

# Introduction: Usefulness of This Community Education Kit



*Anybody can be addicted to opiates...  
College students, fashion models, stockbrokers...  
Your next door neighbor...  
Your own child...*

The need to support the success of individuals in methadone-assisted recovery, and the recent availability of new pharmacologic treatment options for opioid dependence, calls for an information tool that underscores the evidence-based benefits of medication assisted treatment for opioid dependence.

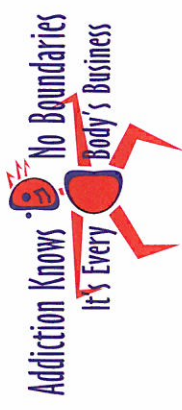
The U.S. Department of Health and Human Services' Substance Abuse and Mental Health Services Administration (SAMHSA), produced this education kit in collaboration with a host of opioid dependence treatment professionals, service providers, and individuals in recovery from opioid dependence. This tool addresses key questions related to new and existing opioid dependency medications and the new roles for opioid dependence service delivery systems.

The materials included here can be used by local alcohol and drug treatment providers to broaden the knowledge base about methadone and other medication-related options for the treatment of opioid dependence. This education kit also includes information on how to best approach and sustain an ongoing dialogue with key community stakeholders about the establishment, expansion, or sustainability of community-based treatment programs that use medication-supported treatment options.

Most importantly, this kit contains key suggestions as to how to develop a coordinated community education effort aimed at reducing the stigma associated with opioid dependence and its service delivery systems.



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SAMHSA's Center for Substance Abuse Treatment's *Changing the Conversation: National Treatment Plan Initiative to Improve Substance Abuse Treatment*, published in 2000, recognized that stigma surrounding drug use is an obstacle to treatment. Moreover, stigma associated with drug use and dependence supports a set of negative beliefs or attitudes that often impedes those who are in recovery from realizing their full potential and discourages those who are in need of treatment from seeking help. This education kit provides the knowledge necessary to dispel negative public attitudes, and points the way for supporting those in recovery. We hope that its message is well received in your community.

#### Disclaimer

The views and opinions expressed are those of the contributors and reviewers and do not necessarily reflect the official position of the Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services (HHS). The guidelines proffered in this document should not be considered as substitutes for individualized client care and treatment decisions.

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#### Acknowledgments

Numerous people contributed to the development of this education kit with the Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services (HHS). The information contained in this education kit was compiled and edited by American Association for the Treatment of Opioid Dependence Public Relations Committee members and affiliates: Dorrie Burke; William Gouldman; Susan Guercio; Herman Joseph, Ph.D.; Dan McGill; and Gerry Migliore.

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# Public Relations Inside Treatment Facilities

*Good public relations begin at home. A public relations program engenders a sense of personal responsibility for successful treatment and helps counteract stigma.*

## Public Relations With Staff and Other Professionals

- **Create a Mission Statement:** Provide a clear sense of direction and purpose within the organization. Keep treatment patient-focused and keep clinicians and administrators on track in program development.
- **Develop Personal Relationships With Referral Agencies:** Be available and responsive to agencies that are new to working with patients in opioid pharmacotherapy treatments by providing support and in-service training.

## Public Relations With Patients

Accreditation requires, and quality opioid pharmacotherapy treatment includes, a plan for input from patients to assure patient involvement in treatment planning and improvements in the practices and policies of the organization.

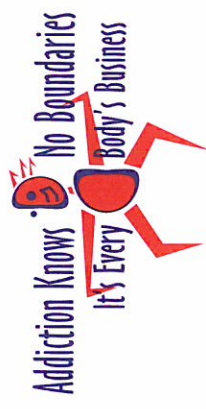
Medication assisted treatment programs need to foster a patient-based treatment environment in which patients understand and are fully part of the care they receive.

- **Create a Patient Committee to:**

- Advise on policies and procedures.
- Participate in public education projects and programs support initiatives.
- Encourage civic involvement.
- Involve recovery patients in the agency's community and media relations to counteract stigma.
- **Empower Patients in Their Treatment:**
  - Conduct patient satisfaction surveys.
  - Introduce and encourage participation in medication assisted treatment advocacy groups.
  - Establish and support open self-help groups, such as a Methadone Anonymous and/or Narcotics Anonymous meetings.
  - Provide patient recognition ceremonies.
  - Provide updates as program rules and services change.



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## Public Relations With and for Families

A satisfied family member is your best spokesperson in support of medication assisted treatment.

- Educate family members about the program's services and the principles of medication assisted treatment.
- Invite family members to be involved in education efforts to promote the benefits of medication assisted treatment.

## Public Relations With Physicians

Although most psychiatric residency programs in the United States now include training in treating substance use disorders and addiction, this information is not always included in medical school curricula. While psychiatrists provide the majority of medical treatment for patients experiencing substance use disorders, it is the primary care physicians who frequently first encounter these patients in their daily practices. It is imperative that primary care physicians be able at a minimum, to screen, provide a brief intervention, and refer patients for appropriate treatment.

Substance misuse and addiction have a significant impact on the general health and wellbeing of individuals. Physicians in general practice, family practice, obstetrics and gynecology, pediatrics, and trauma settings must be aware of substance use—both legal and illegal—to safely and effectively treat their patients for other health problems.

All medical students must learn the fundamentals of the action and interaction of all drugs on the human body, including differences based on gender, age, and other factors. They must be taught that they often are the first line of defense against the misuse of substances. They must be taught that screening for alcohol and drug use is an integral part of a physical exam, and that they often can make a difference merely by addressing the issue with their patients. They must be taught that treatment is effective and that they can work collaboratively with substance use disorder treatment providers.



# Establishing Community Relations

*Treating patients is treating communities, as well. Many opioid pharmacotherapy treatment programs do, and others can, enjoy a positive and naturally occurring relationship with their “community-at-large.”*

## Why Community Relations?

- **Patients Reflect Their Communities:** Patients mirror their communities' needs for adequate health care, employment, economic viability, basic safety, housing, and education. Quality care for patients means promoting patient reintegration, acceptance, and success of patients. It means understanding community values, needs, and resources, and working collaboratively with community members and organizations.

- **Programs Affect Community Life:** Programs impact community health, education, and well-being, and are uniquely positioned to provide resources.

## Proactive Community Relations Plans

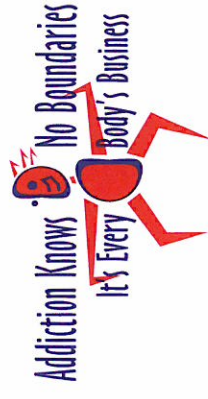
Medication assisted treatment programs that have proactive community relations plans help place their programs in the mainstream of community services. Proactive plans establish ongoing relationships with community leaders and organizations to further the interests of patients and communities.

- **Set Community Relations Mission, Goals, and Protocols:**

- Learn about community structures. Know who represents and leads the community in government, business, health, education, and other community systems. Identify ways that the program can partner with these groups to help meet community needs.
- Designate program staff as community liaisons or coordinators.
- Actively participate in your network of services.
- Recruit and hire qualified personnel from the community.
- Establish feedback mechanisms to hear, monitor, and effectively follow up community concerns about program impact. Address such issues as loitering near the clinic, and work closely with local law enforcement to address these and other community concerns.
- Establish a community-based Board of Directors or Advisory Council.



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- **Collaborate with the Community to Identify Appropriate Sites for Treatment Facilities:**
  - Acquire knowledge of all laws and regulations pertaining to new clinic siting, relocation, or expansion.
  - Consult with community leaders and planning agencies to identify potential program sites.
  - Provide an ongoing forum to discuss and address community concerns.
  - Assure quality physical plant design and a clean, professional external appearance.
  - Establish convenient program hours that do not impede community traffic.
  - Maintain a “barrier-free” facility that does not impede pedestrian or vehicular flow in the program vicinity.
- **Open Dialogue with Community Leaders:**
  - Contact and communicate with elected representatives, human services agencies, business organizations, local police and law enforcement, and the faith community.
  - Establish a community liaison or advisory group that meets to share and exchange information about the program and to discuss issues of mutual concern.
- Host community liaison events to allow community interaction with program staff and patients.
- Participate in community forums.
- **Proactively Serve the Community-at-Large:**
  - Promote accurate information about substance abuse and addiction treatment.
  - Develop a volunteer corps to assist with community development and enhancement activities.
  - Sponsor community events.
  - Form a speakers bureau.
  - Publish informational brochures and/or a newsletter.
  - Engage patients and staff in collaborative community improvement projects.
  - Serve on community health and social services boards.
  - Encourage staff and patients to join community organizations.
  - Conduct effective media relations. See “Media Relations and Outreach” in this kit.



# Media Relations and Outreach

*Successful media relations and outreach enhance the image of an agency, contribute to the public's understanding of the program's mission and quality of care, and generate community support.*

## The Value of Media Relations

Outreach to the media can generate positive focus on a program's mission and quality of care. Media exposure demystifies treatment, counteracts stigma, enhances program image, and improves the potential for a more balanced reaction when negative incidents or views threaten to undermine patients, the program, or treatment.

## Adopting Media Strategies

An array of approaches may be incorporated into a treatment program's media campaign.

### • Identify Media Outlets and Publications:

- Identify and get to know reporters, editors, and radio/television producers who have knowledge of, or report on, health, health care, social welfare, and/or treatment issues and developments.
- Offer your expertise to reporters, editors, and radio and television stations as a credible source on treatment issues and developments.
- Radio, particularly "all news" stations, is the most effective media for airing "breaking news" stories.
- Utilize community newspapers and ethnic press.

- **Pitch a Story:** A good story about treatment and patients portrayed through the media can both educate and promote program support. Broadcasters are looking for unique and interesting stories.

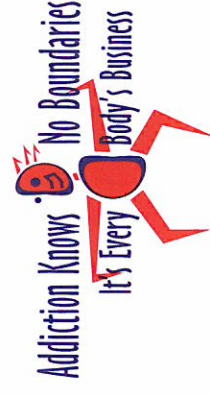
- The best stories tie the personal concerns of the public to the positive activities of the program.
- Generate media interest and maximize potential for coverage through a pitch that reflects newsworthiness, emphasizes something people in the community would want to know and/or has relevance to current community events or concerns.

- **Develop Fact Sheets - Useful Tools for Encouragers with the Media:** Provide media sources with figures and basic information that will be useful in preparing their stories.

- Prepare program fact sheets of one or two pages of clearly presented program information including the mission, program description, including history and types of services offered, and data on patients served.
- Interact with the local health department to get accurate data to prepare general fact sheets on health status trends, including addiction. Include brief descriptions or "bullets" on local addiction and health-related or social issues.



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- Develop a program web site and include the organization's history, mission, programs and services, outcomes, admission requirements, activities, hours of operation, and driving directions.

- **Write Letters to Newspaper Editors:** Bring attention to important treatment issues by responding to newspaper articles that may affect your program or patients.

- Send letters to the editor within 48 hours of appearance of the original article to maximize probability of publication.

- Make letters brief, succinct (250 words or less), and clearly tied to issues presented in the article.

- **Place Op-Ed Pieces:** Most newspapers publish opinion columns opposite their editorial page. The op-ed page is an excellent place to raise awareness of important issues about treatment and recovery.

- Identify the news publications in the program's community that publish op-ed pages and learn about their publication policies and criteria.

- Introduce the op-ed at a time when opioid dependence is a hot topic in the community, such as local special events or a conference in the community.

- Submit the op-ed piece with a cover letter that identifies the author, affiliation, and description of the author's expertise. Include background information about the provider agency, a statement of the topic, and why the views are important.

- **Issue Press Releases:** Many news stories are triggered by a timely press release. Press releases provide the opportunity to publicize and promote knowledge about the program treatment modality, or specific activities. The best time to get news coverage of a public interest story or

event is on the weekend, which is a "slower" news time, so time press releases accordingly. Examples of noteworthy press releases:

- The introduction of new services, significant changes to existing services, or dedication of a new facility.
- The appointment of a new director or high-level staff person.
- Receipt of a grant or donation.
- Promotion of the local impact of a national event.
- Unique research findings or outcomes at the program, or a grant to conduct research.
- Formation of a special task force.
- Presentation of special seminars, fairs, conferences, or workshops open to community members, or featuring an expert lecturer or speaker of local or national prominence.
- Plans for local activities and events to tie into celebration of a well-known day, week, or month.
- Receipt or conferring of honors or awards to or by the organization, its staff, or its patients.
- Details of a specific, unique program offered to patients or community.
- Agency commitment to the community to identify available community-based services.
- Human interest story about a particular patient's noteworthy treatment success or accomplishment.
- Brief human-interest story of a unique, effective intervention between the provider and patients.



## Press Release Tips

- Follow the standard format of press releases – no more than two pages, double-spaced, short sentences and paragraphs, reproduced on official organization letterhead, with name and phone number of a contact. Refer to the Sample Press Release in this kit for specific format specifications.
- Be sure the press release is professional and accurate. Answer the five questions – “who, what, where, when, and how?” Avoid using slang or technical terms, or explain them if necessary. Spelling, statistics, names, and titles should be accurate. Editorial comments or other opinions are expressed only in direct quotes.
- Use photographs or visuals to enhance or depict the information presented in the press release. Attach a caption to the photo. Use of patient’s photos, name, identity, or likeness requires prior written authorization from the individual.
- Distribute press releases to local print (including neighborhood weekly newspapers), radio, and television reporters in the community. Follow up to encourage them to write or air a story. Try to schedule an interview with an official or representative of the provider organization.
- **Develop and Place Radio Public Service Announcements:** Public Service Announcements (PSA) provide free air time if used to promote a nonprofit organization or public service. Stations often will accept pre-written scripts from organizations.
- Contact local radio stations to identify Public Affairs Directors and policies or options for submission of PSAs and underwriting opportunities.
- Script brief and to the point PSAs. Include a phone number that can be used to find out more about treatment services. Fax or mail copies of PSA scripts along with an agency contact name and telephone number. Sample 30-second and 15-second radio PSA scripts available for use are in this kit. See *Sample PSAs*.
- **Use Press Clips, Fact Sheets, Press Releases, and Public Service Announcements to Build Constituencies:** Collect and document published or transcribed media reports, fact sheets, press releases, PSAs, and other forms of media outreach such as interviews, and share them with program constituents. Distribute them to local community leaders, government, civic and elected officials, and colleagues to highlight your media outreach and program accomplishments.
- **Responding to Media Inquiries/Working with the Press:** As an outgrowth of providing service to the public, directors of programs should be prepared to respond to or address members of the local press when called upon, or when events make this necessary.
- The first step in good media relations is practicing quality treatment and responsibly operating medication assisted treatment (MAT) programs with consideration of community needs and concerns. This positions MAT providers to interact honestly and with confidence when addressing media inquiries.





- Opioid treatment programs (OTPs) operating within larger institutions should consult with institutional public affairs professionals who have local media contacts and can assist in preparing for media interviews or coverage.
- Appoint a media contact in the organization. Restrict the number of staff with authority to speak to the media on behalf of the organization. Educate other staff members on who is the official designee and main contact for media inquiries. Train the designated contacts on the proper response and organization protocol.
- Always respond in a timely manner to calls from the media. Go over the “ground rules” and deadlines with the reporter/journalist in advance of interviews or coverage.
- The job of a reporter is to get a story. Good reporters attempt to get all sides, but ultimately, the story and the deadline sometimes can impede the full presentation of fact and viewpoint. Be sure that responses are provided within agreed upon time frames.
- Be sensitive to journalist integrity and motives in producing a story or news item about or impacting the program. Know the journalist.
- Honest and credible responses to journalist/reporter inquiries about a treatment program are critical. Know the subject matter. Prepare for interviews by reviewing background information and facts.
- Know the most recent information about addiction to heroin, prescription painkillers, and other opiate drugs as well as information about medication assisted treatment. Have fact sheets available.

- Keep responses to reporters and journalists simple and concise. Prepare your own “sound bites,” of five to ten seconds or less. Prepare and practice short, direct phrases to get your message across.
- During interviews, if you cannot answer a question, explain why, or inform the interviewer that you will research and provide response in a reasonable time, and do so. It is better to say why you cannot comment than to say “no comment.” This is particularly true on issues that may pertain to patient confidentiality.
- Be sensitive to leading questions that could be taken out of context. Clarify questions. Be as objective, positive, and flexible as possible in your response.
- Anticipate sensitive or surprising questions. Avoid negative or angry assertions. Do not challenge the credibility of the reporter, or that of other public figures, colleagues, or programs. Focus on your credibility and professional response.
- Update stories when facts change before the story is published or aired.
- If you give a reporter the name of another “expert,” be certain to notify that person that you have referred the reporter to him or her.



# Media Outreach - Sample Press Release

[On letterhead of Organization - Name and Contact Information]

For Immediate Release

Contact: [Contact Person]

[City, State], Date

[Telephone and Fax Numbers]

## Treatment Program Reports Positive Outcomes

The [Name of Program] has achieved positive treatment outcomes following the introduction, one year ago, of an expanded continuum of innovative medical services to its long-established medication assisted treatment program. [Name of Program Director or Medical Director] reports the findings in the program's Annual Report. The report showed improvement in patient retention in treatment, continued decrease in use of heroin and other drugs, reduced incidence of infectious disease, and better use of medical services. The [name of program] has served as a major provider of addiction treatment for community members since [date].

"For more than three decades, studies have shown that medication assisted treatment with methadone medication is highly effective in improving the overall health of patients, greatly reducing heroin and other addictions, and significantly reducing the rate of HIV infection," noted [name source of quote - Program Director or Medical Director]. "Previous studies indicated that 92.4% of methadone patients remained heroin free for over a 4.5-year period and 71% of those in treatment for over a 1-year period remained drug free." The current program findings have yielded similar benefits of medication assisted treatment, and demonstrate that expanded on-site health assessments and on-site primary medical care at the program can significantly continue to improve patient outcomes.

The [name of program]'s Annual Report is available to the public. To receive a copy, and for information on the program's medical and behavioral health services, call [telephone contact].

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# Media Outreach - Sample PSAs

## Radio PSA Scripts

### (30 Seconds)

If you know someone who is struggling with addiction to heroin, prescription painkillers, or other opiate drugs, know this: there is a place to turn for help. Your community offers medication assisted treatment programs using methadone and other pharmacotherapy medications, that can help individuals with opiate addiction and their families lead safe and productive lives. Talk to a counselor about a medication assisted treatment program and take the first step toward reclaiming your life. To find out about the medication assisted treatment programs in your area, call [program telephone number]. That's [program telephone number]. A public service of this station and [program name].

### (30 Seconds)

Addiction knows no boundaries. Addiction to heroin, prescription painkillers, or other opiate drugs is a disease that affects all segments of our community. Medication assisted treatment programs that use methadone and other effective pharmacotherapies, give hope to men and women caught in the devastation of addiction. Your community medication assisted treatment program can offer help to restore your health, self-respect, integrity, and well-being. If you are addicted to opiates, or know someone who is, do something about it. If you are 18 years or older, call [program name], your community medication assisted treatment provider, at [program telephone number]. A public service of this station and [program name].

### (15 Seconds)

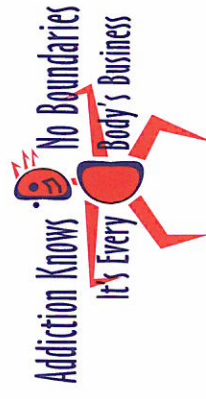
If you know someone who is struggling with addiction to heroin, prescription painkillers, or other opiate drugs, know this: There are effective medical treatment programs in your community. Help them find the help they need. Call [name of program], your community medication assisted treatment provider, at [program telephone number]. A public service of this station.

### (15 Seconds)

Addiction to heroin, prescription painkillers, or other opiate drugs destroys lives. Methadone treatment programs can restore them. Let us help mend your life, your family, and community. Addiction knows no boundaries, it's everybody's business. Call [program name], your community medication assisted treatment provider, at [program telephone number]. A public service of this station.



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# Voices of Methadone Patients

*“I am an addict and now feel normal again. There is success in recovery.”*

**John Mihalega**, Ohio

**Raphael Agostini**, New York - “Methadone has changed my life for the better because it keeps me out of trouble and off the streets.

I have better communication with my family and I understand and appreciate them so much more.”

**Mark Beresky**, Vermont - “As a teenager, something was missing in me. Heroin filled the emptiness that gnawed away at my life. It wasn’t long before I realized that it was destroying my life.

I tried every possible way to quit. Then I found methadone. Methadone treatment helped me rebuild my shattered life. My life was handed back to me because methadone treatment gave me the opportunity to try. I now have a good job and feel that I am making my own family better and stronger.”

**Jay Clarke**, Virginia - “Methadone has saved my life. Five years after beginning treatment, I graduated cum laude from college with a B.S. in human services counseling.

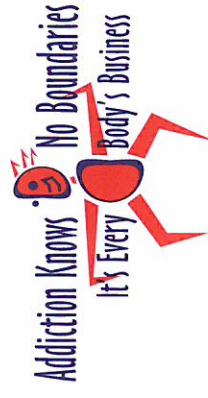
Thanks to this wonderful medication, I am now able to give something back to the community.”

**Amy Courtney**, New Jersey - “I am a Methadone Maintenance Therapy (MMT) patient with four years clean. The conditions at my clinic were going from bad to worse and I knew I had to do something about it. I started by searching the Internet, and when I entered the sites that I found, my whole life was instantly changed.

I discovered a whole community of people who were working toward the betterment of MMT all over the country. Our goal is that every patient in every clinic in New Jersey is aware of their rights and can demand the quality treatment that they deserve.”



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**Thelma Gonzalez**, *New York* - "People can do anything when drug-free, stabilized on methadone, and involved in support groups and counseling. These are the most important steps towards recovery and independence.

Before entering the program, I didn't know who I was. I was frustrated and emotionally exhausted. With the help, I have attained personal and professional goals.

I have obtained a lot of blessings, and give back to those in recovery. As a result of my overall growth, my self-esteem has increased. I am currently a child care worker and the president of the Patient's Advisory Committee in my program."



**Debbie "D.J." Jones**, *Arkansas* - "I struggled with opiate addiction for over 20 years until I found methadone. My life was a mess. I just wanted to lead a normal life, but I couldn't. I had no friends other than opiates until a caring doctor referred me to a methadone program.

Since then, I have been building my new life. I have a committed relationship with a loving partner, and we are buying our own home. I am back in school and plan to open my own computer repair and small network consultant business this year.

Today I have hopes and plans for a real future."



**Suzanne Gandolfi-Lapham**, *New Hampshire* - "I became a patient in 1998. Until then, I did not realize the burdens a methadone patient must endure and that we do not have a voice in regard to our treatment. The oppressive stigma that surrounds Methadone Maintenance Therapy does nothing to empower the patients, who for the most part are just average people, maybe even your neighbor.

Until MMT is assimilated into the medical mainstream, myself and other patients will be kept busy fighting for the rights of this ignored minority."



**Julia Lania**, *New York* - "My husband, brother and oldest son were all heroin addicts and were shot dead in the streets. My youngest so, was also a heroin addict for 20 years. He has been clean and sober for 14 months now.

I too am a former heroin addict and am in methadone treatment. I have been clean and sober for 12 years.

I now have a good job and live in peace. Yes, I have to work hard, but I know that I could not have made it alone. God bless methadone and the counselors who never gave up on me or my son."





**Liz Meeth, Michigan** - "I started MMT in 1996. A few weeks later, I lost my only sibling, my beloved brother, to a heroin overdose. I decided that I wanted to educate myself and others much more thoroughly about the disease of opiate addiction and Methadone Maintenance Therapy, which is currently the best treatment available for this disease. I feel that it is important to educate patients and staff about the big changes that have happened in the past two years."



**John Mihalega, Ohio** - "One of the hardest and most fearful experiences of my life was telling my family I was in treatment for addiction and receiving methadone."

My recovery thus far has been successful and I pray that with all hope, it will continue to be so. I am an addict and now feel normal again. There is success in recovery."



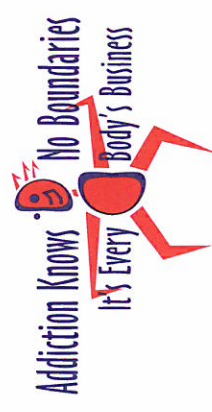
**Renee Willis, New York** - "I began Methadone Maintenance Therapy (MMT) on August 11, 2001. After receiving my first dose, I have not used a single opiate or any other legal or illegal drug since, including alcohol."

Rather than living the grim life I predicted for myself as an MMT patient, I now lead a reasonably happy, full (and more than anything) typical life with my 4-year-old son."

I feel that my future is getting brighter every day because methadone has enabled me to be responsible, productive, and enthusiastic--both in the workplace and in my personal life."



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# Resources and References



## Resources:

**U.S. Department of Health and Human Services (HHS)**

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**Substance Abuse and Mental Health Services Administration (SAMHSA)**

**Substance Abuse and Mental Health Services Administration (SAMHSA)**

240-276-2130; 240-276-2135 (fax)

[www.samhsa.gov](http://www.samhsa.gov)

**SAMHSA's National Clearinghouse for Drug and Alcohol Information (NCADI)**

1-800-729-6686, 301-468-6433 (fax)

[www.ncadi.samhsa.gov](http://www.ncadi.samhsa.gov)

**SAMHSA's National Treatment Referral Helpline**

1-800-662-HELP, 1-800-487-4889 (TDD)

**SAMHSA's National Treatment Locator**

[www.findtreatment.samhsa.gov](http://www.findtreatment.samhsa.gov)

**Center for Substance Abuse Treatment (CSAT)**

**Division of Pharmacologic Therapies**

240-276-2700; 240-276-1630 (fax)

[www.samhsa.gov](http://www.samhsa.gov)



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[www.samhsa.gov](http://www.samhsa.gov)

**Center for Substance Abuse Treatment (CSAT)  
The Patient Support and Community  
Education Project**

[www.samhsa.gov](http://www.samhsa.gov)

**Office of the Director, Consumer Affairs**

240-276-2750; 240-276-2760 (fax)

[www.samhsa.gov](http://www.samhsa.gov)

**U.S. Department of Health and Human Services (HHS)**

**SAMHSA's National Treatment Locator**

[www.findtreatment.samhsa.gov](http://www.findtreatment.samhsa.gov)

**Center for Substance Abuse Treatment (CSAT)**

**Division of Pharmacologic Therapies**

240-276-2700; 240-276-1630 (fax)

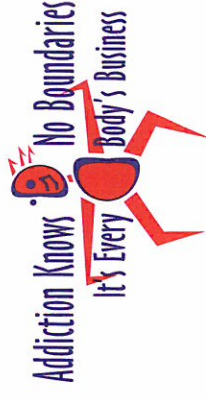
[www.samhsa.gov](http://www.samhsa.gov)

**Food and Drug Administration**

**Center for Drug Evaluation and Research**

Narcotic Treatment Program Director

[www.fda.gov/cder/compliance/ntpd/ir.pdf](http://www.fda.gov/cder/compliance/ntpd/ir.pdf)





**National Institutes of Health (NIH)**  
**National Institute on Drug Abuse (NIDA)**  
301-443-6460  
[www.nida.nih.gov](http://www.nida.nih.gov)

**Executive Office of the President**  
**Office of National Drug Control Policy**  
202-395-6700  
[www.whitehousedrugpolicy.gov](http://www.whitehousedrugpolicy.gov)

**U.S. Department of Justice**  
**U.S. Drug Enforcement Administration**  
**Office of Diversion Control/Liaison Unit**  
202-307-7292 or 202-307-4875  
[www.usdoj.gov/dea](http://www.usdoj.gov/dea)

**Other Resources:**

*The following list is not exhaustive and inclusion on this list does not imply endorsement by SAMHSA, CSAT or HHS.*

**Addiction Treatment Watchdog**  
P.O. Box 585  
Springfield, MO 65801  
816-674-9510  
<http://www.atwatchdog.org>  
[info@atwatchdog.org](mailto:info@atwatchdog.org)

**Advocates for Recovery Through Medicine**  
P.O. Box 90337  
Burton, MI 48509-0337  
615-354-1320  
<http://www.methadonetoday.org>  
[armorg@comcast.net](mailto:armorg@comcast.net)

**Advocates for the Integration of Recovery and Methadone**  
455 East Bay Drive  
Long Beach, NY 11561  
516-897-1330 (days); 516-889-8142 (evenings)  
516-897-1149 (fax)  
<http://www.methadonetoday.org/afirm.html>  
[afirmfwc@aol.com](mailto:afirmfwc@aol.com)

**American Association for the Treatment of Opioid Dependence**  
217 Broadway, Suite 304  
New York, NY 10007  
212-566-5555, 212-349-2944 (fax)  
[www.aatod.org](http://www.aatod.org)

**National Alliance of Methadone Advocates**  
435 Second Avenue  
New York, NY 10010  
212-595-6262 (phone/fax)  
<http://www.methadone.org>  
[nama.president@verizon.net](mailto:nama.president@verizon.net)

**Opiate Dependence Resource Center**  
167 Main Street, Suite 304  
Brattleboro, VT 05301  
802-251-0066; 1-800-711-8680; 820-246-1026 (fax)  
<http://www.methadone.net>  
[askus@methadone.net](mailto:askus@methadone.net)



**Texas National Alliance of Methadone Advocates**

978-246-6510 (fax)  
<http://www.methadone.org/texnama/>  
texnama@aol.com

**Virginia Alliance of Methadone Advocates**

3447 Budd Court  
Norfolk, VA 23518  
757-853-2013  
<http://vamehadvocates.org/>  
jayccclarke@netzero.net

**Washington Association of Methadone Maintenance**

4802 South Holden Street  
Seattle, WA 98118  
206-722-1001  
kumarsdad@msm.com

**References:**

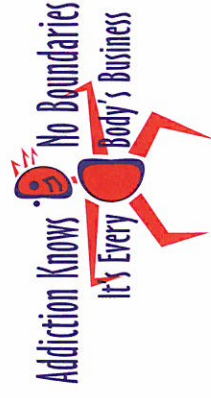
U.S. Department of Health and Human Services, National Institutes of Health, National Institute on Drug Abuse (1999) *Principles of Effective Treatment*. Washington, D.C.

U.S. Department of Health and Human Services, National Institutes of Health Consensus Panel Report (1997) *Effective Medical Treatment of Opioid Addiction*, NIH Consensus Development Conference on Effective Medical Treatment of Heroin Addiction, Washington, D.C.

The Institute of Medicine (IOM) Federal Regulations of Methadone Treatment, Rettig RA, Yarmolinsky A, editors. Washington (DC): National Academy Press; 1995.



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# Opioid Pharmacotherapy Treatment and Accreditation

Opioid agonists are drugs that activate receptors in the brain. Agonists occupy receptors and switch them on. As a result, they produce an effect in the brain and body. Therefore, opioid agonists switch on one or more opioid receptors. Methadone, an opioid agonist medication, is recognized by the American Medical Association, which affirmed “the proven public health and patient health benefits of methadone maintenance and other similar opioid replacement programs in reducing the use of heroin.”<sup>1</sup> This 1999 declaration followed a report from The Institute of Medicine (IOM) in 1995 and the conclusion of a 1997 National Institutes of Health (NIH) Consensus Development Panel. Both the IOM and the NIH Consensus Panel recommended that opioid addiction be treated more like other medical conditions and that efforts be made to reform the methadone treatment system. To modernize the treatment system, the Secretary of the U.S. Department of Health and Human Services promulgated regulations that became effective May 18, 2001, to transfer oversight of opioid treatment programs from the Food and Drug Administration to the Substance Abuse and Mental Health Services

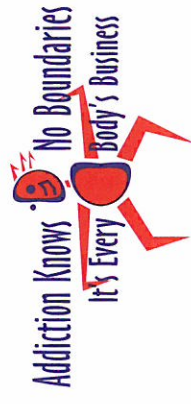
Administration (SAMHSA). One of the key requirements of the regulations (42 CFR Part 8) is that opioid treatment programs become accredited, just like the process required for other mainstream health care facilities.

**What does this requirement mean for patients, programs, and the community?**

- Accreditation demands a higher standard of care for people receiving opiate agonist<sup>2</sup> treatment for addiction to heroin and other opiates, by shifting responsibility for treatment decisions from regulators to clinicians.
- Accreditation allows for greater clinical discretion and medical judgment in determining appropriate individualized treatment, particularly in managing methadone doses.
- Accreditation ensures that patients are appropriately assessed and matched to the right treatment, that treatment is individualized, and that the need for ongoing care is professionally assessed and monitored for quality.



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- Accreditation provides patients and the community with assurance that quality treatment is being provided to those who are addicted to heroin and similar opioids.
- Accreditation's focus on quality of care integrates opiate agonist treatment into the mainstream of the nation's health care system and helps reduce the stigma associated with that treatment.
- Accreditation promotes state-of-the-art treatment services, with emphasis on outcome measures, especially those pertaining to reductions in crime and drug use, and engagement in productive employment. These changes enhance patient rights as well as outline patients' responsibilities.

Additionally, opioid treatment programs are regulated by the U.S. Department of Justice, Drug Enforcement Administration for their security and accounting of their medications, and by individual state authorities for compliance with state program standards.

<sup>1</sup>The American Medical Association, "Reduction of the Medical and Public Health Consequences of Drug Abuse: Update," adopted as AMA policy, 1999 AMA Annual Meeting.

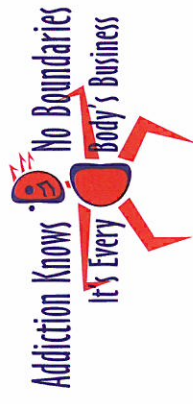
<sup>2</sup>At proper doses, agonist therapy relieves the physiological craving for opioids, blocks the euphoric effects of opioids, and normalizes the physiology of the body impaired by opioid dependence.

# Comparison Chart of Heroin Dependence and Agonist Therapies

<u>Topic</u>	<u>Heroin</u>	<u>Methadone</u>	<u>Buprenorphine</u> <sup>1</sup>
<b>Onset of action</b>	A few seconds	30 minutes	30 to 40 minutes
<b>Duration of action</b>	4 to 6 hours	24 to 36 hours	About 24-48 hours
<b>Route of administration</b>	Injection, snorting, smoking	Oral	Sublingual
<b>Frequency of administration</b>	Several times a day	Daily <sup>2</sup> or more frequently as needed	Every day or every other day
<b>Effective dose</b>	Ever increasing	Blocking dose <sup>3</sup> , usually 80 to 120 mg	2 to 32 mg <sup>4</sup>
<b>Tolerance</b>	Increasing tolerance	Tolerance is stable	Tolerance is stable
<b>Euphoric effects</b>	Euphoria for up to 2 hours	No euphoria when stabilized	No euphoria when stabilized
<b>Overdose potential</b>	High <sup>5</sup> and increased	Rare <sup>5,6</sup> -- Potential if mixed with other depressants	Very rare <sup>5,6</sup>
<b>Overall safety</b>	Potentially lethal	Very safe <sup>7</sup> -- Possibly associated with rare cardiac irregularities-- Treatment choice in pregnancy	Overall good profile -- Suboxone injection will cause serious withdrawal symptoms in dependent persons -- Not recommended for use in pregnancy or breast feeding -- Caution with liver disease -- Currently under study



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<u>Topic</u>	<u>Heroin</u>	<u>Methadone</u>	<u>Buprenorphine</u> <sup>1</sup>
<b>Withdrawal</b>	Within 3 to 4 hours after last dose	Within 24 to 36 hours after last dose	Within 36 to 48 hours after last dose
<b>Craving</b>	Recurring cravings	Eliminated with adequate dose	Craving may not be totally eliminated due to ceiling effect
<b>Pregnancy and nursing</b>	Heroin dependence poses grave risks for mother and fetus	Safe during pregnancy <sup>8</sup>	Not indicated, however study underway
<b>Experience of pain and emotions</b>	Blunted	Normal pain and full range of emotions	Normal pain, but opioid analgesics may not be effective May need to switch to methadone -- Full range of emotions
<b>Mood</b>	Constant mood swings	Normal <sup>9</sup>	Normal <sup>9</sup>
<b>Physical reaction time and intellectual functioning</b>	Impaired	Reaction time normal Intellectual functioning unimpaired on stable dose <sup>10</sup>	Reaction time presumed to be normal like methadone. FDA cautions driving and operating heavy machinery in the beginning of treatment
<b>HIV &amp; hepatitis C transmission</b>	High rate with needle use and unprotected sex	Reduced/eliminated <sup>11</sup>	Reduced/eliminated <sup>11</sup>
<b>Immune system for HIV positive persons</b>	Rapid progression to AIDS	Progression slowed with methadone <sup>11</sup>	Progression presumed same as methadone -- Data not available for buprenorphine
<b>Immune/endocrine system functioning</b>	Impaired	Normalized during treatment <sup>12</sup>	Presumed normalized during treatment -- Data not available
<b>Stress response</b>	Suppressed	Normalized during treatment	Normalized during treatment

## Topic

## Heroin

## Methadone

## Buprenorphine<sup>1</sup>

### **Criminal activity**

High level

Reduced/eliminated

Reduced/eliminated

### **Personal relationships**

Disrupted

Potential for restoration, improvement with counseling

Potential for restoration, improvement with counseling

### **Employment**

Deteriorating performance, loss of employment

Full functioning

Full functioning<sup>13</sup>

### **Community impact**

Destructive impact; high crime, high death rate, transmission of disease

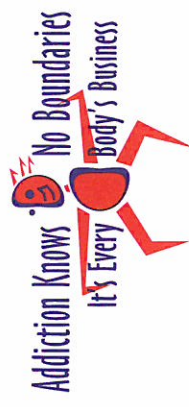
Contributes to public safety, low mortality, increased health

Contributes to public safety, low mortality, increased health

1. Two forms of buprenorphine: *Subutex*® (pure buprenorphine) used for withdrawal and at treatment induction and *Suboxone*® (buprenorphine with naloxone) used after initial treatment phase for longer-term maintenance to address addiction. *Suboxone*® is recommended for all prescription and all out-of-clinic doses.
2. Rapid metabolizers and pregnant women may require dosing twice per day.
3. The dose at which heroin is ineffective and overdose potential practically eliminated.
4. The highest doses are equivalent to about 50# mg of methadone. A ceiling or limit exists for buprenorphine's therapeutic effects.
5. Overdose potential is increased if mixed with other depressant drugs such as alcohol or benzodiazepines (anti-anxiety medications).
6. Overdose is rare with opioid-tolerant individuals in opioid treatment.
7. No serious side effects have been found in opioid-tolerant patients who have been in treatment for over 20 years. Long-term studies show no liver toxicity. Patients with hepatitis C and AIDS can be treated safely with methadone although changes in dose may be necessary.
8. Neonate who shows signs of withdrawal can be treated successfully with paregoric or tincture of opium. HIV-positive/AIDS mothers should not nurse. Mothers with hepatitis C can nurse with caution.
9. Mood remains normal if no other psychiatric or emotional conditions exist.
10. Methadone patients over the last 30 years have worked in all types of jobs and professions, including work with complicated machinery and computers, and professional work requiring advanced degrees.
11. In conjunction with proper education/counseling, these medications stop the use of heroin, but not injection of other drugs nor unsafe sexual practices.
12. Appears to improve immune response when compared to heroin.
13. FDA label warning cautions against heavy machinery use or driving during initial phase of treatment.



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# Fact Sheet: Opioid Use and Dependence: Medication Assisted Treatment

## Opioid Use and Dependence – *how widespread is it?*

tion opioid drugs are now being abused by large numbers of people and are leading to large number of emergency department admissions.

## Heroin

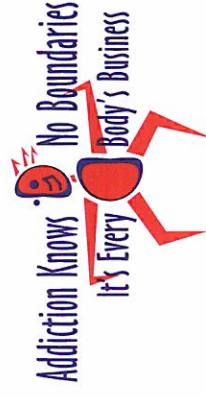
- According to the Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA), in 2002, an estimated 214,000 individuals were heroin dependent or abused heroin during the previous 12 months. SAMHSA's 2002 National Survey on Drug Use and Health (NSDUH) found that approximately 1.5 million individual reported dependence upon or misuse of pain reliever medications. During the 1990's, heroin incidence rose to a level not reached since the 1970s. The survey reports that between 1995 and 2001, the number of new heroin users was consistently greater than 100,000. Moreover, since the mid-1990s, the prevalence of lifetime heroin use increased for both youths and young adults. From 1995 to 2002, the rate among youths aged 12 to 17 increased from 0.1 to 0.4 percent; among young adults aged 18 to 25, the rate rose from 0.8 to 1.6 percent.

- SAMHSA's Drug Abuse Warning Network (DAWN) reported that narcotic pain medications implicated in drug-abuse related emergency room visits rose 20 percent from 2001 to 2002. Emergency department mentions of narcotic pain medications rose from 99,317 in 2001 to 119,185 in 2002. Of those mentions, 40 percent involved either oxycodone or hydrocodone. Between 1994 and 2002, ED mentions of oxycodone and hydrocodone have increased 450 percent and 170 percent respectively. These data point to the fact that many prescrip-

- In 2002, there were 670,307 drug-abuse-related hospital emergency department visits in the continental United States in 2002, about the same as in 2001, according to DAWN. Misuse of anti-anxiety drugs and narcotic pain relievers were each mentioned as often in hospital emergency rooms as heroin in 2002. Narcotic pain medications accounted for 10 per cent of total drug mentions in hospital emergency department visits related to drug abuse in 2002. Over the eight-year period from 1995 to 2002, mentions of narcotic pain medications rose 163 percent from 45,254. Heroin mentions, while statistically unchanged from 2001 to 2002, increased 35 percent since 1995 from 69,556 to 93,519 in 2002.
- Treatment admission rates for misuse of narcotic pain relievers more than doubled between 1992 and 2002, according to SAMHSA. These admissions increased for all ages, but especially among people aged 20 to 30. Between 1997 and 2002, the proportion of new users – those entering treatment within three years of beginning use – increased from 26 percent in 1997 to 39 percent in 2002. The median duration of use before first seeking treatment decreased from nine years of use in 1992 to seven years of use in 1997 to four years of use in 2002. The report is based on SAMHSA data compiled in the Treatment Episode Data Set (TEDS).



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## Prescription Opioids

- Evidence from around the country suggests that a significant percentage of patients in methadone programs are being treated for prescription opioid dependence. For example, Alaska estimates that there are 15,000 prescription opioid abusers in the state and that most methadone patients are not heroin-addicted individuals. One opioid treatment program in southwest Virginia reported that 80 percent of the 290 people in outpatient treatment with methadone named OxyContin<sup>®</sup> as their primary drug of abuse. According to SAMHSA's Center for Substance Abuse Treatment, in 2003, programs in Virginia and Kentucky reported that approximately 85 percent of admissions cite oxycodone as their primary drug of use. According to the 2001 DAWN data, from 1994 to 2001, emergency department mentions of narcotic analgesics and narcotic analgesic combinations were the most frequently mentioned in drug-related emergency department visits in 2001, constituting 9 percent of all emergency room mentions (99,317). Mentions of these narcotic analgesics and combinations rose 44 percent from 1999 to 2001 and 21 percent from 2000 to 2001. Significant long-term increases in emergency department mentions of narcotic analgesics and combinations were found for hydrocodone and its combinations (up 131 percent since 1994), methadone (up 230 percent), morphine and its combinations (up 210 percent), oxycodone and its combinations (up 352 percent) and narcotic analgesics that were not specified (up 288 percent).

One year, from 2000 to 2001, methadone mentions increased by 37 percent and oxycodone and its combinations rose 70 percent. Unspecified narcotic analgesics rose 24 percent. Mentions of analgesics containing hydrocodone were statistically unchanged from 2000 to 2001, but were 41 percent higher than in 1999.

## Opiate Use and Addiction – How are they treated?

A variety of treatments are available for heroin abuse and dependence:

- Long- or short-term residential treatment in a therapeutic community involving counseling in a highly structured residential environment.
- Outpatient programs emphasizing a range of behavioral counseling and psychotherapy.
- Medication assisted treatment that uses agonist or partial agonist medications (see chart at end of fact sheet for definition) such as methadone or buprenorphine to normalize brain chemistry, block the euphoric effects of opioids and relieve physiological cravings, and normalize body functions.
- Use of opioid antagonists (see chart at end of fact sheet for definition), such as naltrexone, to block the effects of opioid drugs; often used to prevent relapse to opioid use in highly selected populations.

While not considered formal treatment, groups such as Narcotics Anonymous and Methadone Anonymous, can be used.

## Methadone Treatment

Methadone treatment provides the patient who is opioid dependent with medication, health, social, and rehabilitation services that relieve withdrawal symptoms, reduce physiological cravings, and allow normalization of the body's functions. Methadone treatment has been available for over 30 years and has been confirmed effective for opioid dependence in numerous scientific studies.



Moreover, in 1997, the U.S. Department of Health and Human Services' National Institutes of Health (NIH) Consensus Panel found the following concerning methadone treatment: "Of the various treatments available, methadone maintenance treatment, combined with attention to medical, psychiatric and socioeconomic issues, as well as drug counseling, has the highest probability of being effective."

Methadone treatment programs are staffed by professionals with medical, clinical, and administrative expertise. Patients receive medication from a health professional. Patients routinely meet with a primary counselor (social worker, caseworker, or certified substance abuse counselor), attend clinic groups, and access medical and social services.

### **Methadone Is Not A Substitution of One Drug for Another**

Methadone is not a substitute for opioids or any other short-acting opioid, and does not affect all individuals in the same way. Methadone does not create a pleasurable or euphoric feeling; rather it relieves physiological opioid craving and is generally chosen by opioid-dependent individuals. Methadone normalizes the body's metabolic and hormonal functioning that were impaired by the use of heroin or other opioids. It is a corrective, not curative, treatment. Unlike the disruptive nature of short-acting chemicals on the brain, methadone has long-acting properties that provide metabolic stability. For example, methadone creates the physical stability that allows female menses to return to normal cycle after its disruption from heroin use. Methadone allows embryos and fetuses to develop in a safe and stable metabolic environment instead of experiencing withdrawal from heroin every six hours due to the mother's use.

### **Absence of Serious Adverse Effects**

When taken as prescribed, long-term administration of methadone causes no adverse effects to the heart, lungs, liver, kidneys, blood, bones, brain, or other vital body organs. Some side effects may arise, such as constipation, water retention, drowsiness, skin rash, excessive sweating, and reported change in sexual drive. These may occur during the initial stages of treatment. These symptoms generally subside or disappear as methadone dosage is adjusted and stabilized, or when simple medical interventions are initiated. The myth that methadone rots bones and teeth, and is otherwise physically harmful, has been scientifically shown to be unfounded.

### **Medication Interactions**

Patients on methadone can be treated with most medications without serious interactions or contraindications. For example, patients with conditions such as hypertension, diabetes, pneumonia, cardiac conditions, cancers, psychiatric disorders, etc. may be treated effectively with routine regimens and medications. However, as with any medication, treating physicians must be aware of all other medication that their patients are taking. Coordination of methadone with certain other medications is necessary. For example, certain medications used to treat HIV/AIDS, epilepsy, tuberculosis, and hepatitis C may prompt the need for the program physician to change the methadone dose level. Medications such as dilantin for epilepsy and rifampin for tuberculosis increase the body's metabolism of methadone and, thus, prompt the need for an adjustment in the methadone dose or possibly splitting the dose to be taken twice daily instead of once. Therefore, it is very important that all physicians (primary care provider, surgeon,



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methadone treatment program physician, etc.) be aware of each other's involvement with the patient.

## **Use of Pain Medication with Methadone Patients**

Methadone patients, at all dose levels, experience normal pain and, therefore, benefit from analgesia following surgical procedures or other painful medical or dental procedures. Pain management, which also may include medication, is required for chronic malignant and nonmalignant pain. Methadone maintenance treatment should be continued without lowering the maintenance dose. Opioids such as morphine, oxycodone, and pain-control analgesia (PCA) and even methadone itself can be used to treat methadone patients. However, because of their tolerance to opioids, methadone patients possibly will require higher doses of opioids and at more frequent intervals.

When prescribing methadone as a pain medication, the regular maintenance dose should be maintained, and the methadone used for analgesia should be prescribed separately three to four times per day, since methadone's analgesic properties last only from four to six hours. Methadone patients should not be prescribed medications for pain that contain opioid antagonists since the antagonists will precipitate withdrawal. According to the NIH Consensus Panel Report, methadone patients can be safely prescribed both opioid and non-opioid analgesics without antagonist properties.

## **Methadone Treatment Truths**

### **Cost-Effectiveness**

Methadone treatment contributes to the reduction of the economic and social burdens linked to opioid abuse. Most methadone-maintained patients are able to secure and maintain gainful employment, remain free of inappropriate

use of opioids, improve health, and reduce the risk of exposure to HIV/AIDS.

Methadone treatment has positive outcomes for the individual and for the community. It has been found to be highly cost-effective. The Institute of Medicine in its 1995 report concluded that "methadone maintenance pays for itself on the day it is delivered, and post-treatment effects are an economic bonus."

The savings to taxpayers also is well documented by the National Drug Court Institute. A comprehensive examination of the economic benefits versus the cost of methadone treatment reveals a ratio of 4:1, or \$4.00 in economic benefits for every \$1.00 spent.

## **Reduction in Heroin and Other Opioid Use**

Methadone treatment dramatically reduces opioid use after admission to methadone treatment and further declines as patients remain in treatment. SAMHSA's Services Research and Outcomes Study (SROS) validated these findings in 1998. The study found that "clients in methadone facilities composed the only group showing a significant decrease in heroin use (27 percent decline). Additional outcome follow-up from the California Drug and Alcohol Treatment Assessment (CALDATA), and the National Treatment Improvement Evaluation Study (NTIES) and Drug Abuse Treatment Outcome Study (DATOS), compiled by Gerstein and Johnson of the National Opinion Research Center (NORC) in 1999, found a 39 percent, 51 percent, and 69 percent reduction in heroin use respectively.

## **Reduction in Criminality**

Methadone treatment also is associated with reducing crime in the offender population as patients enter and remain in treatment. According to the National Drug Court Institute, it has been repeatedly demonstrated that 80 percent of the patients will reduce or eliminate crime as they remain in methadone treatment programs. Decreases in criminal behavior are greater the longer a person is in treatment.



## Reduction in Risk of HIV/AIDS and Hepatitis

The relationship between intravenous (IV) drug use, needle sharing, hepatitis, and HIV/AIDS exposure is well-documented. Higher-dose methadone treatment (over 80 mgs.) is the most effective intervention for reducing the spread of HIV/AIDS and hepatitis, according to the *Mount Sinai Journal of Medicine*.

## Use of Methadone and Pregnancy

Women can conceive and have normal pregnancies and deliveries when maintained on methadone. When the methadone dosage is therapeutically prescribed for women, methadone treatment provides a non-stressful environment for the developing fetus. Because methadone crosses the placental barrier, some babies may be physically dependent on methadone at first and need to be weaned. It is also true that methadone maintained women give birth to babies who do not experience any withdrawal. The myth that methadone produces abnormality in fetuses has no basis in fact. Additionally, children born to methadone-maintained women have been studied longitudinally and develop normally in good postnatal environments. Accordingly, it is medically contraindicated to withdraw pregnant methadone maintained patients from the medication.

## Buprenorphine

The Drug Addiction Treatment Act of 2000 (DATA 2000) permits physicians who are specially trained and meet specific qualifications to prescribe certain Food and Drug Administration (FDA) approved scheduled narcotic medications for the treatment of narcotic dependency. Buprenorphine is the first of these special narcotic medications to be approved by the FDA. DATA 2000 requires the physician to complete a special training course or hold a subspecialty board certification from either the American Board of Medical Specialties or the American Osteopathic Association, or certification from the American Society of Addiction

Medicine. Additionally, DATA 2000 requires physicians to submit a notification for a waiver from the special registration requirements in the Controlled Substances Act for the provision of medication-assisted opioid therapy. This waiver allows qualifying physicians to practice medication-assisted opioid addiction therapy with specially FDA-approved narcotic medications for up to 30 patients.

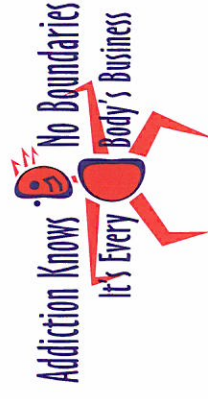
Subutex® (buprenorphine hydrochloride) and Suboxone® (buprenorphine hydrochloride with naloxone hydrochloride) were approved by the Food and Drug Administration on October 8, 2002, for the treatment of opioid dependence. These medications currently are being marketed as sublingual (SL) tablets. Buprenorphine medications will be available through specially trained physicians and opioid treatment programs for the treatment of opioid dependence. Research studies show this medication is similar to methadone in its ability to stabilize functioning so patients can participate in comprehensive treatment for their opioid dependence.

In addition to drugs like heroin, addiction to prescription pain relievers like oxycodone, hydrocodone, and codeine are also treated with the new buprenorphine medications. Like methadone, buprenorphine suppresses withdrawal symptoms and blocks the effects of other opioids. A doctor who is qualified can determine if buprenorphine is an appropriate choice of treatment medications for a patient addicted to prescription pain relievers.

People can transfer from methadone to buprenorphine therapy, but because the two medications are different, patients need to be educated by their treatment provider or physician in the effects of, and differences between, agonist (methadone) and partial antagonist (buprenorphine) type drugs. A number of factors affect if buprenorphine is a good choice for someone who is currently in methadone treatment. It is also possible for patients on



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buprenorphine to be transferred to methadone therapy. Patients interested in learning more about the possibility of transferring therapies should raise the issue with the doctor who is prescribing their medication.

The FDA's New Drug Application Labeling states that patients who are methadone-maintained and are considering transferring to buprenorphine as a maintenance medication need to be at a methadone dose of 30 mgs. or less to make the transition safely, reducing the interaction of the agonist medication (methadone) with the partial antagonist medication (buprenorphine). The likelihood of developing withdrawal symptoms during the transition increases proportionately with doses above 30 mgs. of methadone.

### **Safety**

Because of its ceiling effect and poor bioavailability, buprenorphine is safer in overdose than opioid full agonists. The maximal effects of buprenorphine appear to occur in the 16–32 mg dose range for sublingual tablets. Higher doses are unlikely to produce greater effects.

Respiratory depression from buprenorphine (or buprenorphine/naloxone) overdose is less likely than from other opioids. There is no evidence of organ damage with chronic use of buprenorphine, although increases in liver enzymes are sometimes seen. Likewise, there is no evidence of significant disruption of cognitive or psychomotor performance with buprenorphine maintenance dosing.

Information about the use of buprenorphine in pregnant, opioid-addicted women is limited; the few available case reports have not demonstrated any significant problems due to buprenorphine use during pregnancy. Suboxone® and Subutex® are classified by the FDA as Pregnancy Category C medications.

Currently, methadone remains the standard of care for the medication assisted treatment of opioid-addicted women in the United States.

For additional information, please see the chart at the end of this fact sheet, call 1-800-BUP-CSAT, or visit the SAMHSA Web site at [www.buprenorphine.samhsa.gov](http://www.buprenorphine.samhsa.gov).

### **Naltrexone**

Naltrexone is a drug prescribed to help people maintain abstinence after they have successfully detoxified from heroin or other opioids. It does so by blocking the opioid receptors in the body. Using heroin or other opioids while on naltrexone will have little or no effect.

Naltrexone treatment assists some people to remain free of heroin once they have detoxified, and it does not produce physical or psychological dependence.

### **Considerations for Naltrexone Treatment**

A person's body must be free of heroin for 7-10 days, or up to 14 days, if using methadone. Naltrexone will bring on immediate and possibly severe symptoms if there are opioids in the body. Narcan (naloxone) can be used to test if the body is opioid free and it will immediately bring on short-term withdrawal symptoms.

Liver conditions such as acute hepatitis and alcoholic liver disease may exclude a person from taking naltrexone. It has not been established that using naltrexone during pregnancy or breastfeeding is completely safe. Advice should be sought from a doctor.

There are better outcomes from naltrexone treatment for people who are highly motivated to become opioid-free and who are well-supported by friends and family.



## What Naltrexone Treatment Involves

The treatment involves taking a prescribed course of naltrexone tablets for up to 2 years. These are taken by mouth, once a day, or every couple of days at a higher dose. Naltrexone is supplied as 50 mg tablets in bottles of 30 tablets. This medication can be more effective when combined with counseling and ongoing support from a doctor, family, or friends.

## Other Uses of Naltrexone

Naltrexone is sometimes used in the treatment of alcohol dependence, as it appears to reduce the desire to drink alcohol in some people.

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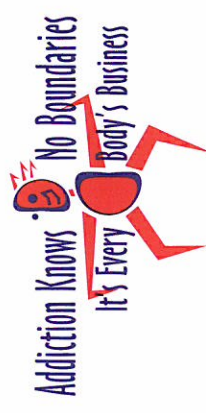
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## Agonist - Partial Agonist - Antagonist Chart

Agonist	Methadone	Binds to opiate receptor* and mimics the internal opiate system.	Methadone can be used for maintenance and medical withdrawal	Methadone begins at 80 mgs oral daily.	Starting at 80 mgs	Effect on Craving	Completely relieved	Methadone over 80 mgs/day is safe and prevents respiratory depression.	Medical Safety
Partial Agonist	Buprenorphine and Buprenorphine combined with Naloxone	Binds to the receptor* but produces minimal agonist effects.	Buprenorphine alone for stabilization and medical withdrawal. Buprenorphine with Naloxone is used for maintenance.	8-32 mgs daily or every other day sublingually dissolves under the tongue in 3-7 minutes.	Starting at 4 mgs	Effect on Craving	For some individuals the craving is completely relieved. Because of the ceiling effect that limits activity, some will experience craving and need full agonists treatment.	For opioid naive individuals, ceiling effect reduces possibility of respiratory depression.	Medical Safety
Antagonist	Naltrexone	Binds to the receptor* and produces no activity, thus blocking the effects of agonists (i.e., morphine, endorphins).	Maintenance	50 mgs daily oral and 150 mgs oral every other day.	At any dose	Effect on Craving	Does not relieve physiological craving and may induce secondary abstinence symptoms resulting in discomfort.	Protects against respiratory depression. Some patients complain of discomfort and can cause inability to experience pleasure and other symptoms of the secondary abstinence syndrome.	Medical Safety





## Agonist - Partial Agonist - Antagonist Chart

	<b>Agonist</b>	<b>Partial Agonist</b>	<b>Antagonist</b>
Withdrawal	Methadone after 24 hours.	After 48 hours	None
Severity of Withdrawal	Methadone symptoms are milder, but longer than heroin (7 days).	Buprenorphine is milder than methadone but more protracted.	None
Patients Acceptance, Retention in Treatment	Good retention with patients in treatment up to 30 years without toxic effect.	Presumed to be good, but long-term data are not available.	Poor, patients leave early because of craving, secondary abstinence syndrome, and discomfort.
Target Population	All adults over 18 including pregnant women.	Individuals age 16 and over with short histories of opioid dependence. Methadone patients on very low doses (i.e., 30 mgs and under). Not recommended for pregnant or nursing women.	Only a small group of opioid-dependent individuals respond. Non-responders should be transferred to agonist or partial agonist therapy.
Pain Management	Effectively treated with other opioids.	No analgesia; action is blocked, and if patient needs pain medication, must be transferred to methadone.	No analgesia; action is blocked, and if patient needs pain medication, must be transferred to methadone.
Pregnancy	Methadone is recommended.	Under study	Contraindicated
Breast Feeding	Methadone is safe with HIV-negative and normal caution with HCV.	Under study	Contraindicated

\*Receptor: Receptors are found throughout the body. However, in the brain, an opiate receptor is where internal opiates, such as endorphins, bind as well as the external opiates such as heroin, methadone, and buprenorphine. They can be thought of as a lock (i.e., the receptor) and key (i.e., the opiate). Methadone has the best fit as the key and most resembles the internal opiates in its action.



# Fact Sheet: Methadone Research Findings

## History and Effectiveness of Methadone Maintenance Treatment

Methadone's effectiveness, and the absence of any serious, long-term side effects from using it, have been demonstrated in numerous studies conducted over the past 30 years. Among the most commonly cited outcomes are:

- **Consumption of all illicit drugs declines** to less than 40 percent of pretreatment levels during the first year and eventually reaches 15 percent of pretreatment levels for patients who remain in treatment 2 years or more according to Ball and Ross, 1991; and Hubbard, et al, 1986.

- **Crime is reduced substantially:** For example, in the most detailed study of treatment outcomes to date, Ball and Ross, 1991, showed that during the first 4 months of treatment, crime decreased from 237 crime days per year per 100 addicted persons during an average year of their addiction to 69 crime days per year per 100 patients, a reduction of more than 70 percent (p. 205), declining further to only 14.5 crime days per year for patients in treatment 6 years or more.

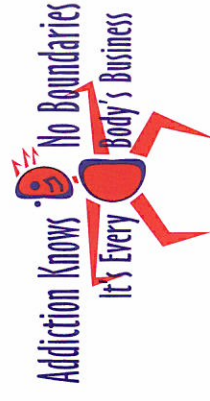
- **Fewer individuals become infected with HIV:** A study by Metzger, et al, 1993, showed that over a 3-year period, 5 percent of patients in methadone treatment became HIV-positive (over and above those already positive at admission), while among a cohort of out-of-treatment addicts in the same neighborhood, 26 percent became HIV-positive (over and above those already positive at baseline).

- **Individual functioning improves, as evidenced in improved family and other social relationships, increased employment, improved parenting, etc.,** according to the Substance Abuse and Mental Health Services Administrations, Center for Substance Abuse Treatment, 1994, and Lowinson, et al, 1992. For example, the 1992 Lowinson study of the first 15 years of methadone treatment documented employment rates of patients just below 60 percent. Even in the 1980s, when the economy weakened, crack use increased, and HIV infection rates increased dramatically, social productivity levels and employment remained at about 40 percent.

Methadone has been shown to be safe. It produces no serious or long-term side effects, and may improve immune system functioning in people who have experienced the deleterious effects of heroin addiction. Methadone's clinical effectiveness has been documented in more than 300 published research studies, Hubbard, et al, 1986; Sells, et al, 1979. Furthermore, "comprehensive methadone maintenance, when combined with appropriate prenatal care, can reduce the incidence of obstetrical and fetal complications...and there is no reported evidence of any toxic effects of methadone in the woman, fetus, or child" according to the Institute of Medicine, 1995. Finally, at an annual average cost of \$4,000/patient, methadone maintenance treatment is cost effective as stated in the *Federal Register*, 1999. The Treatment Outcome Prospective Study (TOPS), analyzed the average cost of treatment; rates of criminal activities; costs to society of various crimes; and economic benefits and costs. Using these data, Harwood, et al, 1988, found that for every \$1 invested in treatment, \$4 is recovered in social costs.



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Substance Abuse and Mental Health Services Administration  
Center for Substance Abuse Treatment  
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