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BU School of Medicine

CARE
Clinical Addiction Research and Education

September 7, 2016

How to Build It: The "Massachusetts Model" of Office Based Opioid Treatment (OBOT) with Buprenorphine

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A New Law

Drug Addiction Treatment Act (DATA) 2000

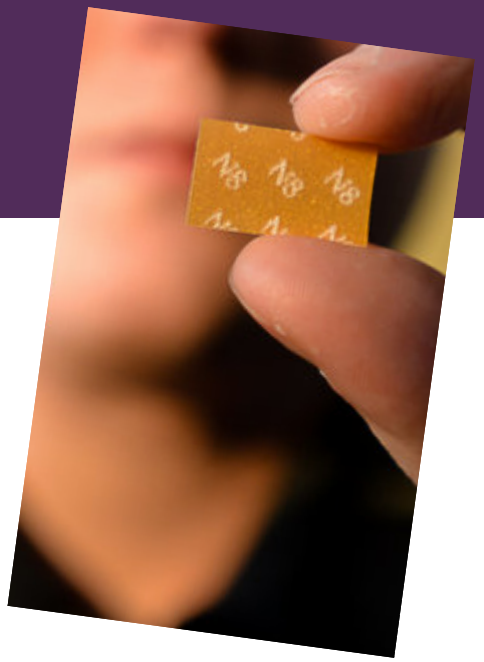
- Amendment to the Controlled Substances Act
- Allows physician to prescribe narcotic drugs scheduled III, IV or V, FDA approved for opioid maintenance or detoxification treatment
  - Prior 10/2002 no drug existed
  - Methadone does not qualify

DATA 2000: Physician Qualifications

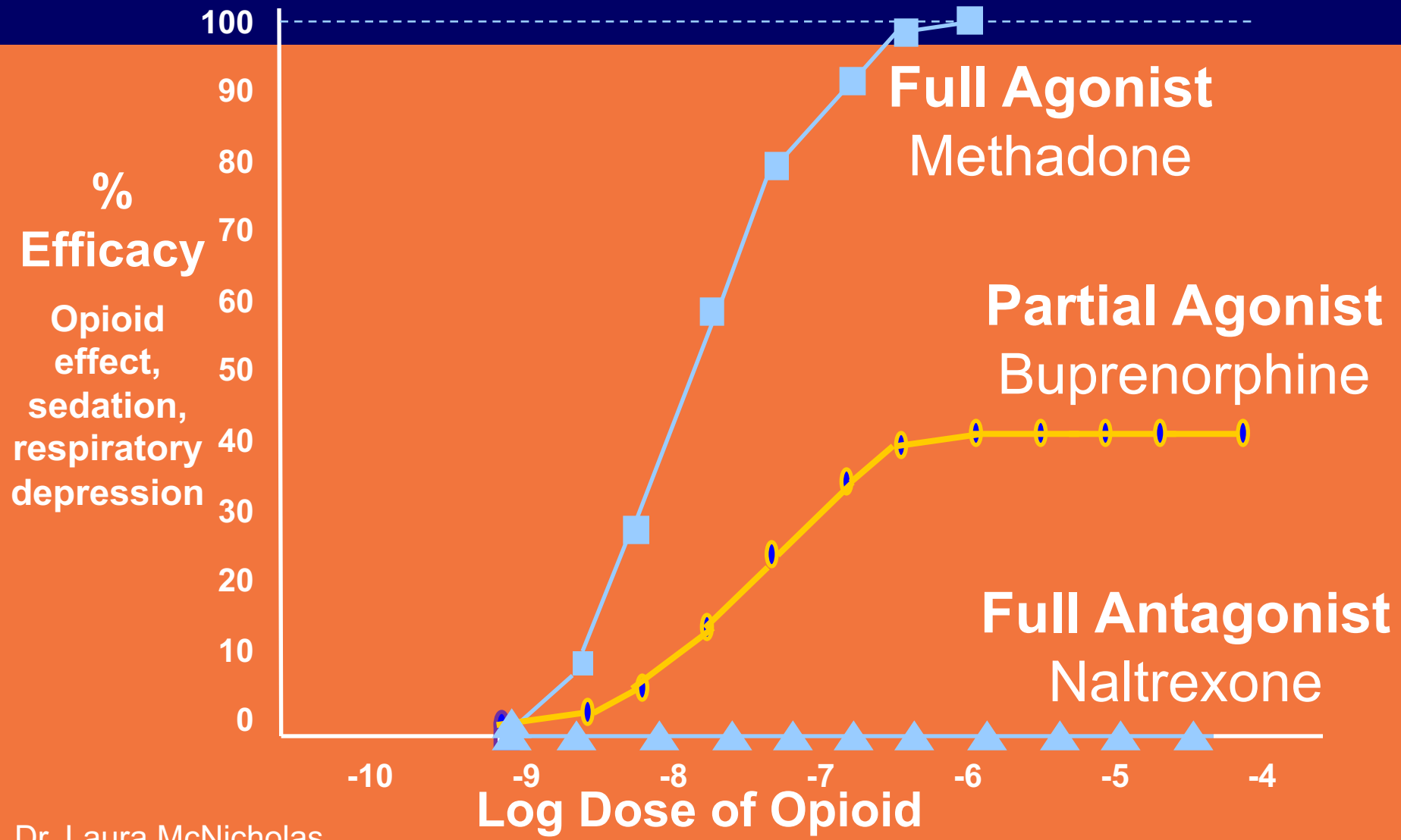
Physicians must:

- Be licensed to practice by his/her state
- Have the capacity to refer patients for psychosocial treatment
- Limit number of patients receiving buprenorphine to 30 patients for at least the first year
- File for a new waiver after first year to increase their limit to 100 patients
- Be qualified to provide buprenorphine and receive a license waiver
- Can apply for new waiver; expand to 275 patients if addiction certified and work in medical settings for 24 hour services

BUPRENORPHINE



Opioid Potency



Dr. Laura McNicholas

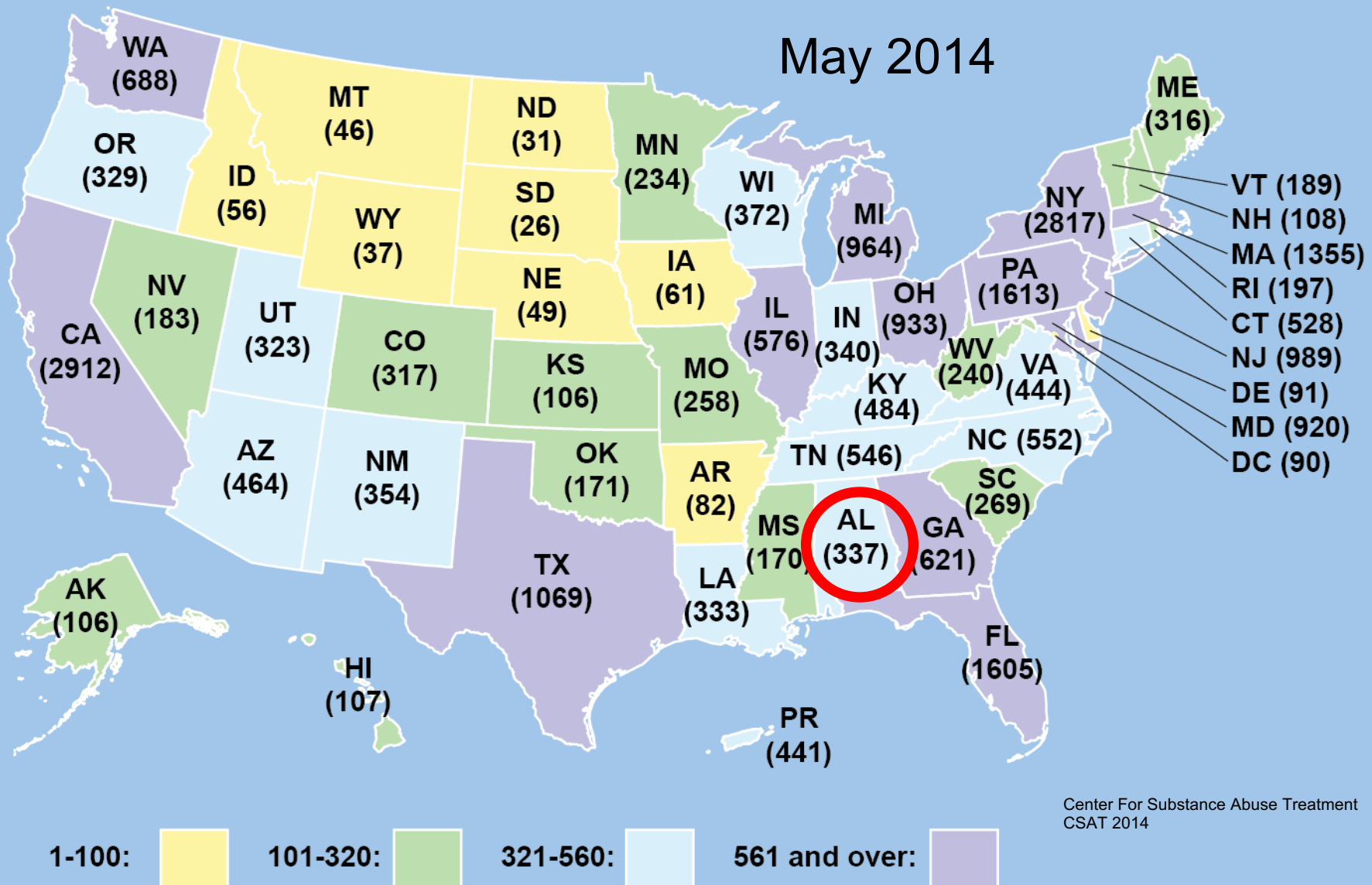
How Does Buprenorphine Work?

- "Ceiling effect" on opioid effects
- High affinity for opioid receptor
- Slow dissociation from opioid receptor
- Formulated with naloxone
  - Naloxone blocks opiate effect if injected
  - Naloxone is degraded (inert) if taking orally

Goals of Pharmacotherapy with Buprenorphine:

- Prevention or reduction of withdrawal symptoms
- Prevention or reduction of drug craving
- Prevention of relapse to use of addictive drug
- Restoration to or toward normalcy of any physiological function disrupted by drug use

Only 4% of Eligible US Doctors are Certified to Prescribe Buprenorphine

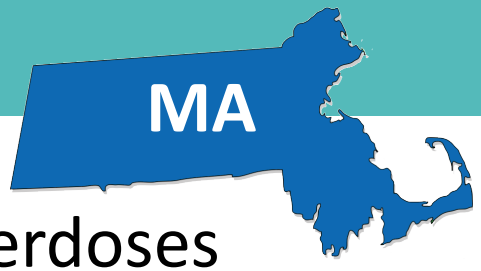


Center For Substance Abuse Treatment
CSAT 2014

Needs Assessment in Massachusetts

- High rate of opioid addiction
- High number of fatal and non-fatal opioid overdoses
- Long waits for opioid treatment, both methadone and buprenorphine
- Some people refuse MMT
- Not enough MA physicians had waivers
- Some waivered physicians were not prescribing

Buprenorphine in Massachusetts



- Opioid-related hospitalizations and fatal overdoses increased since mid-1990s
- Expansion of office-based treatment part of the 2005 state strategic plan
- 2005 – 1% (356/29,959) physicians waivered and many not prescribing
- Massachusetts Department of Public Health surveyed **all 356 physicians** waivered to prescribe buprenorphine

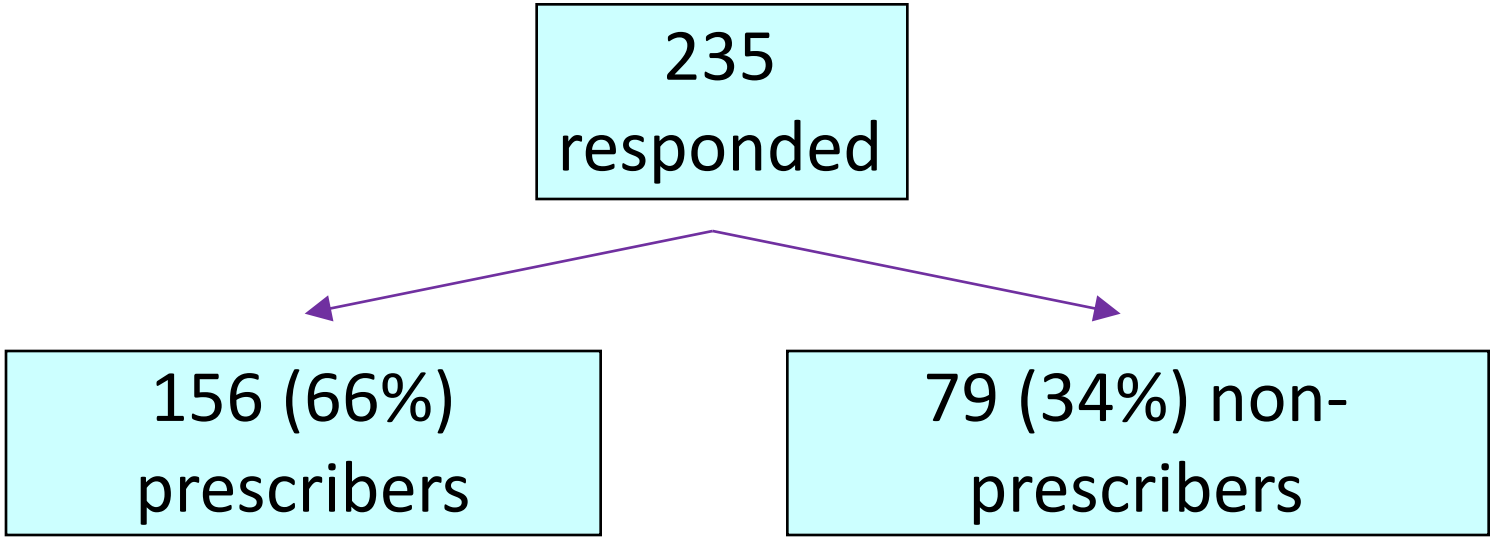
JGIM Journal of General Internal Medicine

Office-Based Management of Opioid Dependence with Buprenorphine: Clinical Practices and Barriers

Alexander Y. Walley, MD, MSc,[1,2] Julie K. Alperen, DrPH,[3] Debbie M. Cheng, ScD,[1,4] Michael Botticelli,[2] Carolyn Castro-Donlan,[2] Jeffrey H. Samet, MD, MA, MPH,[1,5] and Daniel P. Alford, MD, MPH[1]

J Gen Intern Med. 2008;23:1393-1398.

2005 survey to all waivered physicians (n=356)



Walley AY, Alperen JK, Cheng DM, et al. *J Gen Intern Med.* 2008;23:1393-1398.

Barriers to Buprenorphine Prescribing

Insufficient nursing support	20 %
Insufficient office support	19 %
Payment issues	17 %
Lack of institutional support	16 %
Insufficient staff knowledge	12 %
Pharmacy issues	8 %
Low demand	7 %
Office staff stigma	5 %
Insufficient physician knowledge	3 %
One or more barriers	55%

Walley AY, Alperen JK, Cheng DM, et al. *J Gen Intern Med.* 2008;23:1393-1398.

Non-prescribers

- If barriers improved:
- 54% (33/61) of never prescribers said that they will prescribe
- 67% (10/15) of previous prescribers said that they will prescribe

Walley AY, Alperen JK, Cheng DM, et al. *J Gen Intern Med.* 2008;23:1393-1398.

Only physicians can prescribe

*In the future, NPs will be able to prescribe

However, it takes a Multidisciplinary Team Approach for effective addiction treatment

ARCHIVES OF INTERNAL MEDICINE

Collaborative Care of Opioid-Addicted Patients in Primary Care Using Buprenorphine

Five-Year Experience

Daniel P. Alford, MD, MPH; Colleen T. LaBelle, RN; Natalie Kretsch, BA; Alexis Bergeron, MPH, LCSW; Michael Winter, MPH; Michael Botticelli, MEd; Jeffrey H. Samet, MD, MA, MPH

Arch Intern Med. **2011;171:425-431.**

Boston Medical Center (BMC) OBOT in General Internal Medicine

- **5/2003 – Began OBOT**
- **7/2010**
  - 425 patients (3-6 admissions per week)
  - 9 physicians
    - 1 medical director
    - 3 ABAM certified
    - Part-time clinical practices:
      on average, 3 sessions/week (range 1-6)
  - 3 RNs (3 FTE)
  - 1 medical asst (1 FTE)
  - 1 program coordinator (1 FTE)
  - 1 program director (.4 FTE)

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Boston Medical Center (BMC) OBOT in General Internal Medicine

❖**7/2016**

- 7 new admissions per week
- 17 waivered physicians
  - 12 ABAM certified
  - Part-time clinical practices:
    on average, 3 sessions/week (range 1-6)
- RNs (5.5 FTE)
- medical asst (1 FTE)
- program coordinator (.2 FTE)
- program director (.1 FTE)

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BMC OBOT became known as Massachusetts Model of OBOT

- Program Coordinator intake call
  - Screens the patient over the telephone
  - OBOT Team reviews the case for appropriateness
- NCM and physician assessments
  - Nurse does initial intake visit and collects data
  - Physician: PE, and assesses appropriateness, DSM criteria of opioid use disorder
- NCM supervised induction (on-site) and managed stabilization (on- and off-site (by phone))
  - Follows protocol with patient self administering medication per prescription

Nurse Care Managers (NCM)

- Registered nurses, completed 1 day buprenorphine training
- Performed patient education and clinical care by following treatment protocols (e.g., UDT, pill counts, periop mgnt)
- Ensured compliance with federal laws
- Coordinated care with OBOT physicians
- Collaborated care with pharmacists (refills management) and off-site counseling services
- Drop-in hours for urgent care issues
- Managed all insurance issues (e.g., prior authorizations)
- On average each NCM saw 75 patients/wk

Massachusetts Model of OBOT

- Maintenance treatment patient in care (at least 6 months)
  - NCM visits weekly for 4-6 wks, then q2 wks, then q1-3 months and as needed
  - **OBOT physician visits at least every 4 months**
- Medically supervised withdrawal considered based on stability if the patient requested to taper
- Transferred to methadone if continued illicit drug use or need for more structured care
- Discharged for disruptive behavior

Preadmission Factors Associated with Treatment Success

Characteristic	OR (95% CI)
Older age	**1.40** (1.09-1.80)
Employed	**2.24** (1.33-3.77)
Illicit buprenorphine use	**3.04** (1.32-7.00)
African American	**0.50** (0.26-0.99)
Hispanic	**0.45** (0.22-0.93)

Alford DP, LaBelle CT, Kretsch N, et al. *Arch Int Med.* 2011;171:425-431.

Urine Drug Tests (UDT)

Month	3	6	9	12
Illicit Opioid NEG	95%	94%	93%	95%
Cocaine NEG	95%	96%	95%	98%

Alford DP, LaBelle CT, Kretsch N, et al. *Arch Int Med.* 2011;171:425-431.

Table 2. Treatment Outcomes at 12 Months of 382 Opioid-Dependent Patients Entering Office-Based Opioid Treatment in Primary Care

Outcome	Patients, No. (%)
Successful treatment	196 (51.3)
Treatment retention	187 (49.0)
Successful taper after 6 months of adherence[a]	9 (2.4)
Unsuccessful treatment	162 (42.4)
Lost to follow-up	113 (29.6)
Nonadherence despite enhanced treatment[a]	46 (12.0)
Administrative discharge due to disruptive behavior	2 (0.5)
Adverse effects of buprenorphine hydrochloride	1 (0.3)
Transfer to methadone hydrochloride treatment program	24 (6.3)

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Conclusions

- Patient-level outcomes comparable to physician-centered approaches
- Allows efficient use of physician time to focus on patient management (e.g., dose adjustments, maintenance vs. taper)
  - Allowed physicians to managed > numbers of patients due to support of NCM
- Improved access to OBOT and daily management of complex psychosocial needs (e.g., housing, employment, health insurance)

Alford DP, LaBelle CT, Kretsch N, et al. *Arch Int Med.* 2011;171:425-431.

MA Department of Public Health Bureau of Substance Abuse Services Released two programs: In Response to Unmet Need

- Funding for a Nurse Care Manager Model in Community Health Centers (CHC)
  - Required CHC to partner with addictions counseling service providers
- Funding for training and technical assistance to the CHC OBOT programs

Program Funding

- $270,000 per year for Technical Assistance: training, booster sessions, quarterly state educational sessions, conference calls, site visits, support staff and admin assistance, support to statewide providers in nonprofits, accountability of grant deliverables.

- $100,000 per CHC for Nurse Care Manager
  - 1 full time RN
  - 1:100 staff to patient ratio
    - Rolling admission of new patients each week to reach 100
  - 1:125 with addition of Medical Assistant in year 4 of the grant

TA Support

- Nursing training and ongoing support
  - Phone, email, site visits, chart reviews
  - Quarterly statewide NCM meetings:
    - addiction education, support, networking
- Site support:
  - Education all providers
    - Trainings: addiction, buprenorphine, stigma, management, set up
  - Support practice: MD and nursing issues
  - Care for or triage patients to other sites due to closures, staff changes, emergency issues
  - DEA Support: Education and preparation, support at visits
  - Waiver assistance, insurance support, coverage, carrier issues

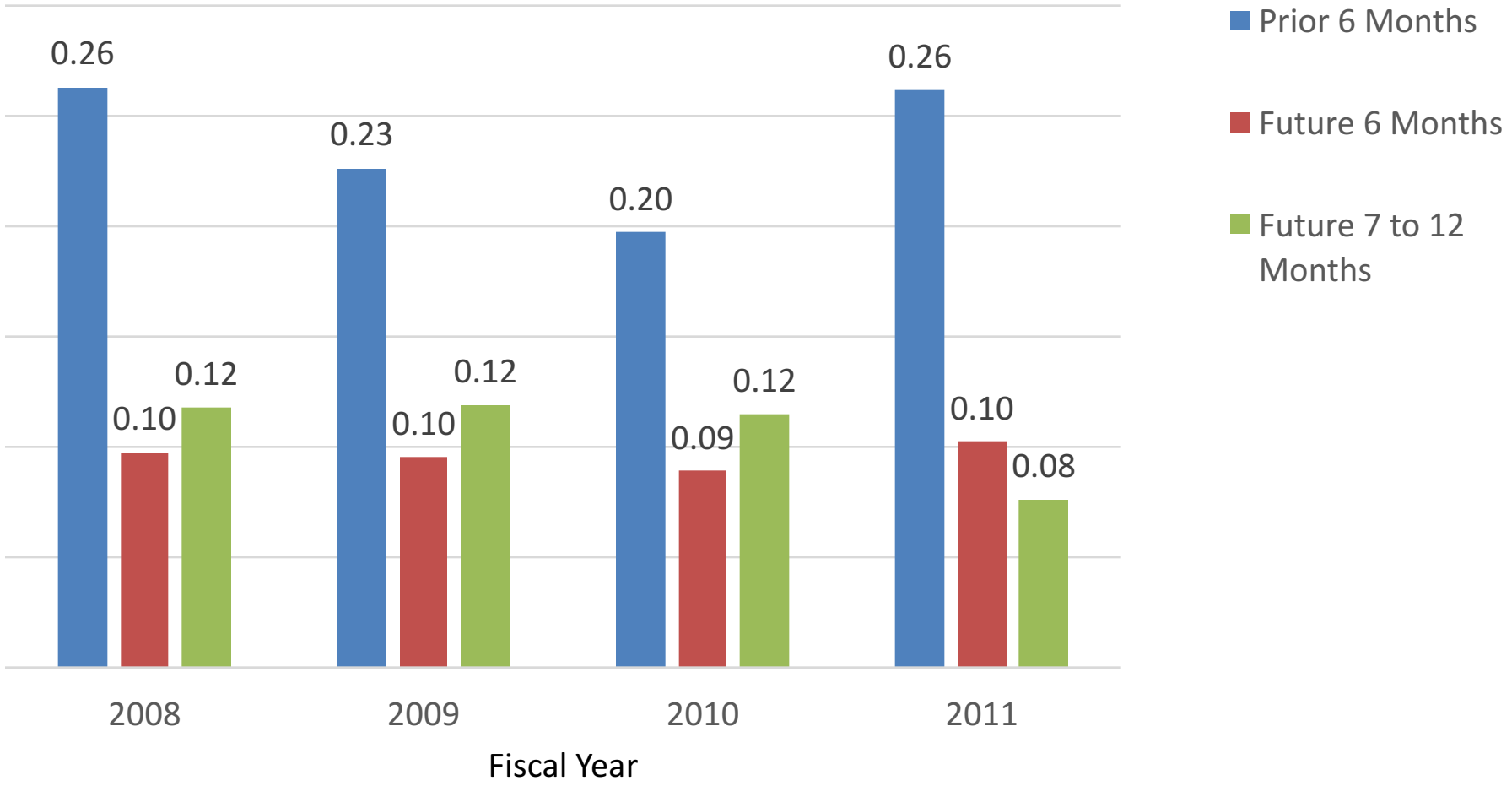
UMass Study Findings in Massachusetts

- Studied 5,600 Mass Health Clients prescribed buprenorphine and methadone (2003-2007)
- Overall Mass Health expenditures lower than for those with no treatment
- Clients on Medications had significantly lower rates of relapse, hospitalizations and ED visits: no more costly than other treatments
- Buprenorphine attracting younger and newer clients to treatment

Clark RE, Samnaliev M, Baxter JD, Leung GY. *Health Aff.* 2011;30:1425-1433.

Hospital Admissions

Average Hospital Admissions Per OBOT Enrollment

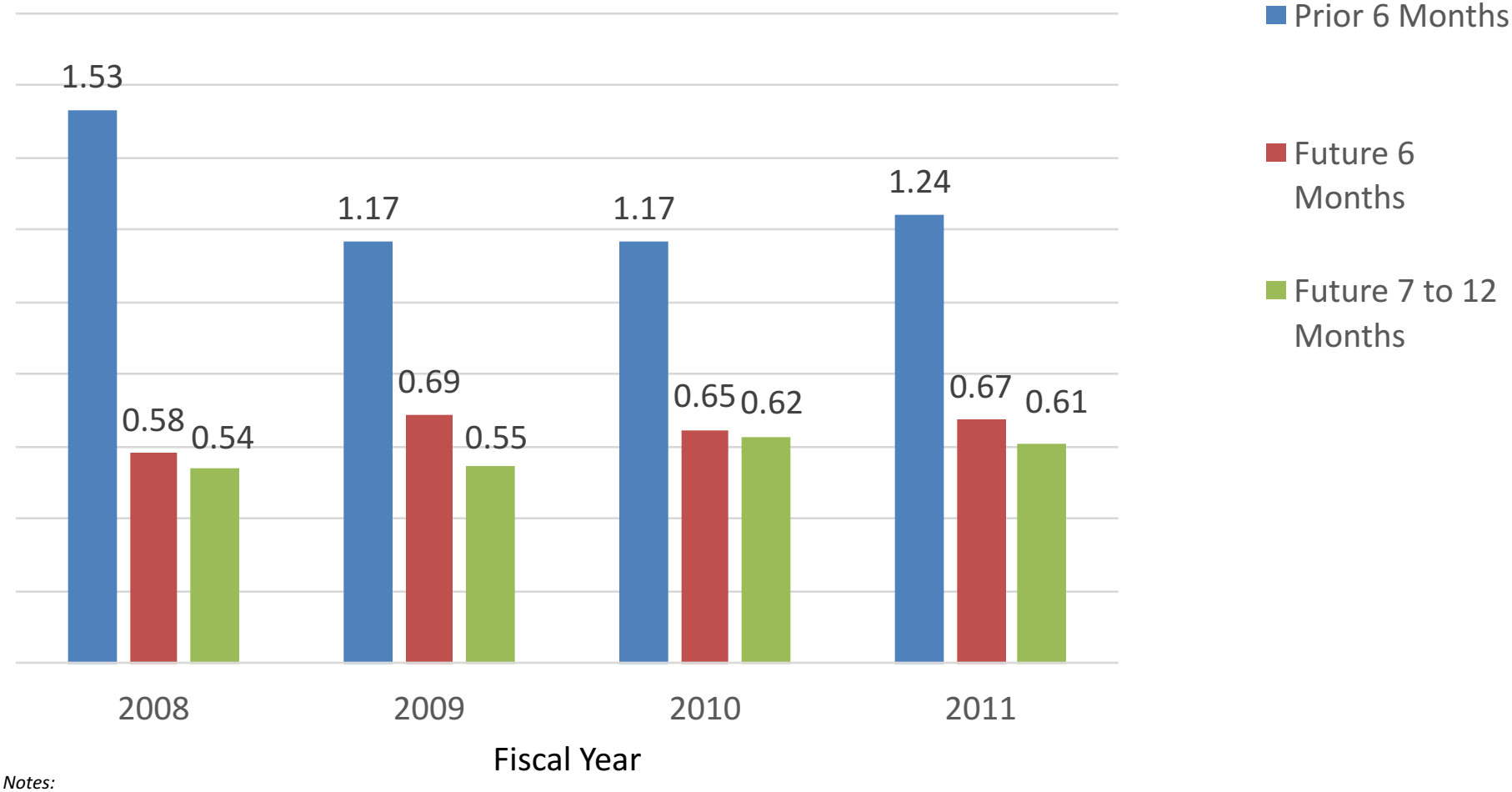


Notes:

- *Hospital data is only available through 9/30/2012*
- *Enrollments must have lasted at least 12 months*
- *Paid amounts are calculated using hospital specific pay to charge ratios*

ER Visits

Average ER Visits Per OBOT Enrollment



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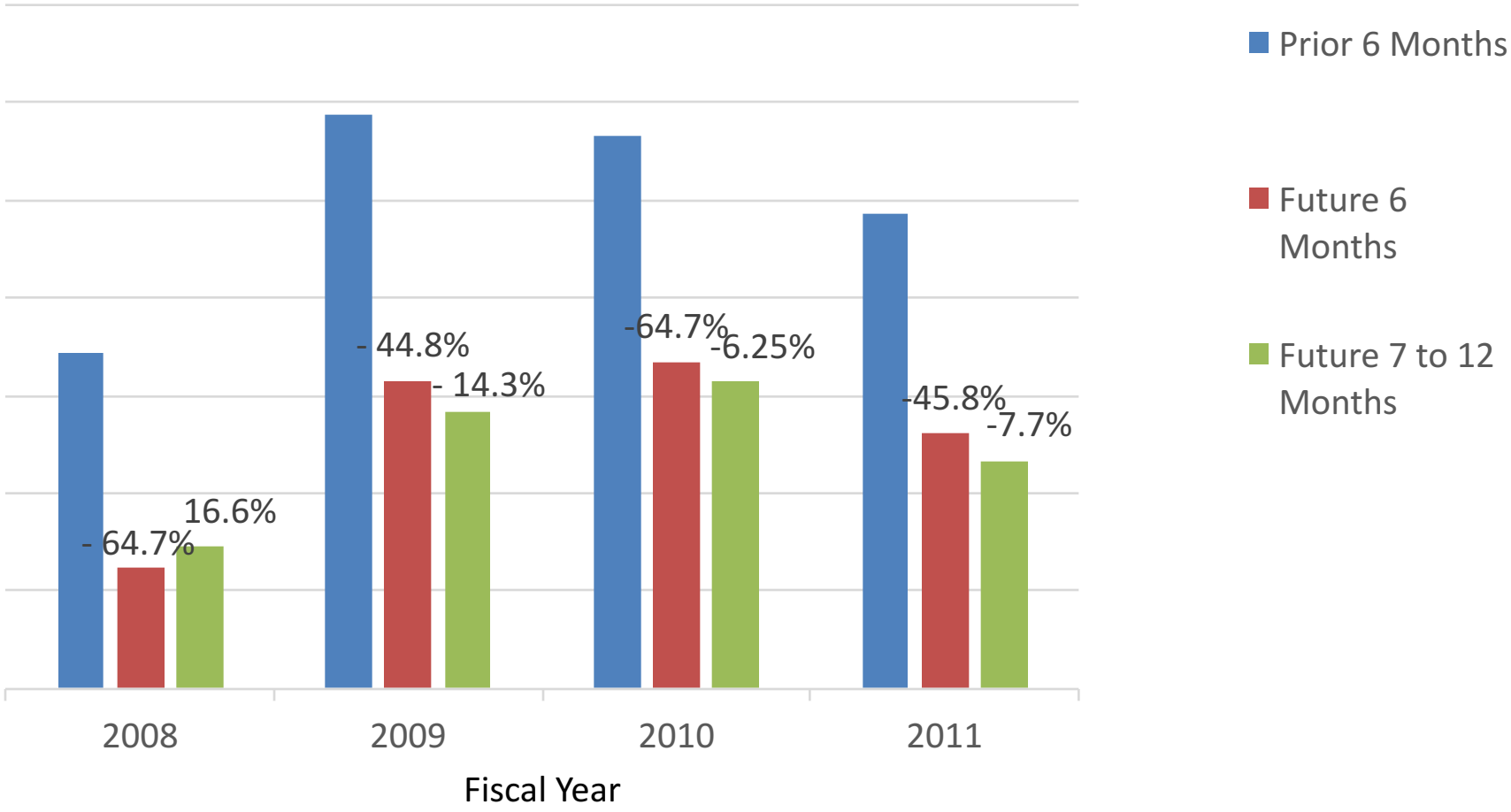
ER Expenditures

Total ER Expenditures: % Difference From Prior 6 Months



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OBOT RN
Nursing Assessment:

- Intake assessment
  - Review medical hx, treatment hx, pain issues, mental health, current use, and medications
- Consents/Treatment agreements
  - Program expectations: visits & frequency, UDT, behavior
  - Understanding of medication: opioid, potential for withdrawal
  - Review, sign, copies to patient and review at later date
- Education
  - On the medication (opioid), administration, storage, safety, responsibilities and treatment plan
- UDT
- LFTs, Hepatitis serologies, RPR, CBC, pregnancy test

OBOT RN Induction Preparation:

Review the requirements program:

- Nurse/ Physician Appointments:
  - frequency, times, location
- Counseling:
  - weekly initially
- UDT:
  - at visits, call backs
- Abstinence:
  - from opioids is the goal
- Insurance verification:
  - prior authorizations, co-pays
- Safety:
  - medication storage (bank bag)

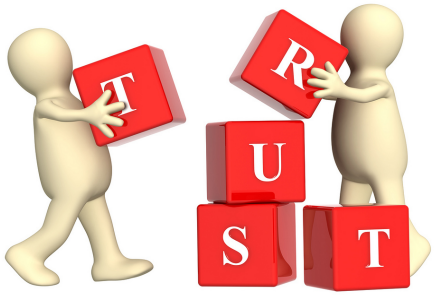
OBOT Team
Patient instructions for induction day:

- Insurance verification
  - Prior authorizations, co-pays
- Dispose of paraphernalia, phone numbers, contacts
- Medication pick up: 2mg/8mg tabs
- No driving for 24 hours
- Plan to be at clinic or office for 2-4 hours
- Bring a support person if possible
- Discuss potential side effects (e.g. precipitated withdrawal)

OBOT MD

- Review of history
  - Mental health, substance use, medical, social
- Physical Exam
- Lab and urine review
  - Assess contraindications, toxicology
- Confirm opioid use disorder diagnosis
  - DSM criteria
- Confirm appropriate for office treatment
- Signs the orders and prescription
- Develop treatment plan with OBOT team

OBOT RN, MD
Planning for Induction:



- Asking patient to show up in withdrawal requires a great deal of TRUST
- Build a relationship: Support
- Review with patient ahead of time usage history, withdrawal and make a plan
- Written materials, ongoing education
- Emergency and contact numbers

OBOT RN
Patient instructions during first dose:

- Put tablet(s) under tongue: sublingual
- Don’t talk, don’t swallow: saliva pools
- May use mirror, watch the tablet(s) gradually shrink as they dissolve
- May drink before and after not during

OBOT RNs
Initial dose buprenorphine

- COWs >8-12
- Objective signs are key to making dx
- Start with 2-4mg sl
- Assess 40min-1 hour after dosing
  - Better, worse, or the same
- Repeat dose of 2mg, assess 1 hour
  - Send home with instructions to call RN

OBOT RN
Frequency of Visits:

- Phone contact daily, or daily visits for first few days or more if needed
- At least weekly until stabilized (usually 4-6 weeks)
  - dose, UDT, counseling
- Progress to every two weeks, monthly, random, q3-4 months

OBOT RN
Comfort Measures:

- Taste perversion
- Headaches
- Nausea
- Sweating
- Insomnia

Consult with OBOT MD if needed

OBOT RN/MD Prescriptions

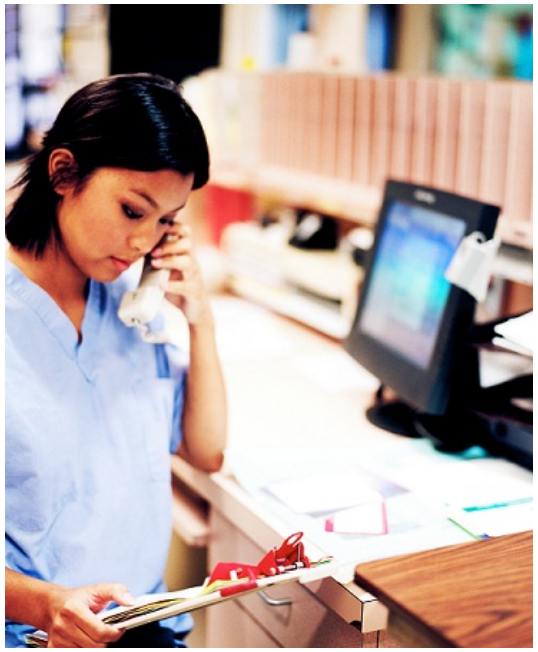
- Early On:
  - Small prescriptions 1 week with refills
  - Increase as patient stabilizes (UDT)
  - 2 week prescriptions with refills
- At point of stabilization:
  - Monthly visits
  - Monthly prescriptions with refills
- Keep file of pharmacy contact info

OBOT RN
Follow up Visits:

- Assess dose, frequency, cravings, withdrawal
- Ongoing education: dosing, side effects, interactions, support.
- Counseling, self help check in
- Psychiatric evaluation and follow up as needed
- Medical issues: vaccines, follow up, treatment HIV, HCV, engage in care
- Assist with preparing prescriptions
- Facilitating prior approvals and pharmacy
- Pregnancy: if pregnant engage in appropriate care
- Social supports: housing, job, family, friends

OBOT Team Monitoring

- UDT
- Pill counts
- Pharmacy Check-in
- Observed Dosing
- Random call backs
- Scheduled visits
- Counseling check in
- Check in with support/family/parent/partner



Next Steps

- Utilizing nurse care manager models to expand treatment to more sites
- Increase level of education among providers in addiction treatment
  - Nurses, doctors, support staff, and administration
- Integrate into the medical home model of care
- Examine and improve retention

Thank you!