

# **Models of Care – Buprenorphine Experience in the Department of Veteran Affairs**

**May 2010**

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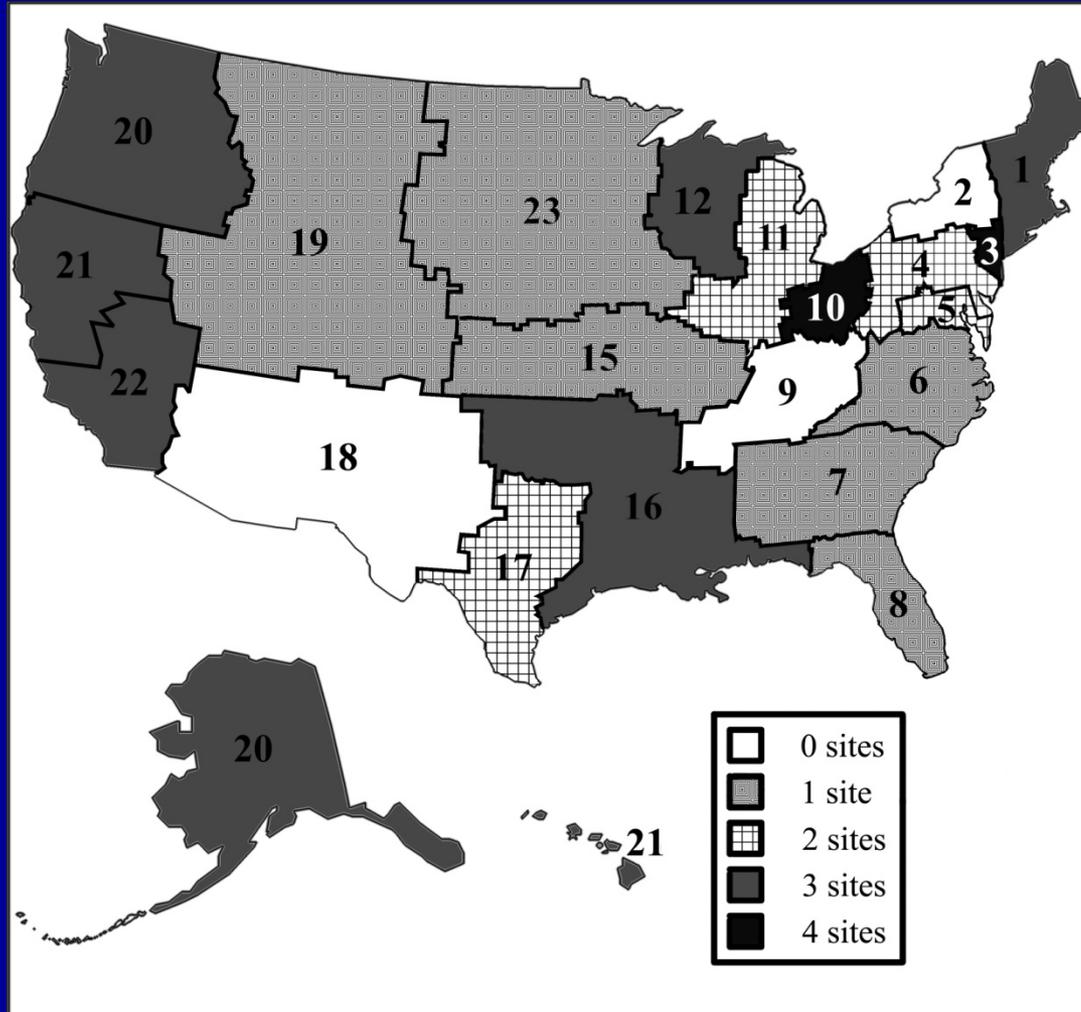
\* Not speaking on behalf of the DVA

\* No conflicts of interest to disclose

# OBJECTIVES

The objectives of this presentation are to provide an overview of the history of Office Based Opioid Treatment (OBOT) in the Veterans Health Administration (VHA), describe initiatives that encourage OBOT care, elucidate the current models of care for OBOT, and describe the trends in OBOT care in the VHA.

# VA Methadone\* Programs



\* At least 10 sites contract for methadone care outside the VA

# Early History of Buprenorphine in the VA

- VA clinicians/investigators were an integral force in clinical trials regarding buprenorphine approval for OBOT
- VA clinicians/investigators helped frame DATA 2000
- Leadership in PCSS
- VA Non-Formulary Criteria for Use established

## **Criteria for Use of**

### **Buprenorphine/Naloxone and Buprenorphine Sublingual Tablets**

VHA Pharmacy Benefits Management Strategic Healthcare Group and the Medical Advisory Panel

Updated by: F. Goodman, PharmD, BCPS; A. Gordon, MD, MPH; D. Kivlahan, PhD;

G. Dalack, MD; L. McNicholas, MD, PhD; D. Oslin, MD; A. Saxon, MD; R. Suchinsky, MD

# Non-Formulary Use of Buprenorphine

Implementation of buprenorphine in the Veterans Health Administration: Results of the first 3 years

Adam J. Gordon<sup>a\*</sup>, Jodie A. Trafton<sup>b,1</sup>, Andrew J. Saxon<sup>c,2</sup>, Allen L. Gifford<sup>d,3</sup>, Francine Goodman<sup>e,4</sup>, Vincent S. Calabrese<sup>e,5</sup>, Laura McNicholas<sup>f,6</sup>, Joseph Liberto<sup>g,7</sup>,  
for the Buprenorphine Work Group of the Substance Use Disorders Quality Enhancement Research Initiative (SUD QUERI)<sup>8</sup>

- Steady *passive* uptake of buprenorphine OBOT in the VA from FY 2003 through FY 2005
- Variability in uptake by regions in the VA

	FY 2003	FY 2004	FY 2005
Patients with OD (n)	25,031	26,231	26,859
Patients (n)	53	340	739
Scripts (n)	212	2752	7076
Scripts/Patient	4.0	8.1	9.9
Providers (n)	14	82	170

# VHA PBM Formulary Guidance

- Guidelines for the FORMULARY application of buprenorphine in the VHA were established in 2005 (revised in 2007)
- Based on formulary status, *every* VA facility should have buprenorphine available
- VA Pharmacy Monographs were also made available

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# VHA PBM Formulary Guidance

## VA CRITERIA FOR USE

### **Provider criteria**

The provider must

- be a *qualifying physician as defined by DATA 2000 (page 3)*. Individual physicians are limited to treating 30 patients under original waivers and 100 patients under second waivers.
- meet all SAMHSA and DEA notification and registration requirements for the Opioid Treatment Waiver Program (available at: <http://www.dpt.samhsa.gov>),

AND either

- have experience in addiction medicine or addiction psychiatry;

OR

- if inexperienced in addiction medicine, treat patients in consultation with a provider in the Physician Clinical Support System (PCSS) mentoring program (<http://www.pcssmentor.org/>). (The inexperienced clinician should consult the PCSS mentor early in therapy; e.g., during the induction phase of therapy, and the PCSS provider should preferably be familiar with the VA criteria for use of sublingual buprenorphine.)

# VHA PBM Formulary Guidance

## Patient criteria

Sublingual buprenorphine is indicated for opioid agonist treatment of opioid dependence (DSM-IV diagnosis), including medically supervised withdrawal, in

1. New patients not currently receiving OAT

2. AND who meet at least one of the following 3 criteria:

- Do not have timely access to a VA-supported OAT center.
- Do not meet regulatory criteria for treatment in an OAT program.
- Will have difficulty adhering to scheduled visits at a VA supported OAT program (e.g., because of restrictive clinic hours).

3. Appropriately selected patients on stable methadone maintenance who have difficulty adhering to scheduled visits at a VA-supported OAT center or may not need close supervision. Opioid treatment programs should determine the criteria for appropriate selection of these patients, and the criteria should take into consideration such factors as the patient's psychosocial adjustment, lifestyle stability, job stability, level of physiologic opioid dependence, and need for higher doses of methadone (e.g.,  $\geq 80$  mg daily) (see discussion on conversion doses under *Patients physically dependent on methadone or other longacting opioids*, page 5).

4. Patients who have a documented severe, uncontrollable adverse effect or true hypersensitivity to methadone.

# Uniform Mental Health Services Package

- Published in September 2008
- Provided guidance regarding expectations of mental health and substance abuse care in the VA

**Department of Veterans Affairs  
Veterans Health Administration  
Washington, DC 20420**

**VHA HANDBOOK 1160.01  
Transmittal Sheet  
September 11, 2008**

## **UNIFORM MENTAL HEALTH SERVICES IN VA MEDICAL CENTERS AND CLINICS**

**1. REASON FOR ISSUE.** This revised Veterans Health Administration (VHA) Handbook defines minimum clinical requirements for VHA Mental Health Services. It delineates the essential components of the mental health program that is to be implemented nationally, to ensure that all veterans, wherever they obtain care in VHA, have access to needed mental health services.

# Uniform Mental Health Services regarding buprenorphine

- “Pharmacotherapy with approved, appropriately-regulated opioid agonists (e.g., buprenorphine or methadone) **must be available to all patients diagnosed with opioid dependence** for whom it is indicated and for whom there are no medical contraindications.
- It needs **to be considered in developing treatment plans for all** such patients.
- Pharmacotherapy, if prescribed, needs to be provided in addition to, and directly linked with, psychosocial treatment and support.”

# Uniform Mental Health Services regarding buprenorphine (cont.)

“Opioid Agonist Treatment can be delivered in either or both of the following settings:

1. **Opioid Treatment Program (OTP).** This setting of care involves a formally-approved and regulated opioid substitution clinic within which patients receive opioid agonist maintenance treatment using methadone or buprenorphine.
2. **Office-based Buprenorphine Treatment.** Buprenorphine can be prescribed as office based treatment in non-specialty settings (e.g., primary care), but only by a “waivered” physician. Buprenorphine is *not subject to all of the regulations required in officially-identified OTPs*, but must be delivered consistent with treatment guidelines and Pharmacy Benefits Management criteria for use.”

# 2009 VA/DoD Revised Guidelines of SUD Care

- VA/DoD Clinical Practice Guideline for Management of Substance Use Disorders (SUD) was recently revised
- The guidelines provide evidence-based and practical matters regarding application of buprenorphine in different settings

**VA/DoD CLINICAL PRACTICE GUIDELINE FOR MANAGEMENT  
OF  
SUBSTANCE USE DISORDERS (SUD)**

Department of Veterans Affairs  
Department of Defense

# Initiatives in the VA: BIV

- Buprenorphine In the VA (BIV) Initiative
- Supported by from the VA CESATE, SUD-QUERI, and VISN 4 MIRECC
- Resources provided:
  - Monitoring of VA buprenorphine and related listserves
  - Phone and email helpline (~40 contacts/mo)
  - Resource Guide (Version 3.0)
  - Protocol Guide
  - Monthly Electronic Newsletters (since 2007; ~40)
  - In-service webinar trainings (10; 100/call 6x year)
  - Peer-reviewed published CME training

## Buprenorphine Questions and Answers: An Expert Roundtable

January 22, 2010

With support from the VA CESATE, SUD-QUERI, and VISN 4 MIRECC

## Buprenorphine and Methadone: Initiation and Transfer considerations

Andrew J. Saxon, M.D. – Puget Sound VA  
Laura F. McNicholas, M.D., Ph.D. – Philadelphia VA  
Adam J. Gordon, M.D., M.P.H. – Pittsburgh VA

## Buprenorphine – Induction Procedures and Perioperative Considerations

### Buprenorphine Consult Service

Adam J. Gordon, MD, MPH, FACP, FASAM  
Laura McNicholas, MD, PhD

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[Laura.mcnicholas@va.gov](mailto:Laura.mcnicholas@va.gov)

## Models for Implementing Buprenorphine Treatment in the VHA

Adam J. Gordon, MD, MPH, Cynthia M.A. Geppert, MD, PhD, MPH, Andrew Saxon, MD, Ann Cotton, PsyD, Timothy Bondurant, MD, Margaret Krumm, BA, Mary Pat Acquaviva, PA, and Jodie Trafton, PhD

Buprenorphine in the VA (BIV Project): Improving Implementation and Outcomes of Office-Based Opioid Dependence Treatment in the VA

## A Tool for Buprenorphine Care

(A series of monthly newsletters about buprenorphine treatment)  
Volume 3 Issue 11—April 2010

### Buprenorphine Web Resources

Buprenorphine (Suboxone) Training and Practice Tools [[BupPractice.com](http://BupPractice.com)]  
Physician Clinical Support System [[PCSSmentor.org](http://PCSSmentor.org)]  
The National Alliance of Advocates for Buprenorphine Treatment [[naabt.org](http://naabt.org)]

### Buprenorphine and Opioid Dependence in the News

What the media is saying and what the public is hearing.

This new feature of the newsletter highlights recent news coverage. If you spot buprenorphine or opioid dependence making the news, feel free to [send a tip](#).

"[New Method for Treating Opioid Addiction Unveiled.](#)" U.S. News & World Report. April 22, 2010.

### Cyber In-Services

Semi-monthly education about buprenorphine

#### Next in-service topic: INDUCTION

Please join us on **Friday, May 21 at 2pm Eastern** for a presentation by Dr. Laura McNicholas and friends. Click [here](#) to add the event to your Outlook calendar.

Click [here](#) to enter the meeting and view slides. (If asked when logging on, the meeting ID is 'induction'.)

To hear audio, call 1-800-767-1750 then enter 13881#.

Slides are available for download from the online meeting interface.

Past presentations are available in the buprenorphine folder at the [SUD SharePoint site](#).

### Research Update

Mouse-over for abstract

Gender issues in the pharmacotherapy of opioid-addicted women: buprenorphine. Unger A, Jung E, Winklbaur B, Fischer G. J Addict Dis. 2010 Apr;29(2):217-30. PMID: 20407978 Free PMC Article

Abuse liability of intravenous buprenorphine/naloxone and buprenorphine alone in buprenorphine-maintained intravenous heroin abusers. Comer SD, Sullivan MA, Vosburg SK, Manubay J, Amass L, Cooper ZD, Saccone P, Kleber HD. Addiction. 2010 Apr;105(4):709-18. PMID: 20403021

Buprenorphine maintenance therapy hinders acute pain management in trauma. Harrington CJ, Zaydfudim V. Am Surg. 2010 Apr;76(4):397-9. PMID: 20420250

### Training Brush-Up: Lab tests that can identify substance use

Certain laboratory tests can raise suspicion of drug use:

- **Liver function test abnormalities** may indicate alcohol use or abuse, as well as acute or chronic hepatitis.
- **Elevated mean corpuscular volume** on a complete blood count is an indication of possible alcohol abuse.
- **Gamma glutamyl transpeptidase elevation** is an indication of possible alcohol abuse.
- **Elevated carbohydrate-deficient transferrin** is an indication of possible alcohol abuse.
- **Indicators of hepatitis infection** (for example, **B and C antibodies**), and **HIV antibody positivity** may indicate injection drug use.

Source: AAAP DATA-2000 Training

This information is supported and provided by the Substance Use Disorder Quality Enhancement Research Initiative (SUD-QUERI), Center of Excellence in Substance Abuse Treatment and Education (CESATEs), the Mental Illness Research, Education and Clinical Centers (MIRECC), and the Program Evaluation and Resource Center (PERC) within the Department of Veterans Affairs. Please contact Margaret Krumm at [margaret.krumm@va.gov](mailto:margaret.krumm@va.gov) or **412-954-5229** with questions or comments.

Contact: [adam.gordon@va.gov](mailto:adam.gordon@va.gov)  
Gordon, Fed.Pract., 2009

# Models of Care

- VA Buprenorphine can be prescribed in:
  - Inpatient settings
  - Drug and alcohol treatment settings
    - Methadone programs (42 and 10 contracted)
    - Other addiction treatment programs (specialty care)
  - Office-based settings
    - Any outpatient clinic (e.g., HIV, pain, GI)
    - Primary Care
- There are requirements and models for care in each setting – not dissimilar to non-VA sites

# Models of Care: OBOT Barriers

- Buprenorphine treatment for opioid dependence can be provided in office-based settings
  - The care is similar to treatments for other medical disorders
- **Barriers to initiate or provide** buprenorphine care occur when providers in office-based settings *attempt to make these environments “feel” like formal substance abuse treatment program environments – they are different!!!*

# VA: F&B of Buprenorphine Care

- To examine and understand system-, provider-, and patient-level factors that facilitate and impede implementing buprenorphine within the VHA facilities
- Three groups interviews conducted in FY 2005 based on no methadone facility and bup use:
  - *No buprenorphine sites (NBS):* <5 scripts
  - *some buprenorphine sites (SBS):* 5-40 scripts
  - *more buprenorphine sites (MBS):* 40+ scripts
- 62 recorded/transcribed interviews

# VA F&B: System Barriers

- Most prominent: lack of time and staff.
  - “this is not the time to do extra stuff.”
- Coverage and continuity of care concerns were also cited as significant barriers for use
- Little concern about pharmacy issues/cost

# F&B: Provider Barriers

- More provider barriers than system barriers
- There was a general lack of knowledge
  - “I know zero about it and have little knowledge”
- Not having a dedicated staff member(s) to develop a “program”
- “We let non-VA facilities to provide that care”
  - “it’s not what we do.”
- Being afraid of an overwhelming response from patients:
  - “we would be buried in dealing with the opiate addicted folks.”

# VA F&B: Facilitators

- A “Champion” or a “role model”
- Just *starting* the treatment or “modeling the way
- Integrated facilities – sites where medical health, mental health, pharmacy, etc. collaborated seemed to be farther along
- Sufficient education regarding buprenorphine

# Education in the VA

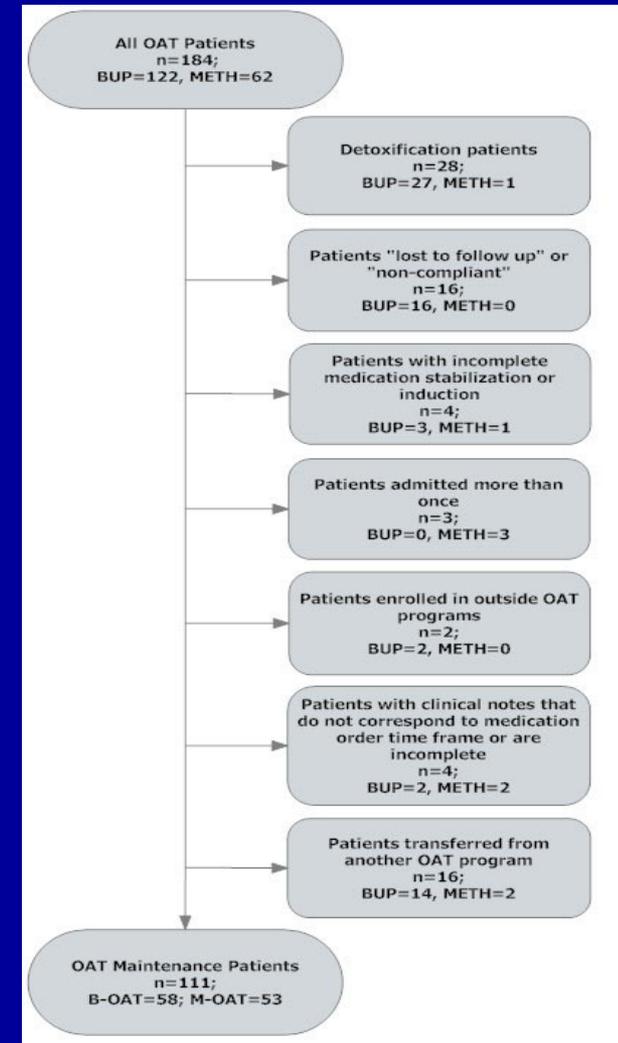
- To expand capacity of buprenorphine OAT in the VHA, in 2006 the VA sponsored two eight-hour VHA Employee Education System Buprenorphine Training Programs
  - Completely *FREE* (including transportation/lodging)
  - Continuing Medical Education (CME) credits
- Ten of 18 (56%) physician participants responded to the 6 month follow up survey
  - 9 attended to qualify for waiver
  - 6 had received the waiver
  - 2 indicated that they were using buprenorphine

# Education in the VA

- Respondents indicated several obstacles in prescribing buprenorphine.
  - delay in receiving waiver (30%)
  - finding time in the clinic (20%)
  - lack of opportunity to care for patients with opioid or heroin addictions (30%)
  - resistance from patients (10%)
  - facility policies or procedures (10%)
  - lack of inpatient buprenorphine use (10%)
  - Time to obtain Drug Enforcement Agency (DEA) number (40%)
  - no obstacle just no interest in prescribing (10%)

# Access to new VA populations

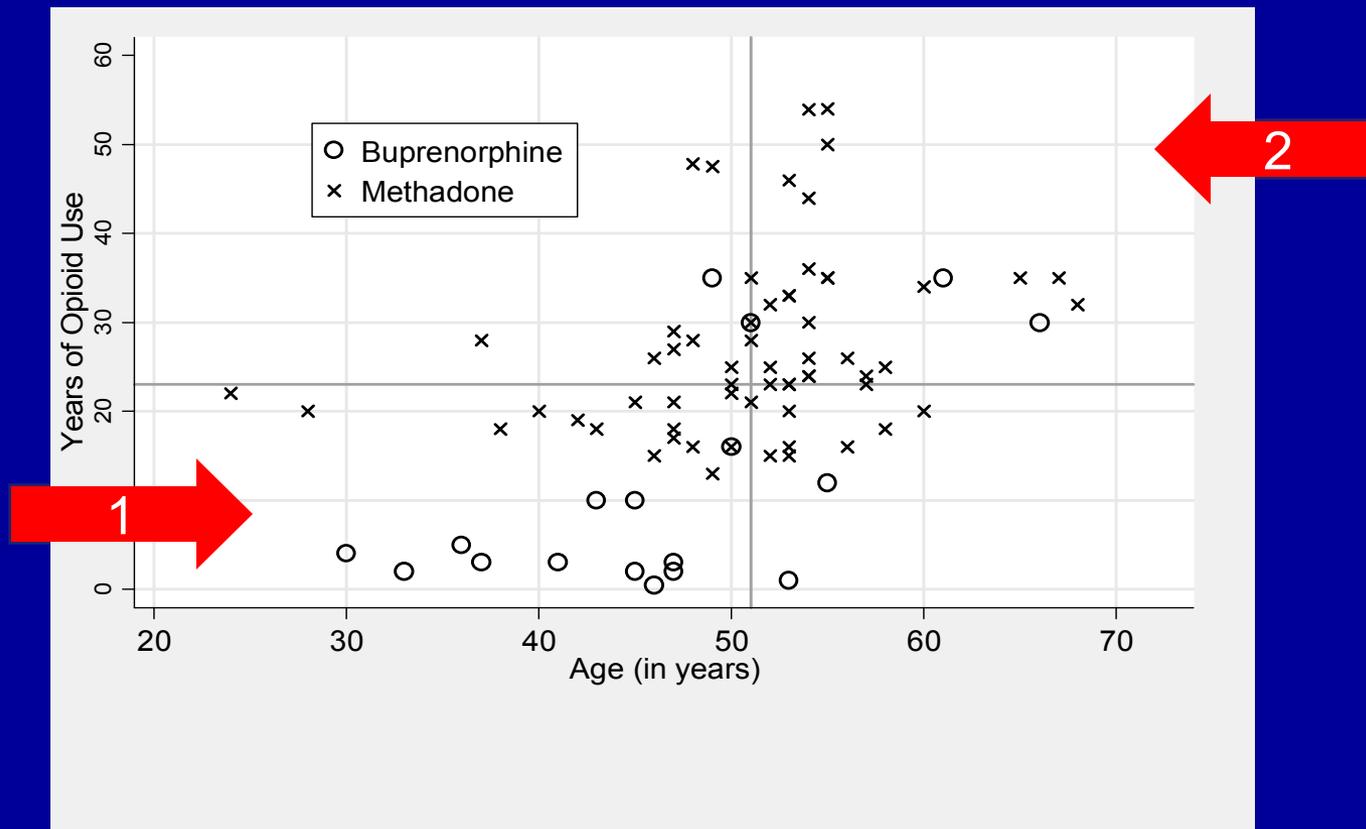
- Retrospective chart review of all patients receiving OAT within one VHA facility with dual availability of meth/bup over a four-year period: 2003 to 2007
- Patient and treatment characteristics of those on maintenance buprenorphine or methadone were compared
- Bup = 58, Methadone = 53



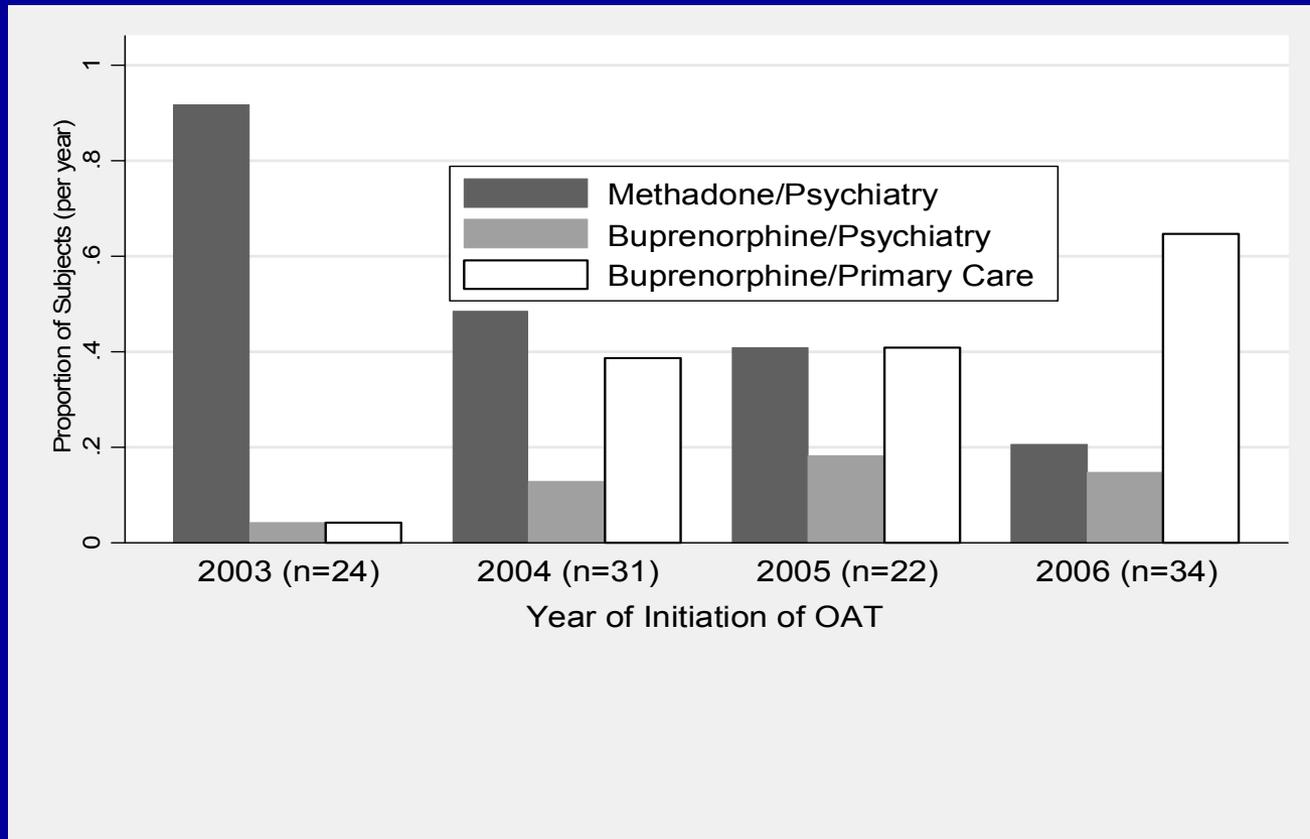
# Access to new VA populations

- Buprenorphine patients were less likely to have :
  - An infectious disease ( $p = .006$ )
  - Hepatitis C ( $p = .003$ )
  - Use marijuana ( $p = .001$ )
- B-OAT patients were more likely to have:
  - anxiety ( $p = .022$ )
  - attempting first-time rehabilitation ( $p = .002$ )
- The proportion of patients receiving B-OAT treatment increased over time ( $p < 0.001$ )

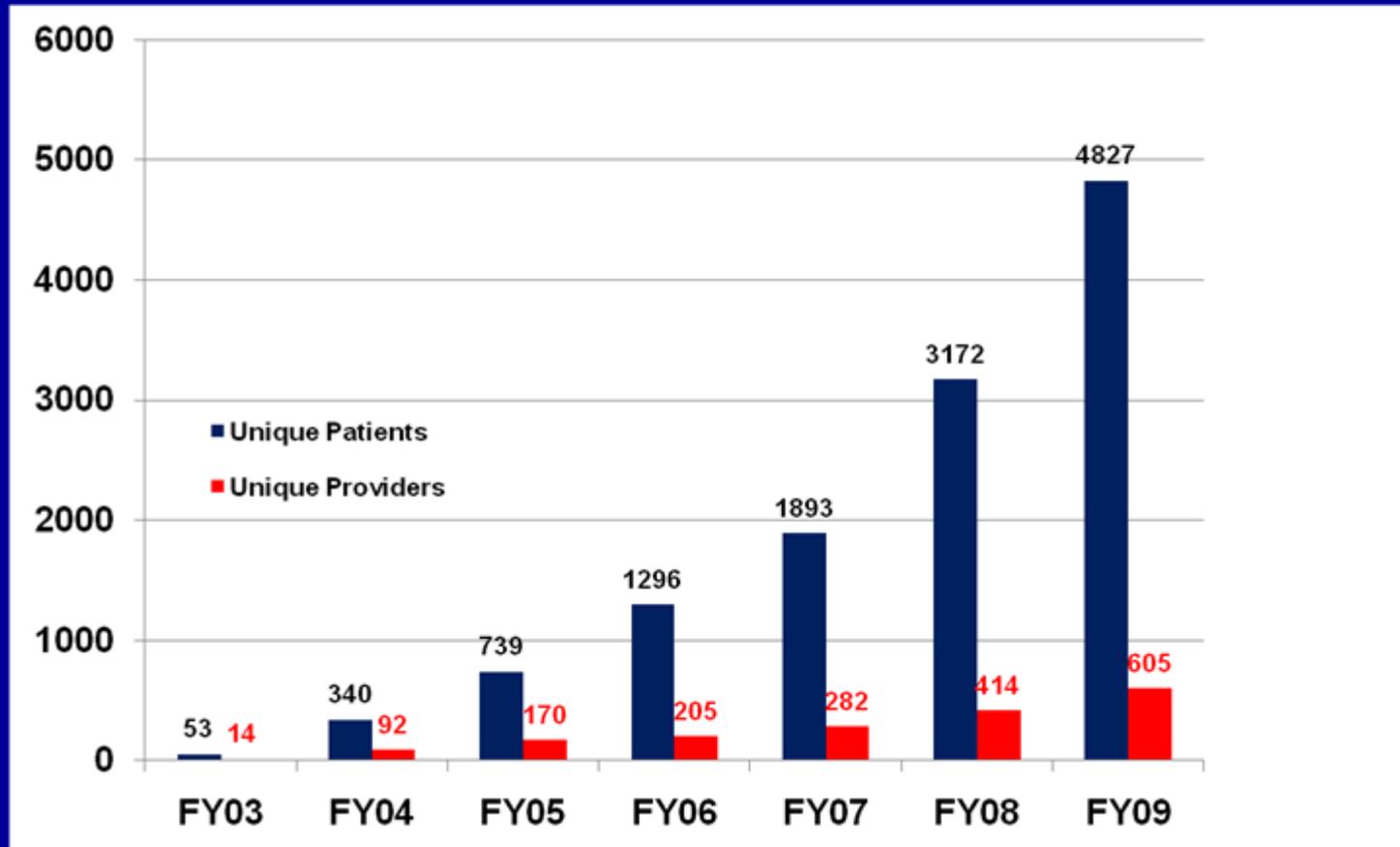
# Access to new VA populations



# Access to new VA populations



# Trends in VA Buprenorphine Use over time



# COMMENTS and DISCUSSION

- VA Buprenorphine Formulary Criteria  
<http://www.pbm.va.gov>
- VA/DoD SUD Guidelines (recently revised!)  
[http://www.healthquality.va.gov/sud/sud\\_full\\_601f.pdf](http://www.healthquality.va.gov/sud/sud_full_601f.pdf)
- Uniform Mental Health Services Package  
[http://www1.va.gov/vhapublications/ViewPublication.asp?pub\\_ID=1762](http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1762)
- VA Models of Care paper  
<http://www.fedprac.com/asp/cme/cmeinfo.asp?CMENo=145>

For any questions on this presentation, please contact:

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