Los Angeles County Evaluation System (LACES): An Outcomes Reporting Program

Vivitrol Evaluation Pilot Results

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Executive Summary

Vivitrol is the injectable form of naltrexone, an opioid receptor antagonist that acts by blocking the mu-opioid receptors in the brain. These receptors are responsible for the “high” or “buzz” individuals feel when alcohol is consumed. When the receptors are blocked, the “high” or “buzz” is no longer achievable and cravings for alcohol are reduced significantly. This paper documents results from a pilot project in Los Angeles County to administer Vivitrol in three large, publicly funded treatment organizations in Los Angeles County. The pilot was designed and implemented by the Los Angeles County Department of Public Health, Substance Abuse Prevention and Control (SAPC). Data regarding the amount of medication doses administered, clients’ urge to drink, side effects, treatment utilization, and treatment outcomes indicate the following:

- Out of the 399 individuals who were provided Vivitrol, 41.1% have taken a single dose thus far. An additional 22.6% participants were administered a second dose, 12.3% had a third dose, and almost 25% had four or more doses.
- Clients’ reported urge to drink decreased significantly over the course of the first month in treatment. The mean score at baseline was 19.3, which decreased to 9.8 in week two, 7.6 in week three, and 6.6 in week four. A score of 10 or more is a sign that the person is in danger of relapse.
- Of the clients who received at least one dose of Vivitrol, 60.2% were in active treatment when Vivitrol was administered, 12.7% were in detoxification, and 27.1% had received Vivitrol but were not active in treatment within the county-contracted system during the time the doses were administered.
- The majority of clients (91.6%) who were admitted to detoxification and were administered Vivitrol, completed the detoxification episode. This is significantly greater than the county average for completed detoxification episodes (76.5%).

- Clients in outpatient counseling who received Vivitrol, reduced their primary drug use from a mean of 11.7 (*SD* = 8.9) days in the 30 days prior to admission to 1.3 (*SD* = 4.9) days during the prior 30 days at discharge.
- Treatment engagement was better for outpatient counseling clients in the Vivitrol pilot (88.2%) as compared to the county average (79.6%), as were treatment completion rates (46.6% compared to 32.9%).
- Clients in residential treatment who received Vivitrol reduced their primary drug use from a mean of 13.8 (*SD* = 8.8) days in the prior 30 days at admission to 0.9 (*SD* = 4.3) days during the prior 30 days at discharge treatment.
- Treatment engagement was also better for residential clients in the Vivitrol pilot (94.3%) as compared to the county average (64.2%), as were the treatment completion rates (64.1% compared to 39.2%) for residential treatment.
- Although there was no difference in retention rates for clients in outpatient counseling (mean days in treatment), retention rates were higher for clients in the Vivitrol group participating in residential treatment (121.3 days) compared to the county average (78.2 days).
- The most common side effects reported for Vivitrol included fatigue, headache, injection site reaction, and nausea. The proportion of clients reporting these side effects differed over the first four weeks of treatment, with side effects reaching a high point in week two with 22.4% reporting fatigue, 18.7% reporting headache, 19.2% reporting injection site reaction, and 15.7% reporting nausea. As of December 2011, only 12 clients (3%) have stopped taking the medication due to side effects.

Overall, the Vivitrol pilot in Los Angeles County substance use disorder treatment programs proved to be quite successful at increasing the number of clients who completed treatment in detoxification, outpatient counseling, and residential treatment programs. Vivitrol also appeared to

- decrease substance use among outpatient counseling and residential treatment clients,

- increase treatment engagement among outpatient and residential clients, and
- increase treatment continuance for residential treatment clients.

However, more research is needed to determine the long-term effects of Vivitrol (i.e., do the cravings go away for good or do they return, and if so, are they at the same level). Furthermore, limitations to the findings in this report include the population under study. A more varied population would add additional external validity to the findings.

Vivitrol Evaluation: Pilot Results

Addiction counseling, behavioral treatments, and self-help groups are the primary interventions used to treat alcohol dependence in the United States (Garbutt et al., 2005). Although these treatments are often effective, a substantial number of patients fail to complete treatment or relapse. Although pharmacotherapies are now available for the treatment of alcohol addiction, adherence to daily oral pharmacotherapies is limited (Garbutt et al., 2005). Furthermore, negative counselor attitudes toward the use of medication and the sometimes high cost of the medication may further limit the feasibility of implementing a medication-assisted treatment program for substance use disorders (Ciraulo, et al., 2008; Kolko, Hoagwood, & Springgate, 2010; Thomas et al., 2011). This paper reviews the findings of a pilot study examining the feasibility of the use of Vivitrol (a long-acting, injectable form of naltrexone) for clients in publicly funded substance use disorder programs in Los Angeles County.

In 1994, naltrexone was approved by the U.S. Food and Drug Administration (FDA) to treat alcohol dependence, after the medication was shown to reduce drinking frequency and the likelihood of relapse to heavy drinking (Garbutt et al., 2005). Although effective, naltrexone was seldom used as a primary or secondary treatment option due to medication adherence issues. Analysis of pharmacy data indicates that among insured patients who fill a first prescription for oral naltrexone, a large proportion does not return to refill the prescription (Ciraulo, et al., 2008). In 2006, the injectable, extended release naltrexone (under the brand name “Vivitrol,” formerly known as “Vivitrex”) was approved by the FDA for the treatment of alcohol use disorders. In conjunction with psychosocial support, Vivitrol is approved for the treatment of alcohol dependence in patients who are able to abstain from alcohol prior to treatment initiation (Pettinati, & Rabinowitz, 2006). In 2011, Vivitrol was also approved for the prevention of opiate dependence relapse.

Vivitrol is a full mu-opioid receptor antagonist that may reduce alcohol’s ability to stimulate this receptor thus inducing pleasure when alcohol is consumed (Garbutt et al., 2005;

Lee et al., 2010; Pattianai et al., 20010 Schmitz et al., 2001). Several studies have found that Vivitrol may be beneficial in the treatment of alcohol dependence by reducing the number of risky and heavy drinking days and improving individuals' quality of life (Garbutt et al., 2005; Lee et al., 2010; Mannelli, Peindl, Masand, & Patkar, 2007; Pettinati, & Rabinowitz, 2006; Schmitz et al., 2001).

For several years, Vivitrol has been used in the private sector and by those with sufficient insurance; however, access to the medication is limited due to its high cost ($750–$1,200/month). There is limited literature regarding the implementation of Vivitrol in a county-funded treatment setting; however, research indicates low utilization of medication-assisted treatment (MAT) among publicly funded treatment programs (Knudsen, Ducharme, & Roman, 2006, 2007). This low rate of utilization indicates a disparity among individuals treated by publicly funded programs who have limited access to evidence-based practices compared to individuals receiving care in the privately financed system (Rodgers & Barnett, 2000).

Given that the majority of treatment services are delivered by publicly funded agencies, understanding the barriers to medication adoption in this sector is critical. A recent study published by Knudsen, Abraham, and Oser (2011) reported that community-based programs that offer MAT tend to employ physicians and nurses, whereas providers who do not offer such treatment are less likely to have physicians and nurses on staff. Additionally, among providers who do not provide MAT, top barriers include regulatory prohibitions, funding restrictions, and lack of access to medical personnel with expertise in delivering medication-assisted treatment (Knudsen et al., 2011). Interestingly, barriers related to insufficient information about MAT and unsupportive staff attitudes were not widely endorsed (Knudsen et al., 2011). Thomas, Wallack, Lee, McCarty, and Swift (2003), on the other hand, found that physicians reported barriers such as inadequate knowledge about the medication, followed by a lack of sufficient evidence regarding effectiveness.

This paper documents results from a pilot project in Los Angeles County to administer Vivitrol in three large, publicly funded treatment organizations in Los Angeles County. The pilot was designed and implemented by the Los Angeles County Department of Public Health, Substance Abuse Prevention and Control (SAPC). Prior to this pilot, Vivitrol had not been available to most patients served by SAPC-contracted treatment agencies; however, some private pay clients did have access to the medication. The following questions are addressed in this paper:

- How many clients were willing to take multiple doses of Vivitrol?
- How did the urge to drink change from baseline (prior to the first Vivitrol injection) to week 1 (post Vivitrol injection) to week 2, week 3, and finally week 4?
- What side effects were reported?
- How many clients admitted to outpatient or residential treatment were engaged (remained for 30 days or more)?
- What was the mean length of stay of clients who took at least one Vivitrol dose?
- What changes in substance use (alcohol and/or opiates) were reported by the clients?
- How many clients completed treatment?

In addition, counselor attitudes toward MAT in general, and Vivitrol specifically, were also assessed before and after trainings were provided on Vivitrol.

Methods

The pilot allowed for the collection and analysis of information concerning alcohol use days, side effects, medication-protocol adherence, counselor attitudes, etc., to evaluate whether and to what degree Vivitrol helped to improve client outcomes. An additional area of interest was to determine if training, education, and technical assistance results in changes in counselor attitudes toward the use of medication in substance use disorder treatment settings.

Participants

A total of 1,014 doses were administered to 399 clients. However, due to errors in data collection, Los Angeles County Participant Reporting System (LACPRS) information was collected on only 387 clients (97%). Of these 387 individuals, about half were male (50.4%). The mean age of the clients was 38 years (*SD* = 10.3). The racial/ethnic breakdown was as follows:

- 205 (53%) White
- 124 (32%) Hispanic/Latino
- 38 (9.8%) African American
- 5 (1.3%) Asian American/Pacific Islander
- 3 (0.8%) Native American
- 12 (3.1%) of mixed race, "other" race, or declined to specify.

About a quarter of the clients (24.8%) received treatment in detoxification facilities. An additional 28.7% were in outpatient counseling treatment, and the remaining 46.3% were in residential treatment. A single individual (0.2%) was enrolled in narcotic treatment when receiving treatment for Vivitrol. Tarzana Treatment Centers dispensed most of the doses (70.0%), followed by Behavioral Health Services (18.8%), and Prototypes (11.2%).

Measures

The data collected to assess the feasibility of the use of Vivitrol in county-contracted SUD treatment programs included the client responses to the LACPRS admission and discharge questions, which measure a wide variety of information on the people who receive alcohol and other drug services in Los Angeles County. Additional information was gathered from the Urge to Drink Scale (Flannery, Volpicelli, & Pettinati, 1999) and a third scale (The Medication Assisted Treatment Survey) developed for the purposes of this evaluation. Counselor knowledge of and attitudes toward the use of medications was also assessed with an instrument developed for use with this evaluation. It should also be noted that because Vivitrol

was approved for opiate dependence in 2011, a small number of opiate users were included in the analysis.

Los Angeles County Participant Reporting System (LACPRS)

The Los Angeles County Participant Reporting System (LACPRS) is a county-mandated data collection system that provides admission, discharge, and outcome data for all patients served by county funds. LACPRS was designed to measure changes in the functioning of treatment participants from admission to discharge. To determine the impact of Vivitrol on outcomes, data was collected from the LACPRS admission and discharge questions and the available encounter data. This database was used to determine participant demographics, reported primary and secondary substances of choice, length of stay in treatment (or "treatment engagement"), prior treatment episodes, and treatment outcomes of Vivitrol patients at one of the three hubs providing the medication. Additionally, LACPRS provided quality of life measures such as employment, homelessness, social support, and medical problems.

Urge to Drink Scale

The Urge to Drink scale has been used in several studies to determine differences in craving scores after medication-assisted treatment (Flannery et al., 1999). This assessment, which after being tested for psychometrics was found to have good internal consistency (Flannery et al., 1999), contains five questions about cravings: frequency, duration, time spent thinking about drinking, craving severity, difficulty resisting, and overall craving. Each question is rated from 0 to 6, with 6 indicating the highest severity. A cumulative score from 0 to 30 is derived. A score of 10 or more is a sign that the person who completed the Urge to Drink scale is in danger of relapse. A copy of this scale is located in Appendix A.

Medication-Assisted Treatment Survey

Prior studies have shown that injection site reaction (painful or a painless nodule) was the most commonly described adverse event related to Vivitrol (Garbutt et al., 2005). Garbutt et al. (2005) also found that discontinuation due to adverse events occurred in 14.1% of the 380-

mg group, 6.7% of the 190-mg group, and 6.7% of the placebo group. In Lee et al. (2010), five out of 65 participants (7.7%) discontinued treatment due to side effects. To assess the possible reasons for discontinuation, UCLA developed the Medication-Assisted Treatment (MAT) Survey. This survey assessed craving reductions in secondary substances used, side effects, and benefits and disadvantages of Vivitrol use. A copy of this survey is located in Appendix B.

Counselor and Staff Attitudes

Counselor and staff attitudes toward medications and new therapies can influence their clients' participation in a new form of therapy. Therefore, UCLA measured counselor attitudes at the beginning of the project. Counselor attitudes were measured again four months after the program staff had participated in education sessions regarding Vivitrol, its uses and effects. This data point was also selected because it provided counselors and staff with an opportunity to observe the impact of medication on their clients. A copy of this survey is located in Appendix C.

Procedures

Three agencies were selected by SAPC to act as "medication hubs" in the pilot (Tarzana Treatment Centers, Behavioral Health Services, and Prototypes). Each hub was selected because it had the infrastructure (staff, examination room, refrigerated and locked location for medication storage) in place to administer medications and had long-standing histories of providing quality substance abuse treatment to a broad range of clients. It was further determined that Tarzana Treatment Centers had the infrastructure and the equipment necessary to manage the Vivitrol doses. As a result, Tarzana Treatment Centers was designated as the "central medication hub," where the medication would be received from Alkermes (the company that makes Vivitrol) and shipped to the other two agencies. Behavioral Health Services and Prototypes requested Vivitrol doses as needed.

In addition to serving their own clients, each of the medication hubs worked with other SUD treatment organizations to administer Vivitrol. A memorandum of understanding was

developed between the hub and the referring organization whereby the referring organization agreed to transport the client to the hub site for the initial physical exams and testing. The medication hubs were then responsible for administering any required medical tests prior to administering Vivitrol, communicating with the clients regarding any question or concerns they had about the medication, and collecting the information required for the evaluation.

Although the medication hubs collected information from clients as part of the Vivitrol pilot, the referring program retained the client for psychosocial treatment. In other words, the referring program continued to provide counseling as usual and other treatment-related services but were responsible for providing transportation to the medication hub so that as many clients as possible, including those not receiving SUD treatment at one of the hubs, could take part in the Vivitrol pilot.

At admission to treatment, clients completed intake forms that were reviewed to determine if they might be candidates for participation in the project (e.g., designation of alcohol as either their primary or secondary substance use problem and/or a score of at least 10 on the Urge to Drink Scale). Clients designated as eligible were informed of the availability of the medication and asked if they would be interested in participating in the pilot. If they agreed, the clients were then scheduled to meet with the medical staff to learn more about Vivitrol and to complete any medical tests.

All clients were required to be examined by a physician or other medical professional (e.g., physician assistant) as part of the screening process. In addition, Behavioral Health Services and Prototypes required blood panels on all clients to screen for elevated liver enzymes or other indications that the client would not be a good candidate for Vivitrol prior to their acceptance into the pilot. At Tarzana Treatment Centers, although clients received a physical exam, they were not required to complete the blood panel to be considered eligible; rather, the decision whether to complete the blood panel was determined by the physician.

Upon receiving medical clearance from the physician, an appointment was made between the client and the medical professional who would administer the dose (e.g., nurse, MD, etc.). In addition, the required evaluation forms (the Urge to Drink Scale and the Medication Assisted Treatment Survey) were completed. At the time of their appointment, clients received their first injection, were provided the evaluation surveys and additional medical forms to complete, and were scheduled for follow-up appointments. The hubs coordinated with the referring program to arrange a time—once a week for the first four weeks and monthly thereafter—to collect the information required for the evaluation. The clients actively remained in treatment at the site where they were originally admitted and continued to go to that program for all of their substance-use related treatment.

Training Sessions

The implementation of a new therapeutic technique can be challenging, given the resistance to change that many counselors and other treatment program staff may experience in the process (Kolko et al., 2010; Thomas et al., 2011). Furthermore, counselors and/or staff sometimes confuse the effects of Vivitrol with other medications. To address this, trainings and technical assistance were made available to all providers and staff on an ongoing basis.

Each training session included representation from SAPC, UCLA, and Alkermes. Specifically, Dr. James Barger, (SAPC's Medical Director) was present to discuss the importance of the use of medication-assisted treatments, why SAPC became interested in medications, and how the pilot projected would be implemented. In addition, at some agencies specific staff members were designated as Vivitrol pilot contacts and provided some information on Vivitrol (e.g., Ken Bachrach at Tarzana Treatment Centers). The staff from Alkermes presented the research behind the medication, how it differs from oral naltrexone, its side effects, and additional details on the medication (indicated populations, black box warnings, etc.). The UCLA staff explained the evaluation process and the need to collect additional data to

examine the impact of Vivitrol on the clients receiving treatment in the county system and provide SAPC data to justify future use and funding of Vivitrol as a treatment.

Trainings were scheduled with each hub site and at other sites that expressed interest in learning more about the medication. The trainings were held multiple times at the hub sites to obtain a good "saturation" rate among the staff and counselors. Informational meetings were also scheduled with agencies that were interested in learning more about Vivitrol but had not made the decision whether to implement medications in their agency.

As of December 1, 2010, over 60 trainings and informational meetings had been conducted at approximately 25 sites since the inception of this project in April 2010. Technical assistance calls were held to inform agencies of the best practices for injecting the medication to ensure the least amount of discomfort for clients. Additional meetings were also held with various stakeholders and other community groups to provide education about the use of Vivitrol (see the Training and Technical Assistance section in this report for further details). At the conclusion of the training, counselor and staff e-mail addresses were collected in order to administer, via e-mail, the counselor survey as part of the evaluation.

Results

There were several questions that needed to be addressed by this pilot. The first of which was, how many clients would take more than a single dose of Vivitrol? Previous research has indicated that medication adherence, particularly with naltrexone, can be problematic. This pilot, however, found that over half (58.9%) of all clients took two, three, or more doses of Vivitrol over the course of their treatment. Out of 399 individuals who were provided Vivitrol, 164 (41.1%) had taken only a single dose of Vivitrol when the data for this report was collected and analyzed (August, 2011); however, it must be noted that some of these individuals may not have yet been eligible for a second dose at that time. An additional 90 (22.6%) were administered a second dose, 49 (12.3%) had a third dose, and 96 (almost 25%) had four or more doses of Vivitrol (see Table 1). Based on these data, it appears that the persistence rate

for Vivitrol is significantly higher than that noted for naltrexone. Prior research on naltrexone demonstrated a refill rate of 14.2% (Kranzler, Stephenson, Montejano, Wang, & Gastfriend, 2008) whereas in this pilot, almost 60% of the participants were administered a second dose of Vivitrol.

Medication Doses and Urge to Drink

For the first four weeks after the first injection, clients' urge to drink and medication side effects were assessed. It must be noted that not every client completed the weekly assessments; thus, the availability of weekly data varies across the four weeks. In addition, in some cases the questions on side effects on the Medication Assisted Treatment (MAT) scale were left blank. It could be inferred from this that considering that the rest of the survey was completed, the lack of completed information on side effects (none of the side effects listed on the survey were endorsed) means that the clients did not experience these side effects; however, this may be an erroneous assumption. Thus, the side-effect information may not reflect all clients who experienced side effects, but rather only those clients who chose to report side effects. To be as conservative as possible in the interpretation of the data, the only surveys included in the following analyses were the ones in which the questions were answered.

Urge to Drink Scores

According to the Urge to Drink scale (Flannery et al., 1999), clients' reported urge to drink decreased significantly over the course of their first month in treatment. As noted in Chart 1, the mean score at the baseline was 19.3, which then decreased to 9.8 in week two, 7.6 in week three, and finally 6.6 in week four. As noted above, a score of 10 or more is a sign that the person who completed the Urge to Drink scale is in danger of relapse. The decrease in the scores indicates that the clients' urge to drink went from a clinically significant score to a score within the range noting little danger of relapse.

Side Effects

The most common side effects reported for Vivitrol included fatigue, headache, injection site reaction, and nausea. The proportion of clients reporting these side effects differed over the first four weeks of treatment, with few reporting side effects in the first week (13.9% fatigue, 15.2% headache, 10% injection site reaction, and 14.9% nausea). The side effects reached a high point in week two with 22.4% reporting fatigue, 18.7% reporting headache, 19.2% reporting injection site reaction, and 15.7% reporting nausea. In week three, clients reported side effects at the same rate or lower than that reported in week one (11.4% fatigue, 12.9% headache, 10.4% injection site reaction, and 12.9% nausea). And in week 4, side effects were reported by less than 10% of the clients (7% fatigue, 7.7% headache, 5.7% injection site reaction, and 7.5% nausea) as noted in Chart 2. As of December 2011, only 15 clients (3.8%) stopped taking the medication due to side effects.

Treatment Utilization and Vivitrol

Of the 387 clients (admission and discharge data could not be located on 12 clients) who received at least one dose of Vivitrol, 60.2% (*n* = 233) were in active treatment when Vivitrol was administered. An additional 49 (12.7%) participated in detoxification services but did not enroll in additional county-funded treatment (e.g., outpatient counseling or residential treatment). The final 105 (27.1%) participants received Vivitrol but were not active in any form of treatment within the county-contracted system during the time the doses were administered. However, these clients had been in treatment at some point as indicated by the availability of prior admission and discharge data, and may have taken part in social support related activities such as Alcoholics Anonymous (AA) meetings. Both demographic and treatment completion information is available on those clients who participated in detoxification, whereas demographic, treatment completion information, and outcomes are available for those clients who participated in treatment.

Treatment Completion: Detoxification Clients

Several clients received a Vivitrol dose either during a detoxification episode or approximately one to two weeks after the conclusion of the detoxification episode. Half of the clients (51%) described in this section were admitted and discharged from a detoxification program but were not admitted to further treatment (outpatient or residential). The other half were also admitted to either outpatient counseling or residential services, in addition to the detoxification treatment. Those admitted to further treatment will also be examined in the next section "Treatment Clients."

A total of 96 clients (67.7% males) were admitted to detoxification. The mean age was 39.8 years (*SD* = 10.6). The racial/ethnic breakdown of the detoxification clients was 67.7% White, 22.9% Hispanic/Latino, 2.1% African American, 2.1% Asian American/Pacific Islander, 1% Native American, and 4.2% "other," mixed, or unknown race.

The majority of this group reported alcohol as their primary drug (74%), with an additional 15.6% reporting heroin as their primary drug (See Chart 3). Of those who did not report alcohol as their primary drug, 7.3% reported alcohol as their secondary drug.

The majority of clients (91.6%) who were admitted to detoxification and were administered Vivitrol completed the detoxification episode. This is a significantly higher completion rate than that for detoxification clients (70.1%) during the 2010–2011 fiscal year (Tom Tran, SAPC, 2011, personal communication).

Treatment Outcomes: Outpatient and Residential

A total of 233 clients (43.3% males) were admitted to treatment (beyond detoxification) while also receiving Vivitrol. Their mean age was 37.9 years (*SD* = 10.3). The racial/ethnic breakdown of the treatment clients was 44.2% White, 38.6% Hispanic/Latino, 12.9% African American, 0.9% Native American, and 3.4% "other," mixed, or unknown race. There were no Asian American/Pacific Islander clients who participated in treatment and received Vivitrol.

Over half of the clients who entered treatment reported alcohol as their primary drug (56.7%), with an additional 11.2% reporting heroin as their primary drug (See Chart 4). Of those who did not report alcohol as their primary drug, 17.6% reported alcohol as their secondary drug.

Days of primary substance use were also examined for those clients who reported any use of their primary substance during the 30 days prior to admission to treatment (*n* = 131). Clients reported significant decreases in the use of their primary substance during the month prior to treatment discharge, which averaged 2.2 days (*SD* = 6.3) when compared to the average days of use during the 30 days prior to treatment admission (14.1 days; *SD* = 9.4). Please see Chart 5.

The majority of the clients were engaged in treatment (90.6%), which is a higher proportion when compared to the overall proportion of clients engaged during the 2010–2011 fiscal year (75.6%) in the county. Almost two thirds of the clients who received Vivitrol completed treatment (63.5%). This is almost twice the number of clients who completed on average (33.6%) according to the 2010–2011 LACPRS.

Outpatient Counseling

Clients in outpatient counseling who also received Vivitrol fared better in treatment than other clients in outpatient counseling who did not receive Vivitrol. Days of primary drug use for clients taking Vivitrol was reduced from a mean of 11.7 (*SD* = 8.9) at admission to 1.3 (*SD* = 4.9) at discharge from treatment. This is in comparison to a mean of 6.9 (*SD* = 9.7) days at admission and 2.4 days (*SD* = 6.2) at discharge for the county average during the 2010-2011 fiscal year.

Length of stay for clients in outpatient counseling who also participated in the Vivitrol pilot (130.1 days; *SD* = 94.8) did not differ significantly from the county average for length of stay for clients in outpatient counseling (132.6 days; *SD* = 132.8).

Treatment engagement was better for clients in the Vivitrol pilot (88.2%) as compared to the county average (79.6%), as were treatment completion rates (46.6% compared to 32.9%).

Residential Treatment

Similar to the results for outpatient counseling, clients in residential treatment who received Vivitrol had better outcomes when compared to other clients in residential treatment who did not receive Vivitrol. Days of primary drug use for clients taking Vivitrol were reduced from a mean of 13.8 (*SD* = 8.8) at admission to 0.9 (*SD* = 4.3) at discharge from treatment. This is in comparison to a mean of 10.4 (*SD* = 11.3) days at admission and 2.1 days (*SD* = 6.1) at discharge for the county average during the 2010-2011 fiscal year.

Unlike for outpatient counseling, the length of stay for clients in residential treatment who participated in the Vivitrol pilot (121.3 days; *SD* = 70.3) was higher than the county average for clients in residential treatment (78.2 days; *SD* = 96.5).

Treatment engagement was better for residential clients in the Vivitrol pilot (94.3%) as compared to the county average for the 2010-2011 fiscal year (64.2%), as were treatment completion rates (64.1% compared to 39.2%).

Changes in Staff Attitudes and Knowledge

The second part of the evaluation involved an analysis of responses to the counselor initial and follow-up surveys. The results of the qualitative analysis of counselor surveys were organized and arranged into the following categories: attitudes toward psychotropics, experience with medication-assisted treatment (MAT), experience with Vivitrol, counselor concerns, and client feedback. Results and supporting quotes from interviewees are presented below.

Attitudes Toward Psychotropics

Because many substance abuse treatment centers work with clients who have a co-occurring psychiatric disorder, it is not uncommon for psychotropic medications to be incorporated into a treatment plan. As a result, more substance abuse counselors are being

exposed to the idea of medication-assisted treatment for those with substance abuse disorders than in the past. While it is assumed that counselors would support the use of psychotropics to improve a client's overall well-being and substance abuse recovery, this evaluation asked about their attitudes toward the use of medications for mental health disorders (such as depression and anxiety) for clients in substance abuse treatment. The overwhelming majority of respondents (91%) had a positive attitude toward the use of psychotropics and indicated that they believed psychotropics can benefit clients. The following are quotes from two respondents:

> *I agree with the use of psychotropics. Both health and substance abuse/dependence disorders are in need of being treated together for a positive outcome.*

> *I think a big percentage of the problem along with substance abuse is also their dual diagnosis, which also needs to be addressed. So I'm very for substance abuse treatment facilities that work closely with [the] dually diagnosed.*

A small percentage of counselors indicated neutral or negative attitudes toward the use of psychotropics for mental health needs among their alcohol and other drug clients. These counselors stated that they either needed more empirical support to form an opinion or that they were apprehensive in creating what they saw as a potential complication by introducing medication.

> *I think it is helpful when needed but at times it seems as if the medication is more of a problem than as [an] assistant.*

Experience with Medication-Assisted Treatment

Counselors were also asked about their experience with, and knowledge of, medication-assisted treatments. Over half (58%) had such experience, and those with experience knew the basics of its purpose.

> *[*Medication-assisted treatments *can lead to] increased success rates with reduced risk of relapse in early sobriety/abstinence.*
>
> *It can definitely assist with craving, mental status.*
>
> *It is a great intervention tool for patients whose withdrawal or urge symptoms impair the ability to allow them to get a fair chance at recovering.*

When asked their opinions on the use of medication-assisted treatments, some respondents were positive, while others expressed more negative attitudes.

> *It's a pro-active and positive way to manage all aspects of a patient's disease.*
>
> *I think medication-assisted treatment is good for clients who need the help to cope during the early recovery period.*
>
> *[Medication-assisted treatment] includes giving methadone to heroin addicts. It is giving a drug to a person who had a drug problem to fix the problem.*
>
> *Sometimes I see clients who are overmedicated; often this can hinder treatment and [they] may become stuck!!!*

Experience with Vivitrol

This evaluation also inquired about counselors' knowledge of and experience with Vivitrol before and after the trainings provided in this pilot project. Findings revealed that those who had knowledge of the drug knew key facts/information about it.

> *Vivitrol is a dose of naltrexone given by injection to release over a 30-day period to reduce cravings and urge to drink for alcohol dependents.*

> *[It] helps block the cravings for alcohol in the part of the brain that drugs and alcohol give pleasure to.*

> *I know Vivitrol offers alcoholics a high[er] chance of recovery and reduces a person's cravings and helps to maintain sobriety. I know each dose is given intramuscularly and lasts 4 to 6 weeks. Vivitrol targets the limbic region of the brain by blocking the opioid receptors, which can prevent excessive opioid release.*

When counselors were asked for their responses to clients who requested Vivitrol, many responded that they referred the client to a physician or someone with more training and experience. Those who felt adequately informed indicated they would explain the medication and its effects to the client.

> *Vivitrol is an option for patients who are unable to remain abstinent and who feel the need to have medication assistance to prevent future cravings and reduce the chances of relapse. Vivitrol used together with counseling and psychotherapy has proven to result in positive outcomes and the ability to remain abstinent. Vivitrol is given accordingly to the patient [with] consent.*

In regard to identifying clients who would benefit from Vivitrol, nearly all counselors indicated that they would use some sort of assessment such as the Urge to Drink scale or identify patients based on their history or inability to maintain focus. The following quotes are from two respondents:

The Urge to Drink scale is a good indicator to assess a client for Vivitrol treatment.

Anyone who has trouble stopping their alcohol consumption once started, (is) hav[ing] more than 4 drinks per day; someone who is constantly thinking about having a drink throughout the day [and] hav[ing] trouble processing triggers and cravings (or) want(s) to stop drinking but cannot on their own.

Counselor Concerns and Client Feedback

Overall, about 70% of counselors indicated that they would recommend Vivitrol. However, concerns about the medication included:

1. The drug's effectiveness,
2. Its effect on the liver or kidneys,
3. Its cost and availability,
4. The pain involved in getting the shot.

Two respondents indicated that they were unsure whether the Vivitrol trainers were being entirely truthful about the drug. The following are quotes from two respondents:

Trainers have given information about patients not being able to feel the effects of alcohol while on Vivitrol. This is not true. Trainers or advocates need to report truthfully.

Someone can overdose on Vivitrol if they continue to abuse drugs and take a higher dose of drug to feel high.

Counselors who have received feedback from clients have heard mostly positive comments.

Of over 25 clients, one hated it, one wasn't sure, the rest all love it - it's really helped dismiss the craving for alcohol and for some people other drugs including nicotine.

Seventy-eight percent of counselors indicated that they would be interested in more information on Vivitrol.

Conclusions and Implications

The Vivitrol pilot in Los Angeles County substance use disorder treatment programs proved to be quite successful at increasing the number of clients who completed treatment in detoxification, outpatient counseling, and residential treatment programs. Vivitrol also appeared to have an impact on decreasing substance use for outpatient counseling and residential treatment clients, increasing treatment engagement for outpatient and residential clients, and increasing treatment continuance for residential treatment clients.

Side effects were reported by less than a quarter of the clients, and those reported were similar to what one would experience after heavy drinking (e.g., headache, nausea, fatigue) all of which decreased significantly by week 3. In addition, only about 3% of clients stopped use of Vivitrol because of the side effects—an indication that the medication was very well tolerated (Lee et al., 2010). Furthermore, the extensive training and technical assistance provided as part of this project also appeared to help improve treatment staff and counselor attitudes toward the use of medications in substance use disorder programs. All of this information taken together

provides support for the use of Vivitrol in county-contracted substance use disorder treatment programs.

Some of the limitations of this report include the fact that this was an evaluation of the implementation of the medication as well as outcomes from that medication's use. This report does not include any sort of experimental manipulation or a comparison group. All comparisons in this report were based on the county means for all outpatient and residential treatment programs. Future data analyses will include a non-equivalent control group to further examine the outcomes of the clients who participated in the Vivitrol pilot as compared to clients with similar demographics and substance use histories. In addition, the demographics of those who opted to take the medication is not as varied as the population of individuals who seek treatment in Los Angeles County (e.g. fewer Native Americans and Asians). A more varied population would increase the external validity of the results noted here. And finally, the long-term effects of Vivitrol are not known. How long the urges are reduced or eliminated once the medication is no longer being used is currently unknown. Furthermore, if the urges do return, do they return at the same level, a lower lever or a higher level as measured on the Urge to Drink scale and if the urges to use do return, how does enrollment in treatment impact the clients' ability to resist the urges and maintain their sobriety? These issues can be addressed in future research and currently a second pilot is being planned to address many of these issues. Despite these limitations, the results from this pilot are quite promising and demonstrate how the addition of a medication, such as Vivitrol, may be used to further advance the positive impact of substance use disorder treatment.

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Table 1. Participant Characteristics (*N* = 387)

	Overall *N* (%)	Detoxification Participants *n* (%)	Treatment Participants *n* (%)
Total	387 (100%)	96 (24.8%)	233 (60.2%)
Male	195 (50.4%)	65 (67.7%)	101 (43.3%)
Female	192 (49.6%)	31 (32.3%	132 (56.7%)
Race/Ethnicity			
White	205 (53%)	65 (67.7%)	103 (44.2%)
Hispanic/Latino	124 (32%)	22 (22.9%)	90 (38.6%)
African American	38 (9.8%)	2 (2.1%)	30 (12.9%)
Asian American/Pacific Islander	5 (1.3%)	4 (2.0%)	0 (0.0%
American Indian/Alaskan Native	3 (0.8%)	1 (1.0%)	2 (0.9%)
Other	12 (3.1%)	2 (2.1%)	8 (3.4%)
Mean Age	38.0 years	39.8 years	27.9 years

Table 2: Vivitrol Doses by Site for the Total Sample (*N* = 399)

	Total (N = 399)	*Tarzana (n = 290)*	*Prototypes (n = 39)*	*BHS (n = 70)*
Average # of Doses	2.49 ± 2.022	2.47 ± 2.123	2.74 ± 1.831	2.74 ± 1.576
Mode	1	1	2	1
Minimum # of Doses	1	1	1	1
Maximum # of Doses	12	12	7	7
Injections Received				
One Dose Only, % (n)	41.1% (164)	45.5% (132)	28.2% (11)	30.0% (21)
Two Doses Only, % (n)	22.6% (90)	22.1% (64)	30.8% (12)	20.0% (14)
Three Doses Only, % (n)	12.3% (49)	11.4% (33)	15.4% (6)	13.3% (10)
Four or More Doses, % (n)	24.0% (96)	21.0% (61)	25.6% (10)	36.7% (26)

Chart 1: Changes in Urge to Drink Scores for First Month Post Vivitrol Dose

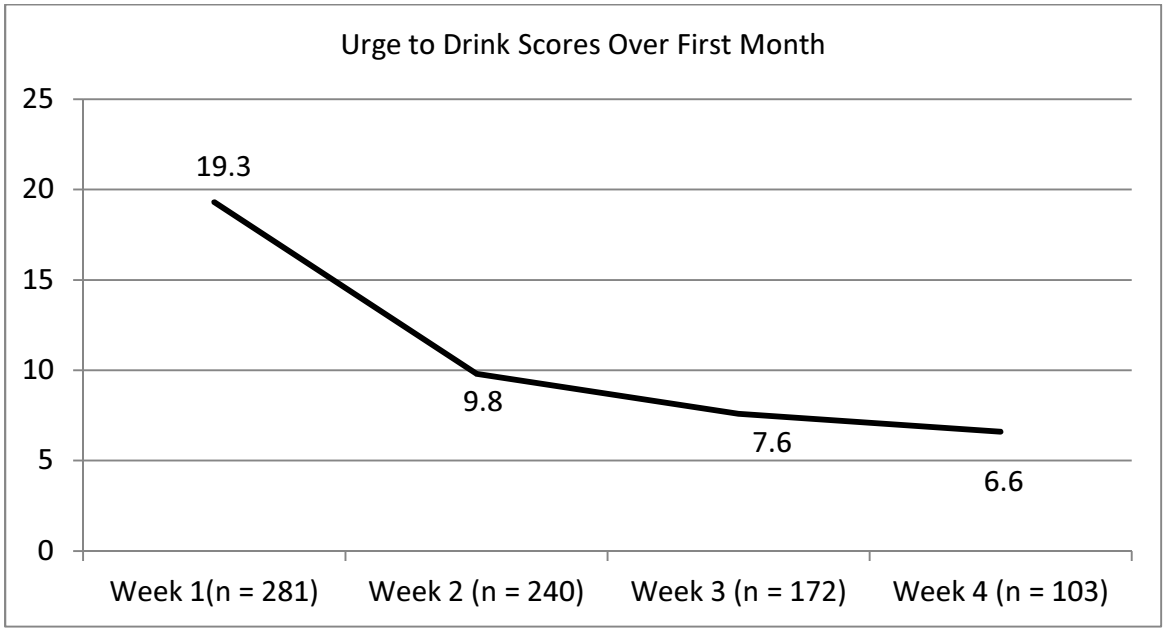


Chart 2: Side Effects for Weeks 1 – 4 After First Dose

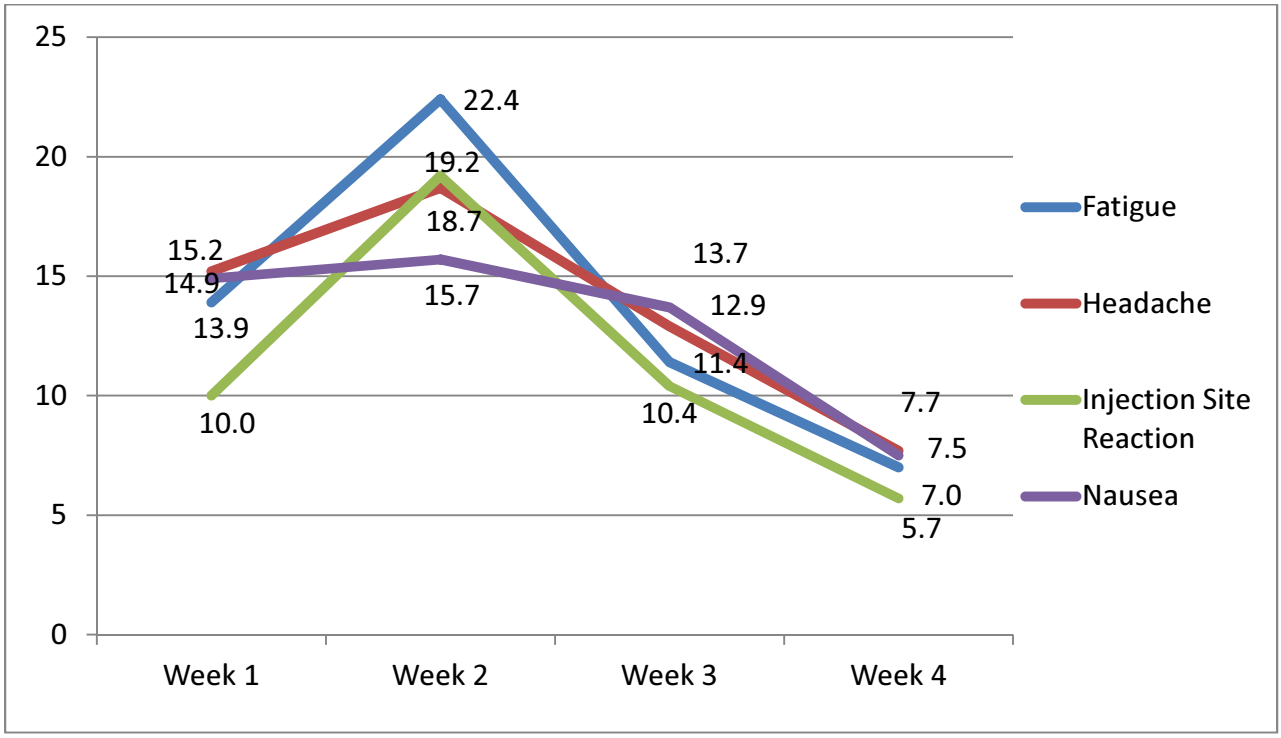


Chart 3: Primary Drug for Detoxification Clients

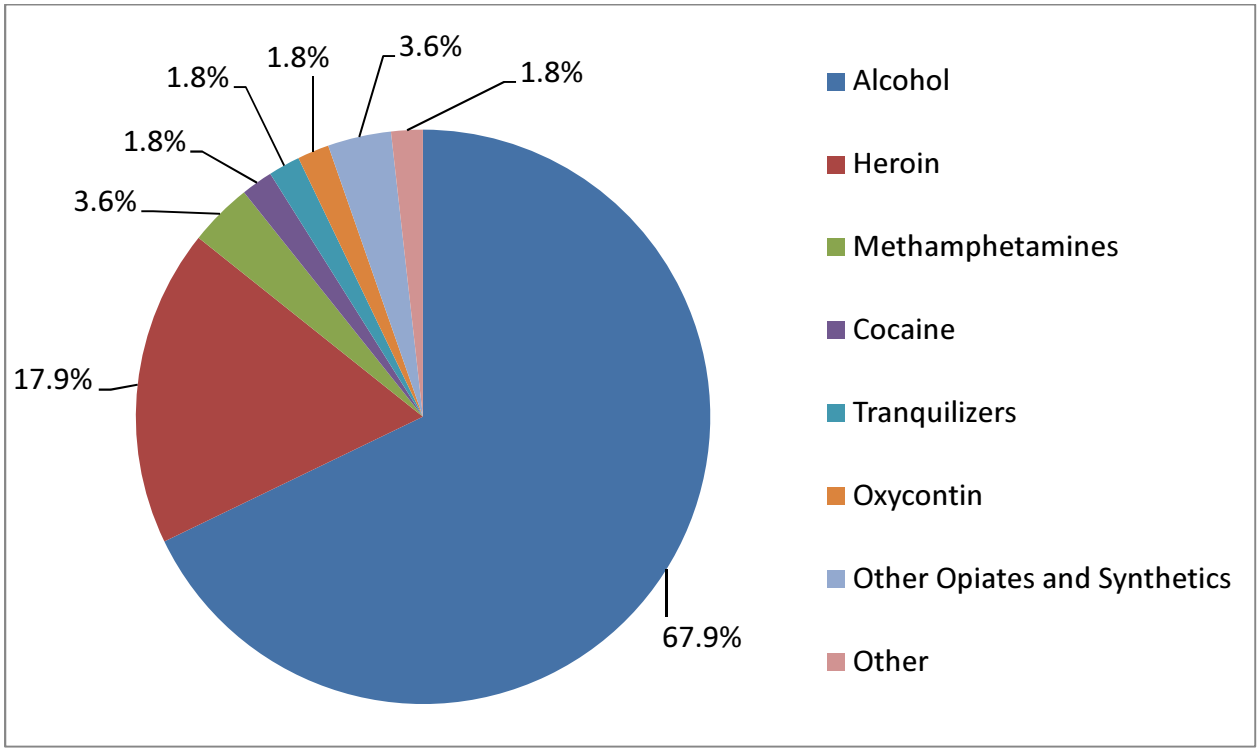


Chart 4: Primary Drug for Treatment Clients

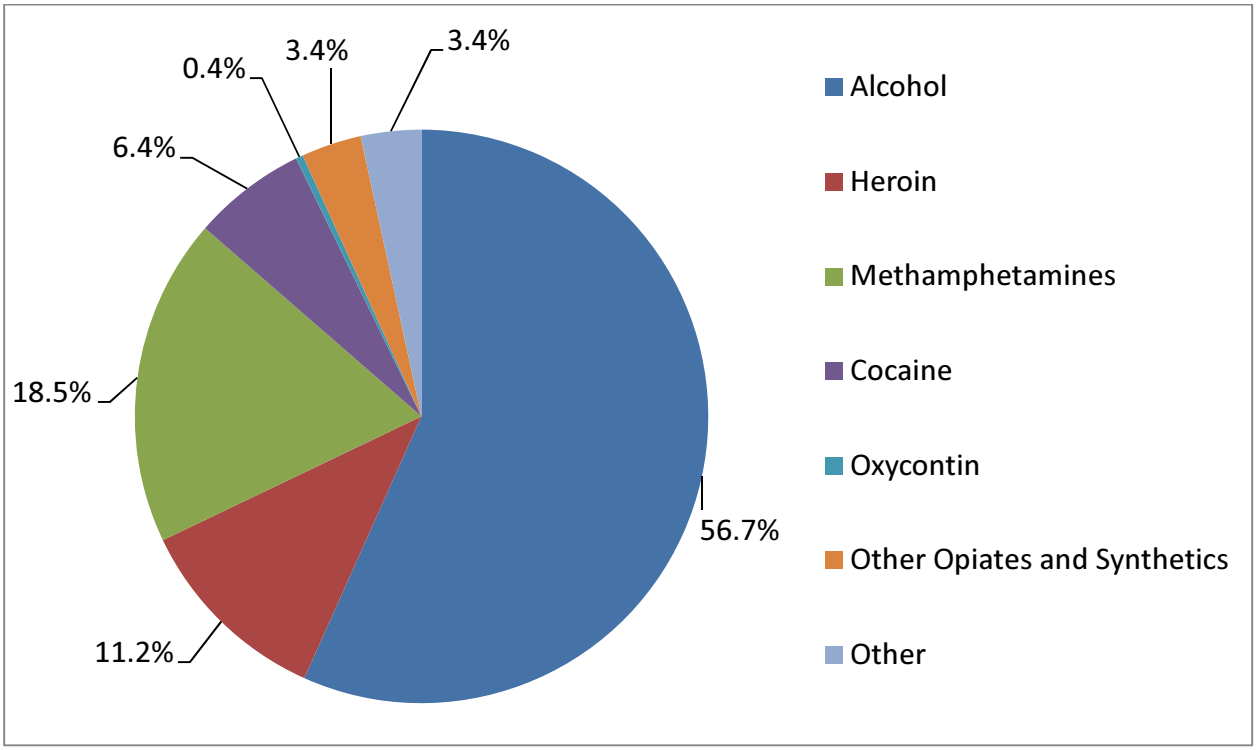
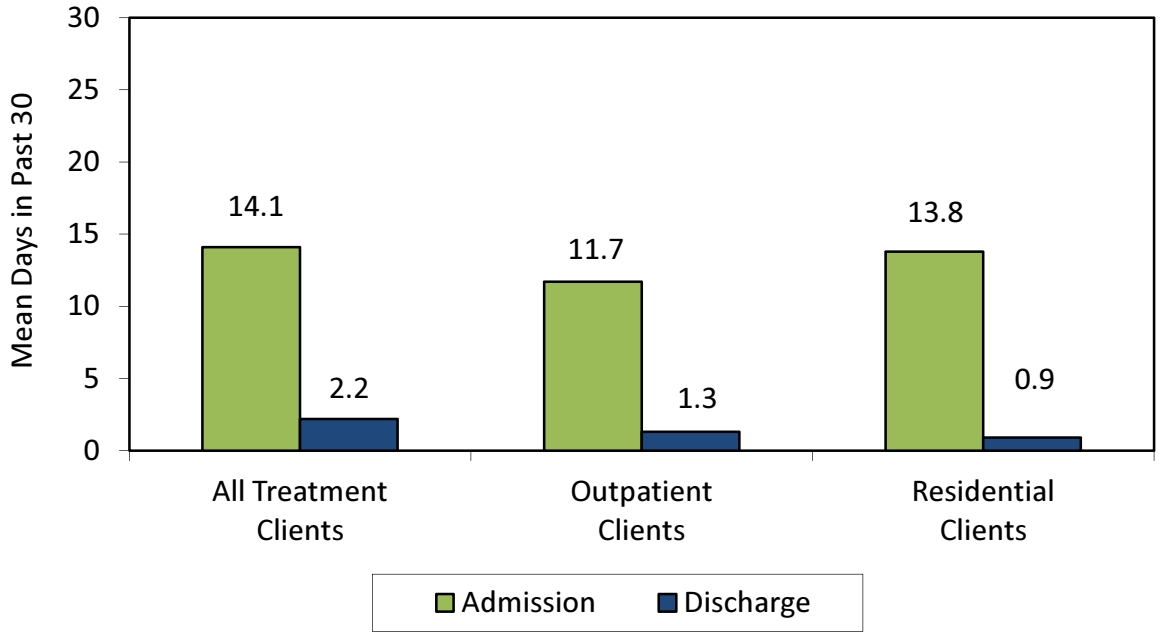


Chart 5: Reduction in Primary Drug Use Days for Treatment Clients



Appendix A

Urge to Drink Scale

INSTRUCTIONS: The following questions are designed to help you assess an important aspect of your recovery status: the urge to drink. Complete this form by thinking about the <u>past week</u> and placing a check mark next to the response that is most true for you.

1. How often have you thought about drinking or about how good a drink would make you feel during this period?

__ Never, that is, 0 times during this period of time.(0)
__ Rarely, that is, 1 to 2 times during this period of time.(1)
__ Occasionally, that is, 3 to 4 times during this period of time.(2)
__ Sometimes, that is, 5 to 10 times during this period or 1 to 2 times a day.(3)
__ Often, that is, 11 to 20 times during this period or 2 to 3 times a day.(4)
__ Most of the time, that is, 20 to 40 times during this period or 3 to 6 times a day.(5)
__ Nearly all of the time, that is, more than 40 times during this period or more than 6 times a day.(6)

2. At its most severe point, how strong was your urge to drink during this period?

__ None at all.(0)
__ Slight, that is, a very mild urge.(1)
__ Mild urge.(2)
__ Moderate urge.(3)
__ Strong urge but easily controlled.(4)
__ Strong urge and difficult to control.(5)
__ Strong urge and would have drunk alcohol if it were available.(6)

3. How much time have you spent thinking about drinking or about how good a drink would make you feel during this period?

__ None at all.(0)
__ Less than 20 minutes.(1)
__ 21 to 45 minutes.(2)
__ 46 to 90 minutes.(3)
__ 90 minutes to 3 hours.(4)
__ Between 3 to 6 hours.(5)
__ More than 6 hours.(6)

4. How difficult would it have been to resist taking a drink during this period of time if you had known a bottle was in your house?

__ Not difficult at all.(0)
__ Very mildly difficult.(1)
__ Mildly difficult.(2)
__ Moderately difficult.(3)
__ Very difficult.(4)
__ Extremely difficult.(5)
__ Would not be able to resist.(6)

5. Keeping in mind your responses to the previous questions, please rate your overall average urge to drink alcohol for the stated period of time.

__ Never thought about drinking and never had the urge to drink.[0]

__ Rarely thought about drinking and rarely had the urge to drink.[1]

__ Occasionally thought about drinking and occasionally had the urge to drink.[2]

__ Sometimes thought about drinking and sometimes had the urge to drink.[3]

__ Often thought about drinking and often had the urge to drink.[4]

__ Thought about drinking most of the time and had the urge to drink most of the time.[5]

__ Thought about drinking nearly all of the time and had the urge to drink nearly all of the time.[6]

*The Urge to Drink Scale is a modified version of the PACS. The rationale and psychometric properties of the PACS can be found in: Flannery BA, Volpicelli JR, Pettinati HM. Psychometric Properties of the Penn Alcohol Craving Scale. Flannery. *Alcohol Clin Exp Res.* 1999;23(8):1294. With permission.

Visit **www.touchpointsprovidersupport.com** for additional resources.

Appendix B

SAPC MAT Survey (Monthly)

Unique Participant ID _____ Date: _____

(*Found in LACPRS after completion of admission form*)

1. Has the client completed the "Urge to Drink" scale on this visit? _____Yes _____ No
2. What was the score? _____
3. What is the date of the client's next Vivitrol shot? _____
4. In the past month, how many days has the client drunk any alcohol? _____
5. In the past month, how many days has the client drunk to *intoxication*? _____
   (*Intoxication is 5 or more drinks in a day for males and 4 or more for females*)
6. If no alcohol has been consumed in the past month, when did the client last drink alcohol?

_____

7. On a scale of 1 to 10, how does the client's cravings this month compare to last month?

1	2	3	4	5	6	7	8	9	10
Significantly Less				About the Same					Significantly Greater

Additional comments or description:

_____

_____

Has there been any effect on cravings of other substances used by the client (nicotine, opiates, etc.)?

_____Yes _____ No If yes, what is the drug? _____

If no, skip to question 10

Rate the change in cravings this month compared to last month using the 1 – 10 point scale below.

1	2	3	4	5	6	7	8	9	10
Significantly Less				About the Same					Significantly Greater

Additional comments or description:

_____

_____

Any changes in cravings for other substances?

_____Yes _____ No If yes, what is the drug? _____

If no, skip to question 10

Rate the change in cravings this month compared to last month using the 1 – 10 point scale below.

1	2	3	4	5	6	7	8	9	10
Significantly Less				About the Same					Significantly Greater

Additional comments or description:

_____

_____

Additional substances should be described in the "Notes" section at the end of this survey

8. Has the client experienced any of the following in the past month:

_____ Injection Site Reaction _____ Fatigue

_____ Nausea _____ Headache

9. Has the client noticed any other changed or problems in the last month?

_____

_____

Note: If the client reports any symptoms, report this to the physician, nurse, or to the staff member your agency has designated, immediately.

10. Has the client noticed any benefits from Vivitrol?

_____

_____

Does the client have any concerns about Vivitrol?

_____

_____

Does the client expect to take the next dose? _____Yes _____ No *Why or why not?*

_____

_____

How would the client describe treatment staff attitudes towards his or her use of Vivitrol?

_____

_____

Does the client have any questions at this time?

_____

_____

Additional Notes:

_____

_____

_____

_____

Appendix C

Counselor Questions Concerning Medication Assisted Treatment

1. What do you think about the use of psychotropics (e.g., antidepressants, anti-anxiety medications, anti-psychotics) with clients who are in treatment for a substance use disorder?
   Open response

2. Do you have any experience with medication-assisted therapy?
   Yes/No

3. What do you know about medication-assisted therapy?
   Open response

4. What do you think about medication-assisted therapy?
   Open response

5. Are you interested in more information about medication-assisted therapy?
   Yes/No

6. What do you know about Vivitrol?
   Open response

7. Are you interested in more information about Vivitrol?
   Yes/No

8. If someone at this facility asked you about Vivitrol, what would you say to him or her?
   Open response

9. Are you currently involved in the Vivitrol pilot being conducted at this program?
   Yes/No

    a. If no – Skip to 10
    b. If yes – Are you a counselor or other clinical staff?
       Yes/No

        i. If no – skip to 10
        ii. If yes - How do you identify clients who you think would benefit from Vivitrol?
        Open response

10. Do you know anyone who has used Vivitrol?
    Yes/No

    a. If yes, what did they say about Vivitrol?
       Open response

11. If you are a counselor or other staff person who has contact with clients, would you recommend Vivitrol?
    a. Why or why not?

12. Do you have any concerns with Vivitrol?

13. What have you heard from the clients?

14. Have there been any changed to the program structure since the implementation of the Vivitrol pilot (e.g., new groups, new staff)?

    a. If yes, what are some of these changes?