Buprenorphine: Knocking Out Pill Mills and Minimizing Diversion

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DISCLOSURES (Part 2)

- This presentation will be given by both doctors and lawyers
- If you feel a need to flee in terror, please do so quietly at this time

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Objectives

1. Discuss the problem of buprenorphine diversion and pill mills
2. Understand policy strategies to control buprenorphine diversion and pill mills
3. Outline effective clinical approaches to reduce buprenorphine diversion and pill mills

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What is buprenorphine?

- It is a special kind of opioid ('partial agonist'). It is nearly impossible for an adult to die from overdose of just buprenorphine
- One of three medicines to treat opioid addiction
  - Methadone and naltrexone are the others
  - Buprenorphine also used to treat pain
- Trade names for buprenorphine = "Subutex" (also called "mono-product")
- Trade names of buprenorphine + naloxone = "Suboxone", "Zubsolv", "Bunavail" (also called "combo-product"); the naloxone is there to discourage IV use
- Both mono and combo products are called "bupe"

What is buprenorphine?

- Buprenorphine or methadone are the best single components of a full treatment plan for opioid addiction

- Extremely strong scientific evidence base for effectiveness (morbidity, mortality and functionality) and cost effectiveness

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Opioid addiction

- Opioid addiction, also called severe opioid use disorder, is a chronic brain disease
- People with opioid addiction lose control of their drug use, then lose control of their lives because of their drug use
- People can become physically dependent without becoming addicted (without losing control of drug use and life)
- People can become addicted by taking medications exactly as prescribed by their doctors

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What happens when people get addicted to opioids?

- Their brain changes…..permanently

- When they stop using, within hours or at most a few days, they get SICK (throwing up, diarrhea, goose bumps, runny nose, stomach cramps, aches, insomnia)
  - Within an hour of using an opioid, that sickness STOPS

- People with chronic diseases need chronic maintenance care with components of biological, psychological and social interventions. They are never "cured". Some people must stay on buprenorphine for life, just like some people will be on insulin for life.

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Who Advocates for Increased Access to Buprenorphine Treatment?

- National Institute of Drug Addiction (NIDA)
- Substance Abuse and Mental Health Services Administration (SAMHSA)
- Centers for Disease Control and Prevention (CDC)
- Center for Medicare and Medicaid Services (CMS)

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Who Advocates for Improved Access to Buprenorphine Treatment?

- The American Society of Addiction Medicine (ASAM)
- The American Medical Association (AMA)
- The National Governors Association
- The John's Hopkins School of Public Health and Public Policy
- Center for Lawful Access and Abuse Deterrence (CLAAD)
- Patient Groups (Young People in Recovery; Faces and Voices of Recovery)
- Hazelden – Betty Ford Foundation

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Special Chemical Properties of Buprenorphine

- Special chemical properties:
  - If people take enough every day to cover up their brain receptors, they are not high/impaired, don't feel cravings, and cannot get high from other opioids
  - If people are in opioid withdrawal, it stops withdrawal
  - If people are high, it throws them into withdrawal
  - If people are sober and not in withdrawal, taking it can be used to get high

- **HOWEVER…….**The pharmacological characteristics that make buprenorphine effective (i.e., opioid agonist properties) to patients are the same characteristics that create the risk of misuse and diversion

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More Definitions

- Misuse: incorrect use of the medication by patients (wrong time, wrong dose, wrong purpose) (SAMHSA)

- Abuse: maladapted pattern of substance use leading to significant impairment or distress. (SAMHSA)

- Diversion: unauthorized rerouting or appropriation of a substance (theft, buying others meds, fake prescriptions, etc)

[1]ASAM Board of Directors

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What Rxs are diverted?

- On a national survey, 23% admitted that they shared their rx drugs with others, and 27% had borrowed rx medication from another person.[1]
  - 22% pain relievers
  - 25% allergy medications
  - 21% antibiotics

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How Does This Compare to Patients in Medication Treatment for Opioid Addiction?

- Surveys of patients enrolled in outpatient opioid addiction treatment (with either methadone or buprenorphine) report that 18-28% have sold, given away their medication, removed it while under supervision, or shared other prescribed medication

- vs. 23 % diversion of antibiotics and allergy medications
- vs. 22% diversion of pain pills

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What is a “Pill Mill”?

(Florida Office of Drug Control)

– “A ‘pill mill’ is a doctor’s office, clinic, or health care facility that routinely colludes in the prescribing and dispensing of controlled substances outside the scope of the prevailing standards of medical practice in the community or violates the laws of the State of Florida regarding the prescribing or dispensing of controlled prescription drugs”.

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And now a word

(several words)

from our team lawyer….

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Round One

- Florida's opioid analgesic-related overdose deaths grew by 84.2% percent 2003-2009
- The number of Florida pill mills posing as pain clinics grew 61%
- States enacted strong pill mill laws and regulations (opioid analgesics only)
- Prosecutors cracked down rogue prescribers
- The number of pill mills in operation decreased
- The number of opioid-analgesic related overdose deaths in Florida decreased from 3,201 to 2,666 (-16.7 percent) 2010-2012

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Policy Perspective

- Supply reduction efforts limited to Rx opioid analgesics (vs. all controlled Rx medications)
- Inadequate demand reduction (interventions and treatment)
- Tremendous advances in opioid overdose rescue
- Increases in heroin use and deaths are likely not caused by policy responses; rather, heroin accessibility/price/purity (NIDA 2016)

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Shift in Profiteering Tactics

- Black market drugs and biologics
- Fraud and abuse in urine drug testing
- Buprenorphine pill mills
  - No legitimate medical need
  - Prescribing outside the normal course of professional practice
    - Evolving standard of care determined by medical community
    - Precautions to prevent harm are necessary

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Black Market Buprenorphine

- Buprenorphine is now the third most confiscated drug by law enforcement (DEA)
- Individuals who seek buprenorphine on the black market may do so to self-medicate (misuse) rather than to seek a euphoric effect (abuse)
- Contributing factors
  - Federal limits on the number of patients doctors can treat with buprenorphine
  - Payer policies and inadequate coverage

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Knee-jerk Responses

- Piecemeal approach: new laws just for buprenorphine
- Onerous “certificate of need” (NIMBY/regulatory hurdle) requirement
- Limits on buprenorphine coverage under Medicaid
- Regulate doctors’ offices like addiction treatment programs
- Ban telemedicine

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Patient Limit

- Demand for buprenorphine-assisted treatment should be met by professionals who follow best practices (vs. those with minimal training and experience)
- Reasonable approaches
  - Adjust the limit for well-qualified addiction professionals
  - Do not count lower-risk individuals toward patient limits
    - Stable recovery
    - Implantable or injectable
    - Women who are pregnant
- Proposed regulation: Increase Number of Patients to Whom DATA-Waived Physicians May Prescribe Buprenorphine (+/- April 8, 2016)

Policy Recommendations

- Prescriber education
- Medically derived standards for prescribing
- Adequate coverage of safer prescribing activities
  - Mental and physical exam, patient counseling, pill counts
  - Urine drug testing to verify medication use and identify diversion, misuse, or abuse
  - Screenings for pregnancy, HIV, hepatitis C
- Do not consider self-pay programs to be pill mills *per se*
- Mandatory, periodic PMP data checks
- Protect the privacy of prescribers and patients
- Rehabilitate negligent actors
- Prosecute criminals

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Also Address Risks of Other Controlled Rx Medications

- Opioids for pain and dependence
- Stimulants
  - 17% of college students abuse Rx ADHD medications
  - 20% of middle & high school students with Rx are asked by friends for medications; 50% give medications to friends
- Benzodiazepines
  - Overdose deaths quadrupled between 2001 and 2013
  - PA: Present in 50% of drug-related overdose deaths (40% involved alprazolam)
  - GA: Misuse of alprazolam leading cause of drug-related death (35%, 231 out of 644)
- Sedatives
  - Violence
    - "Ambien defense" to murder
    - Zolpidem sleep medication is most common date rape drug (DEA)
  - Impaired driving ("sleep-driving")

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What kind of a practice is this?

- Patients drive long distances
- Patients may car pool with family members
- Doctor is self-pay only (no insurance)
- Minimal if any physical examination
- Large percentage of patients get one or more Rx for controlled substances
- Doctor only in that location once a week

→ normal psychiatrist office!

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Psychiatrist office vs buprenorphine office?

- Low insurance payment rates lead to cash-only practices (50% of psychiatrists are cash only)
- Very limited physician resource leads to doctors traveling to distant (rural) areas
- Doctors work multiple job sites
- Rural patients drive long distances
- Disorders run in families/communities→ “car pooling”
- Psychiatrists prescribe sedatives, hypnotics, and stimulants – each of which is abusable

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Appalachia: Use of Diverted Buprenorphine

- 503 community dwelling prescription opioid abusers identified at baseline and followed over 6-months
- At baseline, asked *"Have you attempted but were unable to get into buprenorphine treatment?"*
- Evaluated for predictors of use of diverted buprenorphine "to get high" over the 6-month follow-up period using multivariable logistic regression
- Limitations: did not ask about formulation used, route of use, or other motivations for use

Lofwall and Havens, Drug and Alcohol Dependence 2012

Predictors of Use of Diverted Buprenorphine

- 471 assessed at 6-month f/u
  - 219 reported use of diverted bupe over the 6 months
  - 252 reported no use of diverted bupe

	Adjusted OR	95% C.I.
Tried & failed access BUP tx	7.31	2.07, 25.8
Past 30 day use:		
OxyContin	1.80	1.18, 2.75
Benzodiazepines	0.53	0.31, 0.89
Methamphetamine	4.77	1.30, 17.5
Alcohol	1.60	1.09, 2.36
DSM-IV GAD	1.69	1.11, 2.56

What did that mean?

– The single most important risk factor for using diverted buprenorphine is lack of access to buprenorphine treatment!

– Question: if you have diabetes and could not access medical care for insulin treatment, would there develop a black market for insulin, and would you use it to get your medicine?

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Balancing Risk and Benefit

- Doctors and Public Health Officials look for treatments to:
  - Decrease morbidity (sickness due to illness, like getting Hep C or HIV)
  - Decrease Mortality (decrease risk of death due to overdose or secondary illness)
  - Improve functionality (return to work, parent children, etc.)
  - Decreased secondary health effects (like others hurt due to impaired driving, or child neglect)

  - →Which leads to improved community safety

- Law enforcement looks to:

  - Decrease unlawful behavior directly related to drug use (drug trafficking, drugged driving)
  - Decrease unlawful behavior driven by drug use (prostitution, child neglect)
  - Decrease secondary unlawful behavior driven by drug use (juvenile crime due to absent parenting, etc.)

  - → Which leads to improved community safety

1. Cicero et al. Drug and Alcohol Depend. 2014

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Balancing Risk and Benefit (cont)

- On one hand, ⇧prescribing/availability/access can lead to ⇧ diversion and misuse[1] , but
- Inability to access bupe treatment in Appalachia leads to ⇧risk of using diverted bupe!

From a public health perspective there is a NET ↓ in overdose deaths with treatment expansion

1. Cicero et al. Drug and Alcohol Depend. 2014

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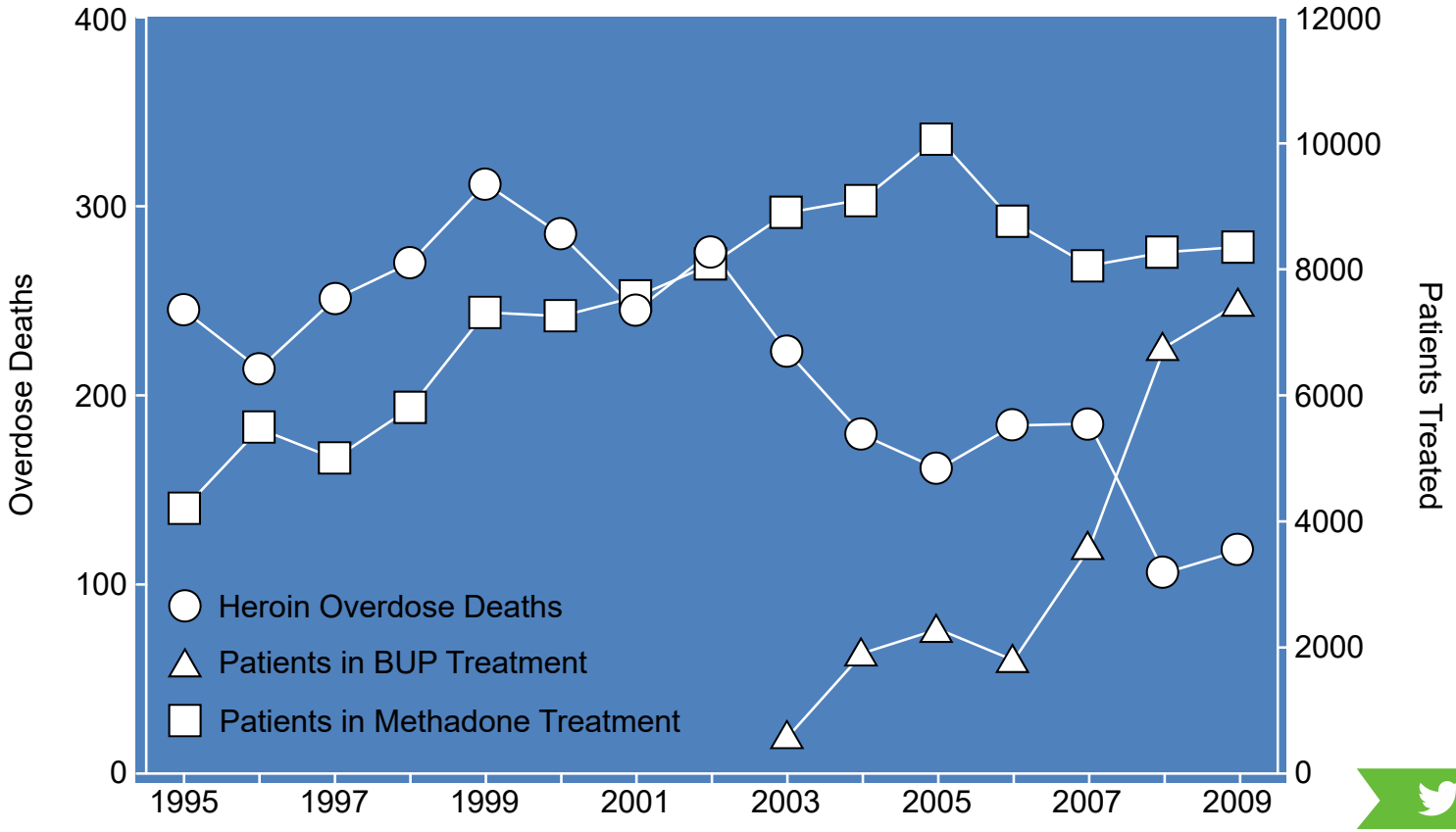
Baltimore: Agonist Treatment & Relationship to Heroin Overdose Deaths



Schwartz, et al., American Journal of Public Health, 2013

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What we know

- Opioid addiction is a chronic brain disease
- The single best treatment is medication
- The longer people stay on buprenorphine, the better they do (morbidity, mortality, functionality)
- Decreased access to buprenorphine is associated with increased risk of buprenorphine diversion

→ improved access to quality buprenorphine decreases risk of diversion and proliferation of buprenorphine mills

Insurance Policies in Place Currently

(failure to distinguish good from bad care)

- Lack of insurance coverage for medication
- Lifetime limits on medication coverage
- Forced taper of dosage
- Requirements for medication coverage which are effective barriers (e.g., requiring counseling but failing to cover counseling, or refusing to cover addiction physician services)

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Additional Regulations

- 30/100 patient limit (low supply and high demand)
- Certificate of need for over 150 patient practice
- Zoning physician offices into industrial areas
- Special licensure for buprenorphine practices

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How to stamp out buprenorphine mills:

- Identify good practice and increase patient access to it:
  - Professionals referring patients
  - Retail pharmacists filling those rx
  - PBMs and health plans gold-carding practices
  - Law enforcement and corrections utilizing those prescribers' expertise

- Identify bad practice and use all professional groups to halt their practice:
  - Professional licensing boards
  - Retail Pharmacists declining to fill
  - PBMs and health plans ejecting from panels
  - Law enforcement where regulations and laws are broken

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Gold Standard Care Looks Like This:

- Consistent with ASAM Guidelines for the Use of Medications in the Treatment of Opioid Addiction
- Consistent with Guidelines of the Federation of State Medical Boards (FSMB)
- Consistent with state laws and regulations

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Good Buprenorphine Care Looks Like This): (what prescribers can do)

- Initial bio-psycho-social evaluation
- Initial physical examination
- Check of PDMP (or commercial equivalent)
- Blood work (liver tests, HIV, Hep C)
- Drug of abuse screen (including nor-buprenorphine /buprenorphine metabolite testing)
- Individualized treatment plan

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Good Buprenorphine Care Looks Like This:

- Initially frequent visits (such as weekly; rural issues may require telemedicine or other considerations)
- Random call backs for drug tests and pill/film counts
- Ongoing use of PDMP (or commercial data)

Needed psychosocial supports:

- Psychosocial assessment and referral to resources as available
- Contingency management (seen less frequently as improves in program via expected drug screens, adherent to treatment plan)
- Motivational enhancement /interviewing
- Supportive contacts with clinicians

Not Necessary for Good Buprenorphine Care:

- Insurance accepting prescriber
- Full time addiction practice
- Individual or group psychotherapy
- Required AA or NA attendance
- Patients from same county

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Not Necessary for Good Buprenorphine Care:

- Abstinence required from all drugs with addiction potential
- Perfect adherence to treatment plan required
- Do we discharge patients from diabetes care if they eat cake and ice cream?
- Buprenorphine only treats opioid addiction – no other substances. Do we stop medications for high blood pressure if cholesterol stays high?

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Red Flags for Buprenorphine Mills (what pharmacists can do)

- High degree of co-prescribing of benzodiazepines, stimulants, muscle relaxants
- Any co-prescribing of opioids
- Lack of compliance with state or federal laws (such as now over 100 pts on buprenorphine)
- Patients over 24 mg Suboxone equivalents, or high % of patients over 16mg Suboxone equivalents;
- Patients on mono- product, rather than combo

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Conclusions

- Opioid addiction is a chronic brain disease
- Buprenorphine is a vital part of treating this population
- Diversion & misuse are common behaviors that are not limited to controlled substances
- Clinical professionals, public health officials, and law enforcement all want the same thing – improved public safety
- We need to distinguish between good practice and bad practice, substantially increasing access to the former and obliterating the latter
- Only with this two-pronged approach can we meet our common goals to deal with this epidemic

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