Long-Acting Injectable Buprenorphine Pilot Report

Virginia Department of Corrections
In Partnership with the Opioid Abatement Authority

Paul V. Targonski, M.D., Ph.D., M.P.H.
Chief Medical Officer, Virginia Department of Corrections

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Brief Overview

This project was framed as an exploratory pilot with support by the Opioid Abatement Authority (OAA) and a primary objective of delivering continuation of long-acting injectable buprenorphine (LAIB) among 30 patients received into the Virginia Department of Corrections who came from jails on active buprenorphine prescriptions from Fall, 2023 through Fall, 2024. Observation for selected impacts associated with the use of LAIB in this project group included outcomes selected to represent health-related, participatory (educational and programmatic), and community conduct (ie, law abiding within the carceral setting) metrics. Given the small sample size of the pilot project, findings are largely descriptive but demonstrate the capacity to deliver and maintain medication treatment for opioid use disorder (MOUD) in prison settings.

Eligibility

Any patient received into the Virginia Department of Corrections during the Fall period of 2023 through Fall, 2024 who had an active and medically appropriate prescription for buprenorphine and in whom LAIB was not contraindicated (ie, pregnant, documented hypersensitivity, etc) could be included. All patients undergo a standard clinical evaluation for continuation of therapy and all medications are administered per VADOC standard protocols based on national guidelines.

Outcomes

The following metrics were examined to evaluate the patients' progress since they began receiving LAIB in VADOC facilities:

1) Health outcomes – emergency department transports, suspected and confirmed overdoses, and deaths
2) Program enrollments – substance use disorder programming and educational (Career and Technical) programming engagement and completion
3) Disciplinary offense convictions – convictions were classified into two levels, minor and major

Rate ratios expressing the difference between crude metric-specific event rates calculated over the project period for the LAIB project population versus the remainder of the carceral population (the general carceral population) were calculated. The statistical significance of the rate ratio was calculated with adjustment for multiple comparisons in this exploratory analysis, acknowledging the small sample size of the LAIB project population.

Findings

As of November 12, 2024, 38 patients in VADOC Facilities who received long acting injectable buprenorphine (LAIB) as continuation therapy for medication management of opioid use disorder (MOUD) during the period of interest were supported by the Opioid Abatement Authority. An

additional 8 patients not supported by OAA but who received LAIB for continuation of MOUD for at least 6 months during the period of interest were also included in this analysis to augment the person-month sample size. The LAIB project group was essentially a consecutive sample given the project time parameters for patient inclusion, and resulted in 44 men and 2 women selected. Women represented 4% (95% confidence interval 1-15%) of the project population, the confidence interval of which is within range of the proportion of women incarcerated in Virginia prisons and therefore reasonably representative of the general VADOC carceral population with respect to gender.

Cost Benefit Analysis

Controversy exists regarding the use of LAIB versus oral buprenorphine, which is substantially less expensive (at the time of this writing, non-subsidized LAIB is approximately 7 times more expensive per month than oral equivalent buprenorphine). However, factors unique to carceral and congregate settings, such as the need for separate medication administration times, location and personnel for MOUD, separate storage and surveillance processes for daily versus monthly administered controlled substance management, and diversion risks require alternative cost benefit analyses than those from community settings. VADOC conducted early analyses accounting for differences in both health care and security staffing, operational management and control of medication and medication administration lines, and medication costs in 2022-2023 and projected that while medication cost was higher for LAIB, this was offset by lower costs in all other areas and produced a small net cost-benefit for LAIB. We did not quantitate diversion-related direct and indirect costs, which most assume substantially favor LAIB as well.

Health Outcomes

There were no deaths or suspected/confirmed overdoses among the pilot project LAIB group during the period of interest, which is an optimal outcome. Neither rate was statistically significantly different than that of the general population, which was expected.

There were 9 emergency department transports in the LAIB pilot population, most of which due to accidents and injuries consistent with this age group based on data from the National Hospital Ambulatory Medical Care Survey, 2016-2022 (National Center for Health Statistics. Emergency Department Visits in the United States, 2016-2022. https://www.cdc.gov/nchs/dhcs/ed-visits/index.htm. This emergency department transport rate was almost three fold higher than that observed in the general carceral population, although given the small LAIB pilot population, this difference was not statistically significant.

Program Participation

Since starting MOUD, the LAIB pilot population included 10 patients who enrolled in Substance Abuse programming (22%) and 2 who enrolled in Cognitive Behavioral programming (4%). The

general carceral population would not be expected to enroll in substance use disorder programming therefore a comparison would be invalid.

Twelve patients (26%) engaged in educational programming – six participated in academic programming but 5 (88%) were removed prior to completion, while another 6 were engaged in a Career and Education (CTE) program (Apprenticeship, Industry Certificate, Refresher, and Vocational courses, although 4 (67%) were removed prior to completion. Equivalent programming data were not available for comparison at the time of this report. However, these data will be considered in the Discussion

Disciplinary Offense Convictions

Minor convictions among the LAIB pilot population occurred at almost the same rate as the general carceral population, 16% higher among the former but a difference that was statistically insignificant. Although also statistically insignificant, major convictions occurred 20% less frequently among the LAIB pilot population than the general carceral population. Convictions for possession of, or being under the influence of, drugs or intoxicants occurred at essentially the same rate between the two groups – 4% lower in the LAIB pilot population during the period of observation, a difference which was statistically insignificant.

Discussion

This exploratory pilot definitively demonstrated that patients with an active ongoing buprenorphine treatment program for the management of opioid use disorder and transitioning from jails to prison environments can successfully continue and maintain their MOUD treatment with long-acting injectable buprenorphine. While the sample size is small and limits definitive findings, provocative observations exist but must not be over-interpreted.

Cost benefit findings currently marginally favoring LAIB over oral buprenorphine have subsequently been corroborated by published medical literature examining carceral settings (Russell C, George TP, Chopra N, Le Foll B, Matheson FI, Rehm J, Lange S. Feasibility and effectiveness of extended-release buprenorphine (XR-BUP) among correctional populations: a systematic review. Am J Drug Alcohol Abuse. 2024 Jun 28:1-20. doi: 10.1080/00952990.2024.2360984. Epub ahead of print. PMID: 38940929.; Wong JSH, Masson S, Huang A, Romm D, Fong M, Porter T, Sharifi N, Azar P, Mathew N. Cost Analysis of Buprenorphine Extended-Release Injection Versus Sublingual Buprenorphine /Naloxone Tablets in a Correctional Setting. J Correct Health Care. 2022 Dec;28(6):368-371. doi: 10.1089/jchc.21.07.0063. Epub 2022 Nov 7. PMID: 36342953.).

That LAIB is superior (or non-inferior) to oral buprenorphine, methadone, or naltrexone for persons with OUD in carceral settings was not a focus of this study and remains unanswered in the literature, largely due to a lack of studies in carceral settings. Anecdotally, many persons with OUD in carceral settings and on/after release do very well with naltrexone, but this may reflect a selection bias for persons highly motivated to avoid relapse (The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update. J Addict Med. 2020 Mar/Apr;14(2S Suppl 1):1-91. doi: 10.1097/ADM.0000000000000633. Erratum in: J Addict Med. 2020 May/Jun;14(3):267. doi:

10.1097/ADM.0000000000000683. PMID: 32511106.). A recent large population based retrospective community cohort study among persons with OUD receiving first time MOUD found higher treatment retention and similar mortality benefit for methadone relative to buprenorphine. (Nosyk B, Min JE, Homayra F, et al. Buprenorphine/Naloxone vs Methadone for the Treatment of Opioid Use Disorder. *JAMA*. Published online October 17, 2024. doi:10.1001/jama.2024.16954). These findings should give us pause in simply assuming that buprenorphine in any form is better than naltrexone or methadone in achieving OUD remission and preventing overdose and death. Hopefully, additional comparative analyses conducted in carceral studies can translate these questions for prison and jail populations, along with cost-benefit analyses, to better inform carceral MOUD practice.

The absence of overdoses and deaths in the LAIB pilot population is substantially reassuring, perhaps associated with MOUD, given the extremely high risk of these health outcomes known to exist in persons with OUD and particularly those in or recently released from carceral settings that can be attenuated with MOUD while incarcerated and after release (Lim S, Cherian T, Katyal M, Goldfeld KS, McDonald R, Wiewel E, Khan M, Krawczyk N, Braunstein S, Murphy SM, Jalali A, Jeng PJ, MacDonald R, Lee JD. Association between jail-based methadone or buprenorphine treatment for opioid use disorder and overdose mortality after release from New York City jails 2011-17. Addiction. 2023 Mar;118(3):459-467. doi: 10.1111/add.16071. Epub 2022 Nov 16. PMID: 36305669; PMCID: PMC9898114; Bovell-Ammon BJ, Yan S, Dunn D, et al. Prison Buprenorphine Implementation and Post release Opioid Use Disorder Outcomes. *JAMA Netw Open*. 2024;7(3):e242732. doi:10.1001/jamanetworkopen.2024.2732).

The increase in need for emergency department transports among the LAIB project population, particularly given the occurrence of accidents and injuries, could be speculated to represent a sedative adverse effect of buprenorphine leading to a greater propensity for accidents and injuries but is substantially more likely an observational anomaly. LAIB could be associated with drowsiness, dizziness, vision changes or other sequelae, particularly if inadvertently combined with interacting medications or predisposing medical conditions. However, the reality is that LAIB has a more consistent delivery than oral buprenorphine and our findings are both statistically insignificant compared to the general carceral population and similar to national emergency department visit diagnoses for this demographic group.

Regardless of the MOUD selected, clinicians must adhere with clinical guidelines in evaluating, treating, and reassessing patients to protect patients' health and safety, whether for induction or continuation. We have seen several examples of patients who were started on buprenorphine in the community, but who had elevated risk for adverse outcomes of buprenorphine use by virtue of medical conditions or other medication use, including cardiac issues such as reversible prolongation of the QT interval and clinically significant inflammation of the liver.

The lack of an increase in disciplinary offense convictions among persons continuing MOUD with LAIB compared with the general carceral population is also suggestive of an important benefit, acknowledging that statistical power would be lacking to likely detect even moderate differences between the groups. Nonetheless, our findings observed numerical equivalence or reductions in offense metrics among the LAIB group for major offenses rather than worse outcomes in the LAIB group. This is especially exciting in that possession and intoxication offenses, which would be expected to be much higher among persons with OUD (the LAIB group) compared to those without (the vast majority of the general carceral population), appeared to be rendered similar with MOUD.

Notably, approximately 70% of major convictions among the LAIB group occurred within 6 months of arrival to prison and initiating continuation rather than in the latter stages of the project period. Does this suggest some pharmacologic stabilization period for LAIB in which the benefit is less pronounced? Our data cannot answer that question, and the effect of LAIB continuation versus reception to prison cannot be disarticulated since they occur simultaneously. This time frame represents a highly stressful time for any patient – entry into a new carceral environment. Future evaluations could compare to a control group composed of persons with actively treated OUD newly received to a prison setting with non-LAIB agents or among OUD patients who refused treatment, and for longer periods in order to determine if the time-related reductions observed in our project do reflect real treatment effects and stabilization of behaviors over time.

The observed lower rate of program participation, as well as a perceived high rate of removal from educational programming, is not consistent with the observations of neutral to better health and disciplinary outcomes, although again, overall numbers are small and confidence in the point estimates obtained are wide. Like disciplinary actions, there is a possibility that encountering a new environment with associated stressors could reduce the probability of successfully engaging programmatically, particularly if compounded by the presence of an OUD in treatment or transition. Alternately, could buprenorphine produce subtle difficulties in cognitive focus or other areas necessary to succeed in high focus tasks? A review of the literature is more supportive of the former hypothesis but suggesting either for the group observed in this project is substantially conjectural based on the size of the population followed.

There is reasonable consistency in the observations gleaned from this project that largely suggest LAIB appears largely effective in reducing adverse health and disciplinary offense conviction among persons with OUD on LAIB to rates similar to that seen in the general carceral population, although program participation is more difficult to interpret. We must be cautious to not over-interpret findings limited by small sample size and the inability to account for intervening variables that may influence these findings. Nonetheless, the findings are reassuring, and the overarching theme of this project is that medication continuation is possible in carceral settings. Additional setting-specific knowledge is critically needed, rather than extrapolating findings from community studies, the results of which may not be applicable in carceral settings.