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Sen. Patricia Miller, Chairperson
Sen. Lindel Hume
Rep. Steve Davisson
Rep. Charlie Brown
Kathleen O'Connell
Margie Payne
Ronda Ames
Valerie N. Markley
Bryan Lett
Caroline Doebbling
Kurt Carlson
Chris Taelman
Jane Horn
Rhonda Boyd-Alstott
Dr. Danita Johnson Hughes
Dr. Brenna McDonald



COMMISSION ON MENTAL HEALTH AND ADDICTION

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Authority: IC 12-21-6.5

MEETING MINUTES¹

Meeting Date: October 1, 2013
Meeting Time: 1:00 P.M.
Meeting Place: State House, 200 W. Washington St., Room 233
Meeting City: Indianapolis, Indiana
Meeting Number: 3

Members Present: Sen. Patricia Miller, Chairperson; Rep. Steve Davisson; Rep. Charlie Brown; Kathleen O'Connell; Margie Payne; Valerie N. Markley; Bryan Lett; Kurt Carlson; Chris Taelman; Dr. Danita Johnson Hughes; Dr. Brenna McDonald.

Members Absent: Sen. Lindel Hume; Ronda Ames; Caroline Doebbling; Jane Horn; Rhonda Boyd-Alstott.

Chairperson Patricia Miller called the meeting to order at 1:00 p.m.

Use of Methadone and Opioids

Mr. Kevin Moore, Division of Mental Health and Addiction (DMHA), provided information concerning Indiana's 13 state regulated Opioid Treatment Program (OTP) clinics, including the number, age, and gender of the patients treated in 2012. See Exhibit 1. Mr. Moore

¹ These minutes, exhibits, and other materials referenced in the minutes can be viewed electronically at <http://www.in.gov/legislative> Hard copies can be obtained in the Legislative Information Center in Room 230 of the State House in Indianapolis, Indiana. Requests for hard copies may be mailed to the Legislative Information Center, Legislative Services Agency, West Washington Street, Indianapolis, IN 46204-2789. A fee of \$0.15 per page and mailing costs will be charged for hard copies.

stated that continuum of care is important and that OTP clinics fill a niche in the state for the treatment of addiction. Mr. Moore said that admission into an OTP clinic for treatment requires a person to be currently addicted to opiates and to have been addicted for more than one year. Mr. Moore stated that OTP clinics are required to comply with federal and state laws as well as be accredited by a recognized national body. Mr. Moore referred to a central registry to which OTP clinics report the name of patients receiving treatment at the time of admission in order to ensure that the patient is only enrolled at one OTP clinic. Mr. Moore provided information on the cost of medications and stated that eight OTP clinics accept third party payments. See Exhibit 1. Mr. Moore discussed take home medication and that the requirements related to the time in treatment as well as other factors and assessments that occur in order for a patient to be given medication to take away from the clinic. Mr. Moore stated that a minimum of eight drug tests are required for a patient during each 12 months following admission. Mr. Moore said that of the drug tests (including the initial screening) given in 2012, about five percent tested positive. Mr. Moore discussed client outcomes. See Exhibit 1.

Dr. Leslie Hulvershorn, Deputy Medical Director, DMHA, provided a history of Methadone. See Exhibit 2. Dr. Hulvershorn made a distinction between Methadone clinics where treatment is provided to treat addiction and pain clinics where Methadone is prescribed to treat pain. Dr. Hulvershorn explained that Methadone for the treatment of addiction assists a patient by eliminating withdrawal and cravings and is provided in liquid form which is released slowly through the body. Dr. Hulvershorn stated that research has determined that Methadone is helpful in the treatment of addiction and provided the pros and the cons of treatment with Methadone. See Exhibit 2. Dr. Hulvershorn discussed Buprenorphine and Naltroxone and the pros and the cons of use of these drugs for addiction treatment. Dr. Hulvershorn discussed women who are pregnant and said that stopping the use of opiates and detoxing could result in spontaneous abortions.

Dr. Eric Wright, IUPUI, discussed the use of medication in addiction treatment. See Exhibit 3. Dr. Wright stated that Indiana is experiencing a rise in heroin abuse and there is a rising demand for addiction treatment. Dr. Wright stated that OTP clinics are effective, especially since counseling is included with the treatment. Dr. Wright stated that this treatment is also cost effective, providing a four to one return on investment and resulting in lower crime and increased productivity/employment. Dr. Wright recommended that a comprehensive opiate treatment policy be established for Indiana and to remove the current statutory ban on new OTP clinics.

Mr. Tim Bohman, President of Indiana Association for the Treatment of Opioid Dependency, stated that there is a regulation that requires each clinic to report the names of newly enrolled patients to other clinics within 125 miles to avoid duplication. Mr. Bohman stated that in addition to the state audits that occur at least one time per year, the federal DEA also audits the clinics every two to three years and the accrediting agency audits the clinic every three years. Mr. Bohman testified that Methadone is used for addiction treatment because the drug eliminates opiate cravings, reduces or eliminates withdrawal symptoms, and blocks receptors so that an individual cannot get high. Mr. Bohman stated that 31 states fund Methadone treatment for addiction through the state's Medicaid program but that Indiana does not. Mr. Bohman informed the Commission that each clinic is required to have a diversion control policy.

Mr. Dean Babcock, Midtown Community Health Center, informed the Commission that drug abuse trends have changed over the years, with more prescription drugs starting the addiction and with the average population age decreasing by ten years. Mr. Babcock discussed the big commitment it takes for an individual to participate in an OTP, requiring the individual to make daily trips to the clinic to receive medication. Mr. Babcock distributed

testimonials from former patients. See Exhibit 4.

Dr. R. Andrew Chambers, IU School of Medicine, provided a history of Methadone and discussed the efficacy of Methadone for opiate addicts. See Exhibit 5. Dr. Chambers stated that evidence is uncertain on the efficacy of using Methadone to treat pain. Dr. Chambers discussed a resolution brought by the Indiana State Medical Association (ISMA) in 2012 concerning the elimination of Methadone clinics and voiced his concern against the resolution. Dr. Chambers stated the resolution resulted from a membership with a lack of expertise in the area and ultimately did not pass. Dr. Chambers presented issues with Indiana's current Methadone treatment infrastructure, including: (1) lack of parity and health insurance coverage for this care; (2) lack of integration of Methadone clinics into not-for-profit mental health and addiction treatment systems; and (3) lack of a requirement that doctors have specialized training and expertise in psychiatry or addiction treatment before prescribing Methadone. Dr. Chambers made the following recommendations: (1) require health insurance coverage for Methadone treatment for opiate addiction; (2) expand Methadone treatment programs that are embedded in not-for-profit full service treatment centers; (3) require physicians prescribing Methadone in treatment programs to be psychiatrists who are board certified. See Exhibit 5.

Mr. David Waters, pharmacist, discussed the drugs Subutex, Suboxone, and Methadone. See Exhibit 6. Mr. Waters explained that Subutex and Suboxone are solely indicated for use in the treatment of opiate dependence whereas Methadone is indicated for use for both pain and opiate dependence. Mr. Waters relayed some experiences he has had at the pharmacy in receiving prescriptions for these drugs, including that the drugs are being prescribed with no reduction in dose and maintaining opiate dependence. Mr. Waters discussed federal and state regulations concerning the prescribing of drugs, federal and state monitoring, and the practice of pharmacy. See Exhibit 6. Mr. Waters stated that he has noticed a sharp increase in the use of Subutex and Suboxone over the past five years and that he believes the office-based non-program practitioner is enabling the sharp increase in opiate use that is detrimental to public safety. Mr. Waters provided the following recommendations: (1) prohibit the use of Subutex and Suboxone for the treatment of pain and limit sale of these drugs to an individual to six months; (2) require individual non-program practitioners to register opiate treatment practice with the state; (3) require a practitioner to file a treatment plan with a program similar to the controlled substance database INSPECT; (4) establish a six-month limit for an individual non-program practitioner to treat a patient using these drugs; (5) establish detoxification and cessation as the outcome of treatment by an individual non-program practitioner; and (6) require patients to enroll in a well-regulated opioid treatment program that would monitor the patient after 6 months.

Ms. Marty Cangany, MSN, discussed statistics concerning overdoses and stated that abuse of Methadone is an epidemic. Ms. Cangany distinguished between the use of Methadone to treat pain versus the use to treat addiction. Ms. Cangany said that her son overdosed on Methadone when he was 18 years old and she now goes to schools to speak to children as a mother and as a health care representative about drugs.

Mr. Coby Smith told the Commission about his experience being treated at a OTP clinic and stated that the treatment has given him his life back. Ms. Kelly Cuellar, mother of Coby, stated that she is lucky that Coby is alive and that the OTP clinic has helped her son be a successful citizen.

Mr. Mike Rinebold, ISMA, provided the Commission with information on a resolution ISMA is supporting concerning the screening and treatment for pregnant women who are addicted. See Exhibit 7. Mr. Rinebold stated that ISMA supports screening instead of

mandatory drug testing.

Senator Miller provided the Commission with a letter from the Wayne County Coroner discussing the alarmingly high rate of deaths due to drug overdoses, particularly Methadone. See Exhibit 8.

Senator Miller adjourned the meeting at 4:00 p.m.



The Indiana Family and Social Services Administration

IN Opioid Treatment Programs

Kevin Moore, Director, Division of Mental Health and Addiction
Commission on Mental Health and Addiction

October 1, 2013





Number of Patients Treated in Opioid Treatment Programs (OTP)

- 14,470 total patients treated in CY 2012.
- Treatment admission requires person to be currently addicted to opiates and has been addicted for more than one year.

Breakdown by age (years)						
	<18	18-24	25-34	35-49	50-59	>60
% of Patients	.17%	11.71%	48.9%	28.57%	8.78%	1.87%

Breakdown by gender		
	Male	Female
% of Patients	56.62%	43.38



OTP Locations

- Charlestown
 - Southern IN Treatment Center
- Gary
 - Edgewater**
 - Semoran Treatment Center
- Indianapolis
 - Midtown**
 - Indpls Treatment Center
- Lawrenceburg
 - East IN Treatment Center
- Merrillville
 - Northwest IN Treatment Center
- Fort Wayne
 - Center for Behavioral Health
- Marion
 - Premier Care
- Richmond
 - Richmond Treatment Center
- Valparaiso
 - Porter-Starke Recovery Center**
- South Bend
 - Victory Clinical Services
- Evansville
 - Evansville Treatment Center



Clinic Operations

- Must meet DMHA certification standards
- Annual application/re-certification
- Comply with federal laws
 - SAMHSA guidelines
 - DEA requirements
- Accreditation by recognized national body
- Licensing/inspection in accordance with local codes
- Central registry of patients
- Use of INSPECT (12/13 clinics)



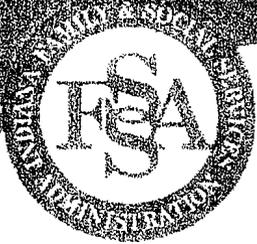
2012 OTP Patients (14,396)

State of Residence	
Indiana	9,700
Kentucky	3,029
Ohio	1,518
Michigan	56
Illinois	70
Other	23
Total	14,396



Medications Used CY 2012

- Methadone
 - Used in all OTP clinics
 - 4.6 million doses dispensed
- Buprenorphine
 - Used in 8 OTP clinics
 - 43,000 doses dispensed



Medication Cost

- Methadone
 - Wholesale cost \$11.49/100mg
 - Client cost \$65 to \$101.50 per week
- Buprenorphine
 - Wholesale cost \$17.00/100mg
 - Client cost \$70 to \$300 per week
- Total patient payments in 2012: \$40.3 m
- 8 OTP clinics accept 3rd party payments



Take Home Medication

Time in treatment	Allowed take home dose
< 90 days	1 dose/week
90-179 days	2 doses/week
180-270 days	3 doses/week
270-365 days	6 doses/week
> 1 year	14 days
> 2 years	30 days



Take Home Medication Snapshot

Time in treatment	Number of clients
< 90 days	360
90-179 days	599
180-270 days	438
270-365 days	1,265
> 1 year	1,528
> 2 years	661



Monthly Program Requirements

Time in treatment	Requirement
< 90 days	4 hours counseling/month
90-179 days	2 hours counseling/month
180-365 days	1 hour counseling/month
> 1 year	Based on individual need



Drug Testing

- Current rule requires a minimum of 8 drug tests during each 12 months following admission.
- Of the 14,470 patients served in 2012, there were 5,196 total positive drug screens including initial screens. This represents a 5% positive drug screen rate.
- In 2012, OTP clinics administered 101,235 drug screens



Time in Treatment

- 56.04% of patients continue to receive treatment.
 - 8,098 patients
- 2.15% of patients were deemed to have successfully completed treatment.
 - 311 patients

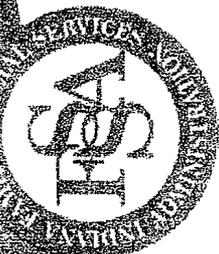
Length of treatment							
	< 90 d	90-1y	1-2y	2-3y	3-6y	6-10y	>10y
% of Patients	17.93%	27.04%	18.27%	11.10%	15.02%	6.64%	4.01%



Client Outcomes - 2012

- 83% of clients had a reduction in use of prescription opiates
- 90% of clients had a reduction in illegal use of non-prescription opiates
- 87% of clients had a reduction in use of other illegal drugs
- 58% had reduced criminal behavior
- 79% had improved employment
- 83% reported improved family relationships

Questions?



Treatment for Opiate Use Disorders: An Overview

Leslie Hulvershorn, MD
Deputy Medical Director,
Division of Mental Health and Addiction
Commission on Mental Health and Addiction
October 1, 2013

Summary

- What are opiates?
- What are opiate use disorders?
- What are the treatment options?
- Why methadone?
- How successful is methadone replacement?
- What about pregnant women and their babies?

Opiates

- Prescription pills: morphine/morphine like substances (e.g., OxyContin, Percocet, Vicodin, Lortab, Opana, methadone)
- Pills are ingested, snorted or injected
- Heroin: Street drug, derived from morphine
- 23% who try will become addicted
- Powder is injected, snorted, smoked
- Produce euphoria and then sedation

Opiate Use Disorders: DSM-5

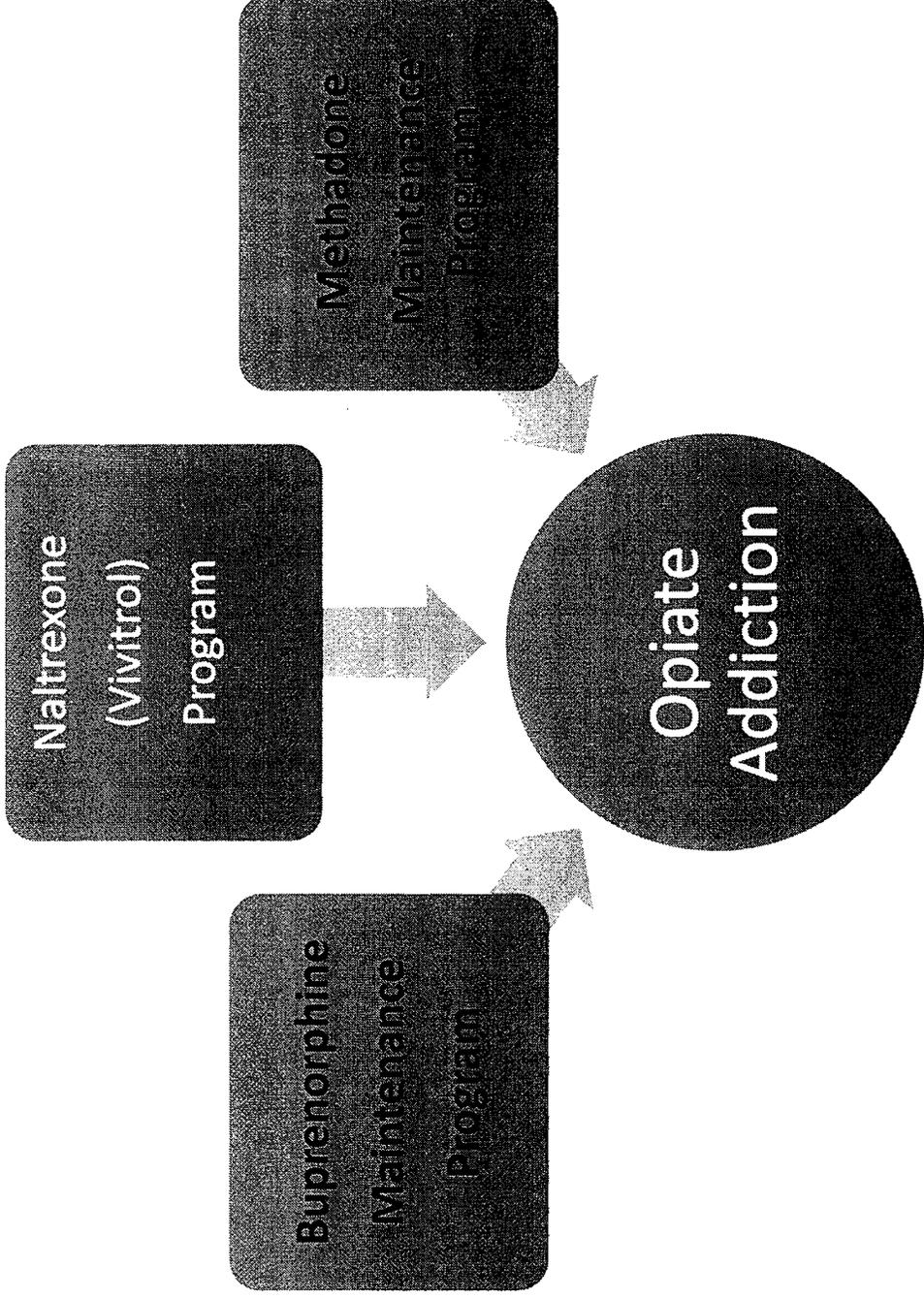
“Opiate Addiction”

- Take more than intended
- Desire/unsuccessful efforts to cut back or quit
- Time spent using, obtaining or recovering
- Craving
- Failure to fulfill work, school, home obligations
- Continued use despite problems (social, psychological, physical)
- Activities given up
- Use in hazardous situations
- Tolerance
- Withdrawal

Consequences of Opiate Use Disorder

- Overdose: respiratory depression
- Use of narcotic analgesics resulted in nearly ½ million visits to U.S. ED's in 2007
- Injection: HIV and Hepatitis
- Overdose mortality has been reported with both methadone and buprenorphine

Treatment Options



History of Methadone

Synthesized in
Germany:
Less addictive
than
morphine
1930s

Used in US for
pain
1947

Research
demonstrated
efficacy for
heroin
addiction
1964

Federal
regulations
developed for
methadone
maintenance
treatment
1971

Federal
regulations
updated to
allow more
effective and
consistent use
2001

Federal and State Rules for OTPs



Federal Register

Wednesday,
January 17, 2001

Part II

**Department of
Health and Human
Services**

Substance Abuse and Mental Health
Services Administration

21 CFR Part 291

42 CFR Part 8

Opioid Drugs in Maintenance and
Detoxification Treatment of Opiate
Addiction; Final Rule

IC 12-23-18

**Chapter 18. Methadone Diversion Control and Oversight
Program**

IC 12-23-18-0.5

Opioid treatment program; requirements for operation

Sec. 0.5. (a) An opioid treatment program shall not operate in Indiana unless:

- (1) the opioid treatment program is specifically approved and the opioid treatment facility is certified by the division; and
- (2) the opioid treatment program is in compliance with state and federal law.

(b) Separate specific approval and certification under this chapter is required for each location at which an opioid treatment program is operated.

As added by P.L.116-2008, SEC.2. Amended by P.L.1-2009, SEC.108.

IC 12-23-18-1

Rules

Sec. 1. (a) Subject to federal law and consistent with standard medical practice in opioid treatment of drug abuse, the division shall adopt rules under IC 4-22-2 to establish and administer an opioid treatment diversion control and oversight program to identify individuals who divert opioid treatment medications from legitimate treatment use and to terminate the opioid treatment of those individuals.

Methadone Maintenance

- Maintenance=help avoid negative consequences of illicit opiate misuse
- Dosed once daily
- <80-100 mg daily
- When properly managed, reduce narcotics related deaths, users' involvement in crime, the spread of AIDS, and helps users gain control of their lives
- If used correctly, few side effects, no high

Methadone: Does it work?

- 11 clinical trials
- More effective than non-methadone treatments at keeping people in treatment, staying off of opiates

(Cochrane Review, 2009)

Opioid Treatment Programs (OTPs)

- Only source of methadone for maintenance
- (Reminder: Also prescribed by physicians for pain)
- Provide a multi-modal approach including medication, counseling, and other supportive services, to treat opioid addiction
- Heavily regulated by state and federal agencies

“Take Homes”

- Privilege earned through clean drug screens
- Incentive for “good behavior”
- Improves compliance, sobriety from other drugs

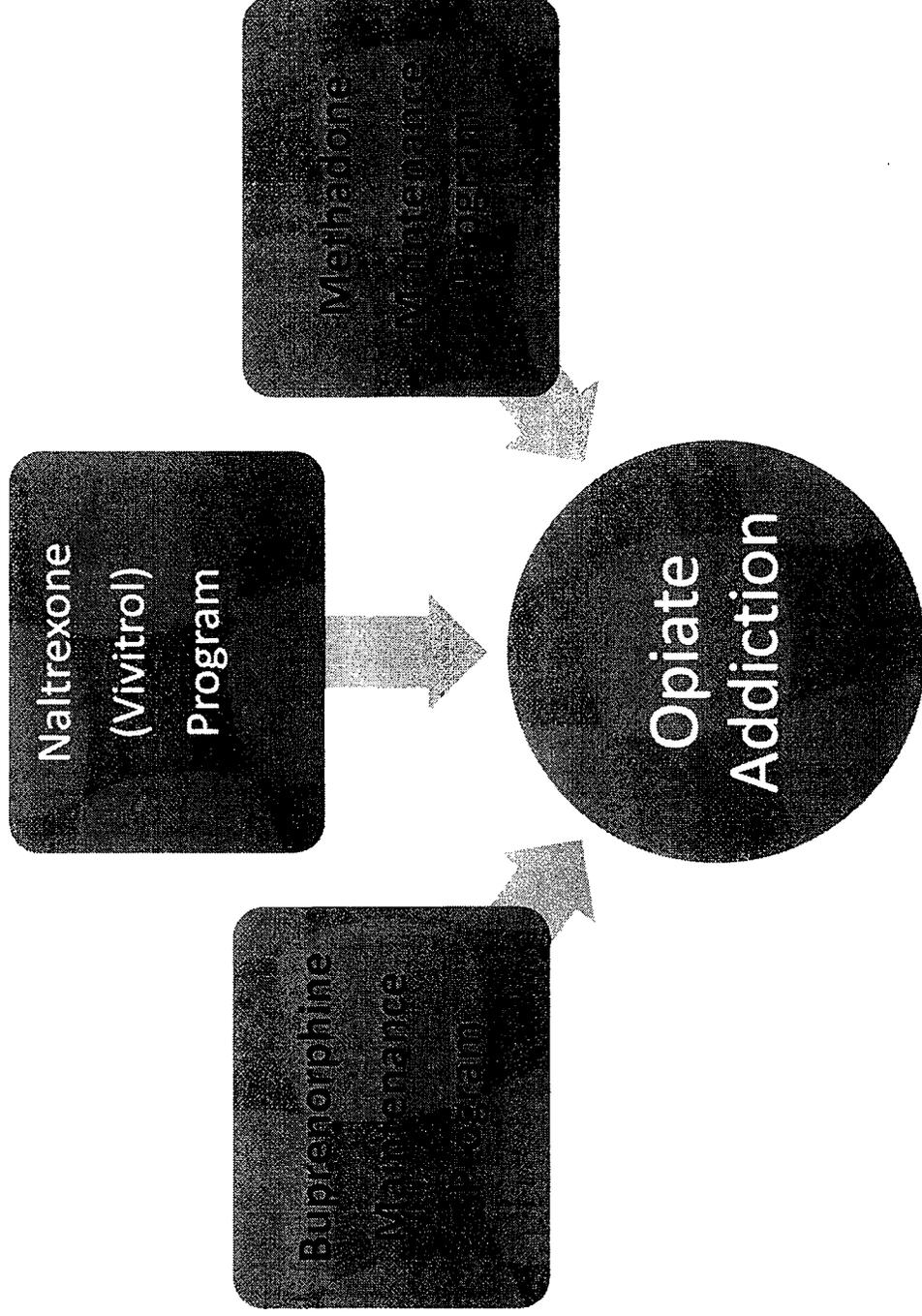
PROS

- Close supervision: daily dosing
- Enforce therapy
- Incentivize “take homes”
- Most effective treatment

CONS

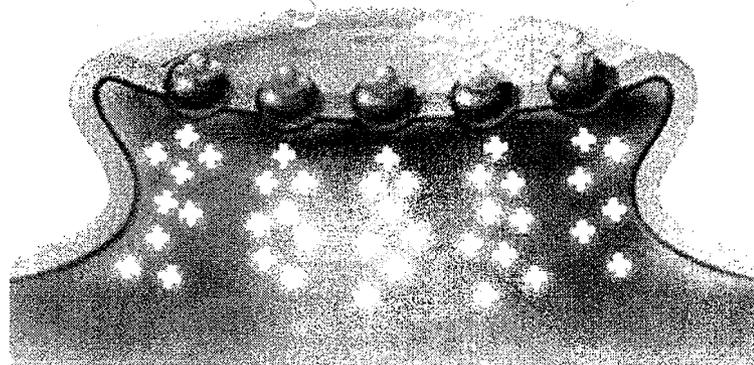
- Hassle: interfere with employment, parenting, etc.
- Expensive
- Societal consequences for take homes

Treatment Options

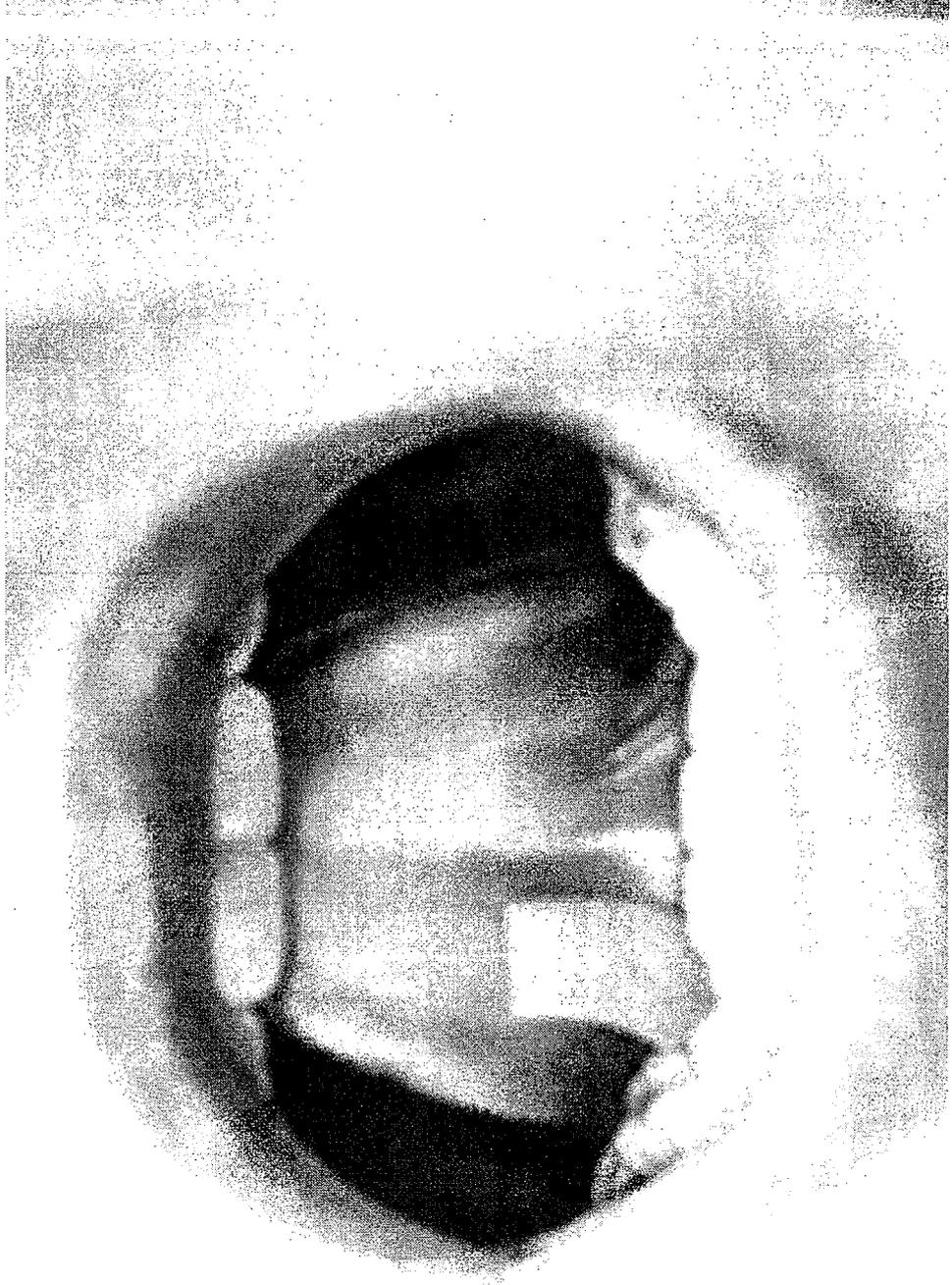


Buprenorphine/Naloxone

- Semi-synthetic partial agonist (limited effects) + antagonist
- Does not require daily dispensing
- Safer in overdose = much less regulation
- Easier to stop than methadone, milder withdrawal



Sublingual Film



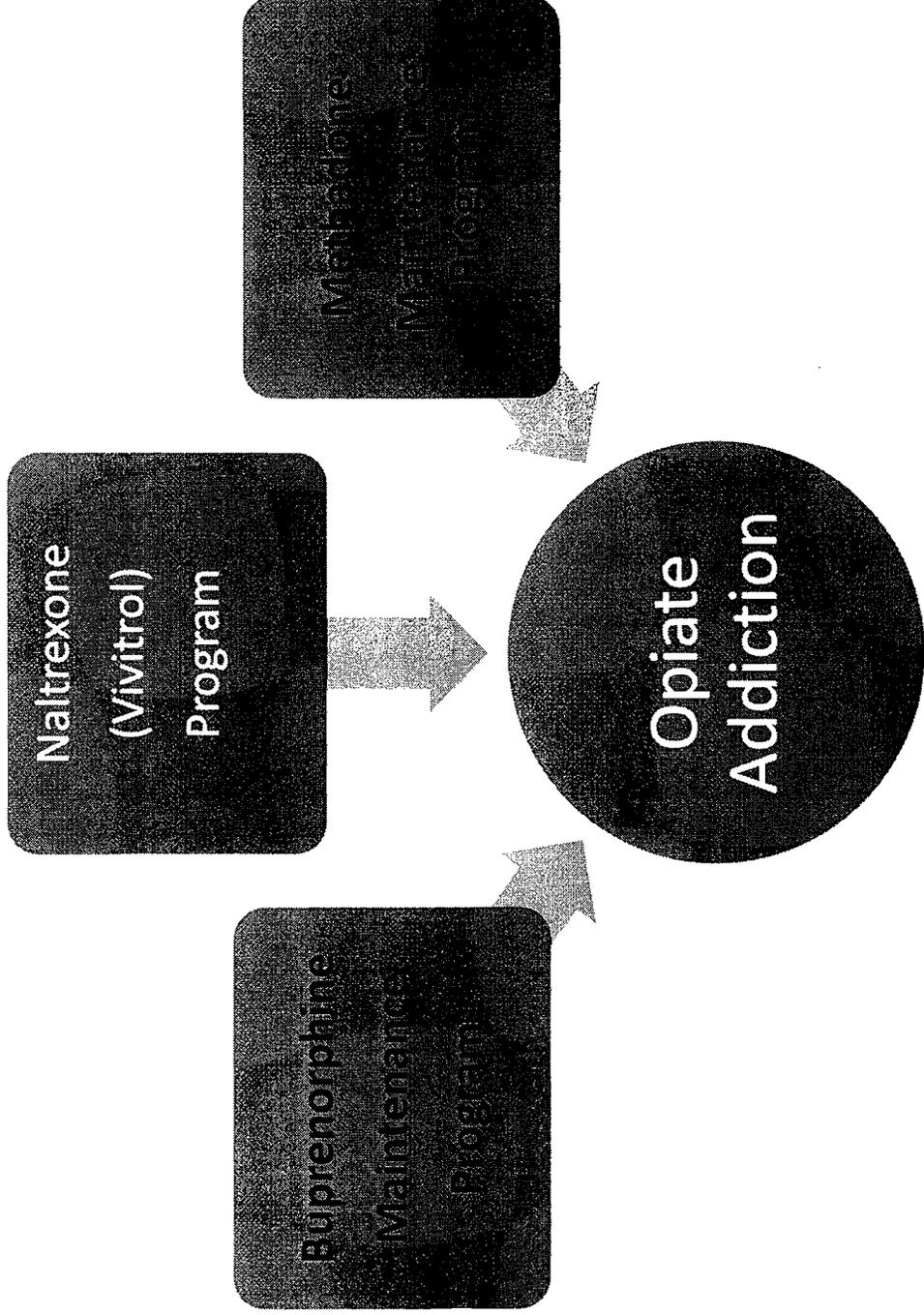
PROS

- Convenient
- Safer to have at home
- Easier to stop

CONS

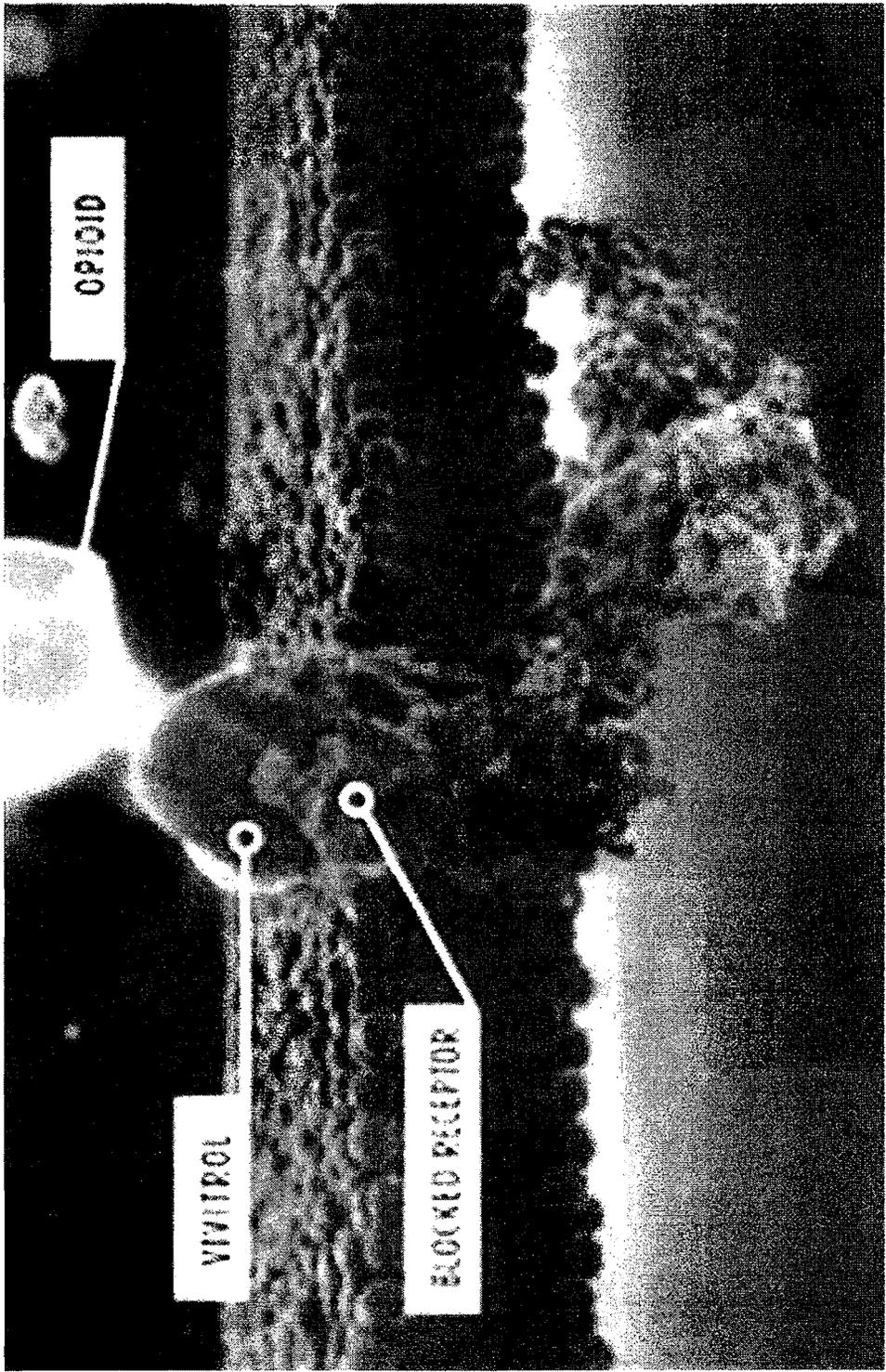
- \$\$\$\$ (now generic)
- Still on an opiate
- Hard to find qualified providers
- Less effective than methadone

Treatment Options



Naltrexone

- Vivitrol (monthly intramuscular injection)
- FDA approved for alcohol, opiate use disorders
- Opiate antagonist: blocks receptor



PROS

- Non-narcotic
- Cannot decide to “miss a dose”

CONS

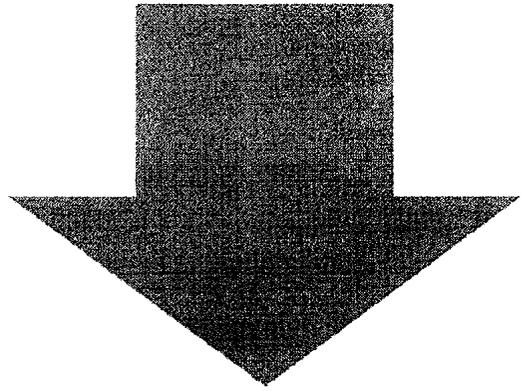
- \$\$\$\$
- Can cause liver damage
- Occasional overdoses
- Must be off opiates for 2 weeks to start

Opiate Use Disorders and Pregnancy

- Detoxification is associated with high rates of spontaneous abortions in the first trimester and premature delivery in the third trimester
- Babies exposed to heroin have lower birth weights
- Babies exposed to heroin were more likely to require morphine than those with methadone treated mothers (40% vs. 19%)
- **Current recommendations: Treat with Methadone or Buprenorphine**

Neonatal Abstinence Syndrome

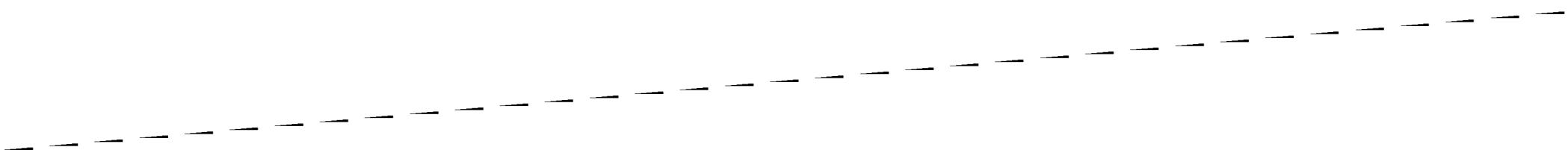
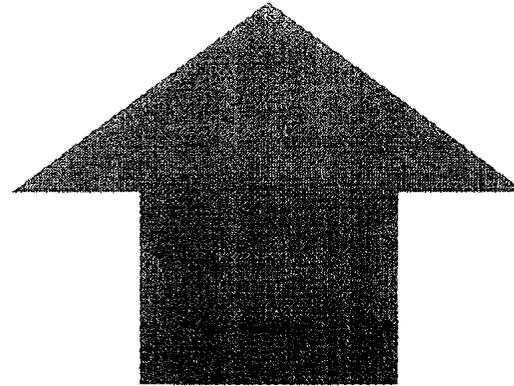
- “Neonatal abstinence syndrome is an expected and treatable condition that follows prenatal exposure to opioid agonists.”
-American College of Obstetricians and Gynecologists



Risks: side effects,
costs, take home
doses



Benefits: Decrease
drug use, improve
health, reduce high
risk behaviors,
increase employment



Questions?

Opioid Treatment Programs in Indiana: The Use of Medication in Addiction Treatment

Presentation to the Indiana *Commission on Mental Health and Addiction*
October 1, 2013

Eric R. Wright, PhD

Chair, Indiana State Epidemiology and Outcomes Workgroup

Director, Center for Health Policy

Professor & Chair, Department of Health Policy and Management

IU Richard M. Fairbanks School of Public Health at IUPUI

Nonmedical Use of Prescription Psychotherapeutics, General Population Ages 12+, Indiana and U.S., National Survey on Drug Use & Health (NSDUH)

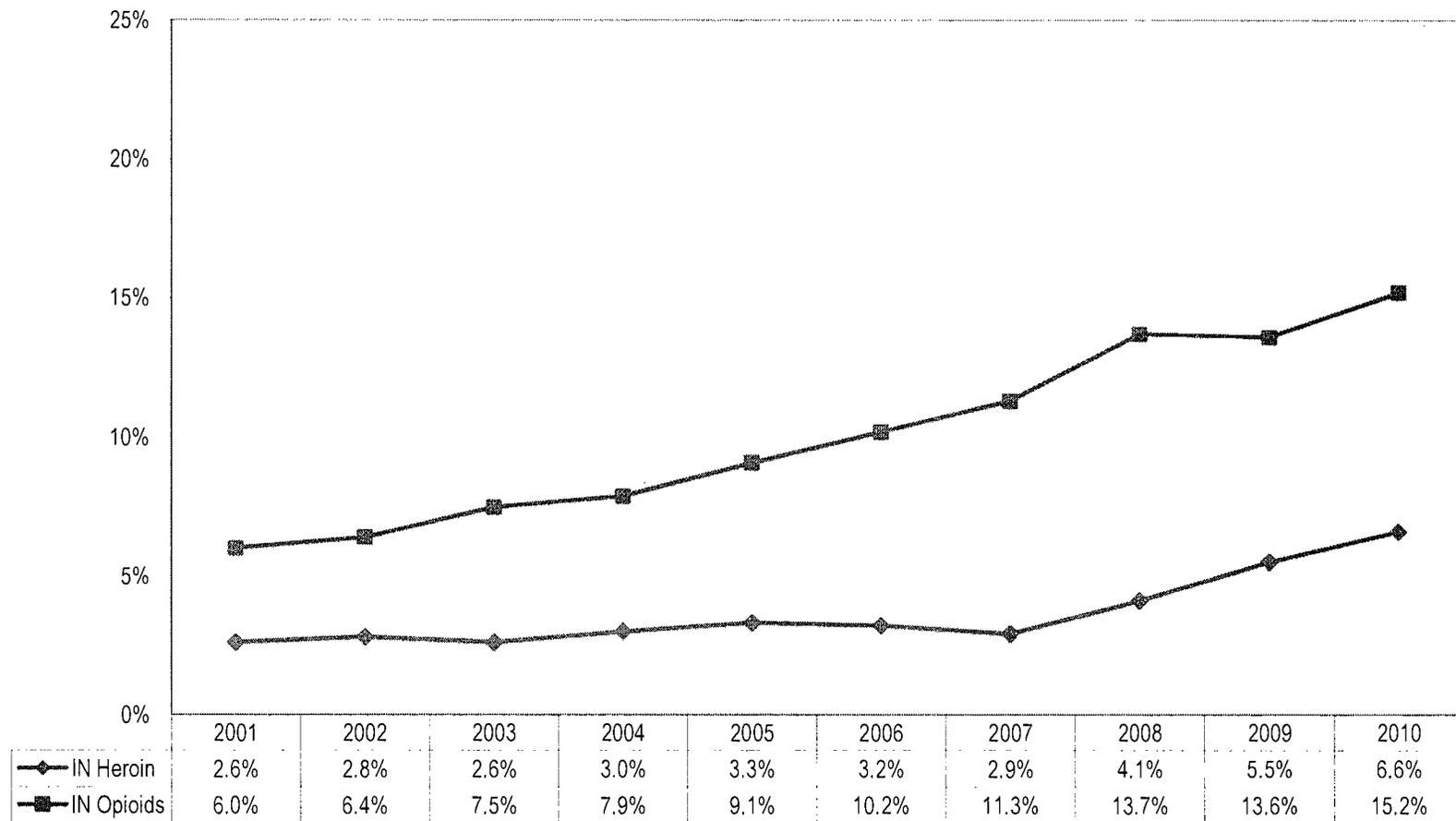
*Highest Rx
prevalence for
opioids.*

	Lifetime Nonmedical Use		Past-Year Nonmedical Use		Past-Month Nonmedical Use	
	Indiana	U.S.	Indiana	U.S.	Indiana	U.S.
All Psycho- therapeutics	20.7%	19.9%	7.6%	5.7%	2.7%	2.4%
Pain Relievers	15.0%	13.3%	6.1%	4.3%	2.0%	1.7%
Tranquilizers	9.1%	8.4%	2.8%	2.0%	0.8%	0.7%
Sedatives	3.9%	2.9%	0.4%	0.2%	0.1%	0.1%
Stimulants	8.3%	7.9%	1.7%	1.0%	0.8%	0.4%

Note: U.S. rates are based on 2011 NSDUH results. Indiana rates are estimated based on annual NSDUH averages from 2002-2004; this is the most recent estimate, since these rates are not continuously computed at the state level.

Source: Substance Abuse and Mental Health Services Administration, 2013

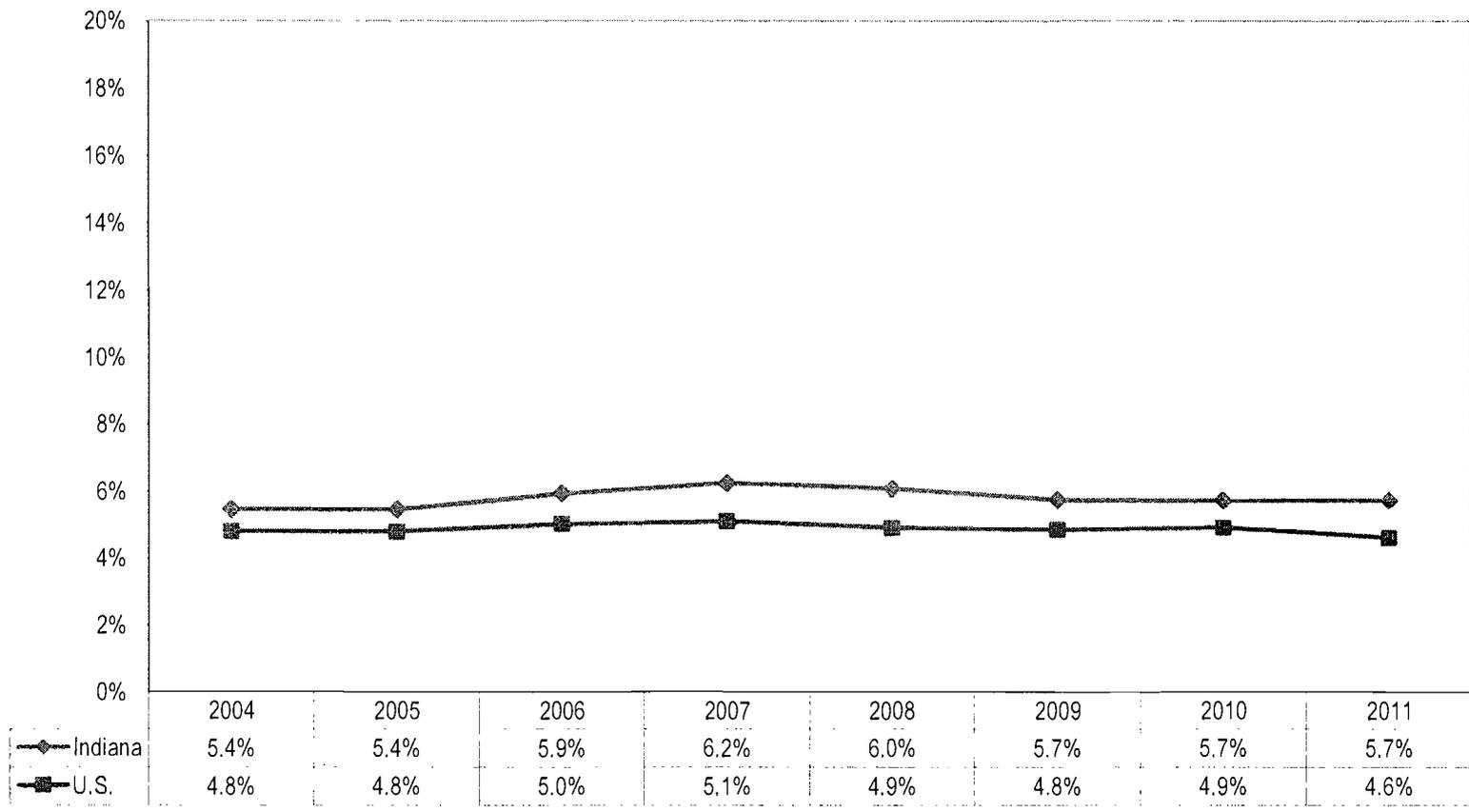
Percentage of Indiana Treatment Episodes with Heroin Use and Nonmedical Opioid Use Reported at Admission (TEDS, 2001-2010)



Source: Substance Abuse and Mental Health Data Archive, 2010

Past-Year Nonmedical Prescription Pain Reliever Use, Ages 12+, Indiana and U.S., 2004-2011, NSDUH

Stable trend over past 8 years in general population.



Source: Substance Abuse and Mental Health Services Administration, 2013

Opioid Treatment Programs (OTPs)

Scientific research has shown that OTPs are:

- ✓ Effective in treating opioid dependence
- ✓ Most effective when they provide a multi-modal approach to care that includes medication, counseling, and other supportive services, to treat opioid addiction

Number of Controlled Substances Dispensed in Indiana (INSPECT, 2008-2011)

	2008	2009	2010	2011
Methadone	110,237	118,038	104,468	117,453
Buprenorphine	2,582	5,549	27,462	33,413
All Controlled Substances	11,635,092	12,713,931	11,341,539	12,743,236

Cost-effectiveness of OTPs

- Annual cost of opioid addiction is an estimated \$20 billion
- Cost for healthcare system alone \$1.2 billion per year
- One study found 4:1 ROI for methadone maintenance & inpatient treatment
- Another study indicated even small increase in available treatment slots would be cost effective

Positive Outcomes of OTPs

- Decrease treatment dropout rates
- Decrease in use of opioids and other drugs
- Decrease in health problems
- Decrease in high-risk behaviors, including needle-sharing and unprotected sexual activity
- More likely to be employed full-time

OTPs and HIV

- IDU is linked to HIV, hepatitis C, tuberculosis, and STDs
 - In 2008, IDU was associated with 12.9% of all new HIV cases
- OTPs are required to provide counseling on both preventing exposure to and transmission of HIV
- Methadone maintenance programs reduce likelihood patient will become HIV+
- Buprenorphine has less adverse effects overall than methadone among HIV patients concurrently treated with antiretroviral medication

Barriers to Treatment

- Treatment costs can be a potential barrier
 - Buprenorphine treatment alone (without counseling or ancillary services) is estimated at \$200 per month per patient, compared to \$30 for methadone.
 - In Indiana in 2009 , the estimated annual out-of-pocket expenses per patient, including medication, counseling, drug testing, and other supportive services, was \$3,467-\$4,829 for methadone maintenance and \$6,640 for buprenorphine treatment.
- Buprenorphine is not in widespread use though highly effective
- Limited access to OTPs in Indiana

Public Policy Concerns

Policy-related criticisms regarding OTPs include:

- OTPs simply substitute one drug for another
 - Proper methadone maintenance has been shown to reduce both the medical and social harms produced by opioid abuse.
- OTPs do not stop IDU entirely
 - These programs have been shown to reduce the spread of HIV

Concluding Thoughts for Policymakers

To increase access to effective opioid treatment, implementation of evidence-based programs, policies, and procedures, the State of Indiana should consider:

- Establishing a comprehensive opioid treatment policy
- Removing the current ban on creating new OTPs
- Integrating substance abuse treatment into healthcare and expand recovery services

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Opioid Treatment Programs in Indiana – The Use of Medication in Addiction Treatment

Addiction to opioids (e.g., heroin, morphine, prescription pain relievers) is a serious health problem with wide-ranging social and economic implications. In 2010, more than 2 million Americans were affected, with 1.9 million U.S. residents addicted to prescription opioids and 359,000 addicted to heroin. Abuse of opioids, particularly heroin, has been associated with unintentional overdoses and transmission of hepatitis, HIV, and sexually transmitted diseases [1].

Interventions that have been found effective in patients with opioid dependence include opioid treatment programs (OTPs). OTPs are medication-assisted approaches that use pharmaceuticals (primarily methadone and buprenorphine), in combination with counseling and other supportive services to treat severe, chronic, and long-term opioid addiction; this may include detoxification from short-acting opioids, medically supervised withdrawal treatments, and pharmacotherapy to stabilize patients [2]. Since controlled substances are dispensed as part of the program, OTPs are highly regulated by federal as well as state agencies [3].

The use of medications to treat addiction is controversial, because many view addiction not as a disease, but as a choice made by the user, and also because of the belief that this type of treatment represents trading one addiction (e.g., heroin) for another (e.g., methadone) [4]. OTPs are often further stigmatized because they are thought to “bring down” the area around them by attracting “undesirable” people, which will subsequently increase crime and drug dealing rates [4, 5].

Currently, there are 1,200 OTPs in the United States, with the heaviest concentration found in the Eastern regions [6]. In Indiana, there are 13 OTPs under the state’s supervision. The number of patients treated in Indiana’s programs quadrupled from 3,646 in 1998 to 14,269 in 2011 (this excludes the Richard L. Roudebush Medical Center, which is operated by the U.S. Veterans Administration). Historically, patients entering Indiana’s OTPs were predominately males and non-Hispanic whites; most were Indiana residents, but services were also provided to patients from surrounding states [3, 7].

OTPs are highly regulated in the United States and must be registered with the Drug Enforcement Administration (DEA) [8, 9]. Additionally, addiction treatment providers in Indiana have to be certified by the Family and Social Services Administration’s Division of Mental Health and Addiction [9]. Indiana law currently prohibits

the establishment of new OTPs in the state [3, 10].

The focus of this policy brief is on methadone and buprenorphine in the treatment of opioid addiction and not on their use in pain management. Though some physicians still utilize these analgesics to relieve patients’ pain, the drugs are primarily used in OTP settings [11, 12].

What are Opioids?

Opioids are psychoactive substances with analgesic (pain relieving) properties that bind to opioid receptors located primarily in the brain, spinal cord, and digestive tract. Opioids are among the oldest known drugs. Opium and its derivatives have been used for thousands of years in medicine [13].

Although ‘opiate’ and ‘opioid’ are often used interchangeably, there is a clear distinction between the terms. Opiates are natural alkaloids that are derived directly from opium (the opium poppy, *Papaver somniferum*), including morphine (and its further derivative, heroin) and codeine [13, 14]. In contrast, opioids are a much broader category and include (a) opiates; (b) synthetically derived opioids that emulate the effects of natural opium (though chemically different) and can be classified as either semi-synthetic (e.g., oxycodone, buprenorphine) or fully-synthetic (e.g., methadone, fentanyl); and (c) naturally occurring endogenous opioids within the human body, such as endorphins [14].

Adverse effects of opioid use include drowsiness, mental confusion, nausea, constipation, and, depending on the amount of drug taken, respiratory depression [15, 16]. For some users, opioids produce a euphoric effect, since these drugs also affect the reward areas of the brain, hence reinforcing the drug’s addiction potential. Opioids can be effective in managing pain when taken as prescribed, and addiction rarely occurs when used properly for short-term medical purposes [16]. When opioids are consumed in large doses, serious health problems such as severe respiratory depression and death can result. Also, when taken over long periods of time, opioids can potentially lead to physical dependence and addiction [16].

Medication-Assisted Treatment

Methadone, buprenorphine, and (in some cases) naltrexone have been found effective in treating opioid addiction. These pharma-



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ceuticals work by binding to opioid receptors and (a) suppressing withdrawal symptoms and cravings (agonistic action), or (b) blocking the effects of other opioids such as heroin and morphine (antagonistic action). The benefits of medication-assisted treatment are that these pharmaceuticals (1) decrease compulsive drug-seeking behaviors and hence reduce related criminal activities; (2) decrease risky behaviors, such as injection drug use (IDU), needle-sharing, and high-risk sexual activities; and (3) help patients to become more receptive to counseling and behavioral approaches [17-19].

Methadone, a Schedule-II narcotic, is a synthetic opioid analgesic that traditionally has been used for pain relief [20-24], but now is primarily utilized in the treatment of opioid dependence.

Buprenorphine, a Schedule-III narcotic, has been increasingly used as a safe alternative to methadone in treating opioid dependence [24-26], because of buprenorphine's "ceiling effect," i.e., after reaching a plateau, any increased dosage of the drug will have little to no effect on the user, resulting in a lower risk of abuse, addiction, and adverse effects, such as lower toxicity from overdose [25-28]. Unlike methadone treatment, which requires the patient to visit a licensed methadone clinic, buprenorphine can be dispensed by physicians in office-based settings once they have completed a specialized, eight-hour training [29].

Dispensation of Methadone and Buprenorphine over the Past Decade

The number of methadone and buprenorphine prescriptions dispensed has increased considerably in the United States. Methadone prescriptions nationwide rose from 863,039 in 2000 to 4,439,850 in 2008, a 400-percent increase. Although methadone is primarily utilized now as a maintenance treatment for opioid addiction, some physicians still prescribe it to treat pain [12]. The use of buprenorphine also increased substantially; from 2004 to 2008, prescriptions for Suboxone® rose from 225,014 to 3,154,795 (a 1,300-percent increase), while prescriptions for Subutex® rose from 42,211 to 263,878 (a 500-percent increase) during that time period [30]. Nearly one-fourth of U.S. residents in substance abuse facilities received methadone or buprenorphine in 2007; of these, the majority (262,684 persons or 99 percent) received methadone [30].

In Indiana, 13,485 patients received pharmacological opioid treatments in 2009. Buprenorphine was used at seven OTPs for 155 patients that year, representing only 1.2 percent of all treated patients at Indiana OTPs; all others were treated with methadone. As a result of treatment, the following percentages of the treatment population showed improvement in the recovery indicator categories below:

- 67.1 percent eliminated or reduced illicit use of prescription opioid drugs;
- 74.4 percent eliminated or reduced use of non-prescription opioid drugs, predominantly heroin;

- 69.1 percent eliminated or reduced illicit use of drugs other than opioids;
- 71.5 percent eliminated or reduced criminal behavior;
- 74.0 percent eliminated or reduced risky behavior related to spread of infectious disease;
- 64.8 percent eliminated or reduced alcohol abuse;
- 45.1 percent improved education or vocational training;
- 56.9 percent improved employment status; and
- 74.3 percent improved family and social relationships [3].

In Indiana, more than 12.7 million prescription drugs (i.e., controlled substances, Schedules-II to V) were dispensed in 2011, including 117,453 prescriptions for methadone (0.9 percent of all controlled substances) and 33,413 prescriptions for buprenorphine (0.3 percent of all controlled substances) (see Table 1) [31].

Compared to buprenorphine, methadone has lower treatment costs; is more effective in treating patients with higher tolerance to opioids; and has generally higher treatment retention rates [28, 32]. Buprenorphine, on the other hand, is safer and has a lower risk of toxicity; opioid withdrawal is less severe after stopping treatment as compared to methadone; the drug has a lower abuse potential; and it is available through primary care physicians in office-based treatment [28, 32].

Table 1: Number of Controlled Substances Dispensed in Indiana (INSPECT, 2008-2011)

	2008	2009	2010	2011
Methadone	110,237	118,038	104,468	117,453
Buprenorphine	2,582	5,549	27,462	33,413
All Controlled Substances	11,635,092	12,713,931	11,341,539	12,743,236

Source: Indiana Board of Pharmacy [31]

Nonmedical Use of Opioids and its Consequences

Opioid abuse can result from both the use of illegal (e.g., heroin) and legal substances (e.g., prescription opioid pain relievers). In Indiana, 1.1 percent of residents ages 12 and older used heroin at least once in their life, 0.2 percent used it in the past year, and less than 0.01 percent used it in the past month [33]. Prevalence rates for nonmedical prescription pain reliever use were considerably higher, with 15.0 percent of residents ages 12 and older reporting lifetime use, 6.1 percent of residents reporting past year use, and 2.0 percent residents reporting past month use [33].¹

Results from the 2009 Treatment Episode Dataset (TEDS) show that nonmedical methadone use did not play a major role in treatment admissions for standard (i.e., non-OTP) services. Nonmedical methadone use was only reported in 0.7 percent of all treatment admissions in Indiana (U.S.: 0.7 percent); and percentages were higher among females (1.0 percent) than males (0.6 percent), and among whites (0.9 percent) than blacks (0.2 percent) or other races

¹ Estimates are based on annual NSDUH averages from 2002 through 2004 and are the most recent state-level data available.

(0.5 percent) [34].

Since methadone is normally prescribed as a treatment for opioid addiction, some patients consider it less dangerous than illicit drugs, such as heroin [22]. This misperception can result in accidental overdoses because the drug has no “ceiling effect,” that is, at high doses, methadone may cause depressed respiration, vomiting, fluid accumulation in the lungs (pulmonary edema), heart attacks (cardiac arrhythmias), or death [22, 28, 30, 32]. Approximately 70 percent of methadone-related deaths in the United States were due to nonmedical or diverted use [22]. Some patients have reported unintended side-effects with methadone treatment, including discomfort, numbness, fatigue, and impaired memory [22]. Buprenorphine is generally considered safer than methadone, because as a partial opioid agonist it has a ceiling effect; that is, the drug’s maximal effects are less than that of a full agonist and will plateau at a maximum level, even with further increases in dosage [22, 25-27]. Patients taking buprenorphine in detoxification treatment programs have reported less severe withdrawal symptoms from cessation of treatment than when they were prescribed methadone [22].

In 2007 in the U.S., there were almost 4 million drug-related emergency department (ED) visits, and 483,612 of these involved narcotic analgesics [30]. The number of ED visits for methadone increased from 48,864 visits in 2004 to 69,506 visits in 2007; 78 percent of methadone-related ED visits in 2007 were due to nonmedical use, while 7 percent involved patients who had adverse reactions to the medication. ED visits for buprenorphine (including its combinations with naloxone) increased from 1,001 in 2004 to 10,229 in 2007; 70 percent were attributable to nonmedical use, while 16 percent were caused by adverse drug reactions [30].

Combining methadone or buprenorphine with additional drugs can be particularly harmful. The use of opioids together with other drugs that depress the central nervous system can result in reduced heart and respiration rates, and may potentially lead to death. Between 2004 and 2007, there was an 83 percent increase in ED visits that involved methadone in combination with other pharmaceutical drugs. During the same time period, there was a 233 percent increase in cases involving combinations of methadone, alcohol, illicit drugs, as well as other pharmaceuticals [30].

Low overdose mortality has been reported with both methadone and buprenorphine. A study from Germany noted that overdose mortality was lower in groups receiving either drug in treatment compared to those taking the drugs outside of a treatment setting [32]. Between 2000 and 2008, 654 deaths due to methadone were reported to U.S. poison control centers, and 9 deaths due to buprenorphine were reported during that same time period [30].

Cost-Effectiveness of Opioid Treatment Programs

Numerous studies have shown the effectiveness of medication-assisted approaches in addiction treatment. Methadone, which has been officially recognized as a potential substitution therapy for illicit narcotic use since the 1960s, has been the most systematically studied and successful pharmacotherapy for treating patients with opioid addiction [23, 35]. Positive outcomes of methadone or buprenorphine treatments include a decrease in clients’ treatment dropout rates; a decrease in the use of opioids and other substances; a decrease in health problems; and a decrease in high-risk behaviors, including needle-sharing among injection drug users and unprotected sexual activity. Also, those in treatment are more likely to be employed fulltime [18, 19, 35-42].

Opioid dependence, and its effects on individuals, families, and society, has been estimated at \$20 billion per year [43]. The cost on the healthcare system alone is estimated at \$1.2 billion per year [43]. An important consideration in health policy decision-making is the cost-effectiveness of treatment.

One study found a 4:1 return on taxpayer dollars for methadone maintenance and inpatient treatment of opioid dependence [43]. Those patients who are enrolled in methadone maintenance programs have been shown to make more than twice the amount of earnings from jobs than those opioid-dependent patients not enrolled in treatment. Reduction in overall crime rates for patients in opioid replacement programs have also resulted in additional cost savings to society [22, 43].

Another study indicated that even a small addition of slots in methadone maintenance programs would be cost-effective, even at twice the cost and half the effectiveness rate of current methadone maintenance programs [44].

OTPs and HIV

Injection drug use (IDU), typically associated with heroin use, has been linked to increased rates of HIV, hepatitis C, tuberculosis, and sexually transmitted diseases (STDs) [43]. In 2008, IDU was associated with 12.9 percent of all new HIV cases, of which about one-fourth were among women and adolescents [6]. Many patients in HIV treatment centers are also dependent on opioids [45, 46].

When patients enter OTPs, they go through an extensive medical background/history check and physical medical examination to determine such things as length of stay and dosage of opioid treatment drugs in the program [47]. A complete medical record of the patient is produced, which includes a determination if the patient had been exposed to such diseases as HIV [47]. OTPs are also required by the federal government to provide counseling on both preventing exposure to and transmission of HIV for every patient admitted (or readmitted) to a maintenance or detoxification treatment [6, 8, 47, 48].

Methadone maintenance programs have been cited as decreasing the likelihood a patient will become HIV positive through both sexual- and injection-related means, though less is known about the effects of other treatment programs on HIV reduction [43, 49]. Studies have shown that the integration of HIV treatment and substance programs may improve the overall health of a patient through both a reduction in risk behaviors associated with contracting HIV and a reduction in substance abuse generally [6, 44]. Furthermore, separating HIV treatment from substance abuse treatment has been posited to lead to a miscommunication among the different healthcare providers, possibly resulting in patient-provider conflict; unintended adverse poly-drug interactions; and overall decreased benefits of either treatment program [6].

Buprenorphine has been shown to have less adverse effects overall than methadone and fewer drug-drug reactions among HIV patients concurrently treated with antiretroviral medication [6, 27]. Buprenorphine therapy may be a possibility for opioid-dependent patients at HIV treatment facilities, since the medication can be dispensed in office-based settings by prescription [6, 49]. HIV treatment facilities that are interested in prescribing buprenorphine must obtain a special waiver directly from the Substance Abuse and Mental Health Services Administration (SAMHSA) [6, 50].

Pregnancy and Opioid Replacement Therapy

Opiate use during pregnancy may result in premature deliveries that have serious complications, as well as delayed child development and reduced parenting skills on the part of the mother [43]. Studies have indicated that anywhere from 60 to 90 percent of infants born to mothers who abuse drugs experience withdrawal symptoms, though the biochemical and physiological processes governing withdrawal are still poorly understood [22]. In addition, women who engage in IDU have been reported to give birth to children who represent over half of all pediatric AIDS cases [43]. It is estimated that 75 percent of all new HIV cases for women and children are attributed to IDU [44].

Women in methadone maintenance therapies are more likely to receive prenatal care for their unborn children than those women not currently enrolled in opioid treatment programs [43]. Prenatal care can include antiretroviral therapies that can reduce the transmission of HIV during pregnancy from mother to child [43]. Opioid replacement therapy has also been associated with improved outcomes in pregnant women, including greater gestational age, higher birth weight, and fewer consequences compared to IDU [27].

Normally, prior to admittance to an OTP, patients must be addicted to opiates for a one-year period per DSM-IV² addiction guidelines [8, 51]. Pregnant women may get an exception to the federal one-year rule and enter treatment much sooner by having a program physician certify their pregnancy [8]. Once enrolled in OTPs, pregnant women are to be given both gender-specific services and prenatal care, either through the OTP directly or through referral to other healthcare providers [8]. A preference is also given to pregnant women to be enrolled in interim maintenance treatment, if they are unable to be placed in a public or private OTP both within a reasonable geographic area and 14 days after submitting an application for entrance into a treatment program [8].

Children born to mothers on methadone treatment are at a high risk for developing neonatal abstinence syndrome (NAS), also known as neonatal withdrawal [27]. Though buprenorphine studies are not as numerous as those on methadone (due to the current use for opioid treatment beginning in 2002), children born to mothers who were undergoing buprenorphine therapy were less likely to develop severe NAS-related issues than children born to mothers on methadone therapy [22, 27, 30].

²The Diagnostic and Statistical Manual of Mental Disorders – Fourth Edition (DSM-IV) is the leading classification manual for mental disorders and illnesses (American Psychiatric Association, 1994). A later text revised edition was also released and is referred to as the DSM-IV-TR (American Psychiatric Association, 2000).

Barriers to Treatment and Public Policy Concerns

Nationally, the demand for OTPs often exceeds treatment availability and some programs have waiting lists for services. Longer waiting times for patients can increase stress and reduce the likelihood of patients actually entering treatment [52]. Only an estimated 15 percent of those in need of opioid dependence treatment are able to enter existing programs and people can be on waiting lists for months in some areas [53]. Fortunately, Indiana OTPs have the capacity to treat those in need of their services and do not need to employ waiting lists.

A policy-related criticism of OTPs is that some view methadone maintenance as just substituting one drug for another. However, the scientific evidence clearly suggests that proper methadone maintenance, when compared to other medical treatments, can help to reduce both the medical and social harms produced by opioid abuse [53].

Another criticism is that methadone maintenance programs do not result in a total discontinuation of injection drug use. In fact, only around 3.5 percent of patients per year enrolled in treatment programs completely stop IDU [44]. Nevertheless, these programs have been shown to reduce the spread of HIV [44]. Studies have shown that the reduction of behaviors associated with contracting HIV associated with methadone maintenance programs are more cost-effective than other types of HIV risk behavior reduction programs (e.g., educational or voluntary screening programs) [44].

Though buprenorphine has been shown to be a highly effective treatment for opioid addiction, it is not in widespread use in treatment [25, 26, 54]. One study showed that within four years of buprenorphine entering the market as an opioid treatment, 75 percent of treatment facilities surveyed in four large metropolitan areas chose not to implement buprenorphine [54]. Educating the treatment organizations on newer types of opioid dependence medications may not be enough. Many organizations are hesitant to switch from methadone, which has been used for years as a treatment, to buprenorphine [54]. One significant reason for treatment organizations resisting new treatments is their “cultural system,” which incorporates the attitudes, philosophy, and goals that shape what sort of treatment (including medication) is offered in treatment organizations [54].

Another potential barrier is treatment cost. In the United States, buprenorphine treatment alone (without counseling or ancillary services) is estimated at \$200 per month per patient, compared to \$30 for methadone [28, 29]. In Indiana, the estimated annual out-

of-pocket expenses per patient, including medication, counseling, drug testing, and other supportive services, was \$3,467-\$4,829 for methadone maintenance and \$6,640 for buprenorphine treatment, in 2009 [3].

Thoughts for Policymakers

Opioid dependence is a public health concern that costs society billions of dollars in direct and indirect costs [43]. Research shows that effective treatments, such as OTPs, can reduce drug use, overdose deaths, and crime; increase social productivity; and prevent the spread of infectious diseases, including HIV [53]. Current Indiana law states that no new OTPs can be established in the state, potentially affecting access for people who do not live near treatment locations [3]. To increase the effectiveness of and access to opioid treatment, implementation of evidence-based programs, policies, and procedures are recommended [3-5, 53-55], as follows:

- Establish a comprehensive opioid treatment policy that combines education, the dispelling of misconceptions about opioid addiction treatment, and the required use of new, effective treatments such as buprenorphine.
- Remove the current ban on creating new OTPs in the state, so that these treatment modalities can be promptly established to offer services, should the need arise.
- Integrate substance abuse treatment into healthcare and expand recovery services (e.g., expanding addiction treatment in Community Health Centers) while creating training opportunities to increase access. Under the Affordable Care Act, insurance companies will be required to address drug addiction as both a preventable and treatable ailment.

Opioid dependence is a serious and complex issue that affects thousands of Indiana residents per year [33]. Though OTPs can be effective in treating opioid dependence, their work is often misunderstood. Policies that help dispel the stigma that these treatment facilities and their patients face, while expanding new and effective opioid abuse treatments, will be crucial in treating opioid addiction and reducing its negative consequences.

These policy recommendations only focus on the use of pharmaceuticals, such as methadone and buprenorphine, as a treatment option for opioid dependence and not for pain management. The challenges involved in treating pain, particularly non-cancer chronic pain, are manifold and not addressed in this issue brief.

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The mission of the Center for Health Policy is to conduct research on critical health-related issues and translate data into evidence-based policy recommendations to improve community health. The CHP faculty and staff collaborate with public and private partners to conduct quality data driven program evaluation and applied research analysis on relevant public health issues. The Center serves as a bridge between academic health researchers and federal, state and local government as well as healthcare and community organizations.

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RECOVERY AT MIDTOWN METHADONE CLINIC

We asked our clients to describe what treatment and achieving recovery at our clinic has meant to them?

Recovery, to me, means life in full bloom. In recovery I have a chance to give back and help others which is what we are supposed to do. It has taken me 30 years to bloom, but in recovery I feel younger than I did at 27.

-C.M. (56 year old)

I no longer feel withdrawals stopping me from enjoying life. I go to work now and I can be there for my kids.

-J.S. (28 year old mother of 3)

I've felt so much better about myself since I've stopped drug-seeking behavior. Group has given me support that I didn't get from all the old people, places, and things that were keeping me stuck in my addiction.

-E.L. (33 year old department store clerk)

Recovery is an ongoing process that has a lot of different phases. I messed up a lot in treatment before, but now I get it. I'm learning a lot about myself and learning to live life on life's terms.

-S.S. (46 year old factory worker)

Midtown gave me the tools to get clean. I dedicate my entire recovery to my Dad. If I ever think I can't stay clean and sober I think of him.

-M.R. (29 year old)

I am so thankful for Midtown for saving my life. I now live my life the way that I want as a loving, responsible woman. The classes I take gave me happiness and knowledge. Most of all I thank Jesus for my putting Midtown in my life.

-A.F. (42 year old wife and mother of 2)

Before my recovery I couldn't find a job. I have a job and my own place. The people here help me every day and make me want to stay in recovery. If it wasn't for this place I don't know where I'd be.

-W.R. (26 year old waiter)

It helped me be closer to my family. It helped me deal with people better. It made my family trust me more. I have a job now and can save more money to pay my bills.

-J.K. (33 year old convenience store clerk)

I've been coming to the clinic since 2011. I used to think you (Midtown) were too strict with all your rules. I relapsed a lot in the beginning, but now I am stable with my medication and in life. I haven't had a dirty drop (drug screen) in over 8 months. Life is better with my wife and I spend more time with my kids.

-R.M. (42 year old construction worker)

My recovery was my life changer and it honestly has been the best feeling.

-C.P. (29 year old mother of a newborn)

I've been at the clinic for 2 years and no longer use drugs. It has helped me keep a job. My sister has been a big help. Without her love and support I would still be using drugs.

-B.D. (36 year old painter)

Understanding Methadone: Myths and Mixed Blessings

Presentation to Mental Health Commission, Indiana State Legislature
Oct. 1, 2013

R. Andrew Chambers, M.D.

Associate Professor of Psychiatry
IU School of Medicine

Director, Lab for Translational Neuroscience of Dual Diagnosis & Development
Director, Addiction Psychiatry Fellowship Training Program
IU Department of Psychiatry

Indiana Attorney General's Taskforce on the Opioid Addiction Epidemic

History of Methadone

- 70 years of clinical experience: First synthesized in Germany and tested in England as a treatment for opiate withdrawal and dependence in the 1940s.
- First clinical trials showing efficacy for treatment of opioid dependence at Rockefeller Institute in NY, 50 years ago (early 1960s)
- Subsequent research around the country and world has thoroughly tested and replicated the efficacy of methadone for treatment of opiate dependence.
- First modern Methadone clinic (established in Canada in 1967).

Efficacy of Methadone for Opiate Addiction

- Prevents opioid withdrawal
- Blocks euphoria of heroin
- Decreases craving and drug seeking behavior
- Reduces the medical illness and death associated with heroin addiction (patients are 3x more likely to die without methadone than those on methadone).
- Decreases risk of HIV.
- More effective than non-pharmacological treatments in the suppression of heroin use and treatment retention.
- Reduces illicit and other drug use (including cocaine, sedatives, marijuana, amphetamines).
- Psychiatric Stability

Methadone for Pain

- The Evidence base and clinical experience with methadone has long been predominantly based on its use as a treatment for opioid addiction.
- However, changes in cultural norms (1990's and 2000's) in health care that supported the profit motives of major pharmaceutical companies, and promoted the aggressive treatment of pain with opioids, with the desire of government and private insurance to treat pain as Cheaply as possible, led to the uncontrolled and poorly-evidence based utilization of methadone for pain on a massive scale.

Clinical Uses of Methadone: The good, the bad, and the Ugly

	<u>For Pain</u>	<u>For Addiction</u>
	Primary care/pain program	Psych/OP maintenance programs
Evidence base	Poor; not well established	very Strong; > 40 years
Risk of causing New addiction	High with chronic use	none
Risk of lethal overdose	significant	extremely rare
Risk of diversion	significant	extremely rare
Regulated (req. drug testing Psychotherapies Professional expertise)	none no specific expertise needed	very tight addiction psychiatry or methadone certification
Insurance Coverage (Private/Indiana Medicaid/medicare)	total coverage, unrestricted no PA's needed	Non-existent*; Patients pay \$240-400/ months no matter how poor or mentally ill they are No matter what their insurance is.
		*Unless pregnant

*

Legislative Agenda of Indiana State Medical Association

Summer/Fall 2012

RESOLUTION 12-25A

ELIMINATING METHADONE/METHADONE CLINICS

Action: Substitute Resolution 12-25A was adopted in lieu of Resolution 12-25.

Adopted as amended

RESOLVED, that ISMA take action as it deems appropriate to seek and support legislation banning clinics for the maintenance of opioid addiction with methadone in Indiana; and be it further

RESOLVED, that the ISMA support the continued availability of methadone in Indiana for the treatment of chronic pain but not necessarily a drug of first choice.

WHAAAAT?

Clinical Uses of Methadone: The good, the bad, and the Ugly

For Pain

Primary care/pain program

Poor; not established

High with chronic use

significant

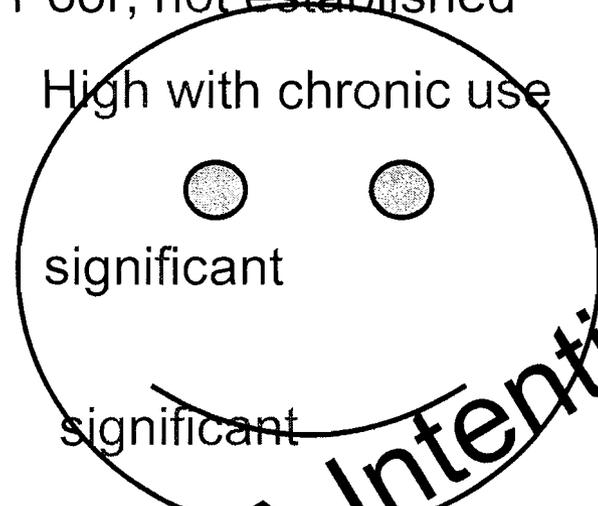
significant

none

no specific expertise needed

total coverage, unrestricted

no PA's needed



For Addiction

Psych/OP maintenance programs

very Strong; > 40 years

none

extremely rare

extremely rare

very tight

addiction psychiatry
or methadone certification

Non-existent*; Patients pay
\$240-400/ months no
matter how poor or mentally
ill they are No matter what
their insurance is.

*Unless pregnant



Evidence base

Risk of causing

New addiction

Risk of lethal
overdose

Risk of diversion

Regulated

(req. drug testing

Psychotherapies

Professional expertise)

Insurance

Coverage

(Private/Indiana

Medicaid/medicare

*

Explanation for ISMA stumble the Methadone issue:

1. Lack of sufficient professional training and Expertise, and workforce in Indiana in Psychiatry, Behavioral Health, and Addictions:

Results in insufficient understanding or representation of these fields within the ISMA .

2. Still, there is an important point here in what the ISMA may have been trying to get at:

Indiana's Methadone treatment infrastructure is far from perfect and is in great need of major reform to improve access and quality of care.

Serious issues with Current Methadone Treatment Infrastructure in Indiana

1. Lack of Parity and Health Insurance Coverage for this Care:
 - High out of pocket costs for treatment can lead some patients to continue to break the law to acquire funding to pay for treatment.
 - Has created a system of private/ for profit methadone clinics (owned by Corporations or individuals headquartered outside Indiana) that are silo-ed off from the rest of psychiatric/addictions or medical care.
 - Perpetuates a massive epidemic of health care fraud in which doctors and patient are financially incentivized to inaccurately frame the clinical problem as pain instead of addiction.
2. Lack of integration of Methadone Clinics into not-for profit Mental health and addiction treatment systems:
 - opiate dependence is not being treated via other modalities,
 - comorbid addiction to other drugs is not being expertly treated
 - comorbid mental illness (the norm) is not being expertly treated.
3. No requirements that Doctors prescribing Methadone at Methadone treatment Programs in Indiana have any expertise, formal training or certification in psychiatry And/ or addictions.

Reform to improve Access and Quality of Care for Opiate Addiction with Methadone in Indiana must include:

1. Establish and Require by Law Full-on Health Insurance Coverage Parity for Methadone treatment for opiate Addiction.
2. Expansion Methadone Treatment Program venues in Indiana with Elimination of Stand-Alone Methadone Clinic's that are not embedded in Full service mental-health and Addiction Treatment Centers.
3. Requirements that Physicians prescribing methadone in methadone treatment Programs must be Psychiatrists who are board certified:

by the American Board of Medical specialties in Addiction Psychiatry

or American Board of Addiction Medicine

Thanks/Questions?

Lab for Translational Neuroscience of Dual Diagnosis & Development
Addiction Psychiatry Fellowship Training Program

IU Department of Psychiatry

Indiana Commission on Mental Health and Addiction

October 1, 2013

Presentation by David Waters

I. Introduction

Thank you for the opportunity to speak. My name is David Waters. I hold licenses to practice pharmacy in Indiana and Colorado. I am presently employed as floater pharmacist working an itinerant schedule fulfilling staffing needs at various locations around central and southern Indiana. I appear before you today by my own volition as a concerned pharmacist and citizen. I do not represent my employer.

I am here today to speak about the drugs Subutex, Suboxone and Methadone. The sole indication of use for both Subutex and Suboxone is the treatment of opiate dependence. Methadone is indicated for use for both pain and opiate dependence.

In successive order, I will present some recent experiences with these drugs that I have had with two doctors and two patients; some federal and state citations concerning these drugs; some FDA information and a closing.

II. Recent Experiences

A. Doctor One - Maintenance

A patient presented a purported prescription for Subutex. The words "for chronic pain" were omitted and the DATA 2000 waiver identification number was provided. After reviewing the patient profile, I telephoned the doctor to inquire about the treatment plan for opiate dependence since the patient had, at least, a four-month history at this pharmacy of using the drug with no reduction in dose.

When speaking with the doctor, I learned that no plan to reduce the use of the drug existed and the doctor's sole intent for prescribing the drug was to maintain the patients opiate dependence.

This doctor provided knowledge led me to conclude that this was not a prescription as defined by Indiana and I refused to honor the piece of paper as a prescription.

B. Doctor Two – Complaint

Three patients concurrently presented prescriptions for Suboxne from the same doctor and dated that day. On all three prescriptions, the words "for chronic pain" were omitted and the DATA 2000 waiver identification number was provided. After reviewing the patient's profiles, I telephoned the doctor to inquire about the treatment plan for opiate dependence since the patients had, at least, a four to six month history at this pharmacy of using the drug with no reduction in dose.

When speaking with the doctor's nurse, I learned that the patient would decide when to reduce the dose and terminate use. When I asked if the doctor took any role in this decision making process, the nurse countered with asking what

business of it is mine. She asked for my name again and the pharmacy from which I was calling. At that point, we ended the call.

As it happened, a business card of a state pharmacy inspector was lying next to the telephone. My co-workers informed me that the inspector visited inquiring about the prescribing practice of a doctor and his use of Subutex and Suboxone. Immediately after ending the call with the nurse, I called the inspector. I was later informed that while I was speaking to the inspector, my co-worker noticed that each successive patient received a call from the doctor's nurse telling them to not fill the prescription at that pharmacy and take their prescription elsewhere.

C. Patient One - Methadone

A patient presented a prescription for 1,050 tablets of 10mg methadone, which was to last 30 days. After reviewing the patient's profile, I learned that the patient had been receiving monthly prescriptions for this amount from this doctor for quite a number of months. My co-workers told me stories about how this doctor practiced. They expressed dismay over his continued ability to practice. They told me that other pharmacists had questioned his practice by reporting the doctor to the state and the DEA.

The next day, I called the DEA to report this doctor and question the legality of such an order. Simply put, the DEA was not interested.

D. Patient Two – Heroin

A patient called to inquire about the status of a prior authorization requirement imposed by Indiana Medicaid for her prescription of Suboxone. I reprocessed the claim that moment and received the same message that indicated a prior authorization was needed. The patient asked if she could purchase some doses without involving Medicaid or any other third party payer. I informed her that Medicaid regulations prohibited the pharmacy from selling the drug to her without billing Medicaid and that per regulation she could lose her coverage for purchasing medicine without billing Medicaid. Her retort immediately before hanging up was "What do they want me to do start using heroin again!"

III. Federal regulation

The Drug Addiction Treatment Act of 2000 (DATA 2000) opened the door to office-based opioid addiction treatment and ushered the use of buprenorphine. Below is a link to DATA 2000.

<http://buprenorphine.samhsa.gov/fulllaw.html>

The act established the needed licensing and authorized the Secretary of Health and Human Services to establish regulations. Below is a link to the rule in the Federal Register.

<https://www.federalregister.gov/articles/2012/12/06/2012-29417/opioid-drugs-in-maintenance-and-detoxification-treatment-of-opiate-addiction-proposed-modification>

In the rule, under section II, Background, paragraph B, Buprenorphine in Office-Based Opioid Treatment, the following statement can be found.

Qualifying physicians are permitted to dispense, including prescribe, Schedule III, IV, and V narcotic controlled drugs approved by the FDA specifically for maintenance or detoxification treatment without being separately registered as a narcotic treatment program by DEA (21 U.S.C. 823(g)(2)(A)).

In the rule, under section V, Regulatory Impact and Notices, Executive Order 13132: Federalism, the following can be found.

The Secretary is publishing this final rule to modify treatment regulations that provide for the use of approved opioid agonist treatment medications in the treatment of opiate addiction. The Narcotic Addict Treatment Act (NATA, 93) modified the Controlled Substances Act (CSA) to establish the basis for the Federal control of narcotic addiction treatment by the Attorney General and the Secretary. Because enforcement of these Sections of the CSA is a federal responsibility, there should be little, if any, impact from this rule on the distribution of power and responsibilities among the various levels of government. In addition, this final rule does not preempt State law. Accordingly, the Secretary has determined that this final rule does not contain policies that have federalism implications or that preempt state law.

I believe the federal government has control over opiate addiction programs. However, I believe DATA 2000 establishes individual practitioners that practice independently and are not associated with a program, therefore, not governed by rules from the Secretary of Health and Human Services. Furthermore, those individual practitioners are governed by the state in which they practice.

IV. State Regulation

Below is a link to the compilation of laws and regulations governing the practice of pharmacy in Indiana.

http://www.in.gov/pla/files/2013_Law_Compilation.pdf

IC 25-26-13-16(b) reads as follows with my highlight.

A pharmacist has a duty to honor all prescriptions from a practitioner or from a physician, podiatrist, dentist, or veterinarian licensed under the laws of another state. Before honoring a prescription, the pharmacist shall take reasonable steps to determine whether the prescription has been issued in compliance with the laws of the state where it originated. The pharmacist is immune from criminal prosecution or civil liability if he, in good faith, refuses to honor a prescription because, in his professional judgment, the honoring of the prescription would:

- (1) be contrary to law;*
- (2) be against the best interest of the patient;*
- (3) aid or abet an addiction or habit; or*
- (4) be contrary to the health and safety of the patient.*

856 IAC 2-6-2(c) reads as follows with my highlight.

Controlled substances prescriptions issued by individual practitioners in adjoining states to Indiana or other states are considered valid prescriptions if the practitioner issuing the prescription has a current and valid Drug Enforcement Administration certificate registration number. It is the pharmacist's responsibility as with all controlled substances prescriptions, to be sure beyond reasonable doubt in his or her professional judgment that the practitioner is issuing the prescription in good faith and has a valid Drug Enforcement Administration certificate of registration.

856 IAC 2-6-3 reads in full as follows with my highlights.

Sec. 3. Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose in a reasonable quantity by an individual practitioner acting in the usual course of his professional practice. 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. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription, within the meaning and intent of IC 1971, 35-24.1-3-8 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended, and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of continuing his dependence upon such drugs in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program.

V. Federal Monitoring

The federal regulation of opioid treatment calls for monitoring of programs. Information regarding monitoring can be found in the DAWN Report, which stands for Drug Abuse Warning Network. The DAWN Report dated January 29, 2013, started with these four points.

- Emergency department (ED) visits involving buprenorphine increased substantially from 3,161 in 2005 to 30,135 visits in 2010, as availability of the drug increased
- In 2010, most buprenorphine-related ED visits were classified as nonmedical use of pharmaceuticals (52 percent, or 15,778 visits), followed by patients seeking detoxification or substance abuse treatment (24 percent, or 7,372 visits) and adverse reactions (13 percent, or 4,017 visits)
- Buprenorphine-related ED visits involving nonmedical use of pharmaceuticals increased 255 percent from 4,440 visits in 2006 to 15,778 visits in 2010
- Additional drugs were involved in 59 percent of buprenorphine-related ED visits involving nonmedical use of pharmaceuticals in 2010

Below is a link to this DAWN Report.

<http://www.samhsa.gov/data/2k13/DAWN106/sr106-buprenorphine.htm>

An additional report is N-SSATS Report, which stands for National Survey of Substance Abuse Treatment Services. The N-SSATS Report dated April 23, 2013 included these charts.

Figure 4. Number and Percentage of Facilities without Opioid Treatment Programs (Non-OTPs) Providing Buprenorphine: 2003 to 2011

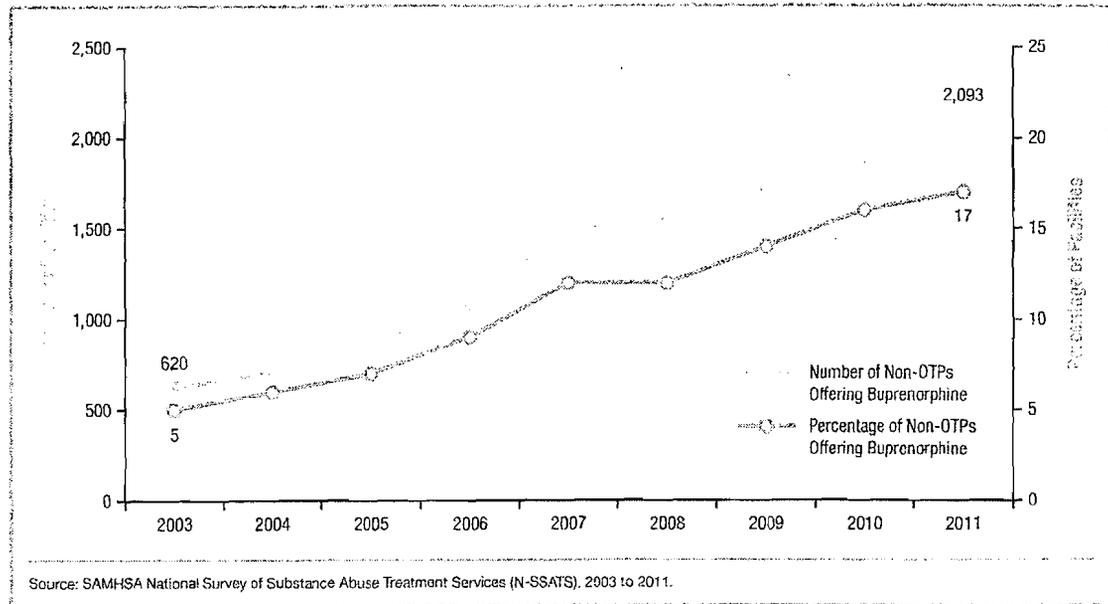
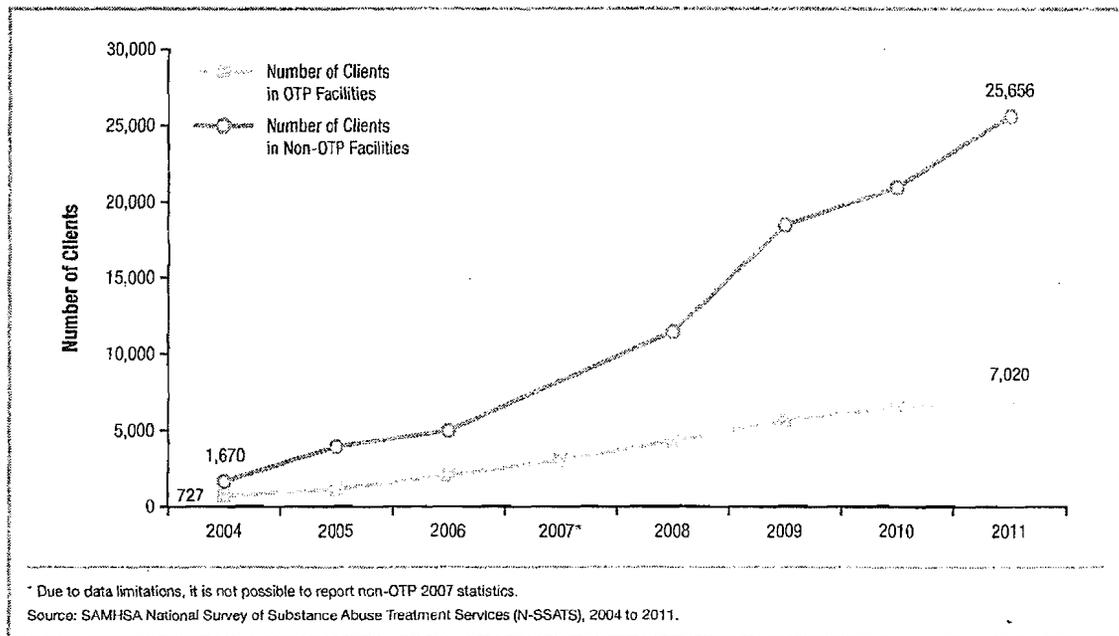


Figure 5. Number of Clients Receiving Buprenorphine at Opioid Treatment Programs (OTPs) and in Facilities without OTPs (Non-OTPs): 2004 to 2011



Notice the sharp increasing trend in patients in non-program facilities. Does this mean these patients are being treated with no oversight from the Secretary of Health and Human Services since these are non-program facilities?

Below is a link to this N-SSATS Report.

<http://www.samhsa.gov/data/2k13/NSSATS107/sr107-NSSATS->

VI. State Monitoring

The following information was obtained from FSSA.

Total Suboxone and Subutex Utilization

Calendar Year	Claims	Distinct Users	Paid Amount	Billed Amount	Per Member Per Month	Claims per 10,000 Member Months	Percent of Total Claims	Percent of Total Paid
2008	7,489	1,165	\$ 1,254,377.71	\$ 1,622,846.99	\$ 0.11	6.79	0.08%	0.24%
2009	15,429	2,064	\$ 3,410,419.20	\$ 4,262,380.04	\$ 0.28	12.69	0.13%	0.57%
2010	18,177	2,420	\$ 4,505,761.43	\$ 5,873,533.65	\$ 0.35	14.18	0.15%	0.68%
2011	21,685	2,825	\$ 5,762,409.72	\$ 7,609,987.57	\$ 0.44	16.68	0.18%	0.78%
2012	26,460	3,256	\$ 7,084,714.17	\$ 9,430,130.28	\$ 0.54	20.07	0.22%	0.92%

Total Pharmacy Program Utilization - All Drugs

Calendar Year	Claims	Distinct Users	Paid Amount
2008	9,678,917	694,116	\$ 515,071,414.68
2009	11,685,573	791,386	\$ 597,213,438.52
2010	11,839,324	816,401	\$ 660,476,626.83
2011	11,984,260	831,390	\$ 734,219,684.87
2012	11,923,870	836,025	\$ 771,811,502.40

Utilization: The claim counts for Suboxone and Subutex increased 353% (RE: Claims) from calendar year 2008 to 2012. Factoring in the changes in membership, the utilization trend from calendar year 2008 to 2012 demonstrates an increase of 296% (RE: Claims/10,000 Member Months) over the 5 year period.

Members Being Treated With Suboxone/Subutex: The number of unique members being prescribed Suboxone or Subutex for opiate addiction increased 279% (RE: Distinct Users) over the 5 years.

Expenditures: The expenditures associated with Suboxone or Subutex drug claims increased 565% (RE: Paid Amount) over the 5 years. Factoring in the changes in membership, the expenditure trends from calendar year 2008 to 2012 increased 491% (RE: Per Member Per Month). The average cost per claim increased 160%, from 2008 (\$168 per claim) to 2012 (\$268 per claim). The average drug therapy cost per user increased 202%, from 2008 (\$1,077 per treated member) to 2012 (\$2,176 per treated member).

VII. FDA Information

The FDA has established a Risk Evaluation and Mitigation Strategy (REMS) for buprenorphine treatment for opioid addiction. Below is a link to the REMS.

<http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM340914.pdf>

The REMS discusses treatment in terms of detoxification and maintenance. I noticed that no discussion of an end to maintenance treatment was given.

VIII. Closing

I have noticed the sharp increase in the use of Subutex and Soboxone over the past 4

or 5 years. I see many patients who have been taking these drugs for as long as their on-line profile shows. The ages of these patients I have seen range from 19 to over 60 years of age. It seems that the most frequent patient age would fall in the range of 24 to 30 years of age. I believe the information presented above shows that the office-based, non-program practitioner is enabling the sharp increase in opiate use and is detrimental to public safety. I believe these drugs are a valuable commodity on the street, allow people to continue to use illicit drugs and allow people to “party” without the nasty effects of heroin.

I think Indiana should do the following:

1. Prohibit the use of Subutex and Suboxone for the treatment of pain
2. Require individual, non-program practitioners to register their opiate treatment practice with the State
3. Require a practitioner to file a treatment plan with a program similar to INSPECT
4. Establish a six month limit to the time an individual, non-program practitioner can treat a patient
5. Establish detoxification and cessation as the outcome of treatment by an individual, non-program practitioner
6. Require patients to enroll in a well regulated opioid treatment program that supplies the patient with the drugs if six months is not long enough
7. Prohibit the sale of Subutex and Suboxone to any person with a six month total history of use

Indiana State Medical Association



focused on the future of medicine



RESOLUTION 13-34

IMPROVEMENT OF PREVENTION, SCREENING
AND TREATMENT FOR SUBSTANCE USE AND
ABUSE DURING PREGNANCY

Introduced by:

John Ellis, M.D., FAAP, and James J. Nocon,
M.D., J.D., Professor Emeritus, IU School of
Medicine, Department of Obstetrics and
Gynecology

Referred to:

REFERENCE COMMITTEE 4

Whereas, prenatal alcohol exposure is associated with significant maternal and fetal health risks, including spontaneous abortion, prenatal and postnatal growth restriction, birth defects and neurodevelopment deficits, including fetal alcohol syndrome (the most common cause of mental retardation - 1/1000 live births);¹ and

Whereas, smoking during pregnancy increases the likelihood of placenta previa, abruption, premature rupture of membranes, preterm delivery, fetal growth restriction, low birth weight, as well as increasing the incidence of orofacial cleft defects and sudden infant death syndrome after birth;¹ and

Whereas, illicit drug use during pregnancy, especially cocaine use, has been linked to increased risk of low birth weight, prematurity, perinatal death, abruption placenta, and small for gestational age births;¹ and

Whereas, in 2010, a total of 15,323 deaths among women were attributed to drug overdose, a rate of 9.8 per 100,000 population;² and

Whereas, deaths from opioid pain relievers (OPRs) increased fivefold between 1999 and 2010 for women, while OPR deaths among men increased 3.6 times;² and

Whereas, in 2010, there were 943,365 emergency department (ED) visits by women for drug misuse or abuse; and the highest ED visit rates were for cocaine or

¹ R.L. Floyd, et al. "The clinical content of preconception care: alcohol, tobacco, and illicit drug exposures" *American Journal of Obstetrics & Gynecology* December 2008 (Vol. 199, Issue 6, Pages S333-S339)

heroin (147.2 per 100,000 population), benzodiazepines (134.6) and OPR (129.6); and ED visits related to misuse or abuse of OPR among women more than doubled between 2004 and 2010.;² and

Whereas, the *2011 National Survey on Drug Use and Health*² found that 9.4 percent of pregnant women reported current alcohol use and 2.6 percent reported binge drinking (greater than five drinks on the same occasion), and 16.7 percent of pregnant women reported tobacco use during pregnancy; and

Whereas, the *2011 National Survey on Drug Use and Health*³ found 5 percent of pregnant women reported they were current illicit drug users, and the rate of current illicit drug use was 20.9 percent among pregnant women aged 15 to 17, 8.2 percent among pregnant women aged 18 to 25, and 2.2 percent among pregnant women aged 26 to 44; and

Whereas, a variety of evidence-based, validated screening tools have been introduced to properly screen and identify pregnant women using alcohol, tobacco and illicit drugs, including the 5 As of tobacco, TACE for alcohol and FRAMES for other drug use;⁴ and

Whereas, pregnancy provides a powerful opportunity for long-term recovery;^{5,6} and

Whereas, identification and appropriate management, including motivational counseling, may substantially reduce the potential risk to the mother and the fetus of use of such substances;⁶ and

Whereas, one study showed that by merely identifying the pregnant substance user and the particular substance(s) used, 54 percent of women stopped using after brief physician advice and a urine drug screen at each prenatal visit;⁶ and

Whereas, in one treatment facility from 2002 to 2008, detection and simple intervention resulted in 274/323 (84.8 percent) substance-free births, with a pre-term rate of 22.2 percent (pre-term delivery rate for all patients in this hospital was 19.6 percent);⁶ and

Whereas, in that same facility, of the patients who were identified with a positive urine drug screen who did not return for prenatal care but who did return for delivery, 26/49 (53 percent) had substance-free births, suggesting that the process of detection may be an intervention in and of itself;⁶ and

Whereas, the American Congress of Obstetricians and Gynecologists endorses universal screening of pregnant women for toxic substances as an ethical obligation;⁷ and

² <http://www.samhsa.gov/data/NSDUH/2k11Results/NSDUHresults2011.htm#2.6>

Whereas, the ISMA supports a healthy prenatal intrauterine environment;⁸ and

Whereas, the ISMA supports initiatives to help those who are addicted to drugs ask for help, and supports government initiatives to implement substance abuse programs that are appropriately designed and monitored for quality, cost effectiveness and reduced recidivism;⁹ therefore, be it

RESOLVED, that the ISMA actively support and encourage appropriate screening of all pregnant women in Indiana for legal and illegal use of prescription medications and other substances that might adversely affect their health, their pregnancies or the health of their fetuses, including alcohol and tobacco, through use of the aforementioned evidence-based, validated screening tools and motivational counseling; and be it further

RESOLVED, that the ISMA develop policy to actively support and encourage pregnant substance users by:

- Emphasizing Encouraging appropriate medical care, rather than criminalization
- Encouraging management and referral of services appropriate to their needs
- Identifying and developing adequate addiction treatment services
- Encouraging better reimbursement for addiction treatment services
- Encouraging addiction treatment programs to accept pregnant women

And be it further,

RESOLVED, that the ISMA actively support and encourage an educational program for all Indiana physicians regarding prevention, validated screening, motivational counseling and evidence-based treatment of pregnant women for the legal and illegal use of prescription medications and other substances potentially harmful to them and their fetuses, including alcohol and tobacco.

³ <http://www.samhsa.gov/data/NSDUH/2k11Results/NSDUHresults2011.htm#2.6>

⁴ *American Journal of Obstetrics & Gynecology* December 2008 (Vol. 199, Issue 6, Pages S333-S339)

⁵ I.J. Chasnoff, et al. **The 4P's Plus Screen for Substance Use in Pregnancy: Clinical Application and Outcomes.** *Journal of Perinatology* (2005) 25, 368–374.

⁶ James. J. Nocon, M.D., J.D., Director Prenatal Substance Use Clinic, Wishard Memorial Hospital, 1001 West 10th Street, F5102, Indianapolis, IN 46202

⁷ *American College of Obstetricians and Gynecologists.* "At-risk drinking and illicit drug use: ethical issues in obstetric and gynecologic practice." ACOG Committee Opinion No. 422, December 2008.

⁸ Summary of Relevant ISMA Policy:

RESOLUTION 11-05 - RESOLVED, that the ISMA seek legislation to regulate methadone clinics in Indiana, to identify those clients who are pregnant and supply them with accurate information about the effects of methadone on fetus development, and to educate pregnant clients on neonatal abstinence syndrome.

⁹ **Summary of relevant AMA Policy:**

The AMA: (1) adopts the following statement: Transplacental drug transfer should not be subject to criminal sanctions or civil liability; (2) encourages the federal government to expand the proportion of funds allocated to drug treatment, prevention, and education within the context of its "War on Drugs." In particular, support is crucial for establishing and making broadly available specialized treatment programs for drug-addicted pregnant women wherever possible; (3) urges the federal government to fund additional research to further knowledge about and effective treatment programs for drug-addicted pregnant women, encourages also the support of research that provides long-term follow-up data on the developmental consequences of perinatal drug exposure, and identifies appropriate methodologies for early intervention with perinatally exposed children; (4) reaffirms the following statement: Pregnant substance abusers should be provided with rehabilitative treatment appropriate to their specific physiological and psychological needs; (5) through its communication vehicles, encourages all physicians to increase their knowledge regarding the effects of drug and alcohol abuse during pregnancy and to routinely inquire about alcohol and drug use in the course of providing prenatal care; and (6) will address the special needs of pregnant drug abusers within the context of its ongoing Health Access America programs. (H-420.962 Perinatal Addiction - Issues in Care and Prevention, CSA Rep. G, A-92; Reaffirmation A-99)



10/11/13 COMHA Exhibit 7

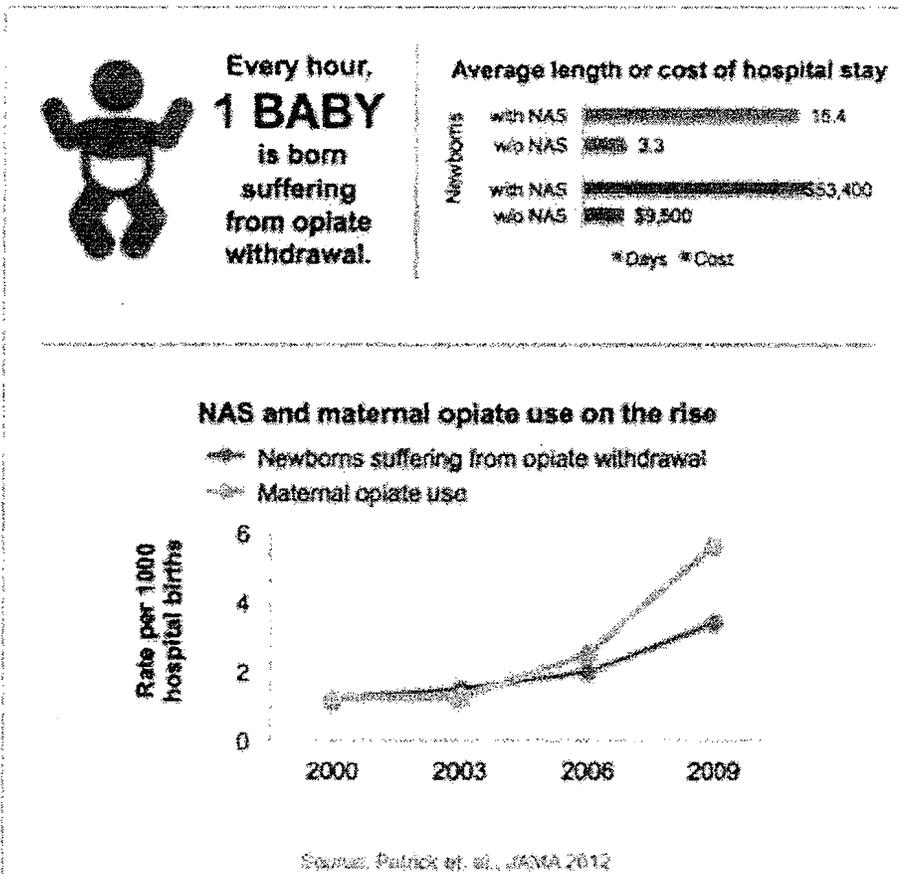


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Maternal opiate use and newborns suffering from opiate withdrawal are on the rise in the U.S.

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Text Description of Infographic

Use of opiates during pregnancy can result in a drug withdrawal syndrome in newborns called neonatal abstinence syndrome (NAS). A new study to determine the extent, context, and costs of NAS found that incidence of NAS is rising in the United States. The proportion of babies born with NAS tripled from 2000 to 2009, when an estimated 13,539 infants were born with NAS —equivalent to one baby suffering from opiate withdrawal born every hour. Newborns with NAS were more likely than other babies to also have low birthweight and respiratory complications. The number of delivering mothers using or dependent on

opiates rose even more—nearly five-fold—from 2000 to 2009, to an estimated 23,009. In 2009, newborns with NAS stayed in the hospital an average of 16.4 days (compared to 3.3 days for other newborns), costing hospitals an estimated \$720 million; the majority of these charges (77.6%) were paid by state Medicaid programs, reflecting the greater tendency of opiate-abusing mothers to be from lower-income communities. The rising frequency (and costs) of drug withdrawal in newborns points to the need for measures to reduce antenatal exposure to opiates.

Top Left Graph: Every hour, 1 baby is born suffering from opiate withdrawal.

Top Right Graph: Average length or cost of hospital stay graph. Newborns with NAS stayed in the hospital for an average of 16.4 days compared to 3.3 days for those without NAS. The hospital costs for newborns with NAS were \$53,400 on average compared to \$9,500 for those without NAS.

Bottom Graph: NAS and maternal opiate use on the rise graph.

The rate of babies born with NAS per 1,000 hospital births was 1.2 in 2000, 1.5 in 2003, 1.96 in 2007, and 3.39 in 2009. The rate of maternal opiate use per 1,000 hospital births was 1.19 in 2000, 1.26 in 2003, 2.52 in 2006, and 5.63 in 2009.

This page was last updated October 2012



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HEALTH

More newborns showing ill effects of maternal opioid use

■ The number of newborns diagnosed with neonatal abstinence syndrome nearly tripled in 10 years due to increasing opiate use among pregnant women, a new study shows.

By **CHRISTINE S. MOYER** ([HTTP://WWW.AMEDNEWS.COM/APPS/PBCS.DLL/PERSONALIA?ID=CMOYER](http://www.amednews.com/apps/pbcs.dll/personalia?id=cmoyer)) — Posted May 21, 2012

Many newborns wail inconsolably in the Knoxville, Tenn., neonatal intensive care unit where Mark S. Gaylord, MD, works.

They often sweat with fever and struggle to breathe. The skin on their bottoms cracks from diarrhea. In more serious cases, they have seizures and remain hospitalized for up to two months.

The diagnosis for these babies is neonatal abstinence syndrome, a group of problems caused by maternal opiate use during pregnancy. The incidence of such cases has nearly tripled in the past decade, data show.

In 2009, the syndrome was diagnosed in newborns at a rate of 3.4 per 1,000 hospital births per year. That was up from 1.2 diagnoses per 1,000 births per year in 2000.

“It was a common problem in the 1980s [to have babies born to mothers addicted to crack cocaine], but it didn’t fill up hospital beds like what I’m seeing now,” said Dr. Gaylord, a neonatologist at the University of Tennessee Medical Center. “It’s not just a problem for all those poor folks or just for people in East Tennessee. This is a systemic problem from rich to poor, white to black and Latino.”

Neonatologists say it is unclear what percentage of neonatal abstinence syndrome cases are due to mothers appropriately taking opioids that were prescribed to them and how many cases are caused by mothers using the drugs illicitly. But they agree that the rise in use and abuse of pain medications in the United States likely is contributing to the rise in diagnoses.

Health professionals and policymakers are grappling with ways to remedy the abuse problem as addiction to prescription painkillers is occurring at alarming rates. More than 40 states have implemented prescription drug monitoring programs that identify patients who receive opioids from multiple physicians. In Florida, where prescription drug abuse and neonatal abstinence syndrome diagnoses are particularly high, the state Legislature passed a bill this year that calls for a task force to evaluate the extent of the syndrome among the states’ infants.

Health professionals say primary care doctors nationwide should be prepared to care for these children and their mothers. But even if family physicians and internists do not have pregnant patients who are taking opioids, they can help keep the problem from escalating, experts say.

For example, before prescribing an opioid to women of childbearing age, physicians should discuss the potential negative health effects the drug could have on a fetus if the patient becomes pregnant, said Mark L. Hudak, MD, a neonatologist at the University of Florida College of Medicine-Jacksonville.

Addiction psychiatrist David Sack, MD, encourages doctors to consider giving a urine toxicology screen to all pregnant women to identify any who are abusing opioids. He said some physicians might hesitate to conduct such testing routinely, because many states require doctors to report a pregnant woman’s drug abuse to social services. But he said the urine toxicology screen is effective in identifying substance abuse and ultimately will help ensure the health of the unborn child.

“We need to be clear that this is an illness, and we need to help and support these women so they can have healthy babies,” said Dr. Sack, CEO of California-based Elements Behavioral Health, which offers addiction treatment programs at facilities across the country.

Opiate use climbing in pregnant women

Nationally, an estimated 13,539 newborns had neonatal abstinence syndrome in 2009 compared with 4,682 babies in 2000, according to a study published online April 30 in *The Journal of the American Medical Association*. To put that in perspective, about one child born every hour had the syndrome, said lead study author Stephen W. Patrick, MD, MPH.

The increase is significant, because it is occurring in a population that usually has no health complications, said Dr. Patrick, a fellow in the University of Michigan Health System’s Division of Neonatal-Perinatal Medicine. The number of pregnant women who were dependent on or using opiates when they delivered climbed from 4,839 in 2000 to 23,009 in 2009, he said.

Researchers did not identify the types of opiates mothers were using, such as heroin, methadone or pain relievers, Dr. Patrick said. But, he added, “We know in the general population opioid pain reliever use and abuse has grown substantially. Probably some of the increase we’re seeing [in the *JAMA*] study is attributed to opioid pain relievers.”

Nationally, about 12 million Americans age 12 and older took prescription pain medications for nonmedical reasons in 2010, according to the Centers for Disease Control and Prevention. Overdose deaths from these drugs in the U.S. have nearly quadrupled in the past decade. In 2008, opioid prescription painkillers were involved in 14,800 drug overdose deaths, up from 4,000 in 1999, the CDC said.

The increase comes as national sales of opioid pain relievers to hospitals and elsewhere continue to climb. Sales rose from 1.8 kg per 10,000 people in 1999 to 7.1 kg per 10,000 people in 2010, the CDC said.

Contributing to the abuse of pain relievers is the belief among some patients that prescription drugs are safe because they are administered by physicians and manufactured in legitimate factories, Dr. Sack said. There also are some well-meaning doctors who are misinformed about the benefits and downsides of opioid pain relievers and thus overprescribe the drugs, health professionals say.

In many instances, women taking painkillers during pregnancy were prescribed the drugs at earlier points in their lives and got addicted to them, Dr. Gaylord said.

Pain medicine specialists point out that pain medications can have an appropriate role during pregnancy. “It’s not bad to be on opioids when you’re pregnant if you have good care,” said pain medicine specialist Lynn Webster, MD. He added that more research is needed to determine if women are being treated with opioids appropriately and how pregnancy outcomes would be affected without the drugs.

“There are consequences of not addressing pain in women who are pregnant. That has to be kept in mind,” said Dr. Webster, president-elect of the American Academy of Pain Medicine.

Yet health professionals worry that as abuse of opioids continues to escalate, more babies will be born with neonatal abstinence syndrome, and there is limited information about the long-term health effects of *in utero* exposure to these drugs.

“When moms [who took opioids during pregnancy] ask me, ‘What did I do to my baby?’ I tell them, ‘This can’t be good for their developing brain,’ ” but doctors don’t know exactly how the baby will be affected, said Jonathan Wispe, MD, a neonatologist at Nationwide Children’s Hospital in Columbus, Ohio.

Many with syndrome go unidentified

Babies with neonatal abstinence syndrome often do not begin showing signs of withdrawal until two to three days after birth, depending on when the mother last took the opioid and how much she consumed, Dr. Wispe said. That means there are many babies physicians are unable to identify because the mother and child are released from the hospital before the symptoms appear, he said.

When a baby is diagnosed with neonatal abstinence syndrome, the newborn is kept in an area with low light and little noise, and is held and rocked by nurses and volunteers. The length of the hospital stay can vary from a week to two months.

When the child is released, care often falls to a general pediatrician. Dr. Wispe encourages such doctors to look for signs of withdrawal that can recur in newborns and to link them to specialized care if developmental delays are identified as they get older.

Health professionals agree that family physicians and internists should ask patients in a nonjudgmental way about whether they use prescription or illicit drugs. They also recommend that primary care doctors regularly talk to pregnant patients about the potential harms in drinking alcohol, smoking and using prescription opioids and some over-the-counter medications.

But some experts hesitate to suggest universal urine toxicology screening for all pregnant patients, due in part to the time it would take. A positive test also could prompt social services agencies to get involved.

Instead, several neonatologists interviewed for the story suggest screening individuals who have an increased risk of substance abuse, such as those whose parent or partner abuses prescription or illicit drugs.

“It is a diverse group of mothers who are addicted to opiates. Some of them are abusing street drugs,” Dr. Patrick said. “Some are being treated for chronic pain and others are in methadone treatment programs. Because of that [diversity], this is a complex issue that is going to require answers that are not simple.”

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ADDITIONAL INFORMATION

Health problems of newborns with neonatal abstinence syndrome

The number of U.S. babies diagnosed with neonatal abstinence syndrome nearly tripled from 4,682 in 2000 to 13,539 in 2009. These newborns are more likely to have trouble breathing, low birth weight, feeding difficulties and seizures.

Conditions	Neonatal abstinence syndrome	All other U.S. hospital births
Respiratory diagnoses	30.9%	8.9%
Low birth weight (less than 2,500g)	19.1%	7.0%
Feeding difficulty	18.1%	2.8%
Seizure	2.3%	0.1%

“Neonatal Abstinence Syndrome and Associated Health Care Expenditures, United States, 2000-2009,” *The Journal of the American Medical Association*, published online April 30 ([link](#))

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EXTERNAL LINKS

“Neonatal Abstinence Syndrome and Associated Health Care Expenditures, United States, 2000-2009,” *The Journal of the American Medical Association*, published online April 30 ([link](#):

<http://jamajama.jamanetwork.com/article.aspx?volume=307&issue=18&page=1934>)

“Vital Signs: Overdoses of Prescription Opioid Pain Relievers — United States, 1999-2008,” *Morbidity and Mortality Weekly Report*, Nov. 4, 2011 ([link: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm))

“Neonatal Drug Withdrawal,” *Pediatrics*, February ([link: http://www.ncbi.nlm.nih.gov/pubmed/22291123/](http://www.ncbi.nlm.nih.gov/pubmed/22291123/))

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Huge Increase In Maternal Opiate Use In Nine Years

01 May 2012 [Click to Print](#)



Five times as many pregnant women were using opiates in 2009 compared to 2000, while during the same period the number of newborns with a diagnosis of drug withdrawal syndrome, neonatal abstinence syndrome has increased 3-fold, researchers from the University of Michigan Health System, Ann Arbor, Michigan, reported in *JAMA (Journal of the American Medical Association)*. The authors added that hospital charges related to neonatal abstinence syndrome (NAS) have increased considerably.

According to a recent USA-wide study, 16.2% of pregnant teenagers and 7.4% of pregnant mothers aged from 18 to 25 took illegal drugs, the researchers explained.

Neonatal abstinence syndrome, or **NAS** is a set of problems that newborns experience when they are exposed to addictive prescription or illegal drugs while they were in their mother's uterus. NAS occurs because the mother, while pregnant, took addictive drugs (prescription or illegal), such as cocaine, diazepam, marijuana, opiates (heroin, codeine, methadone), barbiturates, or amphetamines.

The drugs pass through the placenta and reach the embryo/fetus. Along with the mother, the baby becomes addicted. When the problem is related to alcohol, doctors may use the term Fetal Alcohol Syndrome.

The authors explain that low birth weight and higher mortality are also associated with illicit drug use during pregnancy, especially opioids.

The following signs and symptoms may be associated with neonatal abstinence syndrome:

- Feeding intolerance
- Hypertonia (heightened muscle tone)
- Irritability
- Respiratory distress
- Seizures
- Tremors

60% to 80% of newborns who had been exposed to methadone or heroin while in the womb are reported to

have NAS signs and symptoms.

However, there are not national estimates on how many newborns in the USA have NAS symptoms due to maternal opiate use.

Stephen W. Patrick, M.D., M.P.H., M.S., and team carried out a study to look at the patterns in the national incidence of NAS and maternal opiate usage at the moment of childbirth, and to characterize trends in national health care expenditures linked to NAS during the first nine years of this century.

The researchers found that between 2000 and 2009:

- The rate at which newborns were diagnosed with NAS rose from 1.20 per 1,000 hospital births per year to 3.39 per 1,000.
- The number of pregnant mothers using or dependent on opiates rose from 1.19 per 1,000 hospital births per year to 5.63 per 1,000.
- The amount hospitals charged, on average for newborns diagnosed with NAS rose by 35%, from \$39,400 to \$53,400
- Estimates for total hospital charges nationwide, adjusting for inflation, rose from \$190 million to \$720 million
- It was estimated that 14,539 babies were born with NAS in 2009

The researchers wrote:

"Compared with all other hospital births, newborns with NAS were significantly more likely to have respiratory diagnoses (30.9 percent), to have low birth weight (19.1 percent), have feeding difficulties (18.1 percent), and have seizures (2.3 percent). Newborns with NAS were also more likely to be covered by Medicaid (78.1 percent) and reside in zip codes within the lowest income quartile (36.3 percent)."

In an Abstract in the same journal, the authors concluded:

"In conclusion, newborns with NAS experience longer, often medically complex and costly initial hospitalizations. The increasing incidence of NAS and its related health care

expenditures call for increased public health measures to reduce antenatal exposure to opiates across the United States.

In addition, further innovation and standardization of treatment of NAS may mitigate NAS symptoms and reduce hospital LOS. States are poised to seek innovative solutions to decreasing the burden of NAS, because the majority of hospital expenditures for this condition are shouldered by state Medicaid programs."

Accompanying Editorial

Marie J. Hayes, Ph.D., of the University of Maine, Orono, and Mark S. Brown, M.D., of Eastern Maine Medical Center, Bangor wrote:

"Future directions in NAS research must address the need for clinical trials of new medications to establish optimal protocols for maternal opiate dependence with particular focus on methadone treatment induction of the mother early in pregnancy, maternal adherence to treatment, ancillary alcohol use monitoring, and psychiatric care.

Postnatally, early identification and aggressive opiate replacement in infants with early signs of NAS may help to decrease severity and LOS. As suggested by Patrick et al and other studies, breastfeeding may reduce treatment rate and LOS in opiate-exposed infants in all categories. Clues to fetal-neonatal dependence and NAS risk are emerging from studies of placental transfer of opiates across gestation, relation to maternal dose change, infant pharmacogenomics, and meconium [stool of an infant] metabolites to determine other exposures. This additional information may lead to better postnatal care of infants with NAS."

Written by Christian Nordqvist

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References:

"Neonatal Abstinence Syndrome and Associated Health Care Expenditures - United States, 2000-2009"
Stephen W. Patrick, MD, MPH, MS; Robert E. Schumacher, MD; Brian D. Benneyworth, MD, MS; Elizabeth E. Krans, MD, MS; Jennifer M. McAllister, MD; Matthew M. Davis, MD, MAPP
JAMA Published online April 30, 2012. doi: 10.1001/jama.2012.3951

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Dear Senator Miller,

Thank you for the opportunity of assisting you in some manner with your investigation into the alarming trend of Methadone related deaths. Since taking office in January of this year, we have been plagued with an unusually high rate of death due to accidental or deliberate overdose. Aside from increasing abuse of Heroin, Cocaine, and Prescription drugs i.e. Oxycodone, we are finding mixed "cocktails" so instantly fatal we are again finding decedents with needles still in their veins. The alarming rate of 23% have tested positive for Methadone. We have a clinic located here in Richmond that appears to be very busy, but we were chagrined to recently learn that the practice of sending doses home with program participants exists. If we can be of further assistance to you in any way, feel free to contact us.

Sincerely,

Row Stevens
Wayne Co. Coroner