

**Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services Administration
and the
National Institute on Drug Abuse
National Institutes of Health**

**Buprenorphine in the Treatment of Opioid Addiction:
Expanding Access – Enhancing Quality**

**February 21-22, 2008
Washington, DC**

Summary of the Work Group Reports

The purpose of the 2008 Buprenorphine Summit III was to bring together experts in epidemiology, pharmacology, toxicology, and addiction treatment to (1) assess progress and identify continued barriers to access to opioid addiction treatment with buprenorphine, (2) to identify best practices and useful clinical supports to enhance the quality of such treatment, and (3) to develop strategies to address emerging issues and concerns.

Summit participants were asked to suggest actions and policies that could increase patients' access to buprenorphine, while enhancing the quality of buprenorphine treatment of opioid addiction.

BACKGROUND TO THE BUPRENORPHINE LEGISLATION

In 2000, Congress enacted legislation that dramatically changes the way opiate addiction can be treated in the United States. The Drug Addiction Treatment Act (DATA) permits qualified physicians to prescribe medications for opiate addiction in their offices, using Schedule III, IV, and V narcotic drugs specifically approved by the Food and Drug Administration (FDA) for opiate dependency treatment. For the first time in almost 40 years, individuals addicted to opioids can now be treated in primary health care settings instead of in highly regulated Opioid Treatment Programs (methadone clinics). Buprenorphine, approved by the FDA in October 2002 for opiate dependence, became the first – and so far only – medication to blaze this new path in the mainstream medical care of individuals dependent on or addicted to opiates.

Over a 17-year period prior to the FDA's approval, the National Institute on Drug Abuse (NIDA) and the Center for Substance Abuse Treatment (CSAT) – both together and separately – carried out the clinical studies, research reviews, and policy and planning decisions that shepherded buprenorphine into FDA approval and mainstream medicine. This revolutionary change in opioid addiction treatment required fundamental changes in the U.S. healthcare system and in the relationship between primary care physicians and the drug treatment community. The DATA legislation assigned to the Substance Abuse and Mental Health Services Administration (SAMHSA) primary responsibility for monitoring the initiative. Both SAMHSA and NIDA are committed to encouraging the success of this effort, and to understanding and overcoming any barriers that threaten its progress or ultimate success.

FINDINGS FROM MULTIPLE WORK GROUPS

The following findings represent areas of substantial agreement across the six work groups of Summit participants. The principal points raised by each work group also are summarized separately below.

Buprenorphine Summit II (2005): Participants in the 2008 Summit agreed that the majority of the findings and strategies endorsed in the 2005 Summit remain valid. However, some findings and strategies need to be updated to reflect recent scholarship and subsequent clinical experience⁵.

Data collection and dissemination: SAMHSA is commended for its efforts to collect data on the use of buprenorphine, including any problems with diversion and abuse. These efforts should continue. As with other drugs (methadone, fentanyl), a particular problem is the lack of uniformity in definitions and classifications across databases (e.g., there is no consensus around terms such as “abuse”), including those used by poison control centers and medical examiners. Such lack of uniformity compromises the utility of the data gathered and is a barrier to comparative analysis. SAMHSA should continue its efforts to work with NAME, SOFT and other organizations to promote adoption of a uniform definition and classification system.

It also would be helpful to develop a single platform to coordinate and integrate data from multiple sources, as well as to disseminate data to multiple users. As an interim step, NIDA and SAMHSA should actively promote dissemination of information from their surveillance systems and research studies to clinical practitioners. For example, the visibility of buprenorphine data on the SAMHSA website could be enhanced by adding available surveillance information and up-to-the-minute research findings, active links to other sites, inclusion of relevant conference presentations, etc.

Special populations: The definition of “special populations” should be expanded to include adolescents, older adults, pregnant women, and newborns; patients with acute or chronic pain; persons who are HIV-positive, acutely ill or hospitalized; non-Caucasians; residents of rural areas; criminal justice clients and homeless persons. Clinical guidelines specific to each of these populations should be developed.

Clinical guidelines: To improve the selection of patients who are appropriate candidates for treatment with buprenorphine, physicians and other clinical staff need user-friendly tools, algorithms, and decision trees for patient assessment and drug selection, including help in choosing between buprenorphine and methadone. The current TIP 42 should be augmented with up-to-date information on (1) determining the optimal dose, (2) understanding the relationship of dose to diversion, (3) dosing schedules that discriminate between patients who are opioid-naïve and those in withdrawal, (4) use of detoxification (brief or extended) versus maintenance; (5) determining the duration and intensity of treatment (with the help of placement criteria); and (7) better integrating psychosocial interventions with medication therapy (through use of patient referral and monitoring systems). Finally, physicians need information and decision supports to help them safely transfer patients from methadone to buprenorphine and vice versa.

Education and training: Planning for future educational initiatives should begin with consideration of who, how and what to train, as well as how to provide ongoing support to trainees to help them continue their involvement in office-based addiction treatment. SAMHSA, NIDA, and field organizations need to develop a plan to provide ongoing training and identify sources of funding to support such training, in anticipation of the time that Suboxone and Subutex go off patent in early 2009.

The core curriculum and materials for buprenorphine training should be re-examined and revised to reflect knowledge acquired since they were initially designed. Also, ways should be found to tailor the trainings to specific settings and audiences (such as rural practitioners and allied health personnel who conduct much of the “front line” work in medical offices and addiction treatment programs). A good model is the NIDA multi-disciplinary training programs.

Future training initiatives should be broadened to encompass training of other health care professionals (e.g., physician assistants, nurse practitioners, nurses, counselors, and certified midwives). Find ways to

tailor the trainings to specific populations (such as adolescents or older adults), settings (such as rural areas or criminal justice settings) and audiences (such as allied health professionals).

Also, recent information about child poisonings and diversion by young people underscores the need for better education of patients about the need to store medications in a secure location and to monitor the quantity of drugs consumed. SAMHSA (possibly in collaboration with FDA or leading medical organizations) may wish to consider developing patient information sheets to convey this and other vital information.

Ongoing support: There is an evident need to provide continued support to physicians who complete the buprenorphine training through both existing systems such as the PCSS, as well as newer support modalities, including web-based updates, recertification processes, and new incentive systems. For example, SAMHSA could establish “Regional Support Centers” where prescribing physicians can find the expertise and resources they need, as well as help in linking their patients to psychosocial services.

Mentorship programs should be designed for allied health professionals (nurses and nurse practitioners, physician assistants, and other non-physician personnel), using the PCSS as a successful model. Risk management programs (both face-to-face and online) are needed to teach clinical and administrative practices that improve patient care and minimize personal and professional liability on the part of caregivers.

Finally, SAMHSA should collaborate with Single State Agencies (SSAs) and State Methadone Authorities (SMAs), as well as State and local medical societies and other health professions associations, to develop ongoing outreach to and support for physicians and allied health professionals who use buprenorphine.

Funding issues: Existing CPT and HCPC codes should be examined to determine whether (1) adequate funding for psychosocial and support purposes is possible under the current structure; (2) allied health professionals can be reimbursed at a level that is financially viable; and (3) funding is consistent with the intensity of services delivered. Attention also should be given to better aligning funding policies with those for other chronic diseases. For example, patients should not be required to “fail” trials of non-pharmacologic therapies in order to receive benefits for appropriate medication therapy.

REPORT FROM GROUP 1: IMPROVING DATA COLLECTION AND DISSEMINATION

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Using data to improve practice: SAMHSA is commended for its efforts to collect data on the use of buprenorphine, including any problems with diversion and abuse. These efforts should continue.

It also would be helpful to develop a single platform to coordinate and integrate data from multiple sources, as well as to disseminate data to multiple users. As an interim step, NIDA and SAMHSA should actively promote dissemination of information from their surveillance systems and research studies to clinical practitioners. For example, the visibility of buprenorphine data on the SAMHSA website could be enhanced by adding available surveillance information and up-to-the-minute research findings, active links to other sites, inclusion of relevant conference presentations, etc.

Quality and comprehensiveness of data: As with other drugs (methadone, fentanyl), a particular problem is the lack of uniformity in definitions and classifications across databases (e.g., there is no consensus around terms such as "abuse"), including those used by poison control centers and medical examiners. Such lack of uniformity compromises the usefulness of the data gathered and is a barrier to comparative analysis. SAMHSA should continue its efforts to work with NAME, SOFT and other organizations to promote adoption of a uniform definition and classification system.

Toxicology screens do not routinely include buprenorphine, which is an extra-cost item. Similarly, there is a significant lag time between introduction of a new drug and the availability of data on use of that drugs. As a first step in addressing these issues, it would be helpful to conduct an inventory of real-time surveillance systems that collect medical information (an example is the surveillance system run by the nation's poison control centers).

Dissemination and use of data: No readily accessible systems are in place to channel new information to the treatment community. (Federal confidentiality regulations complicate sharing of information.)

SAMHSA and DEA access to manufacturer postmarketing surveillance information would be most helpful.

Data about diversion and abuse of buprenorphine can be used to educate providers about patient selection and monitoring, as well as to inform patients of the need to safeguard their medications and to closely monitor who has access to them.

REPORT FROM GROUP 2: EMERGING CLINICAL ISSUES

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Patient assessment and selection: To improve selection of patients who are appropriate candidates for treatment with buprenorphine, physicians and other clinical staff need user-friendly tools, algorithms, and decision trees for patient assessment and drug selection, including help in choosing between buprenorphine and methadone. In designing these tools, greater emphasis should be given to the management of mainstream patients, rather than focusing mainly on special populations. For example, a cross-cutting concern involves finding the treatment setting most appropriate for each patient (e.g., through the use of placement criteria that address the needs of these patients).

Patient management. Physicians need information and decision supports to help them determine whether to use methadone, buprenorphine, or no medication for a particular patient, as well as in deciding when and how to taper a patient off medication or transfer him or her from methadone to buprenorphine or *vice versa*. Other areas where more information is needed include (1) determining the optimal dose, (2) understanding the relationship of dose to diversion, (3) dosing schedules that discriminate between patients who are opioid-naïve and those in withdrawal, (4) use of detoxification (brief or extended) versus maintenance therapy; (5) determining the duration and intensity of treatment; and (6) integrating psychosocial interventions, such as intensive outpatient programs (e.g., using patient assessment instruments and placement criteria).

Treatment structures: Workforce expansion will be necessary as the number of patients treated with buprenorphine increases. It would be useful to engage the participation of community health centers through the National Association of Community Health Centers.

Efforts also should be made to win acceptance of buprenorphine in abstinence-based organizations and residential treatment programs, as well as to increase the integration of buprenorphine treatment with 12-Step programs.

Finally, it would be helpful to expand the involvement of mainstream medical societies such as the AMA, APA, AOA, ACPM, and AAFP, in addition to specialty societies such as AAAP, AOAAM, ASAM and COPE.

Pain management. Physicians need education in how to diagnose and differentiate acute and chronic pain. Algorithms are needed to help them (1) manage pain in the addicted patient, (2) manage addiction in the pain patient, and (3) understand the optimal use of buprenorphine in treating both pain and addiction. Revived interest in use of buprenorphine as an analgesic requires attention to these issues.

REPORT FROM GROUP 3: SPECIAL POPULATION NEEDS

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Definitional issues: The definition of special populations should be expanded to include adolescents, older adults, pregnant women, and newborns; patients with acute or chronic pain; persons who are HIV-positive, acutely ill or hospitalized; non-Caucasians; residents of rural areas; criminal justice clients and homeless persons.

Clinical guidelines and other supports: Clinical guidelines for treating these populations should be developed. (Convene expert panels, identify effective programs, fund pilot studies, and disseminate the results to health professionals who care for these populations.) A significant concern is the potential for interactions between buprenorphine and other drugs (PK, PD, PG) in pregnant women, newborns, adolescents, HIV-positive, and elderly patients.

Web-based psychosocial supports for patients (e.g., NAABT.org or Interactive Life Windows) and their family members/significant others would be helpful.

Health service delivery issues: Service delivery varies by population. Among the variables are:

- *Service access for patients in rural areas* (PCSS-type mentoring needs to be tailored to meet the specific needs of rural providers. Also, the role of allied health professionals who practice in rural settings needs to be recognized and supported.)
- *Study the potential of novel service delivery methods* such as mobile units (“one-stop shopping”), use of pharmacy dispensing in situations where the risk of diversion is high, and the creation of central induction sites, with referral for maintenance therapy to primary care physicians, pharmacies, hospitals, and local mental health agencies.
- *Criminal justice issues:* Convene an expert panel to develop practice guidelines on assisting patients with re-entry to the community, maintenance therapy, parole and probation, treatment in correctional settings, and drug courts.

Funding issues: Examine existing CPT and HCPC codes to determine whether:

- Adequate funding for psychosocial and support purposes is possible under the current structure
- Mid-level personnel can be reimbursed at a level that is financially viable for the provision of care
- Funding is consistent with the intensity of services delivered.

Consider ways to better align funding policies with those for other chronic diseases. For example, patients should not be required to “fail” trials of non-pharmacologic therapies in order to receive benefits for appropriate medication therapy.

REPORT FROM GROUP 4: EDUCATIONAL STRATEGIES

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Find ongoing funding and organizational support for training: A wealth of experience, materials, trainers, and training models are available. However, there is no identified plan to continue that training in the future, or to fund the training once Suboxone and Subutex go off patent in early 2009. Therefore, SAMHSA and the organizations that are allowed to offer training under DATA 2000 need to develop a plan to provide ongoing training and to access funding to support that training after Suboxone and Subutex go off patent.

As part of the plan, all medical organizations should be encouraged to incorporate training in the use of buprenorphine and other anti-addiction medications into their RRC requirements for residency training, as the APA and AAAP are doing in psychiatry.

Planning for future educational initiatives should begin with consideration of who, how and what to train, as well as how to support trainees to help them continue their involvement in office-based addiction treatment. The core curriculum and training materials should be re-examined and revised to reflect the knowledge acquired since they originally were designed.

Such a plan also should reinforce the need for continued support following the training experience, both through existing systems such as PCSS as well as through newer support modalities, such as web-based updates, recertification processes, and new incentive systems.

Broaden the educational plan: Future training initiatives should be broadened to encompass training of other health care professionals (e.g., physician assistants, nurse practitioners, nurses, counselors, and certified midwives). Some of these trainings should be tailored to the care of specific populations (such as adolescents or older adults), settings (such as rural areas or criminal justice settings) and audiences (such as allied health professionals).

Also, recent information about child poisonings and diversion by young people underscores the need for better education of patients about the need to store medications in a secure location and to monitor the quantity of drugs consumed. SAMHSA (possibly in collaboration with FDA or leading medical organizations) may wish to consider developing patient information sheets to convey this and other vital information.

REPORT FROM GROUP 5: DEVELOPING SYSTEM SUPPORTS

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Spectrum of supports at the national, regional, State and local levels:

At the *national level*,

- Develop Risk Management CME programs (in person and online) to teach clinical and administrative practices that improve patient care and minimize personal and professional liability of caregivers.
- Update the standard of care and develop a spectrum of supports for practitioners, allied health personnel, patients, and families.
- Develop a mentoring system for allied health personnel that provides supports similar to that provided to physicians through the PCSS.
- On the CSAT website, link the locator of waived physicians with the Treatment Locator.

At the *regional level*, designate Regional Support Centers where prescribing physicians can find the expertise and resources for consultation, as well as help in linking their patients to needed psychosocial services.

At the *State level*, collaborate with Single State Agencies (SSAs) and State Methadone Authorities (SMAs), as well as State and local medical societies and other health professions associations, to develop state-level ongoing outreach to waived physicians and allied health personnel who work with patients in medication-assisted treatment.

At the *national, State and local levels*, encourage the development of buprenorphine update workshops in connection with meetings of mainstream medical organizations and addiction specialty societies.

At the *national and State levels*, encourage accrediting and licensing bodies and training institutions for medicine, nursing, social work, and psychology to enhance the level of teaching about addiction, so as to raise the baseline knowledge of mainstream practitioners. Identify funding sources to support the development and dissemination of these services.

REPORT FROM GROUP 6: IDENTIFYING RESEARCH NEEDS

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Descriptive (observational) studies are needed to examine:

- Characteristics of the treated population;
- Types of physicians who use buprenorphine (primary specialty, practice type, etc.);
- Effective methods of linking specialty programs to primary care;
- Patient outcomes in relation to physician training;
- Subgroup analyses from various population studies;
- Biomarkers and pharmacogenetics for addiction vulnerability and treatment success;
- The effects of various policies on patient outcomes;
- Cost-effectiveness of various methods of treatment delivery;
- Strategies for translating research to practice;
- The effect of novel treatment settings.

Controlled trials are needed to examine:

- The effect of various levels of psychosocial services on patient outcomes;
- Various models for buprenorphine induction;
- Approaches to buprenorphine taper;
- Components of optimal physician training programs;
- Treatment needs of and outcomes for special populations (adolescents, pregnant patients, et al.);
- Optimal psychosocial treatment services for use with buprenorphine;
- Novel drug formulations and delivery mechanisms;
- Buprenorphine outcomes in patients with HCV.

Pharmacology studies are needed to examine:

- Drug interactions with SSRIs, benzodiazepines, antiretrovirals, antipsychotics, anticonvulsants, and oral opioids;
- Acute pain management;
- Neuroimaging (receptor saturation vs. blockade effects);
- Pharmacokinetics of buprenorphine in the treatment of adolescents;
- Novel drug formulations and delivery mechanisms.

Preclinical studies are needed to examine ORL-1 effects.