Medication-Assisted Treatment: An Overview

Joshua Blum MD

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David

52 year old male former gas field worker, now on disability for back injury. Placed on fentanyl patch by worker's comp, began buying additional short-acting opioids from others to supplement. WC physician learned of purchases and discontinued opioids. David now self-medicating by purchasing pills and smoking heroin.

Lauren

35 year old mother of 2 with obesity, depression/ anxiety and longstanding knee arthritis. Started on opioids after failing NSAIDs, steroid injections, hyaluronic acid. Escalating use of oxycodone over past year. Multiple requests for early refills after lost prescriptions and unsanctioned dose escalations. Spends most of the day on the couch ("because of the pain") and coming to medical appointments.

Objectives

- Implement DSM-V criteria to diagnose opioid use disorder
- Understand the unique properties of buprenorphine and the role it plays in primary care addiction treatment
- Appreciate the steps needed for buprenorphine implementation

THE EPIDEMIC

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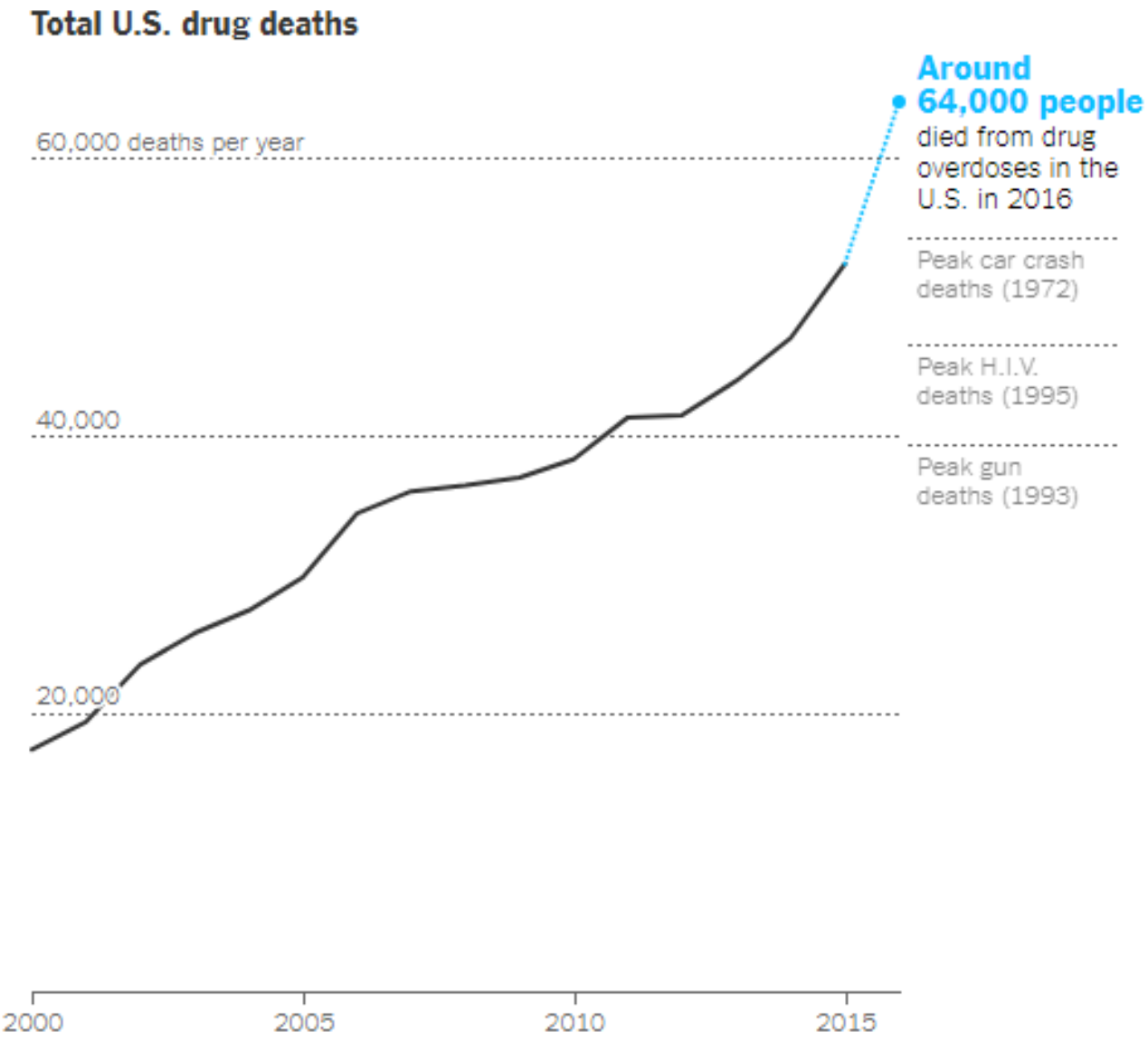
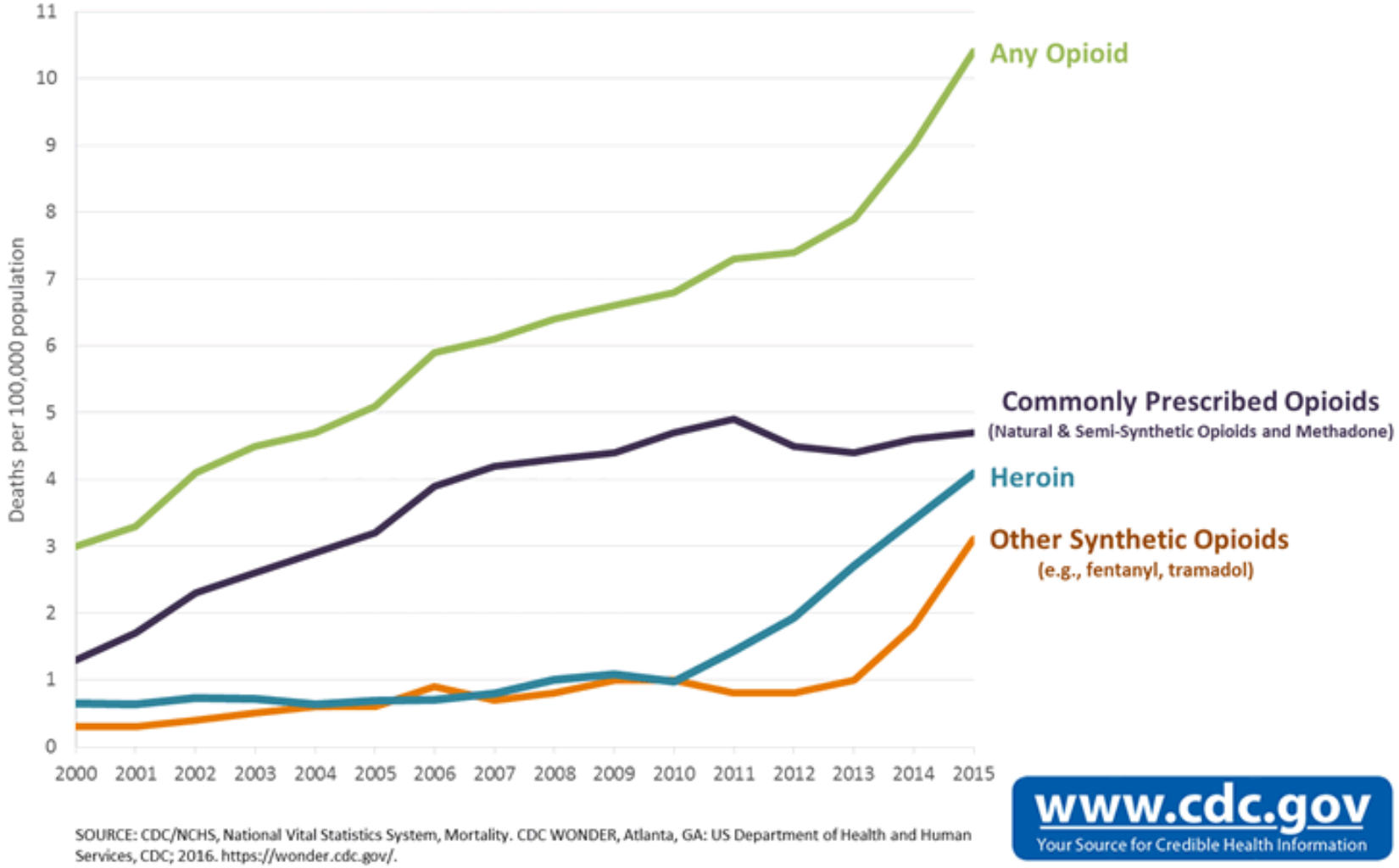
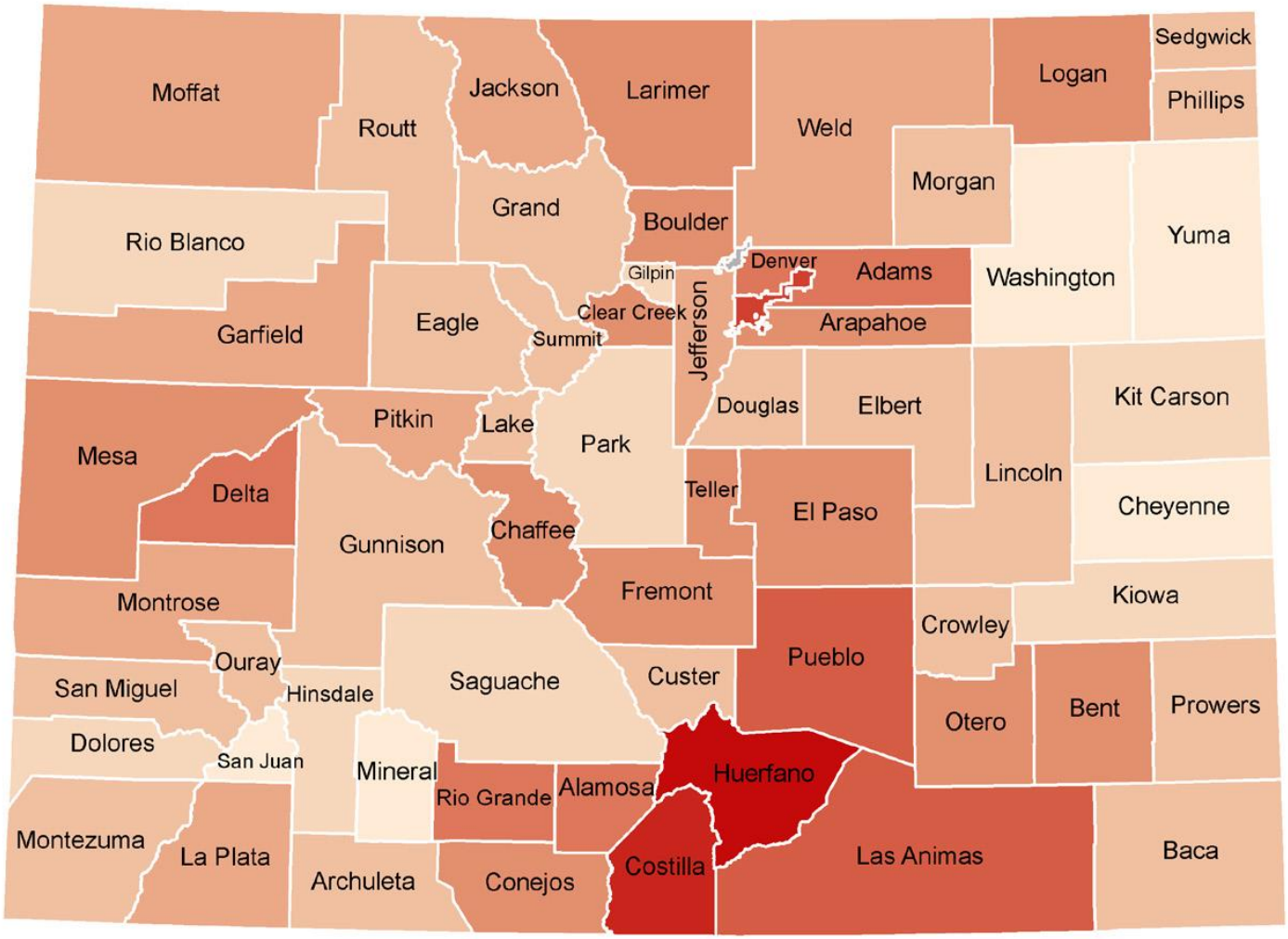


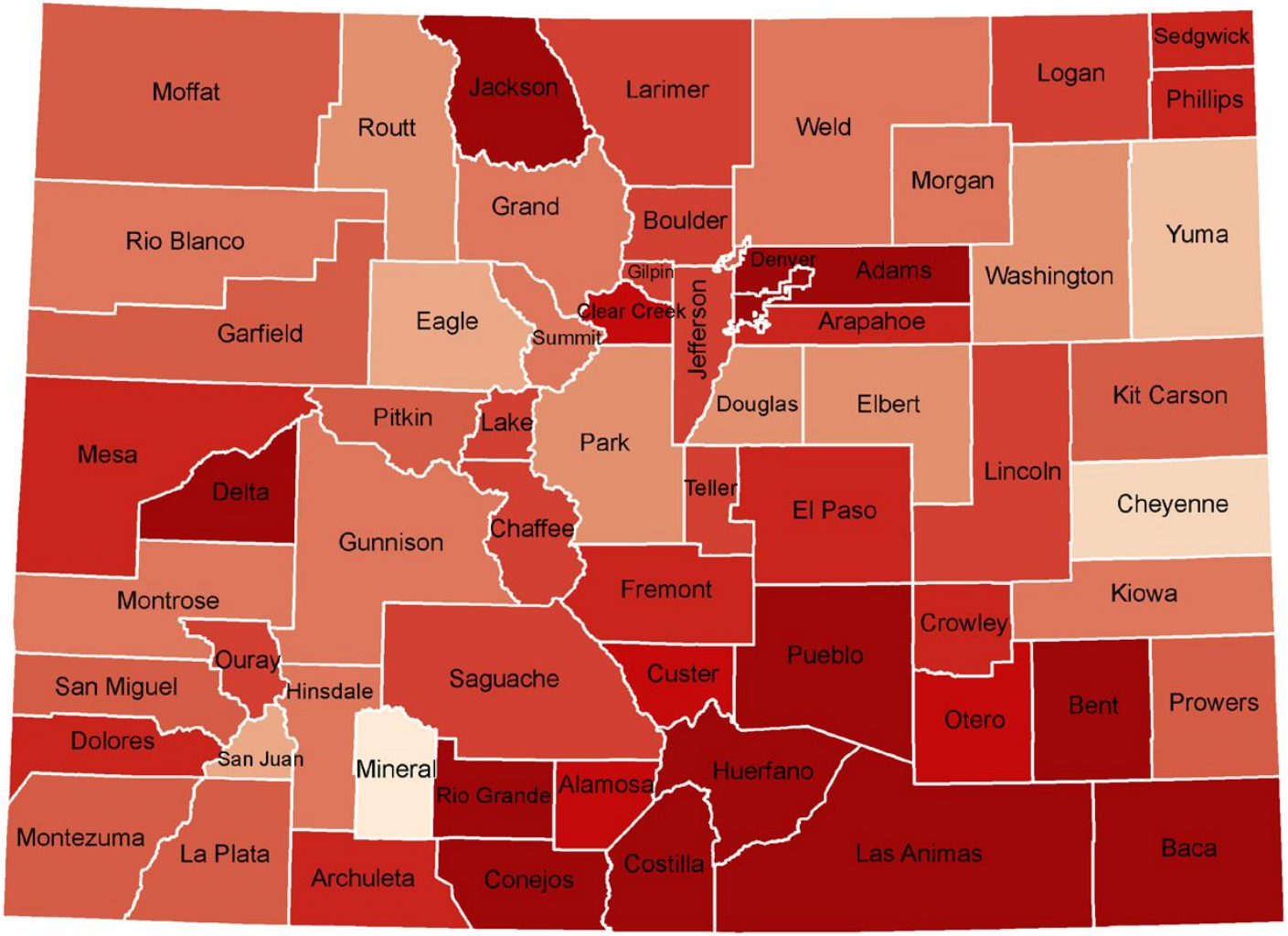
Ref: NY Times *The Upshot* 9/2/2017



SOURCE: CDC/NCHS, National Vital Statistics System, Mortality. CDC WONDER, Atlanta, GA: US Department of Health and Human Services, CDC; 2016. https://wonder.cdc.gov/.



Colorado drug overdose death rates by county: 2002



Colorado drug overdose death rates by county: 2014

NEUROBIOLOGY OF ADDICTION & BUPRENORPHINE PHARMACOLOGY

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One slide about Harm Reduction

"A set of practical strategies that *reduce negative consequences* of drug use, incorporating a spectrum of strategies from *safer use,* to *managed use* to *abstinence*"

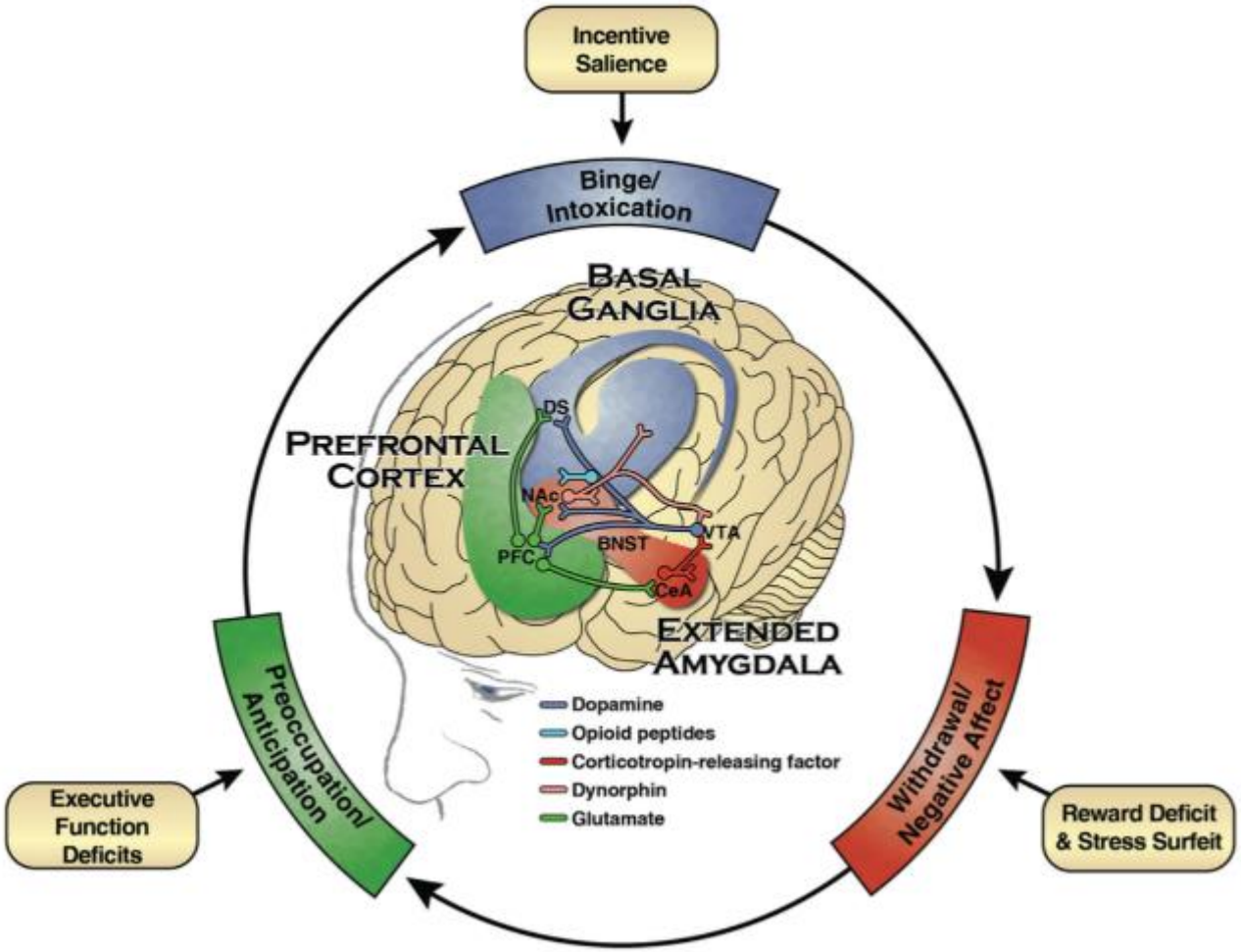
"Harm Reduction is also a movement for ***social justice*** built on a belief in, and respect for, the rights of people who use drugs."

Source: Harm Reduction Coalition (www.harmreduction.org)

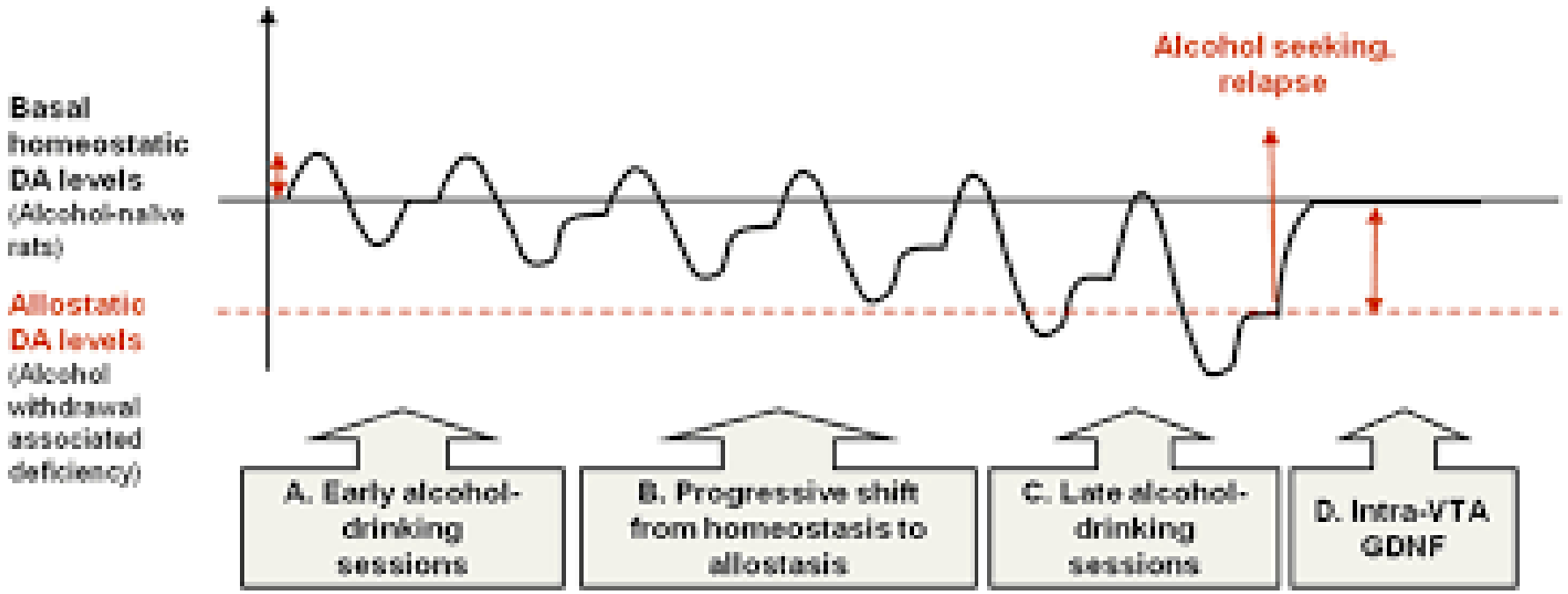
Who are these nice people?
Why are they important?

Methadone: 1972
Buprenorphine: 2002
Naltrexone: 2006

The cycle of addiction



How addiction hijacks the brain

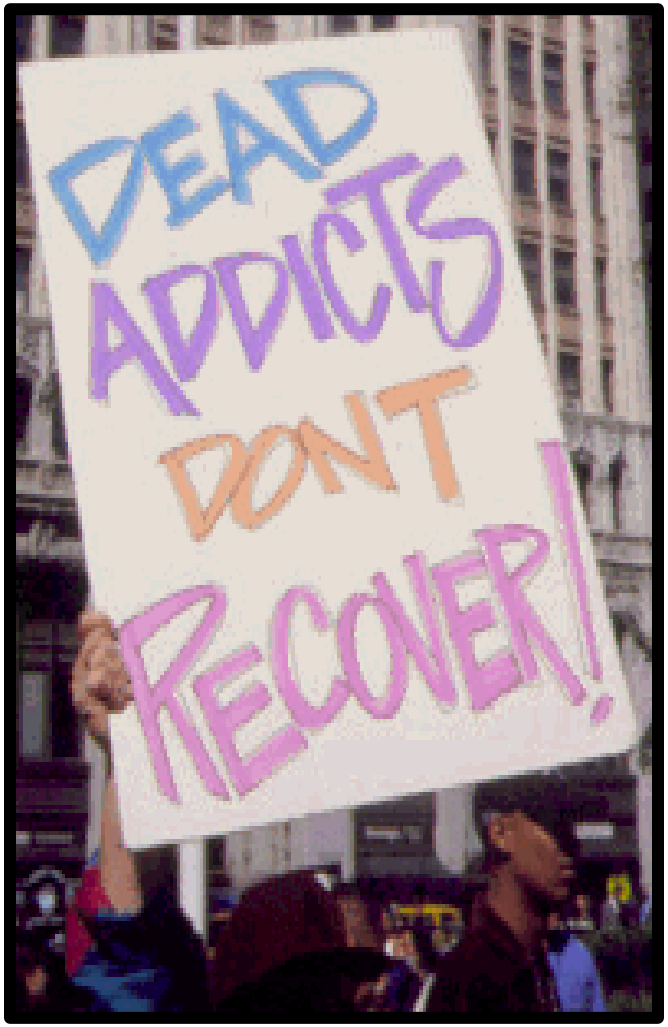


Koob, 2003

Why Use Medications?

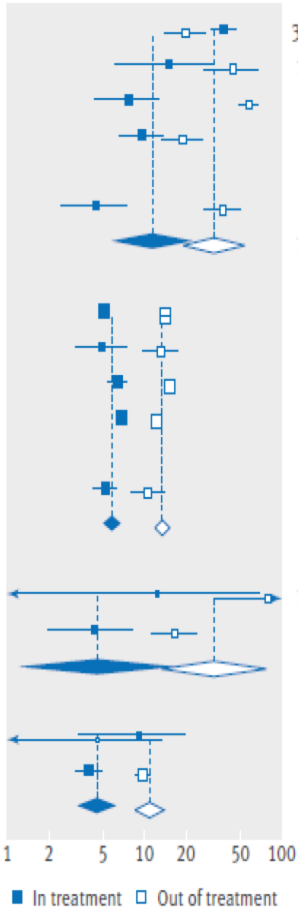
Because they Work…

- 80-90% relapse to drug use without it
- Increased treatment retention
- 80% decreases in drug use, crime
- 70% decrease all cause death rate



Medication Assisted Treatment Review

- Methadone, buprenorphine reduce the risk of death substantially
  - Methadone 11.3% vs. 36.1%
  - Buprenorphine 4.3% vs. 9.5%
- Mortality drops sharply in first 4 weeks of methadone tx
  - **25 fewer deaths per 1000 person-years for those who continue tx**



Sordo L, et al. *BMJ* 2017

Advantages of opioid maintenance

- Reduced illicit drug use
- Reduced euphoria
- Decreased consequences from opioid use
  - HIV infection
  - HCV infection
  - Overdose
  - Criminal behavior
- Extinction of craving, priming, repeated pattern of binge use and withdrawal

Other advantages of opioid maintenance

- Opioid detoxification is difficult!
- Depression and anxiety disorders common among opioid users
  - Buprenorphine and other opioids have significant psychoactive properties
    - Anti-anxiety
    - Anti-psychotic
  - Difficult to distinguish between withdrawal-mediated anxiety/dysphoria vs. underlying psychiatric sx uncovered during drug withdrawal

Treatment gap

- 48 states with opioid abuse or dependence #s > MAT spots
- Gap of nearly 1 million assumes that all DATA-waivered physicians prescribing to their limits
- Only 55% of waivered providers listed on SAMHSA website's treatment locator
- Estimated gap 1.4 million, real gap probably significantly higher

Jones CM et al. *Am J Pub Health* 2015

So why buprenorphine?

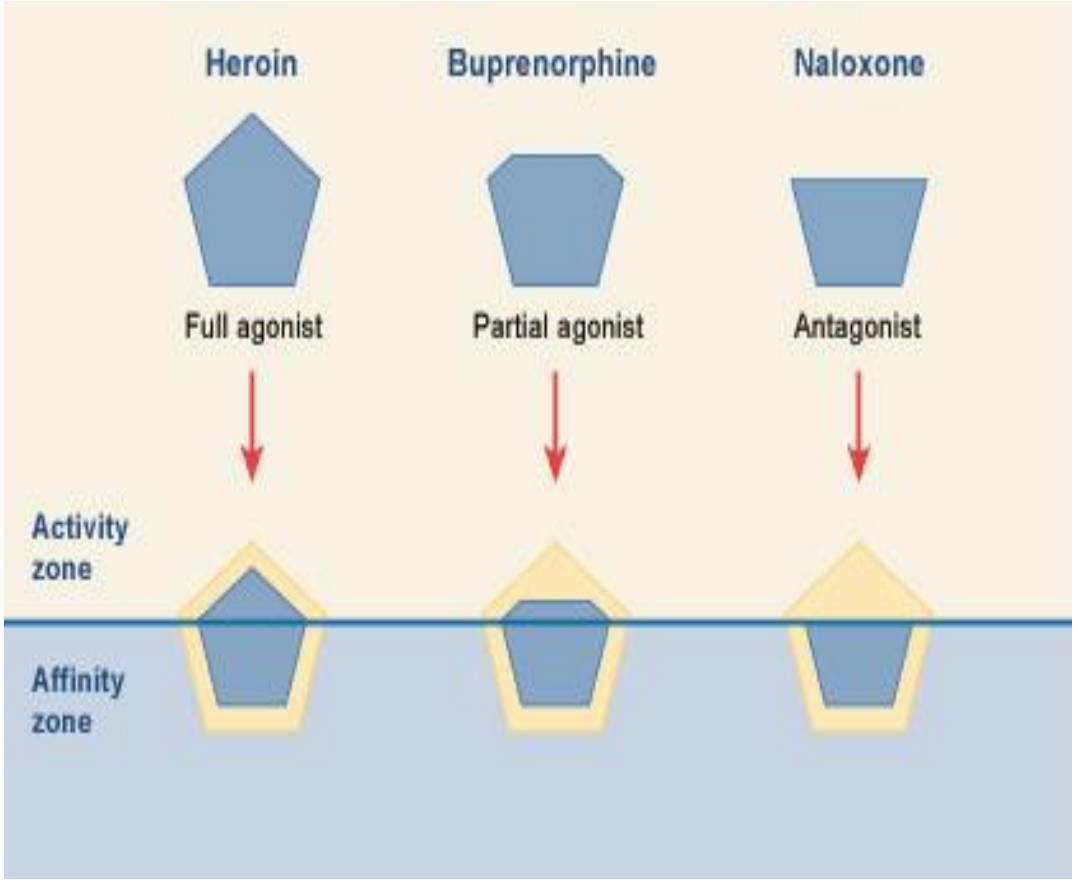
- DEA Schedule III medication
- DATA 2000 waiver allows for outpatient physicians to prescribe
- CARA Act 2016 expanded right to NPs, PAs
  - 24 hours training required
- Buprenorphine combined with naloxone 4:1 to reduce misuse

So why buprenorphine?

- ***Partial mu opioid agonist***
  - Ceiling effect
- ***High receptor affinity***
  - Slow dissociation
- ***Long half life***
  - 36 hours

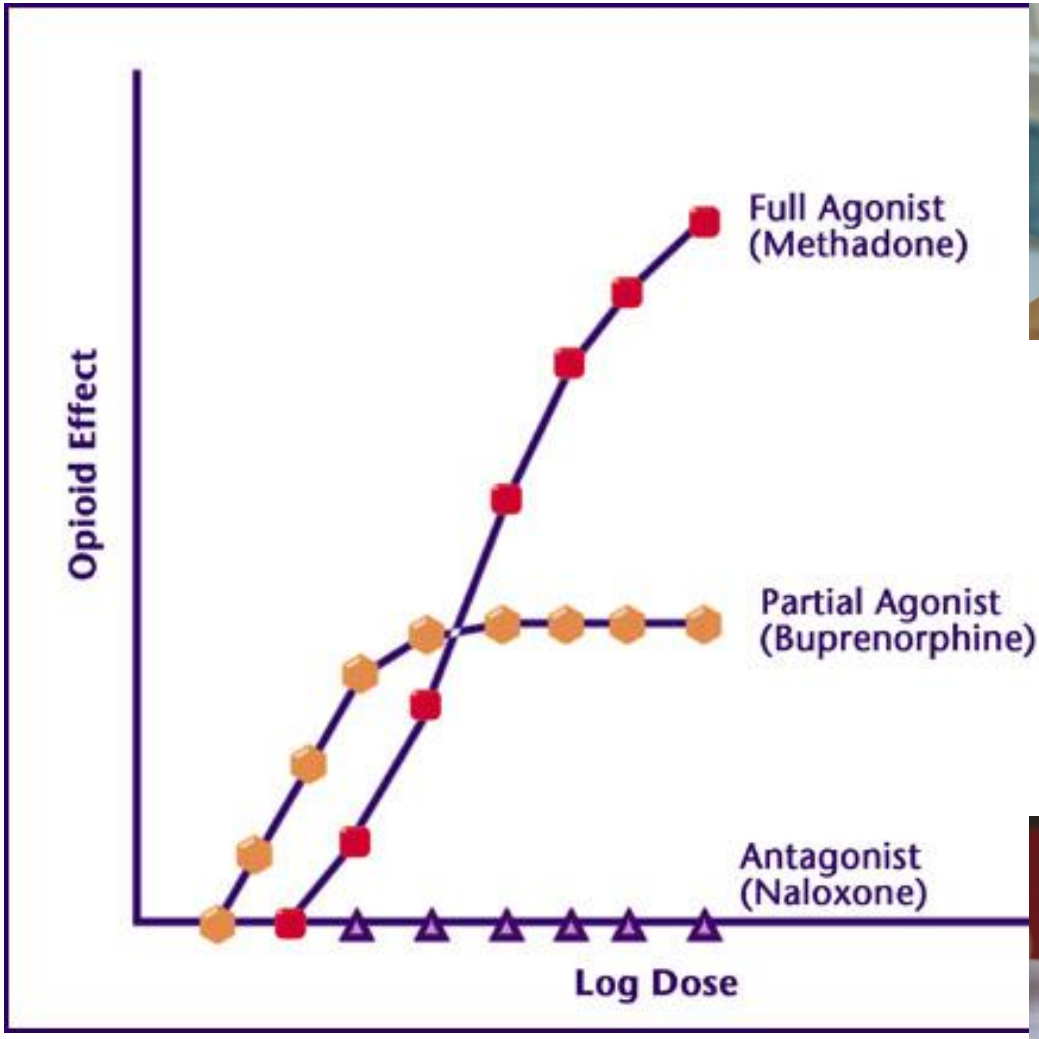
Affinity – how tightly it binds the mu receptor

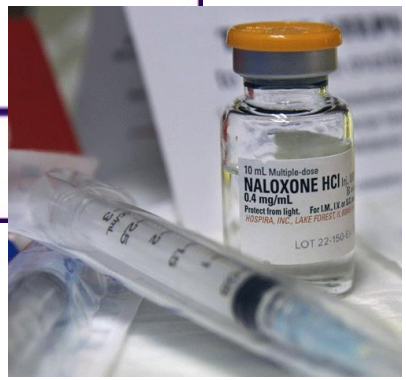
Activity – What does it do? Activate or block, agonist or antagonist



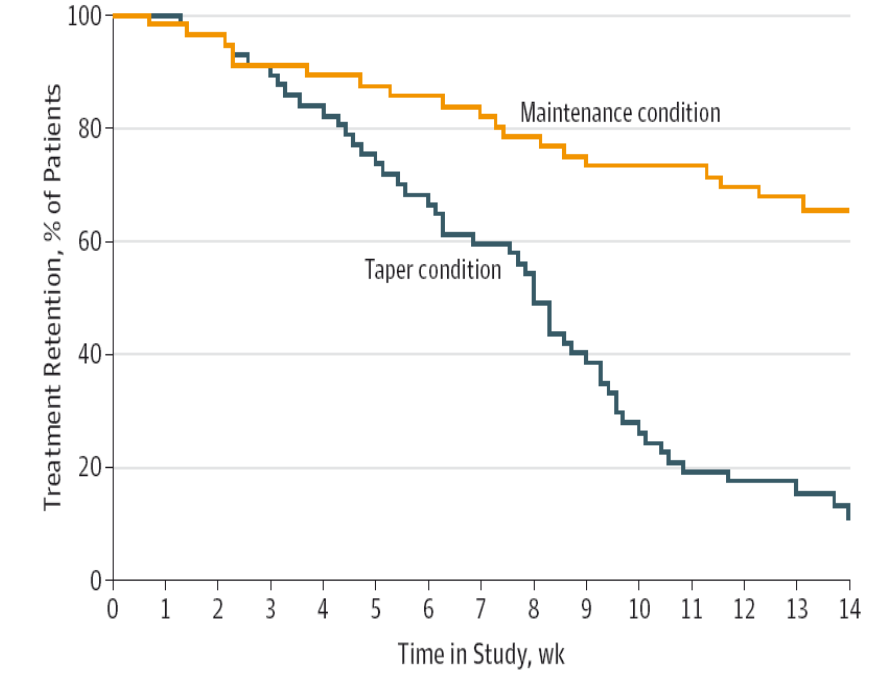
From: Practical Pain Management
https://www.practicalpainmanagement.com/treatments/pharmacological/opioids/office-based-treatment-opioid-dependence

Mu Opioid Receptor Activity





Buprenorphine Maintenance vs Taper
Prescription Opioid Use Disorder



dosage, mg/d

lition	14.9	15.1	15.2	15.3	15.3	16.0	15.9	16.2	16.2	16.6	16.8	16.2	16.1	15.8	14.6
	15.6	15.6	15.4	15.3	14.2	9.7	5.7	3.1	0.6	0.2	0	0	0	0	0

Completion 14 wk trial:

- taper = 11%
- maintenance = 66%

Fiellin DA et al. *JAMA Intern Med.* 2014

Buprenorphine Efficacy Summary

- Studies show buprenorphine more effective than placebo and equally effective to moderate doses (80 mg) of methadone on primary outcomes of:
  - Abstinence from illicit opioid use
  - Retention in treatment
  - Decreased opioid craving

Johnson et al. *NEJM.* 2000.

Fudala PJ et al. *NEJM.* 2003.

Kakko J et al. *Lancet.* 2003.

Abuse Potential of Buprenorphine

- Euphoria in non-opioid dependent individuals
- Abuse potential less than full opioid agonists
- Abuse among opioid-dependent individuals is relatively low
- Combination product theoretically less likely to be abused by IV route
- Most illicit use is to prevent or treat withdrawal and cravings

Yokel MA et al. *Curr Drug Abuse Rev.* 2011.
Lofwall MR, Walsh SL. *J Addic Med.*2014

DIAGNOSIS OF OPIOID USE DISORDER

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Diagnosis of Opioid Use Disorder

- 11 criteria
- Mild: 2-3
- Moderate: 4-5
- Severe: 6 or more

Diagnosis of Opioid Use Disorder: Part 1

- Opioids taken in larger amounts or over longer period than intended
- Persistent desire or unsuccessful efforts to cut down or control opioid use
- Great deal of time spent in activities necessary to obtain, use, or recover from effects of opioids
- Craving/strong desire or urge to use (new to DSM-5)
- Recurrent use resulting in failure to fulfill major role obligations at work, school, or home

Diagnosis of Opioid Use Disorder: Part 2

- Continued use despite persistent or recurrent social or interpersonal problems caused by exacerbated by effects of opioids
- Important social, occupational, or recreational activities given up or reduced because of use
- Recurrent use in situations where physically hazardous
- Use continued despite persistent or recurrent physical or psychological problem likely to have been caused or exacerbated by opioids
- Tolerance
- Withdrawal

⇐Not applicable if prescribed

Diagnosis Take-Home Points

- Three main categories:
  - *Loss of control*
  - *Consequences*
  - *Physiologic dependence*

Questions about Lauren

- Is she benefiting from opioids?
- What are the risks of continuing opioids?
- Do her ‘red flag’ behaviors constitute a use disorder?
- What are her options?

Lauren

Lauren admits she has been unable to take her pills only as prescribed. She has tried to cut back multiple times in the past but has been unsuccessful. Her husband is angry with her constant focus on the medications and he reports that her kids “want their mom back.” She spends most of her day on the couch except when she has medical appointments or has run out of medications and has to find extras. She thinks her depression and energy are worse since taking higher doses.

Question

- Based on this information, do you think Lauren meets criteria for an opioid use disorder?
  A. No
  B. Yes, mild use disorder
  C. Yes, moderate use disorder
  D. Yes, severe opioid use disorder
  E. Not sure

Lauren

Criterion	Present/Absent
Taken in larger amounts/longer period than intended?	✔
Desire to cut down or unsuccessful efforts to control use?	✔
Great deal of time spent acquiring/using/recovering?	✔
Craving/strong desire or urge to use?	N
Failure to fulfill major role obligations at work/school/home?	✔
Continued use despite persistent social/personal problems?	N
Important social, occupational, recreational activities lost?	✔
Recurrent use where physically hazardous?	N
Recurrent psychological or physical problems caused or exacerbated by drug?	✔
Tolerance	N/A
Withdrawal	N/A

SO YOU'VE MADE THE DIAGNOSIS OF OPIOID USE DISORDER. IS THIS PATIENT APPROPRIATE FOR PRIMARY CARE?

A note about clinical inertia

- Changes in the medical management of patients on opioid analgesics following a diagnosis of substance abuse
  - Cohort of patients (N 9,009) without “abuse” diagnoses prior to prescribing who later have these diagnoses
  - Prescribing to patients with documented drug abuse infrequently change prescribing habits

Paulozzi L. *Pharmacoepidemiology and drug safety*. May 2016

Where to treat: ASAM Patient Placement Criteria

- Acute intoxication/withdrawal severity potential
- Biomedical conditions and complications
- Emotional, behavioral, and cognitive conditions
- Readiness for change
- Relapse, continued use, or continued problem potential
- Recovery environment
  - Family, significant other, financial, vocational, legal, etc.

Treatment levels of service

Level	Name	Detox description
0.5	Early intervention	N/A
I	Outpatient	Mild withdrawal; daily or less supervision; likely to complete detox and continue treatment
II	Intensive Outpatient Partial Hospitalization	Moderate withdrawal with all-day or 24 hour support; likely to complete detox
III	Residential: may be low, medium, or high intensity Inpatient: medically monitored	Severe withdrawal; 24-hour nursing/medical care needed; unlikely to complete detox without monitoring
IV	Medically-managed/intensive inpatient	Severe, unstable withdrawal; 24-hour medical care needed to manage medical instability

How can primary care practices use the ASAM criteria?

- Identify uncomplicated patients at low risk for severe complications who may be appropriate for SUD treatment in primary care
- This population may be considered for clinic-based MAT with buprenorphine or naloxone

IMPLEMENTING MAT

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Offer/initiate MAT in non-traditional locations and models

- Emergency department
- Inpatient service
- Jails
- Prisons
- School-based clinics (children/adolescents)
- Interim methadone/buprenorphine
- Residential treatment facilities
- ***Primary Care***

Buprenorphine implementation models

- Practice-based models
  - OBOT
  - BHIVES
  - ”One-stop shop” model
  - Integrated prenatal care/MAT
- Systems-based models
  - Hub-and-spoke (VT)
  - Medicaid health home
  - Nurse care manager (MA)
  - Collaborative opioid prescribing model (MD)

Korthuis PT et al. *Ann Intern Med* 2016

Barriers to implementation

- Organizational
- Regulatory
  - 42 CFR Part 2
- Economic/reimbursement
- Workforce training

Increasing access requires overcoming barriers

Clinic

- Accessibility
- Availability
- Technical
- Logistical
- Strict rules (methadone)
- Reimbursement

Provider

- Communication
  - 42 CFR Part 2
- Workforce capacity
  - Addiction psychiatry
  - Addiction medicine
  - Advance Practice Providers
  - Addictions counselors

Patient

- Stigma
- Engagement & retention
- Insurance coverage

Practice-based model: One-Stop Shop

- Integrated model based in mental health clinic
    - Provided integrated care for:
        - HIV/HCV
        - Mental Health
        - Primary Care
        - Syringe Exchange
- Primary care provider embedded in mental health clinic
- OUD treatment primarily naltrexone-based

Korthuis PT et al. *Ann Int Med.* 2016.

System-based model: ECHO

- Primary care clinic performs initial screening, treatment, monitoring, and follow up
- Mentored buprenorphine prescribing, including internet-based AV network for provider education

Korthuis PT et al. *Ann Int Med.* 2016.

Models of primary care delivery: OBOT

- Designated clinic staff member to coordinate prescribing
    - Typically nurse, SW
- Psychosocial services
    - Brief counseling on site
        - May be provided by physician, other staff
    - Off-site referrals
- Reimbursed by billable visits

Korthuis PT et al. *Ann Int Med.* 2016.

Necessary pieces

- Assessment for OUD
- Complete medical hx, assess for concomitant conditions
    - HIV, Hepatitis, pregnancy, acute trauma
- Physical exam & lab testing: Hep A,B,C and HIV, pregnancy, LFTs
    - Offer vaccines, family planning
- Determine appropriate site of care
- *Must be able to provide counseling or referral to counseling*

Primary Care Medical Management

Critical Elements: Medical

- Monitoring of compliance with buprenorphine maintenance
- Monitoring of patients' drug use, symptoms, and progress
- Education regarding opioid use disorder and buprenorphine maintenance treatment
- Encouragement to achieve abstinence from illicit opioids and to adhere to all treatment recommendations
- Identification and treatment of medical complications of opioid use

Primary Care Medical Management

Critical Elements: Counseling

- Encouragement to attend self-help groups
- Provision of brief advice modeled on the education provided in standard drug counseling, such as encouraging patients to make lifestyle changes that support recovery, and to avoid potential triggers of drug use
- Referrals to specialty services in the community (e.g., vocational, legal, housing or social services) if necessary

Maximize Collaborative Care

Team

- Physician (waivered)
- Nursing
- Social worker
- Counselor
- Medical assistant
- Administrative staff

Care responsibilities

- Screening and intake
- Pretreatment assessments
- Treatment planning
- Medication management
- Monitoring (UDTs, pill counts, PDMP checks)
- Individual and/or group counseling
- Drop in groups
- Family support
- Relapse prevention
- Recovery Monitoring

Alford DP et al. *Arch Intern Med.* 2011.

Anticipate Insurance Issues

- Is buprenorphine a covered benefit?
  - What Tier? What Co-pays?
- Is behavioral treatment covered?
- Beware behavioral health carve outs!
- Are lab services covered?
- Restrictions on duration of treatment?
- Anticipate prior approval procedures
  - Collect forms from each payer
  - Submit forms in advance of fill
  - Consider cash for first few days supply
  - Monitor patient's pharmacy benefits
  - 340B coverage in some Community Health Centers

Billing for OBOT

- OBOT is standard medical care: billing procedures are standard
- The ICD-10 Code for opioid dependence is F11.20.
- Physicians billing codes: (CPT) billing codes, accepted by all payers
- No specific Addiction Medicine codes. Same codes as other ambulatory care services
- More information provided in written materials

Local resources to help implement MAT

- IT MATTTRS2 Colorado
  - Offers on-site practice facilitation, waiver training reimbursement, MATerials
  - http://www.practiceinnovationco.org/itmatttrs2/

- Project ECHO
  - Has a buprenorphine implementation series
  - https://echocolorado.org/

Conclusions

- MAT proven to reduce morbidity and mortality related to drug use and to increase likelihood of abstinence
- Primary care has a major role to play in addressing the opioid epidemic
  - PCPs already great at treating chronic, relapsing diseases
- Increasing access to MAT must be a primary goal
  - Best bet is expanding buprenorphine in primary care and other settings
  - Logistical support and education is crucial

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END