The Role of Pharmacists and Pharmacy Technicians in Addressing the Opioid Epidemic

Snehal Bhatt, MD
Associate Professor, Psychiatry and Behavioral sciences
Chief, Addiction Psychiatry
University of New Mexico

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Disclosures

- I have no financial disclosures.

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Objectives

1. Appreciate that opioid use disorders are chronic illnesses
2. Learn that treatment with medications for opioid use disorders is effective, and saves lives.
3. Appreciate the role of the pharmacists and pharmacy technicians in prevention, monitoring, treatment, and harm reduction efforts

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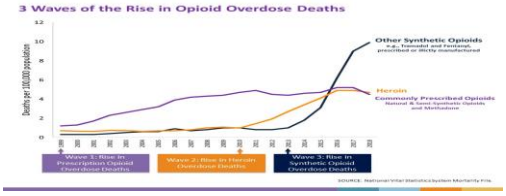

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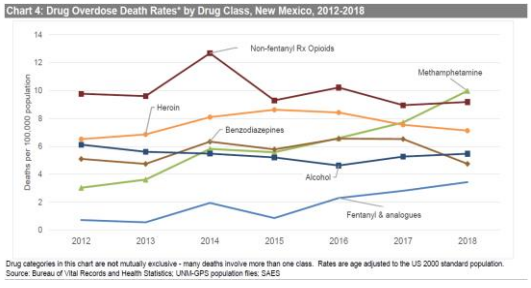

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COVID-19 and Overdoses

- More than 19,000 people died of a drug overdose in the first three months of 2020, nearly 3,000 more than the same time period in 2019 [CDC preliminary data]
- If that rate stays constant or worsens, the U.S. will be on track for an all-time high number of overdose-related deaths in a calendar year.

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Impact of COVID-19 on harm reduction services in NM

Since March 2020

- 39 sites reported increasing drug scarcity
- 40 sites reported increase in price of street drugs
- Only one site reported increased drug overdoses
- 38 sites reported increased cases of opioid withdrawal
- 46 sites reported difficulty maintaining supply stock:
  - Syringes were the most commonly mentioned supply shortage; others included hand sanitizer, masks, gloves, sharps containers and tourniquets
- 7 sites had to discontinue services, most commonly mentioned were:
  - HIV/HPC testing, street outreach, group counseling, complementary medicine (accudetox, Reiki, massage, etc.)
  - 2 sites closed completely

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Similarities with Other Chronic Diseases (Type II Diabetes, HTN, Asthma)

- **Genetic impact is similar**
- **The contributions of environment and personal choice are comparable**
- **Medication adherence and relapse rates are similar.**
- **Long term maintenance treatments proven most effective. (McLellan, JAMA 2000)**

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Implications

- As in all chronic diseases, treatment should be continuous rather than episodic
- Available treatment leads to substantial improvement in:
  - Reduction of alcohol and drug use
  - Increases in personal health and social functioning
  - Reduction in threats to public health and safety
  - Reduction in monetary costs
  - Reductions in mortality

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" Detoxification from heroin is good for many things – but staying off heroin is not one of them"

Walter Ling

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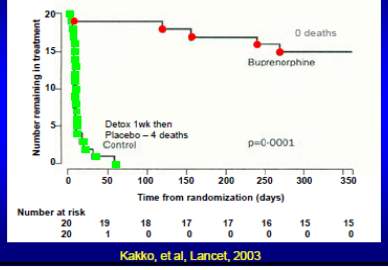
Buprenorphine Maintenance vs Detox. RCT of cumulative retention in treatment



Kakko, et al, Lancet, 2003

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FDA Approved Medications for Opioid Use Disorders

- Methadone- Agonist
- Buprenorphine- Partial Agonist
- Naltrexone [Oral and Injectable]- Antagonist

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Methadone outcomes

- ↓ Heroin use by 50%- 70%
- ↓ HIV 4 fold
- ↑ Employment 24%
- ↓ 60% criminal activity
- Less incarceration
- Less high risk behaviors
- More child support payments
- 3x as likely to remain in treatment
- Improved hepc treatment adherence
- Mortality reduced
- Cost effective
- Drug users out of methadone treatment 6x more likely to become HIV positive than those in methadone treatment [Metzger et al., 1993]

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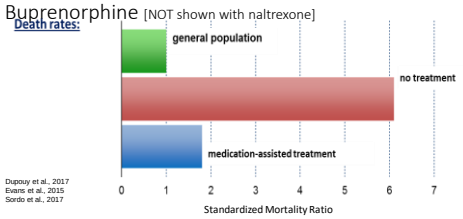
Benefits of Pharmacotherapy:
Decreased Mortality with Methadone and Buprenorphine [NOT shown with naltrexone]



Dupouy et al., 2017
Evans et al., 2015
Sordo et al., 2017

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Other Benefits of Pharmacotherapy

- Medication can be one part of a more comprehensive treatment
- Often the "hook" that leads to treatment engagement
- Importance of treating underlying illnesses [eg PTSD, hepatitis C]
- Importance of helping stabilize life [employment, housing]
- Importance of helping create positive social networks
- Importance of helping learn coping skills, relapse prevention strategies, emotion regulation

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..And yet…Disparate Treatment… Stigma?

- SUD's are the only conditions in which:
  - Non-compliance / lapse are grounds for dismissal
  - Withholding known life saving treatment considered
  - Not all medications are offered
  - Only the less effective medications are offered
  - Medications are withheld based on "personal feelings" or "moral objections"
  - Known life saving treatment withheld or rationed
  - Active disease considered to be a crime problem
  - Pt's expected to discontinue known effective Rx
  - No/limited insurance coverage for effective treatment

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Recommendations from The National Academy of Sciences

1. Opioid use disorder is a treatable chronic brain disease.
2. U.S. Food and Drug Administration (FDA)-approved medications to treat opioid use disorder are effective and save lives.
3. Long-term retention on medications to treat opioid use disorder is associated with improved outcomes.
4. A lack of availability of behavioral interventions is not a sufficient justification to withhold medications to treat opioid use disorder.

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Recommendations from The National Academy of Sciences

5. Most people who could benefit from medication-based treatment for opioid use disorder do not receive it, and access is inequitable across subgroups of the population.
6. Medication-based treatment is effective across all treatment settings studied to date. Withholding or failing to have available **all classes of FDA-approved medication** for the treatment of opioid use disorder in any care or criminal justice setting is denying appropriate medical treatment.
7. Confronting the major barriers to the use of medications to treat opioid use disorder is critical to addressing the opioid crisis.

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Role of Pharmacists and Pharmacy Technicians

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Defining the Role

- "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription."
- *—21 CFR §1306.04*

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Self-Perceived Role [Hartung 2017]

- To monitor and ensure safe medication dispensing
- To identify patients at high-risk of opioid misuse who would benefit from early interventions
- To prevent abuse and misuse
- To act as a member of the care team, with opportunities to collaborate with prescribers
- To educate and share information with patients and prescribers

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Self Perceived Role

- "I think the pharmacist plays a huge role in opioid related abuse and misuse. We often see the patient more than the providers do. So we can more reliably catch patterns of filling early and multiple providers."
- "I view my role as doing all I can to ensure that the patient is not diverting or misusing their medications. I do this by critically looking at the prescription to make sure it's valid, looking at fill history and concomitant medications, addressing DUR problems. I believe that pharmacists' role SHOULD be more proactive with the prescriber in working to get individuals to a lower dose/off the medication; however, I realize as a retail pharmacist that this can be near impossible."
- "I view my role as being highly responsible for abuse/misuse, but with very little resources/strategies to make this determination."

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Screening and Education

Challenge: Balancing Roles [Legal role of monitoring for diversion vs ethical role of ensuring safe, effective and timely access to treatments]

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Screening and Education

- Evaluate prescriptions
- Monitor the PMP [May utilize pharmacy interns or technicians as delegates]
- Use the PMP results to engage in patient centered care and communication
- RESPOND Toolkit: https://pharmacistrespond.org/
- Irwin et al [2020]: Pharmacists' knowledge and attitudes toward OUD, perceived behavioral control to address OUD, resources to address OUD, and perceptions regarding PDMP-associated difficulties improved significantly as a result of the intervention (all $P < 0.001$).

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Step 1: Initial screening

- Prescription:
  - Has missing or unreadable info
  - Appears altered or irregular
  - Is from an unfamiliar prescriber
  - Is from outside surrounding area
  - Is denied coverage by patient's insurance company
- Patient:
  - Is new to the pharmacy
  - Refuses to show identification
  - Is picking up Rxs for multiple people
  - Is paying cash

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Step 2: PDMP Review

- Opioid dosage significantly higher than necessary for a new or chronic user
- Combination of medications poses risk
  - Opioid with benzodiazepine and/or muscle relaxant
  - Long-acting and short-acting dosage forms
- Combination of contradicting medications
- Prescriptions have been filled too frequently
- Patient is seeing multiple prescribers and/or pharmacies

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Step 3: RESPOND. Strategies for effective communication.

- Focus on safety
- Non-judgmental language
- Open ended questions
- Reflective language
- Share safety concerns
- Ask permission before providing education
- Give timeline

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Prescriber Communication- SOAP Note Strategy

- Subjective information verbally or visually provided by patient or prescription
- Objective information gathered from the drug utilization review (DUR), the PDMP, and other sources
- Assessment of situation
- Plan or recommendation for next steps

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What about formal screening?

- Strand et al. [2019]:
- Pharmacy based screening tool and algorithm to identify and provide care to individuals at high risk for opioid misuse and opioid related harms
- 26% of screened individuals were identified as risk for misuse, and 30% were identified as having elevated risk of overdose
- Community pharmacists appreciated having an objective measure and also reported improved communication

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Naloxone Distribution

https://doseofreality.com/toolkit/save-a-life-overdose-and-naloxone/

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Potential Risk Factors for Opioid Overdose

- +PMH for substance abuse; including alcohol, tobacco, marijuana)
- +PMH for non-medical use of opioids
- +PMH or current symptoms of behavioral disorders
- +PMH for obtaining opioid Rxs from multiple providers
- **High opioid dose**
- Opioid rotation
- Use of methadone &/or ER opioid formulations
- Use of ER opioid + prn IR opioid
- Concomitant use of other CNS depressants (benzodiazepines; carisoprodal (Soma®); alcohol, etc.)
- +PMH for hepatic &/or renal disease
- Presence of acute &/or chronic pulmonary disease including sleep apnea

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Why Universal Prescribing of Naloxone?

- Overdose usually witnessed
- Death takes a while
- EMS not routinely accessed
- Naloxone is safe and effective
- May decrease the need for advanced respiratory support
- Possible behavior change
- Between 2007 and 2016, the number of naloxone prescriptions in retail pharmacies increased nearly 100fold, from 1488 to 147,457 prescriptions [Xu 2018]
- McClellan et al. [2018] found that between 2000 and 2014, states implementing naloxone access laws experienced 14% fewer opioid overdose deaths.
- States that granted direct authority to pharmacists to dispense naloxone had the largest effect on naloxone dispensing and opioid related deaths [Abouk 2019]

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Legal Considerations

- Naloxone is not a controlled substance
- Some states have added legal protections/good Samaritan laws
- Prescribing or dispensing based on standing order or directly from pharmacies
- Currently, naloxone is available without a patient-specific prescription from another medical professional in all 50 states and the District of Columbia.
- And yet…
- A study in California, which allows naloxone to be dispensed under a Board of Pharmacy protocol, found that only 24% of surveyed pharmacies indicated they were able to provide naloxone without a prescription [Puzantian 2018]
- In another study, only a third of pharmacies in Philadelphia, where a state-wide naloxone standing order had been in place for more than 3 years, were able to provide nasal naloxone without a prescription [Guadamuz 2017]
- A survey of community pharmacists in Indiana, where access laws are similar, found less than half of pharmacists were comfortable dispensing naloxone [Meyerson 2018]
- great need for pharmacist training and education related to naloxone has been identified [Green 2015]
- Muzyk [2019]: Favorable attitudes but need more training and support

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Harm Reduction Strategies

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Harm Reduction

- Access to Clean needles
  - Associated with decrease in needle sharing [Janulis 2012]
  - No measurable increase in crime or substance use in area[Davidson 2015; Stopka 2014]
  - State laws vary
- Syringe exchange programs
  - Effective at reducing transmission of HIV and hepatitis C virus (HCV), especially when paired with opioid agonist therapy programs [Fernandes 2017; platt 2018]
  - A recent systematic review examining pharmacy-based needle/syringe exchange programs specifically appeared to show an effect in reducing risky behaviors among their clients [Sawangjit 2017]
- Provision of fentanyl test strips?

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Role in Treatment

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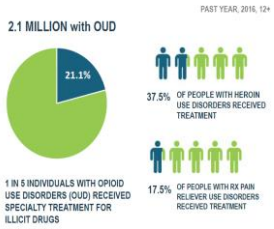
OUD Treatment



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Methadone: treatment barriers

- Out of medical mainstream
- Stigma of specialized clinics
- Location of clinics
- Daily dosing
- Federal regulations
- 96% of all OTPs in the US are located within urban areas, meaning access for non-metropolitan populations can be extremely limited
- There remain three states without any OTPs at all, and another four states with three or less operating OTPs
- Despite the dramatic rise in the prevalence of OUD over the past two decades, the number of OTPs in operation has remained more or less stable since 2003

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Lack of availability of buprenorphine

- Good news:
  - Nationally the number of waivered providers increased by 175% between 2016 and 2018, and patient capacity increased by 211% [Ghertner 2018]
  - Access has improved steadily since passing of CARA
- Concerns:
  - Many US counties [35%] do not have a waivered provider [Ghertner 2018]; the number is 57% in rural counties
  - 20 million individuals live in counties with no buprenorphine waivered provider, with 70% of them in rural counties
  - 30% of rural Americans live in counties with no buprenorphine provider [Andrilla 2018]

	With a Waivered Provider	
	2016	2018
All Counties	54.9%	65.0%
Large Metropolitan	81.3%	87.7%
Small Metropolitan	73.4%	79.5%
Micropolitan	68.5%	79.4%
Rural	29.6%	42.7%

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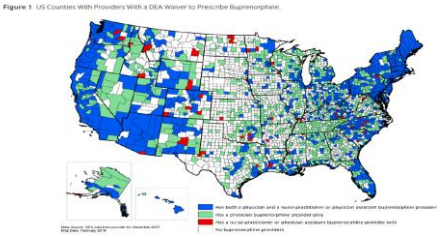

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Pharmacists and Methadone

- Pharmacy based methadone common in other countries including Australia, Canada and UK
- Initial assessment by Addiction specialist >prescription written >daily visits to pharmacy > periodic visits to the prescriber
- More severe OUD treated at OTPs
- Access improved [1500 OTPs vs 67K pharmacies!]
- Cost comparable

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Pharmacists and Methadone

- In Scotland, 79% of pharmacies are actively involved in the distribution of methadone
- In England 79% of pharmacies indicating that they either currently dispense OAT (either methadone or buprenorphine), or would be willing to
- attitudes of pharmacists towards their role increasingly positive over time
- Methadone dispensing pharmacists in Australia: 98% indicate high levels of satisfaction
- Stigma
- Public Perception/acceptance
- Concerns among pharmacists: payments, intoxication, occasional theft/aggression, difficulty communicating with primary provider, patient confidentiality

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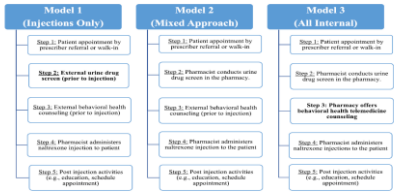
Pharmacists and Naltrexone-XR [Ford et al. 2020]



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Pharmacists and Buprenorphine

- Pharmacists and Pharmacist-Clinicians NOT covered under CARA
- Advocacy work underway to either include pharmacists OR
- "X the X-waiver" [Fiscella 2019; Frank 2018]
- As new forms of extended release buprenorphine emerge, a model similar to naltrexone-XR is also promising
- Ensure adequate buprenorphine supply and timely dispensing as prescriptions rise

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Academic Detailing/Consultations

- Academic detailing:
- Cox [2018]: A pharmacist reviewed the chart of all adult patients scheduled for an appointment who were prescribed greater than 50 MMEs/day and sent recommendations to the provider prior to the appointment. The intervention resulted in a 14% reduction in mean MMEs/day.
- Stewart [2003]: When pharmacists were integrated into a free dental clinic, dentists were 81% less likely to prescribe opioids
- Larson [2018]:
  - Pharmacists provided academic detailing to VA physicians regarding opioid prescribing
  - increased use of the PDMP by physicians
  - increased performance of urine toxicology screening, using multidimensional scales to assess pain, functioning, quality of life, and activity

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Inpatient Management

- Dosing management
- Discharge preparation/counseling/pharmacy led Opioid Exit Plans
- Oyler et al. [2018]: Co-training by pharmacists and physicians on appropriate pain management > significant reduction in opioids prescribed at discharge

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Other Roles

- Research
- Education
- Leadership and program development
- Hep C treatment

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