reaching the six-dose milestone.

RECOMMENDATIONS

The findings from this pilot project provided some insights in possibly expanding the use of Vivitrol in San Diego County moving forward. The following are recommendations put forth based on these results.

EXPAND THE SCALE AND SCOPE OF VIVITROL USE: The intention of the pilot project was to test the waters of using Vivitrol in the courts. The outcomes of the small sample and feedback from clients and program partners indicate support for expanding Vivitrol use to other courts and populations. Increasing the sample size of the study will greatly improve local understanding of factors leading to success and refinement of implementation.

INCREASE VIVITROL AND DRUG TREATMENT RETENTION: Those individuals in the Vivitrol group who received the full dosage of Vivitrol (six or more injections) demonstrated decreased urge to use, did not relapse, and did not reoffend. These positive results are consistent with other research and suggest the need to explore methods to improve retention. Understanding the reasons for attrition could inform this process, including testing different modalities of administering Vivitrol (e.g., in custody versus in the community) and the associated psychosocial therapy (e.g., outpatient versus residential placement).

INCREASE MONITORING OF VIVITROL USE AMONG CLIENTS: While the data are limited, the results suggest that an older, more motivated client might be more prone to success. In addition, a few clients had side effects from Vivitrol, which could be a factor inhibiting success. These two possible predictors of success should be examined more closely if the project continues.

EXPAND THE SCOPE OF THE RESEARCH: The evaluation was limited in its power to

detect significant changes. Increasing the sample size, gathering additional data on treatment services received, including a cost analysis, and instituting stricter guidelines for the comparison group would greatly increase the robustness of the study and allow for stronger analysis and conclusions.

RESEARCH LIMITATIONS

As noted earlier, the evaluation design was limited by several real world constraints. These limitations prohibit the generalizing of the results, but still provide practical findings that encourage further use and monitoring of Vivitrol. Below is a list of the limitations, which should be viewed through the lens that the study was intended as the first step of a more rigorous design.

- ***No Random Assignment:*** Because random assignment was not feasible for this study, the comparison group was selected through a sample of convenience and were not identical to the Vivitrol group. This difference limits the ability to eliminate covariates that could be accounting for any differences (other than Vivitrol) between the two groups.
- ***Small Sample:*** The very small sample limited the use of tests of significance and findings on associations or correlations. It also meant that changes within the sample population, such as loss of contact or use of another anti-dependent pharmaceutical, had substantial impact on the overall analysis because of the large proportional effect on the totals.
- ***Lack of Treatment Data:*** The recommended use of Vivitrol is that it occurs in conjunction with treatment, with the treatment viewed as a critical component in the success of an individual returning for their injections. Because of this symbiotic relationship, it is essential to any comprehensive evaluation of Vivitrol to include treatment data (i.e.,

type, quality, and level) in the design. This level of documentation was not feasible for this pilot project and therefore, inhibited the identification of other possible factors that could be influencing the outcomes. Inclusion of this type of information would make for a more robust study and is recommended for future research.

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