

State Policies and Adoption of Buprenorphine:

Summary Results of Telephone Interviews with State Agency Staff

Funding Source:

Grant No. 053773

Robert Wood Johnson Foundation
Substance Abuse Policy Research Program

Contact info:

Lori J. Ducharme, Ph.D., Project Director

Institute for Behavioral Research

118 Barrow Hall

University of Georgia

Athens, GA 30602-2401

Email: lorid@uga.edu

Web: www.uga.edu/NTCS/bup_policy.htm

November 2007

Project overview:

Buprenorphine (Subutex® and Suboxone®) received FDA approval for use in the treatment of opioid dependence on October 8, 2002. The drug has been widely regarded as heralding a new era in opioid dependence treatment, owing to the unique circumstances in which it is approved for use. For most of the last 40 years, methadone was the only pharmacotherapy for patients dependent on heroin and other opiates. However, daily dosing, highly restrictive treatment settings, and stigma associated with methadone clinics and the drug's diversion potential limits the number of patients who can receive this treatment. Naltrexone, approved for use in the mid-1990s, is available in a wider variety of settings, and has little to no abuse potential. However, patient compliance is a persistent issue among physicians prescribing naltrexone, and it still has not been widely adopted by either community treatment programs (Roman & Johnson, 2002) or primary care physicians (Mark et al., 2003; Thomas et al., 2003). In a sense, buprenorphine combines the more appealing characteristics of methadone and naltrexone: it has demonstrated a high degree of clinical effectiveness, its Suboxone® formulation has a reduced abuse potential and diversion threat, it can be prescribed for less-than-daily dosing, and it is available in settings other than OTPs.

Patients may receive buprenorphine for opioid dependence in one of three treatment settings: opioid treatment programs; community treatment programs (non-methadone) having a "DATA-waived" physician on staff or contract; or from a "DATA-waived" primary care physician in an office-based practice. ("DATA-waived" physicians are those who qualify for a waiver, as specified under the Drug Abuse Treatment Act of 2000, allowing them to prescribe approved Schedule III and IV narcotics for the treatment of opiate addiction.) Community treatment programs may also provide required "counseling and other appropriate ancillary services" for patients receiving buprenorphine in an office-based practice, without themselves dispensing buprenorphine on-site. Clinical practice guidelines for the use of buprenorphine in the treatment of opioid dependence were published in mid-2004 (CSAT 2004).

As Ling and Smith (2002) are careful to note, buprenorphine is not simply a new medication, but a treatment strategy that exists within a complex social and political context. It is unclear whether or how state and federal policies provide incentives for the adoption of buprenorphine by physicians and addiction treatment providers.

In ongoing research at the University of Georgia, we have been tracking the adoption and implementation of a number of pharmacotherapies (including buprenorphine) for the treatment of substance abuse. As we continue to monitor adoption at the treatment provider level, it becomes clear that the state regulatory and funding environment plays an important role in the adoption process, and warrants investigation in and of itself. In our surveys, program directors frequently cite structural barriers to the adoption of buprenorphine, including state policies prohibiting them to prescribe medications; restrictions on insurance reimbursement for the drug; expense relative to methadone; and inconsistent or wholly absent state regulations or guidance on training, credentialing, and approval processes needed to incorporate

buprenorphine into everyday clinical practice. Thus, it is important to better understand state policy issues and their influence on program-level adoption decisions.

The proposed project included multiple phases. The first phase gathered information on the current regulatory and funding (Medicaid) policies in each of the 50 states and the District of Columbia as they pertain to the two established opiate addiction treatment medications (naltrexone and methadone) as well as buprenorphine. These data were gathered from reviews of secondary sources, as well as from brief interviews with key informants within each Single State Agency (SSA) or State Methadone Authority (SMA) office – this varied depending on which office within the state assumed regulatory oversight for matters involving opiate addiction treatment. This report summarizes highlights of the SSA/SMA interviews, which occurred in mid-2006.

These data were then merged with program-level data from SAMHSA’s National Survey of Substance Abuse Treatment Services (NSSATS), which provides broad coverage of the United States. More than 11,000 treatment programs were included in the public use datafile for the 2005 NSSATS. Data on state-level policies were included as predictors in multivariate models of buprenorphine adoption. Those findings are summarized on the project’s website (www.uga.edu/NTCS/bup_policy.htm). Links to published reports of the study’s findings will be made available on that website as they are released.

CSAT (2004) *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction (TIP 40)*. Rockville, MD: Center for Substance Abuse Treatment, SAMHSA.

Ling W & D Smith (2002) Buprenorphine: Blending clinical practice and research. *Journal of Substance Abuse Treatment*, 23:87-92.

Mark T, HR Kranzler & X Song (2003) Understanding US addiction physicians’ low rate of naltrexone prescription. *Drug & Alcohol Dependence*, 71:219-228.

Roman PM & JA Johnson (2002) Adoption and implementation of new technologies in substance abuse treatment. *Journal of Substance Abuse Treatment*, 22, 211-218.

Thomas CP, SS Wallack, S Lee, D McCarty & R Swift (2003) Research to practice: Adoption of naltrexone in alcoholism treatment. *Journal of Substance Abuse Treatment*, 24:1-11.

Summary of Survey Responses

The following data were obtained from interviews conducted in 2006 with SSA representatives in 49 states (1 refusal). Note: For the purpose of this study, "buprenorphine" is used generally to refer to either Subutex® or Suboxone®. OTP = opioid treatment program.

Q1. Are there any regulations or policies in [state] – beyond regulations at the Federal level – that specifically dictate conditions for methadone programs to use buprenorphine?

Only 2 states identified any specific conditions for the use of buprenorphine in OTPs.

Q2. Does the state provide any incentives to encourage methadone programs to begin offering buprenorphine? If so, what are they?

Only 1 state identified any specific incentives to implement buprenorphine in OTPs, and this was limited to a grant earmarked for the training of clinicians in a "high risk" area of the state.

Q3. Are methadone programs required or encouraged to advise patients of the availability of buprenorphine?

- 7 states required OTPs to advise patients about buprenorphine's availability
- 14 states encouraged OTPs to advise patients about buprenorphine's availability
- 28 states had no such policy

Q4. What about non-methadone programs that treat substance abuse clients – are there any regulations or policies in [state] – beyond regulations at the Federal level – that specifically define conditions for these programs to use buprenorphine? [This question does not apply to office-based physicians.]

Only 1 state identified any policies beyond existing regulations; this state had developed provisions for treatment providers to operate as "modified narcotic treatment programs."

Q5. Does the state provide any incentives for non-methadone programs to include buprenorphine among their treatment options?

2 states indicated that such incentives were provided. However, it was unclear whether these incentives (e.g., increased reimbursement rates) were designated specifically for buprenorphine, or to encourage the use of *any* approved addiction pharmacotherapy.

Q6. *Has the state funded any clinician training events on buprenorphine? (This may include physician certification classes for "DATA waivers," or counselor training or information sessions.)*

- 26 states (53%) had offered clinician trainings on buprenorphine
- 23 states (47%) had not offered trainings

Among states that had offered trainings: Most had offered trainings in coordination with the FDA approval of buprenorphine. Most of these states also offered ongoing trainings – usually in collaboration with SAMHSA – for physicians related to DATA waivers. Far less often did states offer trainings aimed at counselors, treatment program administrators, or other line staff.

Q7. *Does the state require treatment programs to utilize "evidence based practices"?*

- 19 states indicated that treatment programs were "required" to use EBPs
- 28 states cited no such requirements
- 2 states did not know; 2 states did not respond

Among states that "require" the use of EBPs, there was no consistent approach to pre-defining treatment practices considered "evidence-based" – that is to say, only 10 of the 19 states indicated that they had compiled a list of approved practices. Among those, only 3 included buprenorphine on the state's EBP list.

Q8. *Has the state agency formally issued any guidance to treatment providers about clinical practice for using buprenorphine?*

- 10 states (20%) indicated that they had issued guidance to treatment providers on using buprenorphine;
- 39 states (80%) had not issued any such guidance

Q9. *The Substance Abuse and Mental Health Services Administration (SAMHSA) recently released two "treatment improvement protocols" or TIPs providing guidance for the use of buprenorphine by physicians and in methadone treatment settings. Has your office distributed those TIPs to treatment providers in your state, or encouraged providers to review them?*

[Note: this question refers to *TIP 40: Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*, and *TIP 43: Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*. Both are available from SAMHSA's information clearinghouse at www.ncadi.samhsa.gov.]

- 11 states had not distributed either TIP or were unfamiliar with them
- 15 states had encouraged programs to obtain and utilize the TIPs
- 23 states had distributed the TIPs (hard copy or electronic copy)

Q10. *Other than through Medicaid, have state funds been used to subsidize the availability of buprenorphine for publicly-funded treatment clients? How?*

9 states indicated some limited subsidies for the use of buprenorphine. In each case, these were grants or other limited use of discretionary funds for pilot tests of buprenorphine in a specific clinic or set of clinics.

Q11. *Other than through Medicaid, have state funds been used to subsidize the availability of counseling and other wraparound services for patients receiving buprenorphine in office-based settings? How?*

11 states indicated that such subsidies were available, generally under limited grants for pilot or demonstration projects in a defined number of clinics.

Q12. *Generally speaking, would you say that the state substance abuse agency...*

- 24 (49%) actively encourage programs to consider using buprenorphine
- 24 (49%) have taken no real position on buprenorphine either way
- None (0%) actively discourage programs from using buprenorphine

Q13. *Under federal requirements, physicians need to be certified under the Drug Addiction Treatment Act of 2000 to prescribe buprenorphine. States can impose additional requirements on physicians before they are permitted to prescribe. Does [state] have any special requirements for DATA-waived physicians wishing to prescribe buprenorphine?*

Only 3 states indicated specific additional requirements for physicians; in each case, physicians were required to register with the state.

Q14. *Aside from what we've talked about, is there any pending legislation that would affect treatment programs' use of buprenorphine, or do you expect any changes to be made to current policies in the near term?*

9 states indicated that there was legislation pending or anticipated. For the most part, these pending actions were related to reimbursement (e.g., Medicaid formularies) or procedural matters (e.g., state pharmacy board procedures). 2 states indicated that they were reconsidering the content of their current OTP regulations.

Q15. *Is methadone maintenance treatment included as a covered benefit in the state's Medicaid plan? (i.e., does Medicaid cover the methadone itself?)*

- 28 states said that methadone was a covered Medicaid benefit
- 17 states said it was not
- 4 states did not answer (could not contact knowledgeable respondent)

Q16. *Is the use of buprenorphine for opioid dependence treatment a covered benefit in the state's Medicaid plan? (Note: it may be listed as Subutex® or Suboxone®)*

26 states indicated that buprenorphine for substance abuse treatment was a covered benefit

Q17. *Is buprenorphine (Subutex® and/or Suboxone®) currently included in the state's Medicaid formulary or drug list?*

28 states indicated that buprenorphine was on the state's Medicaid formulary. The difference between this and the preceding question is that buprenorphine is not exclusively used for addiction treatment, and thus may be on the formulary for other intended uses.

Q18. *If not included on formulary, are there plans to include it in the near-term?*

- 5 states indicated that there were plans to include buprenorphine on the formulary;
- 5 states indicated that there were no plans to do so;
- the remaining states were unsure of plans regarding buprenorphine and Medicaid

Q19. *Thinking about office-based physicians [doctors in practice outside of addiction treatment programs], do the Medicaid benefits cover physician and medication costs for patients receiving buprenorphine in physician's office settings?*

- 19 states indicated yes
- 19 states indicated no
- 11 states did not respond (could not contact knowledgeable respondent)

Q20. *Does Medicaid cover the costs of counseling and other wraparound services for clients receiving buprenorphine from office-based physicians?*

- 17 states indicated yes
- 21 indicated no
- 11 states did not respond (could not contact knowledgeable respondent)