Hazelden's Comprehensive Opioid Response and Educational Solutions

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Death in the Suburbs: How Prescription Painkillers and Heroin Have Changed Treatment and Recovery

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Learning Objectives

- Give accurate data on the extent of the opioid crisis in 2014, including opioid use, admissions, and death by overdose
- Discuss trends in opiate use and consequences associated with use and addiction
- Explain the basic pharmacology and side effects/risks associated with Vivitrol (Extended Release Injectable Naltrexone) and Suboxone
- Describe Medication Assisted Treatment (MAT) for pregnant women and HIV drug users
- Cite research that supports the use of MAT
- Describe organizational experiences and outcomes associated with using MAT within a 12-Step abstinence-based program
- Show how MAT can be compatible with a 12-Step abstinence-oriented treatment system

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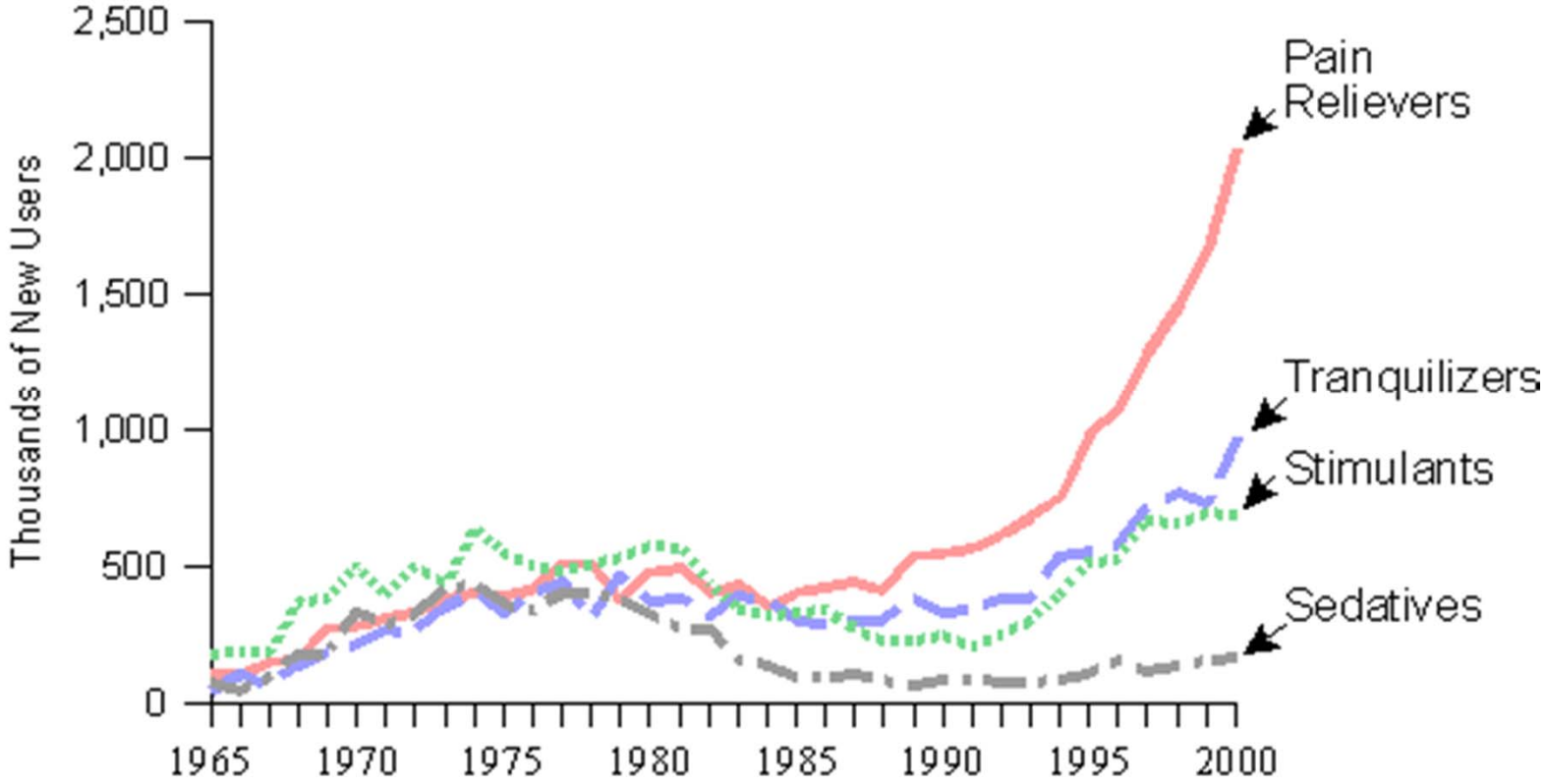
Annual Numbers of New Nonmedical Users of Psychotherapeutics: 1965-2000



Source: Substance Abuse & Mental Health Services Administration(SAMHSA)
National Survey on Drug Use and Health (NSDUH) Survey, 2001
http://www.oas.samhsa.gov/NHSDA/2k1NHSDA/vol1/toc.htm#v1

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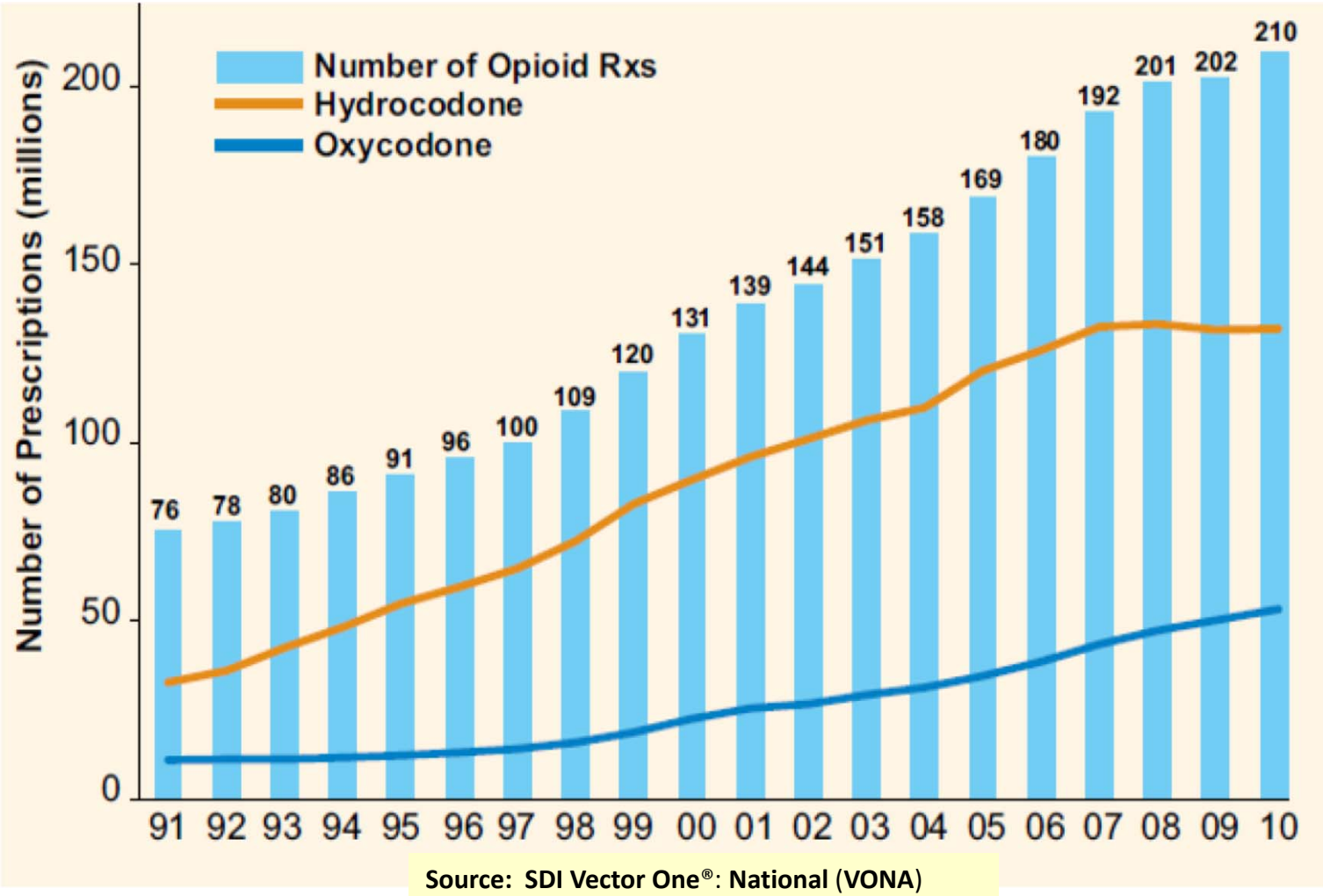
Opioid Prescriptions:

Total Number Dispensed by U.S. Retail Pharmacies: 1991-2010



Source: SDI Vector One®: National (VONA)

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Retail Sales:

Of Opioid Medications (grams of medication 1997-2005)

	1997	2005	% of Change
Methadone	518,737	5,362,815	993%
Oxycodone	4,449,562	30,628,973	588%
Fentanyl Base	74,086	387,928	423%
Hydromorphone	241,078	781,287	244%
Hydrocodone	8,669,311	25,803,544	198%
Morphine	5,922,872	15,054,846	154%
Meperidine	5,765,954	4,272,520	-26%
Codeine	25,071,410	18,960,038	-24%

Source:
http://www.deadiversion.usdoj.gov/mtgs/methadone_alert/facts_and_fallacies.pdf

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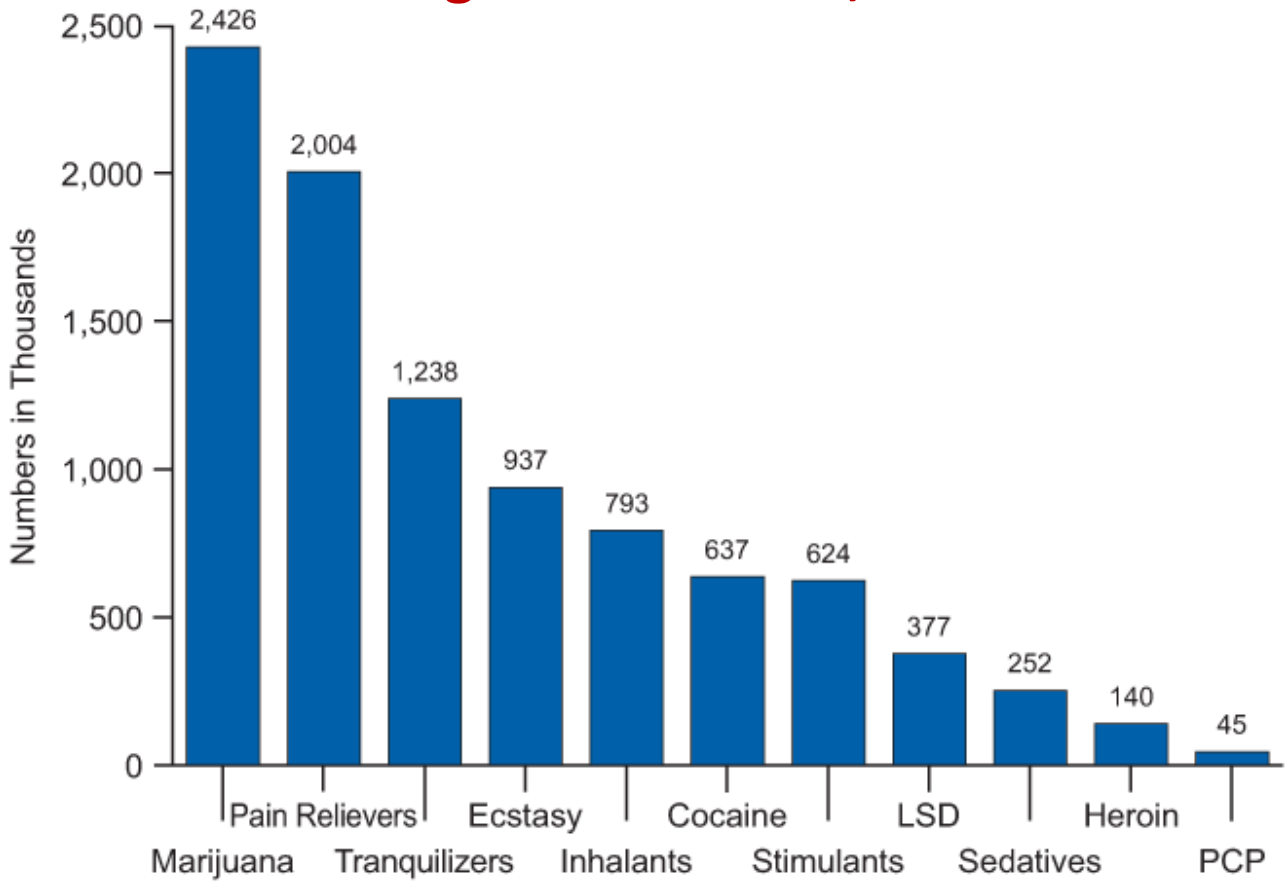
A Frightening Trend:
Past Year Initiates of Specific Illicit Drugs Among Persons Aged 12 or Older, 2010



Source: SAMHSA NSDUH Survey, 2010

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Poll Question #1

On a scale of 1-5 (5 being most critical and 1 being not critical at all), please rate what you believe the severity of the opioid epidemic to be in your community?

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Prescription Opioid Crisis

- Four-fold increase in treatment admissions (U.S. 1998-2008)
- Overdose deaths have increased dramatically (U.S. 3,000 in 1999 → 16,500 in 2011)
- Over 125,000 opioid overdose deaths have occurred in the U.S. in the past decade

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Prescription Opioid Crisis

- In 2010, 60% of drug overdose deaths (22,134) involved prescribed medications.
- Drug overdose became the number one accidental cause of death. Fueled by the dramatic increase in opioid overdose deaths.
- Prescription opioid overdoses for those 15 and older:
  1.6 deaths per 100,000 in 1999-2000 increasing to
  6.6 deaths per 100,000 in 2009-2010

Source: Center for Disease Control

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Prescription Opioid Crisis

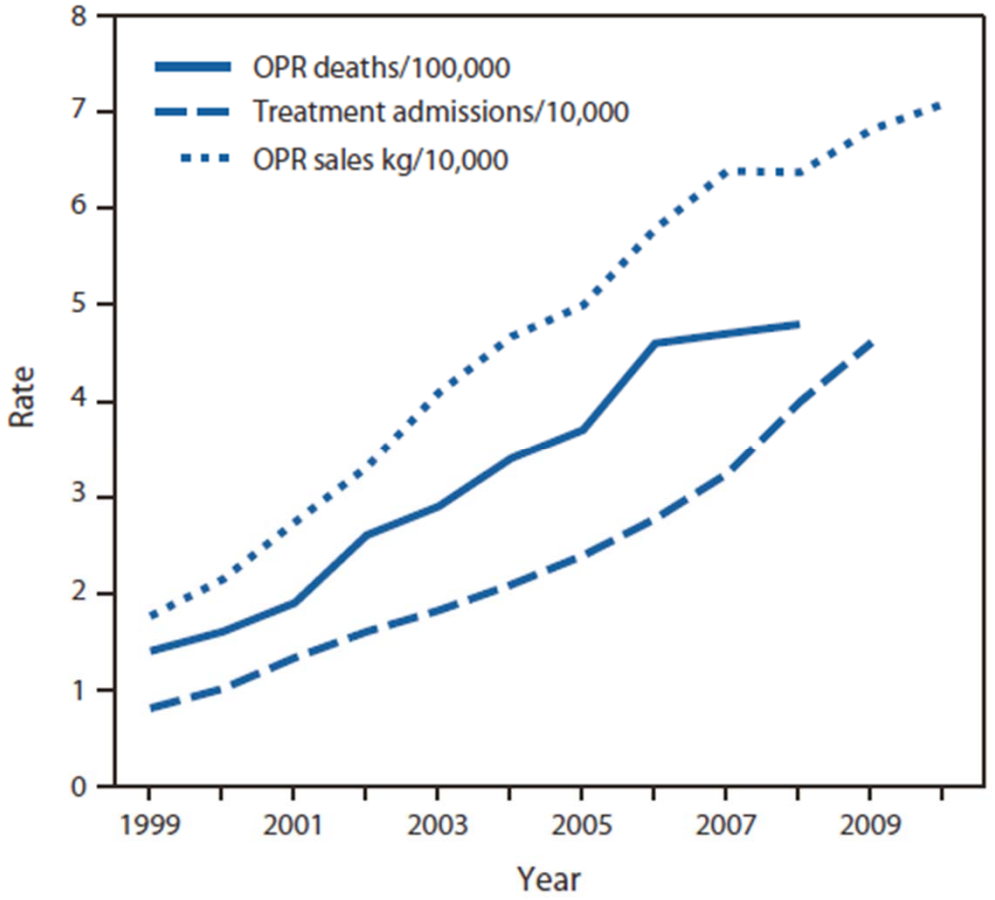
Drug overdose deaths (1999-2010)

- Increased 5 fold in women
- Increased 3.6 fold in men (more men die overall)

Prescription opioids killed at least 9,000 women in 2010, a rate of 18 per day.

Source: *Journal of the American Medical Association (JAMA), August 28, 2013*

Rates* of Opioid Pain Reliever (OPR) Overdose Death, OPR Treatment Admissions and Kilograms of OPR Sold: United States, 1999-2010



* Age-adjusted rates per 100,000 population for OPR deaths, crude rates per 10,000 population for OPR abuse treatment admissions, and crude rates per 10,000 population for kilograms of OPR sold.

Source: *www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm*

Readily Available

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The Changing Face of Heroin

(Treatment Seeking Subjects)

1960's

- Predominantly men (82.5% male)
- Average age of onset: 16.5
- First opioid of abuse heroin (80%)
- Primarily urban population
- Whites and non-whites equally represented

2010-2013

- Men and women are equally involved
- Average age of onset increased to 22.9 years
- 75% started with prescription opioids
- More likely to be from non-urban area (75.2%)
- 90% white

Source: The Changing Face of Heroin Use in the US, *JAMA Psychiatry 2014;366*

Poll Question #2

In your practice, what has been the trend in the increase of opioid overdose deaths related to gender?

Medication Assisted Treatment of Opioid Dependence

- Vivitrol: Extended Release Injectable Naltrexone
- Suboxone: Buprenorphine/Naloxone

Vivitrol®: Extended Release Injectable Naltrexone

- Opioid receptor blocker (opioid antagonist)
- Administered by intramuscular injection, once a month
- Prevents binding of opioids to receptors, eliminating intoxication and reward
- Has been shown to reduce craving and relapse
- Has no abuse potential

Side Effects/Risks

Vivitrol: Extended Release Injectable Naltrexone

- Injection site pain, swelling, blisters, open wound
- Liver enzyme abnormalities
- Serious allergic reactions
- Minor side effects: dizziness, depressed mood, nausea, tiredness, fatigue
- Attempts to over-ride opioid receptor blockade

Suboxone®: Buprenorphine/Naloxone

- A partial opioid agonist, a maintenance treatment
- Administered sublingually on a daily basis
- Binds to and activates opioid receptors, but not to the same degree as true opioid agonists
- Improves treatment retention, and reduces craving and relapse
- Illicit use and diversion are likely

Side Effects/Risks

Suboxone: Buprenorphine/Naloxone

- Respiratory depression (benzodiazepines)
- Sleepiness, dizziness
- Liver enzyme abnormalities
- Serious allergic reactions
- Minor side effects: headache, nausea, sweating
- Simultaneous use of other opioids

Injectable Extended Release Naltrexone

	Naltrexone	Placebo
1. Weeks abstinent	90%	35%
2. Opioid free days	99.2%	60.4%
3. Mean change in craving	10.1%	0.7%
4. Median retention	168 days	96 days

Source*: Lancet 2011; 377:1506-13*

Buprenorphine/Naloxone Treatment for Prescription Opioid Dependence: Study

- Two phase study:
  - 2 week Bup/Nal stabilization, 2 week taper, 8 week follow-up
  - 12 week Bup/Nal stabilization, 4 week taper, 8 week follow-up
- 653 treatment seeking outpatients with opioid dependence
- Randomized to:
  - Standard medication management (SMM)
  - SMM and opioid dependence counseling
- All participants were referred to self-help groups

Source: *Arch. Gen. Psych. Vol 68(No.12), Dec 2011*

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Buprenorphine-Naloxone Results

Phase 1

- Only **6.6%** were successful
- No difference between SMM and SMM with opioid counseling

Phase 2

- 49.2% successful while using bup-nal
- No difference between SMM and SMM with opioid counseling
- Success rates after completion: **8.6%**

Source: *Arch. Gen. Psych. Vol 68(No.12), Dec 2011*

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Recognition

- A large segment of the opioid dependent population was not effectively being reached and treatment was not adequate.

- This high risk population needs the opportunity to engage in long term recovery.

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Hazelden Betty Ford Foundation's Response

- Alter the entire treatment of opioid dependence within our system: COR-12.
- Incorporate two evidence-based medications into treatment protocols for opioid dependence: naltrexone and buprenorphine.
- Study the results.
- Our goal will be discontinuation of medication as patients become established in long-term recovery.

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Organizational Change Process

- Team established
- Literature review
- White paper
- Plan for organization
- Training forums
- Communication

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Program Development

Clinical Practice Protocols

- Education
- Opioid Dependency Group
- Stigma Management Initiatives

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Long Term Approach: Recovery Management

- Residential Treatment
- Outpatient Treatment
- Opioid Dependency Group
- MORE
- Case Management

Compatibility with Twelve Step Abstinence-Based Model

- Extended release injectable naltrexone is already used for alcohol dependence.
- Buprenorphine/naloxone can induce intoxication and is abused, but primarily for detox or to get by.
- Twelve-Step treatment models tend to avoid buprenorphine/naloxone .
- Buprenorphine/Naloxone protocols will blur the line of abstinence-based programming, so the goal will always be discontinuation once long-term recovery is established.

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Hazelden Betty Ford Foundation Research Study

- Naturalistic
- Compare the two medications in practice
- Examine the outcomes of medications in combination with robust Twelve-Step, abstinence-based, treatment
- Examine predictors for response to the medications
- Examine length of treatment with the medications

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COR-12 Patient Participation

Admissions to Center City Primary 1/1/13-12/31/13	
Total number with opioid dependence	424 2270
COR-12: No Medication	38 9%
COR-12: Buprenorphine/Naloxone	30 7%
COR-12: Extended Release Naltrexone	46 11%

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COR-12 Results 2013

- 20.64% of opioid dependent patients who were not in COR-12 discharged atypically.
- Only 11.11% of opioid dependent patients enrolled in COR-12 discharged atypically.
- COR-12 participants were **46% less likely** to discharge atypically.
- 6 former opioid dependent patients deceased in 2013; **Zero** were COR-12 participants.

Medication Assisted Treatment and Pregnancy

- Pregnant women who are dependent on heroin or prescription opioids can safely use MAT. Methadone and buprenorphine are considered appropriate, safe treatments for pregnant women with opioid dependence.
- Methadone and buprenorphine are classified as pregnancy category C medications (adverse effects have been seen in animals; human studies have not yet fully defined the risk, but the potential benefits may warrant use despite the risk).
- Methadone remains the most common treatment due to extensive experience (since the late 1970's).
- Both medications protect the fetus and newborn from the risk of sudden opioid withdrawal.

Poll Question #3

Can pregnant women be safely treated for opioid dependence using a medication assisted treatment method?

Medication Assisted Treatment for HIV Patients

- 30% of HIV infections are related to drug use and associated behaviors
- In an increasing number of studies, medication assisted treatment of drug abuse and dependence has been shown to be an important HIV prevention intervention
- Medication assisted treatment plays an important role in the prevention, care, and treatment of HIV infected individuals who also abuse drugs

Source: National Center for Biotechnology Information, *Medication assisted treatment in the treatment of drug abuse and dependence in HIV/AIDS infected drug users, 2009*

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What Can Be Done?

Universal Precautions in Chronic Pain Treatment

1. Diagnosis with reasonable differential
2. Detailed psychological assessment, including risk of addiction
3. Rational non-opioid therapeutic trial
4. Pre-trial assessment of pain and function
5. Informed consent (verbal and written/signed)

Universal Precautions in Chronic Pain Treatment

6. Treatment agreement (verbal and written/signed)
7. Careful, time limited trial of opioid therapy
8. Reassessment of pain, function and diagnosis
9. Regular assessment of aberrant behavior
10. DOCUMENT

Source: *Gourlay 2004*

Primary Care Triage of Chronic Pain Patients

- Primary Care
  - No history of substance use disorder
  - No major psychiatric comorbidity
- Primary Care with Consultation
  - Increased risk patient: In recovery from addiction, family history, aberrant behavior, current psychiatric disorder
- Referral to Tertiary Care (Addiction Medicine Specialist)
  - Active addiction
  - Major untreated psychiatric disorder

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Center for Disease Control Agenda

- Support and Develop Surveillance Systems: Prescription Drug Monitoring Programs (PDMP's)
- Educate Patients, the Public and Medical Providers
- Policy Change

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Federal Response

- Training
- Tracking and Monitoring (PDMP's)
- Proper Medication Disposal
- Enforcement

Source: *Epidemic: Responding to America's Prescription drug Crisis 2011 (ONDCP)*

What Can Healthcare Professionals Do?

- Screen for addiction and alcoholism
- Refer to an addiction specialist just like any other medical specialty
- Examine your prescribing practices
- Learn more about treatment of chronic pain
- Learn more about pain and addiction
- Prevent diversion in your medical setting
- Naloxone for overdose treatment

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What Else Can You Do?

- Advocate for state and federal law changes
- Educate students, parents, local community, state, law enforcement, legislators, physicians, etc.
- Involve your professional organizations
- Create accountability for the pharmaceutical industry
- Support prescription monitoring programs
- Support the federal agenda

Please Commit to Action!

Summary

- An opioid use crisis exists in the U.S.; opioid use has escalated since the mid-90's with associated increases in emergency room visits, treatment admissions and overdose deaths.

- Medication Assisted Treatment for opioid dependence is effective, safe and can be aligned with abstinence based, Twelve-Step programs to engage more people in long term recovery.

- We have many opportunities to alter the course of this crisis and limit the destruction.

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