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Dr. Danita Johnson Hughes  
Dr. Brenna McDonald



# COMMISSION ON MENTAL HEALTH AND ADDICTION

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Authority: IC 12-21-6.5

## MEETING MINUTES<sup>1</sup>

Meeting Date: September 9, 2013  
Meeting Time: 10:00 A.M.  
Meeting Place: State House, 200 W. Washington St., Room 431  
Meeting City: Indianapolis, Indiana  
Meeting Number: 2

**Members Present:** Sen. Patricia Miller, Chairperson; Rep. Steve Davisson; Rep. Charlie Brown; Dr. Kathleen O'Connell; Margie Payne; Ronda Ames; Valerie N. Markley; Bryan Lett; Caroline Doebbling; Kurt Carlson; Chris Taelman; Rhonda Boyd-Alstott; Dr. Brenna McDonald.

**Members Absent:** Sen. Lindel Hume; Jane Horn; Dr. Danita Johnson Hughes.

Senator Miller (Chair) called the Commission on Mental Health and Addiction (Commission) to order at 10:05 a.m. and began to take testimony concerning prescription drug abuse.

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<sup>1</sup> 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.

**Greg Zoeller**, Attorney General, Office of the Indiana Attorney General

Attorney General Zoeller spoke to the Commission concerning Indiana's prescription drug epidemic (Exhibit #1). His presentation included the following:

- In September of 2012 he launched and chaired Indiana's statewide Prescription Drug Abuse Task Force (Task Force). The Task Force includes individuals from every facet of assistance related to prescription drug abuse.
- The Task Force was modeled after the White House Office of National Drug Control Policy of 2011. However, in Indiana an additional committee was created under the Task Force that focused on treatment and recovery to address ways to increase access to treatment for those addicted to prescription drugs.
- The National Institute on Drug Abuse estimates that seven million Americans currently abuse prescription drugs.
- The 2011 Youth Risk Behavior Survey results showed that more than one out of five Indiana high school students had taken prescription medications prescribed to someone else for non-medical reasons.
- Nationally, every hour a baby is born suffering from opioid withdrawal which is known as neonatal abstinence syndrome (N-A-S).
- Tennessee and Florida have enacted legislation requiring N-A-S to be reported to the state department of health. He would like a similar requirement in Indiana.
- Identification and management of addicted pregnant patients would help reduce the incidents of N-A-S.
- Opiate addiction is a brain disease. Addiction treatment professionals understand this disease and have the expertise to treat it. Unfortunately Indiana has an extreme shortage of these professionals.

In response to questions by the Commission, Attorney General Zoeller stated the following:

- A stronger penalty is needed for medical providers who over prescribe pain medicines other than taking away their license to prescribe. Their license to practice medicine should also be taken away.
- He would like the Task Force to examine the issues concerning the prescription of addictive drugs at hospital emergency rooms.

**Lindsay M. Harmon, M.D.**, Indiana University Health - Methodist Hospital

Dr. Harmon stated that she is an emergency room physician and has witnessed the effects of overdoses. Her testimony included the following information:

- Pain is the number one complaint of patients at the emergency room.
- In the 1990's pain was under-treated. As a result there was a push to treat pain.
- She sees patients about every shift that she suspects of abusing pain medicine.

Dr. Harmon concluded by sharing the story of two patients who were in the pain management program to reduce their dependency on pain medications.

In response to a question from the Commission, she stated that the INSPECT program needs to have a shorter lag time from when information is entered to when it is available to physicians.

**Stephen McCaffrey**, President/Chief Executive Officer, Mental Health America of Indiana

Mr. McCaffrey stated that he was the chair of the Treatment and Recovery Standing Committee of the Prescription Drug Abuse Task Force. His remarks to the Commission (Exhibit #2) included the following information:

- Treatment and recovery are key components to respond to the prescription drug abuse problem.
- Treatment for addiction to prescription drug abuse must include a focus on medication and therapy. Detoxification is an important part of the recovery process.
- Therapy is critical to treatment, but obtaining therapy will become even more difficult in the future. There is already a behavioral health workforce crisis and the workforce crisis will be made larger with the implementation of the Affordable Care Act.
- There is a need for additional addiction field professionals, especially since the existing work force is aging. He encouraged the Commission to legislatively modify the Mental Health Development Program to encourage individuals to enter the addiction field.

In response to a question from the Commission, he stated that the drug formulary at the Department of Correction has improved, mostly because of drugs becoming available as generic drugs. The problem has not been solved but it is being addressed.

**R. Andrew Chambers, M.D.**, Associate Professor of Psychiatry, Indiana University School of Medicine

Dr. Chambers distributed two articles he had written concerning Dual Diagnosis Physicians (Exhibit #3) and he presented a PowerPoint presentation (Exhibit #4) entitled "The Collapsing Psychiatric Workforce In Indiana: Implications and Solutions". Information from the presentation included the following:

- Substance use disorders are the number one cause of medical illness and premature death in the United States and are suffered by 20-30% of the general adult population. Substance use disorders are hyper-concentrated in those with mental illness where rates range from 50-80%.
- In 2007, 30% of state hospital positions, 33% of addiction treatment centers and 11% of community mental health centers (CMHC) psychiatric positions were unfilled.
- Psychiatrists aged 50-54 outnumbered those younger than 35 years old by 3-fold. Other professions within the behavioral health workforce are also not generating enough new professionals to keep pace with the aging-out of professionals in the future.
- Psychiatry is among the lower paid medical specialties.
- Two ways to address work force shortages in psychiatry, addiction psychiatry, and behavioral health include: (1) adequate loan repayment programs; and (2) parity of insurance reimbursement for mental health and addiction treatment services.

In response to questions from the Commission, Dr. Chambers stated the following:

- There is a state loan forgiveness program but it has not been funded.
- Some people are Stage 4 addicts who will need to be on drugs the rest of their life. However, you cannot determine who is a Stage 4 addict until you try to get

them off of drugs.

**Zoe Frantz**, Program Director, Terre Haute Regional Hospital

Ms. Franz indicated that she has served on the Prescription Drug Abuse Task Force. She shared her experience of trying to help her brother receive detoxification services. (Exhibit #5) Her brother was denied Medicaid treatment services for his opiate pain medicine addiction. His addiction lead to an overdose coma that sent him to the hospital. When he was released he was prescribed the same drugs that caused the overdose. It was only through her personal connections that her brother finally received the inpatient treatment that he needed. She would like the rule (i.e. 405 IAC 5-17-5) changed so that services are not denied to other people who seek addiction treatment services.

**Larry Humbert**, Executive Director, Indiana Perinatal Network

Mr. Humbert stated that he has been involved in conducting work shops throughout the state to help train providers to screen pregnant women for drug addiction since 2007. He distributed information concerning N-A-S, the use of the drug buprenorphine during pregnancy, and an article entitled "Opioid Dependence in Pregnancy: An Evidence-based Toolkit" (Exhibit #6). His testimony included the following points:

- Medical providers need to make sure they verbally screen pregnant patients for alcohol, tobacco, and drug use.
- Physicians need more education to know how to manage the treatment of drug addicts during pregnancy.
- More obstetricians need to be certified to prescribe certain drugs that help with the treatment of addictions.
- Information on drug addiction must reach women before they become pregnant (e.g. when prescribing contraceptives). Also, the use of long acting reversible contraception for women of childbearing age with substance use issues should be encouraged.
- Pregnant women who are addicts should not be shamed for their addiction but rather positively encouraged through their treatment.
- Support services must be expanded as addiction treatment increases for pregnant women.

In response to a question by the Commission, Mr. Humbert stated that the medical community already treats women for many different conditions for the health of the baby, and drug addictions should be added to the list of conditions that are treated.

**John Ellis, M.D.**, Indiana State Medical Association (ISMA) Alternate Trustee , Member ISMA Task Force on Prescribing Pain Medications

Dr. Ellis indicated that the ISMA would be releasing a resolution supporting drug testing for pregnant women. Dr. Ellis's testimony included the following:

- There is currently a drug addiction screening tool that physicians can use. Positive responses on the screening help physicians determine if a urine drug test should be performed to confirm the addiction.
- ISMA supports education of all physicians concerning the use of drugs during pregnancy. Some physicians are concerned about the effect of medications on a

fetus and will cut off all prescriptions if they discover that the patient is pregnant.

In response to a Commission question, Dr. Ellis stated that cases of fetal alcohol syndrome are not tracked.

**James Ryser, MA, LMHC**, Program Coordinator, Chronic Pain Rehabilitation Program, Indiana University Health – Methodist Hospital

Mr. Ryser provided information about his experiences with drug addiction and treatment (Exhibit #7) including the following:

- He was born with spina bifida, has had 55 surgeries in his lifetime, and suffers from chronic pain.
- He was prescribed pain medications for his chronic pain and eventually became addicted to opioids. He believed that if something was prescribed it could not be dangerous. He has been free of his addiction since 1999 after completing an abstinence based rehabilitation program.
- Acute pain, cancer pain, and chronic pain are not the same. They should not be treated the same medically or legislatively.
- He fears that legislating pain medications will cause doctors to drop patients, resulting in the patients seeking ways to self medicate. He fears that without legislation addicts will continue to believe that if the drug is prescribed it is safe.
- The INSPECT program should be available to clinical addiction counselors.
- Pain clinics should not be allowed use medications for off-label prescribing.

In response to a question by the Commission, Mr. Ryser stated that addicts need to have access to treatment, but most people do not have the resources to pay for addiction treatment.

**Marty Cangany, MSN, RN, ACNS-BC**

Ms. Cangany has practiced as an advanced practice nurse for the past 23 years. She told the story of her son's death from an overdose of methadone that he purchased on the streets. (Exhibit #8) Methadone accounts for about 2% of all prescriptions but is involved in 30% of drug overdose deaths. She made the following recommendations:

- Institute rules governing the accessibility of prescription pain killers.
- Require prescribing providers to be accountable.
- Enact laws to prevent doctor shopping.
- Provide better access to substance abuse treatment.
- Monitor and review drug prescriptions.
- Educate the public concerning prescription drug abuse.

In response to a Commission question, Ms. Cangany stated that methadone can be prescribed by any physician, not just in methadone clinics. Physicians are starting to prescribe methadone for pain management. Methadone is dangerous because it has a much longer half-life than many other drugs.

**Andrea Hern**, Division of Mental Health and Addiction (DMHA), Family and Social Services Agency

Ms. Hern provided a PowerPoint presentation entitled "Addiction Prevention and Treatment" (Exhibit #9) that included the following:

- Information on DMHA's responsibilities.
- Funding for addiction prevention and treatment.
- The number of certified addiction providers.
- Funding allocations.
- The location of community mental health centers.
- The number of persons served.
- Medicaid coverage for persons with an addiction.

Ms. Hern noted that an addiction is not one of the disability criteria under the Medicaid program.

The Chair concluded the meeting by noting that the federal laws do not allow states to track an individual's methadone use.

The Chair adjourned the meeting at 12:35 p.m.

**Indiana Commission on Mental Health and Addiction  
Remarks by Indiana Attorney General Greg Zoeller  
Sept. 9, 2013**

**GOOD MORNING. THANK YOU CHAIRWOMAN MILLER AND THE MEMBERS OF THE COMMISSION FOR INVITING ME TO SPEAK AT YOUR HEARING TODAY ABOUT INDIANA'S PRESCRIPTION DRUG ABUSE EPIDEMIC.**

**WHILE PRESCRIPTION DRUGS PROVIDE RELIEF TO MILLIONS OF PEOPLE EVERY YEAR WHEN USED APPROPRIATELY, THE ABUSE OF THESE ADDICTIVE AND SOMETIMES DEADLY DRUGS HAS BECOME ONE OF THE GRAVEST ISSUES FACING OUR STATE. THAT'S WHY LAST SEPTEMBER I LAUNCHED INDIANA'S FIRST AND ONLY STATEWIDE PRESCRIPTION DRUG ABUSE TASK FORCE. AS CHAIRMAN, I FELT IT WAS CRITICAL TO ENSURE THE TASK FORCE INCLUDED EVERY FACET OF ASSISTANCE. OUR TASK FORCE INCLUDES STATE LEGISLATORS, LAW ENFORCEMENT, HEALTH OFFICIALS, MEMBERS OF THE MEDICAL COMMUNITY, PHARMACISTS, STATE AND LOCAL AGENCIES AND EDUCATION PROVIDERS.**

**WE MODELED THE TASK FORCE AFTER THE WHITE HOUSE OFFICE OF NATIONAL DRUG CONTROL POLICY OF 2011 -- WITH ONE DISTINCT DIFFERENCE. BOTH MODELS INCLUDE EDUCATION, ENFORCEMENT, PRESCRIPTION DRUG MONITORING PROGRAMS AND SAFE DISPOSAL. INDIANA'S TASK FORCE OFFERS A FIFTH, AND VERY CRITICAL, COMMITTEE-- FOCUSED ON TREATMENT AND RECOVERY TO ADDRESS WAYS TO INCREASE ACCESS TO TREATMENT FOR THOSE ADDICTED TO PRESCRIPTION DRUGS. OUR COMMITTEE MEMBERS WHICH YOU WILL HEAR FROM TODAY HAVE BEEN WORKING TO IDENTIFY POSSIBLE SOLUTIONS TO BARRIERS THAT PREVENT HOOSIERS ADDICTED TO OPIATES TO SEEK TREATMENT.**

**THEY HAVE ALSO EXPANDED THEIR EFFORTS TO TACKLE THE ISSUE OF NEONATAL ABSTINENCE SYNDROME, MORE COMMONLY KNOWN AS N-A-S. THESE EXPERTS WILL BE SHARING THEIR KNOWLEDGE AND EXPERTISE ON THE PROBLEM OF N-A-S.**

**ACCORDING TO THE NATIONAL INSTITUTE ON DRUG ABUSE, 7 MILLION AMERICANS CURRENTLY ABUSE PRESCRIPTION DRUGS – THAT’S MORE THAN THE NUMBER USING COCAINE, HEROIN, HALLUCINOGENS AND INHALENTS COMBINED.**

**IN 2011, 718 HOOSIERS DIED FROM ACCIDENTAL DRUG OVERDOSES, ACCORDING TO THE INDIANA STATE DEPARTMENT OF HEALTH. THIS EPIDEMIC EXTENDS FAR BEYOND THE NUMBER OF OVERDOSE DEATHS. FOR EVERY ONE DEATH, THERE ARE 10 TREATMENT ADMISSIONS FOR ABUSE, 32 EMERGENCY ROOM VISITS FOR ABUSE, 130 PEOPLE WHO ABUSE OR ARE DEPENDENT, AND 825 NON-MEDICAL USERS – INCLUDING OUR YOUTH.**

**THE 2011 YOUTH RISK BEHAVIOR SURVEY RESULTS SHOWED THAT MORE THAN ONE OUT OF FIVE INDIANA HIGH SCHOOL STUDENTS HAVE TAKEN PRESCRIPTION MEDICATIONS PRESCRIBED TO SOMEONE ELSE FOR NON-MEDICAL REASONS. IN FACT, OUR YOUTH RANKED FIFTH HIGHEST NATIONALLY – THAT’S NOT A STATISTIC THAT WE SHOULD BE PROUD OF.**

**ALSO NATIONALLY, SOMEONE IN THE U.S. DIES EVERY 25 MINUTES FROM A PRESCRIPTION DRUG OVERDOSE. AND EVERY HOUR, A BABY IS BORN SUFFERING FROM OPIOID WITHDRAWAL.**

**A LOCAL NEONATOLOGIST AND GUEST SPEAKER OF MY PRESCRIPTION DRUG ABUSE SYMPOSIUM LAST YEAR, DR. PAUL WINCHESTER, SAID THAT IN 2001, HE WOULD SEE AN AVERAGE OF ONE BABY PER YEAR BORN WITH N-A-S...NOW HE SEES *AT LEAST* ONE PER WEEK. IN 2010, IT WAS ESTIMATED THAT INDIANA HOSPITAL CHARGES FOR N-A-S CASES TOTALED NEARLY \$30 MILLION. CURRENTLY, N-A-S IS NOT A DISEASE THAT IS REQUIRED TO BE REPORTED TO OUR STATE DEPARTMENT OF HEALTH.**

**TENNESSEE AND FLORIDIA HAVE ENACTED LEGISLATION REQUIRING N-A-S TO BE REPORTED TO THE STATE DEPARTMENT OF HEALTH. I WOULD SUGGEST THAT MORE CONSISTENT AND ACCURATE DATA NEEDS TO BE COLLECTED ON THIS DISEASE SO WE MAY COME UP WITH BETTER SOLUTIONS TO COMBAT IT.**

**IN INDIANA, OBSTATRICIANS ARE NOT REQUIRED TO SCREEN PREGNANT MOTHERS FOR ADDICTION OF CONTROLLED SUBSTANCES. YET IDENTIFICATION AND APPROPRIATE MANAGEMENT MAY SUBSTANTIALLY REDUCE THE POTENTIAL RISK TO THE MOTHER AND THE FETUS.**

**OUR TASK FORCE SUPPORTS RECOMMENDATIONS TO PUT CRITICAL CHANGES IN PLACE TO COMBAT N-A-S. THESE ARE SMALL STEPS TOWARDS A HUGE PROBLEM, BUT WE RECOGNIZE WE NEED TO START SOMEWHERE.**

**OPIATE ADDICTION IS A BRAIN DISEASE. ADDICTION TREATMENT PROFESSIONALS UNDERSTAND THIS DISEASE AND HAVE THE EXPERTISE TO TREAT IT. UNFORTUNATELY INDIANA HAS AN EXTREME SHORTAGE OF THESE PROFESSIONALS. WE MUST MAKE IT A PRIORITY TO TRAIN AND RETAIN MORE ADDICTION PROFESSIONALS IN OUR STATE TO MEET THE EVER-MOUNTING NUMBER OF OPIATE ADDICTED HOOSIERS, INCLUDING PREGNANT WOMEN, TO TREAT THIS BRAIN DISEASE.**

**WE ARE FACING A COMPLEX PROBLEM THAT REQUIRES ALL STAKEHOLDERS WITH VARIOUS EXPERTISES TO COLLABORATE AND TARGET COMPREHENSIVE SOLUTIONS. THAT'S WHY THE PRESCRIPTION DRUG ABUSE TASK FORCE ENCOURAGES THE INDIANA GENERAL ASSEMBLY TO SUPPORT THE EFFORTS OF THE TREATMENT AND RECOVERY COMMITTEE TO WORK TOWARD THE COMMON GOAL OF HELPING FAMILIES AFFECTED BY THIS EPIDEMIC AND TO SAVE HOOSIER LIVES BEFORE IT'S TOO LATE.**

**THANKS AGAIN FOR ALLOWING FOR ME TO SPEAK BEFORE YOUR COMMITTEE TODAY. I WOULD LIKE TO REQUEST THAT YOU HOLD YOUR QUESTIONS UNTIL YOU HEAR MORE INFORMATION FROM MY VERY CAPABLE TASK FORCE MEMBERS AS THEY ARE THE REAL SUBJECT MATTER EXPERTS ON THESE ADDICTION ISSUES.**

Thank you madam Chair, my name is Steve McCaffrey and I am President and Chief Executive Officer of Mental Health America of Indiana. I very much appreciate the opportunity to speak to you regarding the prescription drug abuse problem in Indiana.

I would like to commend the Attorney General for taking on the issue of Prescription Drug Abuse in Indiana.

Additionally, I would particularly like to commend the Attorney General for recognizing that treatment and recovery is a key component to responding to the Prescription Drug Abuse Problem. Certainly, enforcement is important, but a comprehensive solution must include treatment and recovery.

As a result, the Attorney General created a Treatment and Recovery Standing Committee of the Prescription Drug Abuse Task Force and I was asked to chair the committee. Much of what is on today's agenda came from the recommendations of the committee that were then approved by the full Task Force and several members of the committee will be testifying today.

Prescription drug abuse has become a major epidemic both in Indiana and across the US. Dr. Eric Wright serves on the Task Force and has provided much needed data. To simplify and paraphrase his conclusions:

1. Prescription drug abuse is unfortunately well entrenched in our state. Over the last 8 years, nonmedical prescription pain reliever use in Indiana has hovered around +or-6 % in Indiana and around +or-5% nationally.
2. The highest prevalence has been for opioids among 18-25 yrs.
3. The greatest misuse among Indiana College students is among those without a prescription.
4. A majority of legally dispensed drugs are opioids (46%), exceeding stimulants (11%) and even anti-depressants (30%)
5. The number of drug overdose deaths involving opioid pain relievers has increased dramatically in the last decade (4 fold).
6. The demand for addiction treatment will increase significantly over the next few years due both to increasing rates of abuse and expanding efforts to identify and screen individuals in need of care.

Treatment for addiction to prescription drug abuse must include a focus on medication and therapy. Medications to treat addiction are important to treatment and recovery. As with mental health, appropriate medications must be accessible and addiction medications must be used appropriately.

The Mental Health and Medicaid Quality Advisory Committee was initially created to make recommendations regarding appropriate access to mental health medications in Medicaid. At the request of the Attorney General's Task Force on Prescription Drug Abuse, addiction medications were added by the Indiana General Assembly to the charge of the Quality Advisory Committee. Per SEA 246 the Quality Advisory Committee:

“shall advise the office and make recommendations concerning the clinical use of mental health **and addiction medications**, including the implementation of IC 12-15-35.5-7(c), and consider the following:

- (1) Peer reviewed and medical literature
- (2) Observational studies
- (3) Health economic studies
- (4) Input from physicians and patients
- (5) Any other information determined by the advisory committee to be appropriate”

In addition to medications, Detox from the drug addiction is also important to the recovery process and that will be discussed today as well. 405IAC 5-17-5 permits Medicaid reimbursement with PA criteria that is fairly subjective.

Therapy is critical to treatment, but such will become even more difficult. There is already a behavioral health workforce crisis and such will be made larger with the implementation of the Affordable Care Act. The Division of Mental Health and Addiction recognized this issue and formed the *Transformation Work Group*. That Group recommended the expansion of needed behavioral health professionals in Indiana.

Dr. Andrew Chambers will speak to this issue in detail as a member of the Treatment Committee and the chair of the DMHA committee on Workforce. In terms of Mental Health Commission action we will hope to work with you as you draft PDs to legislatively modify and support the *Mental Health Development Program*. This is a program that would encourage entry into the Addiction field through education loan forgiveness, fellowships, and other methods.

Addiction by women during Pregnancy is also a key issue in Opioid abuse. Sadly, the data now shows skyrocketing opioid use of women during pregnancy. Larry Humbert with the Perinatal Network and Dr Ellis with ISMA task force will discuss the issue in detail. In terms of Mental Health Commission action we will be requesting your support in requiring the screening of all pregnant women as the standard of care.

Madam Chair, I very much appreciate the Commission's willingness to attempt to address this critical issue and I especially appreciate the leadership of the Attorney General.

Thank You.

## GUEST EDITORIAL

# The Addiction Psychiatrist as Dual Diagnosis Physician: A Profession in Great Need and Greatly Needed

R. Andrew Chambers, MD

Addiction is the number one cause of premature illness and death in the U.S., especially among people with mental illness. Yet American medicine lacks sufficient workforce capacity, expertise, training, infrastructure, and research to support treatment for people with co-occurring addictions and mental illness. This essay argues that the addiction psychiatrist is essential in dual diagnosis care. (*Journal of Dual Diagnosis*, 9:260–266, 2013)

**Keywords** *addiction psychiatry, physician workforce shortages, public health crisis*

Substance use disorders are the leading cause of premature illness and death in the U.S. (Mokdad, Marks, Stroup, & Gerberding, 2004). Although people with addictions are still primarily cared for outside of insurance coverage and physician-directed care (Altman et al., 2012), addictions generate a major portion of disease, injury, and early mortality, including cancer, stroke, heart and lung diseases, dementia, HIV, and hepatitis, and many accidental and deliberate forms of injury, such as domestic violence (McGinnis & Foege, 1999). Meanwhile, the economic and social costs of viewing addiction as a criminal-legal problem rather than as an illness have been staggering (Altman et al., 2012; Pew Center on the States, 2009). The “War on Drugs” has cost an estimated \$1 trillion since 1970 and has made the U.S. the world’s leader in per-capita incarcerations (DrugWarFacts, 2012; The Sentencing Project, 2006). States are beginning to spend as much on incarceration as providing college education (DrugWarFacts, 2012; Kingkade & McGuinness, 2012). These trends contribute to skyrocketing health and education expenses for families, harming their economic vitality and educational attainment, with no measureable benefits on preventing or reducing addictions over the last quarter century. Addiction problems are compounded by the large overlap with mental illness, termed *co-occurring disorders* or *dual diagnosis* (Kessler et al., 1994). The ma-

jority of patients with addiction who are seeking treatment experience one or more mental illnesses, and most patients with mental illness have one or more addictions (Grant, 1996; Grant, Hasin, Chou, Stinson, & Dawson, 2004; Kessler, 2004; Kessler et al., 1994; Lasser et al., 2000).

In this essay I argue for the reinvigoration and expansion of addiction psychiatry. Health care for addictions and dual diagnosis patients in the U.S. has long been inadequate due to a lack of integration of mental health and addiction services (Drake et al., 2001). A declining psychiatric workforce, punctuated by extremely low production of formally trained and certified addiction psychiatrists, may undermine integrated dual diagnosis care further.

Building a strong workforce of certified addiction psychiatrists could address the problem of dual diagnosis. Currently, psychiatric addictionology has insufficient numbers and resources to provide an adequate educational and consultative impact within medical schools and psychiatry departments (Renner, 2004). Despite health services research delineating the need to integrate approaches to addictions and mental health (Drake et al., 2001), very few physicians are trained to deliver both addictions and mental health care. Addiction psychiatrists rarely appear in addiction treatment centers or even in integrated dual diagnosis programs (Chambers, Connor, Boggs, & Parker, 2010).

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## THE ADDICTION PSYCHIATRIST AS DUAL DIAGNOSIS PHYSICIAN

Physicians become addiction psychiatrists by completing four goals: (a) general psychiatry residency training (4 years);

(b) certification in general psychiatry via the American Board of Psychiatry and Neurology exam; (c) addiction psychiatry fellowship training (1 year) accredited by the Accreditation Council for Graduate Medical Education (ACGME); and (d) certification in addiction psychiatry (American Board of Psychiatry and Neurology subspecialty exam). At present, this pathway is the only way a physician can be formally trained and certified as an addiction specialist in the U.S., sanctioned by ACGME and the American Board of Medical Specialties (ABMS), and the only way any health care professional can receive training and certification in psychotherapeutic and pharmacological modalities of care for both mental illness and addictions. An alternative pathway provided by the American Society of Addiction Medicine/American Board of Addiction Medicine certifies physicians of any type in addiction medicine. This certification also requires an exam, but not formal training. However, the American Board of Addiction Medicine is pursuing ABMS/ACGME recognition for addiction medicine with a residency training requirement that circumvents psychiatry training (McNamara, 2007). Only physicians certified in addiction psychiatry can be training directors for addiction psychiatry fellowships. Addiction psychiatry training is the only way physicians are formally trained and certified to be dual diagnosis-capable, paralleling the way behavioral health systems are evaluated (e.g., the Dual Diagnosis Capability in Addiction Treatment [DDCAT]) for dual diagnosis capability (Chambers et al., 2010).

#### ADDICTION PSYCHIATRY: HISTORY, WORKFORCE SIZE, AND TRAINING INFRASTRUCTURES

After the American Society of Addiction Medicine first established a certification exam for physicians in addictionology in 1986, the American Board of Psychiatry and Neurology recognized addiction psychiatry as an ABMS subspecialty in 1993 (Galanter, 2011). Over 5 years, 1,776 addiction psychiatry certificates were awarded by exams without training requirements to seed the field (Galanter, Dermatis, & Calabrese, 2002). Subsequently, when fellowship training became required, new entries into the subspecialty sharply declined. From 1998 to 2002, fewer than 190 physicians graduated from addiction psychiatry fellowships nationwide (Tinsley, 2004). In the 2000s, fellowship numbers remained stagnant, filling only 55% of 108 positions in 2003 (Juil, Scheiber, & Kramer, 2004) and 47% of 116 positions in 2006 (McNamara, 2007). In 2000, only 1% of all U.S. psychiatry residents were enrolled in addiction psychiatry fellowships (Tinsley, 2004), decreasing to 0.8% by 2009 (Hales & Delanoche, 2009). Also by 2009, the number of addiction psychiatry programs and positions offered had fallen to 44 programs and 90 positions, with 74% (67) positions filled (Galanter, 2011). With fewer than 50 addiction psychiatry fellowship graduates per year since 1998,

these data suggest that fewer than 1,000 physicians in the U.S. have ever been formally trained and certified in addiction psychiatry. These numbers compare with 4,162 physicians receiving American Society of Addiction Medicine certification by 2007, about half of whom were psychiatrists (McNamara, 2007).

Less than 25% of all 184 American Psychiatry Residency Training Programs in the U.S. offer addiction fellowships (ACGME, 2013; www.acgme.org). In 2009, less than a third of U.S. medical schools and only 28 of 50 states offered an addiction psychiatry fellowship (Galanter, 2011). Large disparities across the states in addiction psychiatry training infrastructures punctuate weak overall workforce production (Figure 1). Only 9 states offer more than 0.05 fellowship positions per 100,000 population (i.e., 1 per 2 million), with New York, Connecticut, and Massachusetts together accounting for a third. The U.S. has a capacity to produce about one addiction psychiatrist for every three million people, while actually filling about 75% of this capacity, producing one addiction specialist for every four million. Given that approximately 25% of the U.S. population suffers with some form of addiction, and addictions collectively represent the leading cause of premature illness and death (Altman et al., 2012; Mokdad et al., 2004), these numbers reflect major health care workforce failures.

The emerging iatrogenic prescription drug epidemic may be related to the deficiency of addiction psychiatrists. Over the last 15 years, fivefold increases in opioid prescribing in primary care (CDC, 2011; Governale, 2010; Lembke, 2012) have resulted in proportional fivefold increases in unintended overdoses and deaths due to prescription drugs (CDC, 2011). By 2010, enough opioid medications were prescribed in the U.S. to maintain every adult on 6 opioid pills a day for a month (CDC, 2011), and Americans were more likely to die from poisoning, often by a prescription drug overdose than from a car accident or suicide (Minino, Murphy, Xu, & Kochanek, 2011). People with mental illness, at the center of this epidemic, are disproportionately vulnerable to and negatively impacted by these prescribing practices (Becker et al., 2009; Boscarino et al., 2010; Richardson et al., 2012). Among returning combat veterans with high rates of dual diagnosis, lethal opioid overdoses are occurring in alarming rates in the context of inadequate mental health and addictions expertise and treatment services at Veterans Administration (VA) hospitals (Bohnert et al., 2012; Institute of Medicine, 2012; Seal et al., 2012; Wallace, West, Booth, & Weeks, 2007). National VA hospital pharmacy data from 2010 characterizes the prescription and dispensation of opioid medications to veterans nationwide. Prescription data like these, and national measures of public health rankings (e.g., from the United Health Foundation, 2009), can be assessed in conjunction with population densities of addiction psychiatry training position offered (Figure 1) across the states, to probe for possible relationships between these measures and the strength of addiction psychiatry training infrastructures.

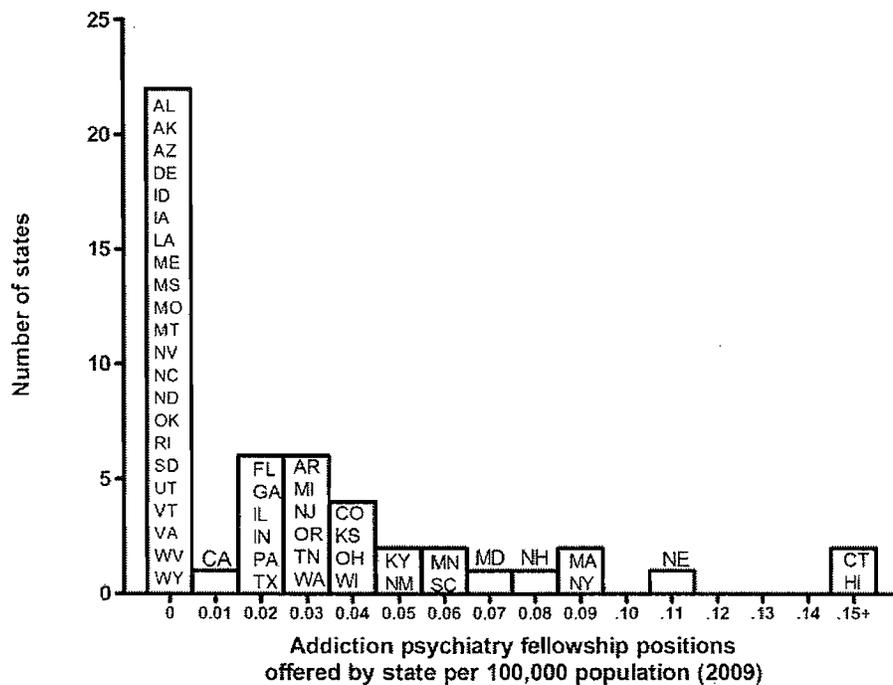


FIGURE 1 Histogram of the states grouped by numbers of addiction psychiatry fellowship positions offered by state per 100,000 population. Data in the figure were compiled from 2010 U.S. Census data (U.S. Census Bureau, 2010) and 2009 addiction fellowship census data from the Center for Medical Fellowships in Alcoholism and Drug Abuse (Galanter, 2011).

#### ADDICTION PSYCHIATRIST AS TRANSLATOR AND EDUCATOR OF ADDICTION NEUROSCIENCE

The view of addiction as a moral-criminal-legal problem rather than a treatable illness is rooted in a general lack of knowledge, even within the medical profession, regarding neural mechanisms and anatomy that underlie the disease. The concept that addiction is an illness explains the involuntary nature of addiction and its prevalence in people with mental illness and adolescents (Altman et al., 2012; Chambers, Krystal, & Self, 2001; Chambers, Taylor, & Potenza, 2003; Renner, 2004). The stigma rooted in lack of understanding addiction as a biomedical problem presents a major barrier to recruiting educational and economic support for expanding evidence-based treatments and increasing professional expertise. Beyond their importance in representing addictionology as a branch of psychiatry and medicine, addiction psychiatrists are needed to educate the public, other physicians, and mental health professionals about addiction neuroscience and its translation to clinical phenomenology and treatment.

The training of physician-scientists in the U.S. is in decline, despite calls from trainees, educators, and scientists to increase neuroscience training of psychiatrists (Naftolin, Lockwood, & Sobel, 2004; Roffman et al., 2006; Rosenberg, 1999). A direct connection between the National Institute on Drug Abuse (NIDA) and addiction psychiatry training programs or trainees has never been established. In 2011, only

59 investigators in the U.S. with MD or MD/PhD degrees were NIDA grant awardees with projects on the basic neuroscience of addictions (R01 or K-Awards). Within this set, only 12 (20%) had primary appointments within psychiatry departments, whereas 80% had appointments in basic science or clinical departments of medical schools (e.g., biochemistry, anesthesia, radiology) that do not treat dual diagnoses or addictions and do not train physicians in these treatments. No addiction psychiatrists were funded to do basic neuroscience in addictions. These trends suggest that NIDA funding for basic translational neuroscience in addiction is not supporting education or research in addiction psychiatry programs.

#### ADDICTION PSYCHIATRY: NEED FOR REVITALIZATION

A realistic dialogue is needed for counteracting three major dynamics driving workforce failures in addiction psychiatry. First, addiction psychiatry draws its recruits from general psychiatry, which is itself facing unprecedented challenges (Katschnig, 2010). As the number of American students entering psychiatry has declined since 1990 (Hales & Delanoche, 2009), medical schools have reduced psychiatric education in core curricula (Cutler, 2012). Psychiatry is now in the poorest condition among all major medical fields in terms of having the most unfavorable balance of aging workforce and average incomes (Figure 2; MGMA, 2012). In Indiana, for

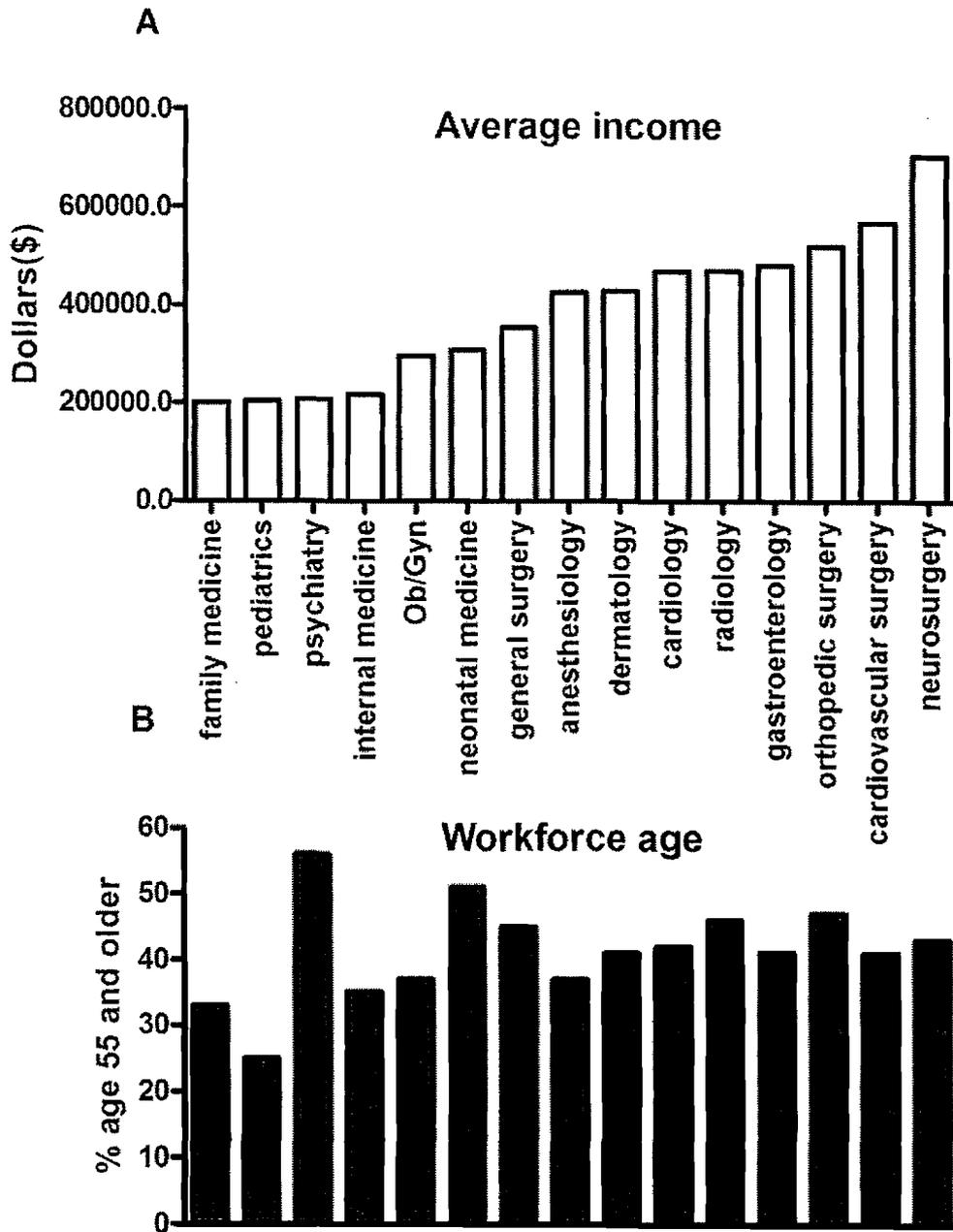


FIGURE 2 Indices of workforce vitality across major physician specialties. MGMA data from 2012 reveals psychiatry to be (a) among the lowest-reimbursed medical specialties (as with other primary care specialties) with (b) the most advanced age of workforce suggestive of a medical profession in decline.

example, about half of all psychiatrists are within a decade of the retirement age of 65, with only about a third as many in practice ages 30 to 34 compared to ages 50 to 54 (Chambers et al., 2010; MGMA, 2012). Similar trends are affecting social workers, psychologists, and nurses, endangering the entire behavioral health field (Lewis, Sheff, Richard, Brandt, & Zollinger, 2012).

Second, the behavioral health system of the U.S., including research, professional training, and clinical care, remains firmly entrenched in a segregated view of addictions and mental illnesses as unrelated entities (Gonzales & Insel, 2004; O'Brien et al., 2004). Even as most behavioral health patients live with dual diagnosis (Grant, 1996; Grant et al., 2004; Kessler, 2004; Kessler et al., 1994; Lasser et al., 2000), and despite mounting evidence suggesting the biological interrelatedness of these diseases (Chambers, 2013; Chambers et al., 2001; D'Souza et al., 2005; Lappalainen et al., 1998; Zhang, Stein, & Hong, 2010), NIDA, the National Institute of Mental Health, and the National Institute on Alcohol Abuse and Alcoholism still primarily fund research that focuses on drug abuse or alcohol abuse or mental illness as separate disorders. Similarly, clinical funding streams, professions, and treatment infrastructures remain segregated. Thus, despite an evidence-based consensus that integrated dual diagnosis services are the most effective and efficient standard of care (Drake et al., 2001; Drake & Wallach, 2000; Minkoff & Cline, 2004), the great majority of patients with co-occurring mental illness and addiction are still unable to access integrated treatments (Power & Demartino, 2004).

Third, without parity for addictions treatment reimbursement from both private and public insurers, addiction psychiatry expertise remains rare and financially unsupported. Fellowship training in addiction psychiatry does not significantly increase earning potential of psychiatrists in distinction to subspecialty training in all other medical fields where further training can double or triple incomes (MGMA, 2012). Meanwhile, no generally recognized clinical-professional standards or privileges empower, support, and require the unique expertise that addiction psychiatrists offer. Insurance companies are as likely to deny addiction treatment provided by an addiction psychiatrist as that provided by an obstetrician. With the exception of a required ACGME quota of two certified faculty addiction psychiatrists per addiction psychiatry fellowship, no standards of hospital accreditation or health insurance programs require addiction, mental health, or dual diagnosis treatment programs or medical schools to have addiction psychiatrists. Further, increasing medical school and undergraduate loan debt rules out careers in addiction psychiatry (let alone psychiatry) for many. While the median medical student loan debt increased from about \$24,000 in 1985 to \$117,000 in 2003 (Jolly, 2005), the costs of undergraduate education have risen similarly, burdening many residents with debts of \$250,000! Under these conditions, few can afford an additional sacrifice of another \$100,000 necessary for pursuing addiction psychiatry training.

## ADDICTION PSYCHIATRY: CREATING A NEW INITIATIVE

New initiatives are needed for reinvigorating and expanding addiction psychiatry as a strategy for avoiding the vast expenditures now spent on illness, injuries, and incarcerations resulting from iatrogenic and untreated addictions. An action plan might include (a) establishing student loan repayment programs for addiction psychiatry fellows; (b) establishing addiction treatment standards (including opiate maintenance programs) that require integrated dual diagnosis capabilities with certified addiction psychiatrists; (c) achieving parity of insurance coverage for dual diagnosis and addiction treatment, contingent on provision of care by certified addiction psychiatrists; (d) strengthening the American Psychiatric Association and ACGME standards for educational requirements in addictions in psychiatry training; (e) enhancing accreditation standards by the Liaison Committee on Medical Education, whereby American medical schools should include addiction psychiatry training programs; and (f) initiating extramural National Institutes of Health granting programs and policies to foster research training for addiction psychiatry fellows, enhancing success rates of basic and clinical neuroscience grant applications from departments that train addiction professionals and treat patients, and creating grant programs explicitly focused on dual diagnosis. Implementing measures like these with modest goals (e.g., of tripling the number of addiction psychiatrists and expanding fellowships to the majority of U.S. medical schools and psychiatry residencies) would require collaboration among many stakeholders and organizations spanning psychiatry, medical education, research, and the insurance industry. Reinvigorating and growing addiction psychiatry could promote a healthier population, a better economy, and a better quality of life in the U.S.

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## DISCLOSURES

The author reports no conflicts of interest and has no financial relationships with commercial interests.

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# The Dual Diagnosis Physician-infrastructure Assessment Tool: Examining Physician Attributes and Dual Diagnosis Capacity

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**Objective:** Inadequate physician training and involvement in addictions treatment are barriers to integrating mental health and addiction services in public behavioral health care. The authors designed and implemented the Dual Diagnosis Physician-infrastructure Assessment Tool (DDPAT) to quantify statewide dimensions of this workforce problem. **Methods:** The DDPAT examined institutional dual diagnosis capability and physician workforce, training backgrounds, and clinical roles across Indiana's 30 community mental health centers (CMHCs), six psychiatric hospitals, and 13 addiction treatment centers. **Results:** All treatment centers and 75% of physicians responded. Sixty-nine percent of all treatment centers and 97% of CMHCs reported dual diagnosis capability. However, 29% of physicians treated both mental illness and addic-

tions, and only 8% had certification in an addiction specialty. Overall workforce shortages, particularly of younger psychiatrists, contextualized these findings. **Conclusions:** The DDPAT identified multiple deficiencies in the physician workforce with respect to dual diagnosis and addictions care in Indiana. The DDPAT may be useful for characterizing similar trends in other states. (*Psychiatric Services* 61:184–188, 2010)

Substance use disorders involving nicotine, alcohol, and drugs collectively represent the leading cause of medical morbidity in the general population (1) and are hyperconcentrated among persons with mental illness, contributing significantly to their premature death rates and the total public health burden (2,3). Research spanning translational neuroscience, clinical epidemiology, and health care delivery shows that addiction and mental disorders are fundamentally linked (4,5), pointing to the need for integrated mental health and addictions services and professional expertise (6).

The development and implementation of tools that gauge clinical systems' capabilities in treating both psychiatric and substance disorders is an important focus of research on integrating care for these disorders (7). The COMorbidity Program Audit and Self-Survey for Behavioral Health Services (COMPASS) (8), the Integrated Dual Diagnosis Treatment (IDDT) Fidelity Scale (9), and the

Dual Diagnosis Capability in Addiction Treatment (DDCAT) (10) examine multiple parameters, including system structure; clinician staffing, responsibilities, and attitudes; availability of screening and treatment; and pathways of follow-up. Despite the comprehensiveness and utility of these instruments, however, none of them directly assess physician workforce size, training background, or clinical roles with respect to dual diagnosis care.

Insufficient training in the neuroscience and clinical care of addictions in medical schools and psychiatry residency programs may underpin a paucity of physician expertise and involvement in the care of patients with dual diagnoses nationwide (11,12). To measure these trends in the public-sector behavioral health physician workforce on a statewide level, the Indiana Division of Mental Health and Addiction (DMHA) sponsored the development of the Dual Diagnosis Physician-infrastructure Assessment Tool (DDPAT). We describe the design and implementation of the DDPAT in examining all public-sector treatment centers supported by DMHA, which, with an operating budget exceeding \$1 billion annually, funds public behavioral health for a Midwestern state with a population size approximating the mean of U.S. states.

## Methods

The DDPAT was constructed as a two-phase, Web-based or paper survey, with each phase consisting of ten

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questions. The box on this page provides a summary of the questions. [The complete DDPAT is available as an online supplement at [ps.psychiatryonline.org](http://ps.psychiatryonline.org).] Questions were designed to efficiently gather general and dual diagnosis-specific information about treatment centers and physicians. Phase I focused on the clinical attributes of treatment centers and asked for contact information of physicians employed by them; phase II focused on each physician's training background and clinical role. We estimated that phase I could be completed by administrative leaders within 15 minutes and phase II could be completed by physicians within ten minutes.

The DDPAT was administered to every treatment facility funded by Indiana's DMHA, including all six state psychiatric hospitals, all 30 community mental health centers (CMHCs), and all 13 stand-alone addiction treatment centers. Data collection was conducted over a nine-month period, from February 1, 2007, to October 31, 2007, primarily via the Internet by using WebSurveyor (Vovici) software. The first author contacted the administrative leadership of each center by e-mail, telephone, or letter to explain the purpose and parameters of the survey and encourage completion of phase I. Upon return of phase I results, the first author contacted individual physicians at each center by e-mail, telephone, or letter. Respondents were ensured that data would be analyzed in aggregate only and not for identifying or characterizing individual centers or physicians. Data collection ended when 100% of treatment centers completed phase I and at least 75% of the statewide physician workforce completed phase II. This study was granted exempt status by the institutional review board of the Indiana University School of Medicine.

## Results

All 49 treatment centers responded to phase I. Treatment centers reported a total of 286 physicians on staff, 215 (75%) of whom completed phase II. Physician response rates ranged from >93% at state hospitals and addiction treatment centers to 67% at CMHCs.

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## Summary of items on the Dual Diagnosis Physician-Infrastructure Assessment Tool

### Phase I: treatment centers

1. Name of organization
2. Number of treatment sites
3. Type of treatment provided (inpatient, outpatient, or both)
4. Primary treatment focus (mental illness, addictions, or both [separately or integrated])
5. Specific addictions services (inpatient detoxification or outpatient opiate treatment)
6. Patient population (primarily children, primarily adults, or both)
7. Number of unfilled physician positions (full-time equivalents)
8. Number of individual physicians on staff
9. Names and contact information of physicians
10. Number of nonphysician prescribers on staff

### Phase II: individual physicians

1. Physician identifier code
2. Age
3. Clinical specialty by residency training
4. Primary clinical role (psychiatric care, general addiction, treatment of opiate addictions, combination of psychiatric illness and addictions, or medical care)
5. Number of hours per week at this center
6. Site of residency training (in state, out of state, or other)
7. American Board of Psychiatry and Neurology (ABPN) certification in psychiatry
8. ABPN certification in addiction psychiatry
9. ABPN certification in child psychiatry
10. American Society for Addiction Medicine certification

Four of six hospitals, 11 of 13 addiction centers, and eight of 30 CMHCs had 100% physician response rates. [Detailed information on treatment center profiles, addiction services provided by treatment centers, the age distribution of physicians who responded to the survey, and the clinical focus of the treatment center and the physicians' treatment roles is available as an online supplement at [ps.psychiatryonline.org](http://ps.psychiatryonline.org).]

Hospitals provided only inpatient services, whereas short-term beds were provided by 22 (73%) CMHCs and four (31%) addiction centers. All CMHCs were composed of multisite outpatient facilities, whereas most addiction centers (N=9, 69%) had only one outpatient facility. Over half of all centers care for children and adults (N=28, 57%). One facility (2%), a state hospital, cares for children only.

Only five of the 19 (26%) hospitals and addiction centers described themselves as providing treatment for both mental illness and addictions. By contrast, 29 (97%) CMHCs reported providing treatment for both, with two-thirds (N=20, 67%) reporting provision of integrated dual diagnosis

care. However, much smaller numbers of CMHCs provided standard addiction services, such as inpatient detoxification (N=16, 53%), outpatient opiate maintenance treatment (N=4, 13%), or both (N=1, 3%). Notably, availability of these services at CMHCs was comparable to, or better than, their availability at addiction treatment centers.

A large majority (N=229, 80%) of the physician staff identified in phase I worked at CMHCs, which also relied on the largest contingent of nonphysician prescribers (20% of their prescribing workforce). Although CMHCs had the largest absolute physician workforce deficit (30 full-time equivalents [FTEs] needed), hospitals and addiction centers taken together had the largest deficits as a percentage of their total number of physician positions (N=25.7 of 82.7, or 31%, compared with N=30.2 of 259.2, or 12%, for CMHCs).

Centers reporting dual diagnosis treatment capability (N=34) had a broader array of available addiction treatment services than centers reporting treatment of mental illness only (N=5) or addictions only (N=10).

However, availability of both inpatient detoxification and outpatient opiate maintenance treatment (present only at dual diagnosis-capable centers) was rare statewide (two of 49 centers, 4%). Centers providing integrated dual diagnosis care employed the largest number of physicians (N=190) and had the largest absolute unmet need for new physicians (36 FTEs needed).

Of the 215 physicians who responded to phase II, 166 (77%) worked in CMHCs, 35 (16%) worked in hospitals, and 14 (7%) worked at addiction treatment centers. All hospitals and CMHCs had physicians on staff, but

four of the 13 (31%) addiction treatment centers did not. Physician workforce profiles aggregated by organization type are shown in Table 1. Only half of the physicians were employed full-time. The mean age of the entire physician workforce was 51.8±11.6 years, with the youngest group working at CMHCs (50.5±10.6 years) and the oldest working at state hospitals (58.6±12.8 years). The age distribution of physicians reflected an aging workforce. Physicians aged 50 to 54 outnumbered those younger than 35 by nearly threefold (N=41 versus N=15). About four in ten (N=82, 38%) were within a decade of or be-

yond a retirement age of 65, but only 34 (16%) were aged 30–39.

The majority of the 215 physicians (90%) were trained in general psychiatry or child psychiatry, whereas 8% were trained in family medicine, internal medicine, or surgery. Only 27% of the entire workforce trained in psychiatry residency in Indiana; 71% of psychiatrists trained out of state.

A majority (62%) described their main clinical role as treating only mental illness. Less than one-third (29%) said they treated both psychiatric and addiction disorders and 3% said they provided only addictions treatment. Six percent of physicians

**Table 1**

Characteristics of physicians who responded to the Dual Diagnosis Physician-infrastructure Assessment Tool, by treatment center

Variable	Hospitals (N=35)		Community mental health centers (N=166)		Addiction centers (N=14)		Total (N=215)	
	N	%	N	%	N	%	N	%
Age (M±SD)	58.6±12.8		50.5±10.6		50.6±14.3		51.8±11.6	
Clinical specialty								
General psychiatry	22	63	124	75	6	43	152	71
Child psychiatry	4	11	37	22	1	7	42	20
Internal medicine	3	9	1	1	0	—	4	2
Pediatrics	0	—	0	—	0	—	0	—
Family medicine	3	9	2	1	6	43	11	5
Surgery	1	3	0	—	1	7	2	1
Neurology	0	—	0	—	0	—	0	—
Emergency medicine	0	—	0	—	0	—	0	—
Other	2	6	2	1	0	—	4	2
Treatment role								
Mental illness	19	54	112	68 <sup>a</sup>	3	21	134	62
Addictions	1	3	1	1	3	21	5	2
Opiate addictions	0	—	1	1	0	—	1	<1
Mental illness and addictions	9	26	50	30	3	21	62	29
Medical care	6	17	1	1	5	36	12	6
Hours per week								
>40	26	74	81	49	4	29	111	52
30–40	2	6	36	22	1	7	39	18
20–29	3	9	30	18	0	—	33	15
6–19	3	9	15	9	3	21	21	10
<6	1	3	4	2	6	43	11	5
Psychiatric residency								
Indiana	7	20	47	28	3	21	57	27
Out of state	21	60	116	70	4	29	141	66
Nonpsychiatrist	7	20	3	2	7	50	17	8
American Board of Psychiatry and Neurology certification								
General psychiatry	16	46	118	71	4	29	138	64
Child psychiatry	3	9	17	10	0	—	20	9
Addiction psychiatry	4	11	3	2	0	—	7 <sup>b</sup>	3
American Society for Addiction Medicine certification	0	—	8	5	3	21	11	5

<sup>a</sup> Missing case excluded; one physician did not respond to treatment role question.

<sup>b</sup> Only three physicians had completed an addictions fellowship; the other four had been “grandfathered in” (that is, certified before the requirement of a completed fellowship in 1998).

reported their primary role as treating medical illnesses. Sixty-four percent of physicians were board certified in general psychiatry (American Board of Psychiatry and Neurology [ABPN]), and 9% were certified in child psychiatry. Seven (3%) physicians were ABPN-certified in addiction psychiatry; of these, only three physicians had completed an addictions fellowship, and four had been "grandfathered in" (that is, certified before the requirement of a completed fellowship in 1998). American Society for Addiction Medicine (ASAM) certification was reported by 11 (5%) physicians: five were psychiatrists and six were internists or family practitioners. One physician was addictions certified by both ABPN and ASAM. Eight percent of physicians were formally certified in addictions.

Although the highest number of addiction-certified physicians worked at CMHCs (N=11 of 166, or 7% of the CMHC workforce that responded to the survey), hospitals and addiction treatment centers employed higher proportions of addiction-certified physicians, representing four of 35 (11%) and three of 14 (21%) of their workforces that responded to the survey, respectively. A majority of ABPN addiction-certified physicians (N=4, 57%) worked at state hospitals, and most ASAM-certified physicians (N=8, 73%) worked at CMHCs. Most addiction-certified physicians (N=14, 82%) worked at centers providing either segregated or integrated dual diagnosis care, but they represented only 8% of the total physician workforce at those centers (14 of 180 physicians). Only a minority of addiction-certified physicians (N=7, 41%) were engaged in treating both addictions and mental illness.

## Discussion

This implementation of the DDPAT in Indiana demonstrates its utility for characterizing a statewide physician workforce engaged in behavioral health care with respect to dual diagnosis capability and related profiles of treatment centers. The brief response time required and the ability of the DDPAT to uncover multiple workforce concerns indicative of the status of behavioral health care, public

health, and professional training will be of interest to our own state and other large regions where it may be implemented.

The DDPAT quantified general shortages in the public-sector behavioral health physician workforce in Indiana. As percentages of the total positions available (FTEs unfilled plus number of full and part time physicians) at state hospitals, CMHCs, and addiction treatment centers, 12% of positions at CMHCs and 31% of positions at hospitals and addiction centers were unfilled. These and related findings have utility for gauging the adequacy of production of new psychiatrists in Indiana. First, the total number of physician FTEs needed (55.9) is more than nine times larger than the annual class size (6) of Indiana's only psychiatry training program at the Indiana University School of Medicine. Second, only 27% of surveyed physicians trained in psychiatry in Indiana, even though this school is the second largest medical school in the United States by medical student class size. Third, progressive decrements in the numbers of employed physicians in age groups below 50 years suggest diminishing production rates of new psychiatrists or rates of entry into public-sector psychiatry.

The DDPAT also found that only a small percentage of physicians were formally trained or involved in addictions treatment. Formal training in addictions indicated by certifications in addiction psychiatry (ABPN) or addiction medicine (ASAM) characterized only 3% and 5% of the workforce, respectively. Then, of the three-quarters of all physicians surveyed who worked at CMHCs, only 29% described their primary clinical role as treating both mental illnesses and addictions, even though 97% of CMHCs reported dual diagnosis capability. Only a minority of addiction-certified physicians (either ABPN or ASAM) identified their primary clinical role as treatment of both mental illness and addictions. The majority of ABPN-certified addiction psychiatrists (57%) were employed at the state hospitals, and the addiction treatment centers hosted the highest overall percentage of addiction-certified physicians (21%), even though

only a minority of these centers reported dual diagnosis capability. Taken together, these findings suggest a disconnect between how centers report their dual diagnosis capability and levels of physician expertise and involvement in dual diagnosis.

Limitations of the DDPAT include the difficulty in recruiting participation among a large pool of geographically dispersed physicians and design features of the instrument itself. Although all treatment centers participated, 25% of the physician workforce did not. Some treatment centers and individual physicians voiced reluctance to participate, because of concerns that results could have a negative impact on their funding or job security; others cited limited time in the face of growing clinical demands. In addition to potentially affecting response rates, a request for data from the state mental health authority might have altered the quality or factuality of responses received. Data from nonresponding physicians could have altered the overall response patterns we detected. However, because our sampling captured a large majority of the workforce, and selection bias resulting from attitudes toward the survey would likely have minimized participation by physicians who may have felt undervalued by it, we have reason to accept our results as a fairly accurate depiction of the physician dual diagnosis workforce in Indiana in 2007.

Although the DDPAT's brevity likely facilitated the high participation rates, another limitation was the relatively simple and limited number of questions posed, despite the complexity of the topic. For example, we did not explore physician involvement in individual or group psychotherapeutic modalities for addictions or dual diagnosis. We used addiction certification and other measures as indicators of group-level trends and not for assessing the competence, interest, or quality of individual physicians or treatment centers. The DDPAT is thus best suited for use across large jurisdictions and possibly as an adjunct to more comprehensive measures of dual diagnosis capability, such as the DDCAT.

Our results in using the DDPAT

should motivate greater collaboration between medical student and residency training programs and state systems of behavioral health care delivery, with a focus on supporting the training of more psychiatrists and allied physicians in addictions and integrated dual diagnosis treatment. National workforce training data suggest our findings are consistent with a broader problem affecting much of the United States. In 2000, seven years after the 1993 inception of the ABPN addiction psychiatry subspecialty, less than 1% of psychiatry residents were enrolled in addiction fellowships (13), against a background total of 1,776 certificates awarded without fellowship training (that is, "grandfathered in") from 1993 to 1998 (14). By 2002 only half of states had addiction psychiatry fellowships, and a total of 186 individuals had graduated from 73% of then-existing programs (13). In 2003 only 55% of 108 available U.S. addiction fellowship positions were filled (12); by 2006 this figure dropped to 47% of 116 positions (15). By 2007 a total of 4,162 physicians had received ASAM certification, with roughly half awarded to psychiatrists (15).

### Conclusions

The DDPAT is an efficient and informative survey tool for measuring dual diagnosis-related health services and physician workforce attributes statewide. In its first large-scale de-

ployment in 2007 in Indiana, the survey identified overall shortages of psychiatrists punctuated by diminishing numbers of younger psychiatrists and deficient numbers formally trained or involved in treating both addictions and mental illnesses. Given the extent to which dual diagnosis presentations are mainstream in behavioral health care, these findings should motivate changes in physician workforce development in Indiana and similar workforce examinations in other states.

### Acknowledgments and disclosures

This work was supported by the Indiana Division of Mental Health and Addiction, the Family and Social Services Administration, State of Indiana (all authors), and a National Institute on Drug Abuse K08-award DA019850 (first author). The authors thank the 49 treatment centers and 215 physicians who participated in this study in Indiana.

The authors report no competing interests.

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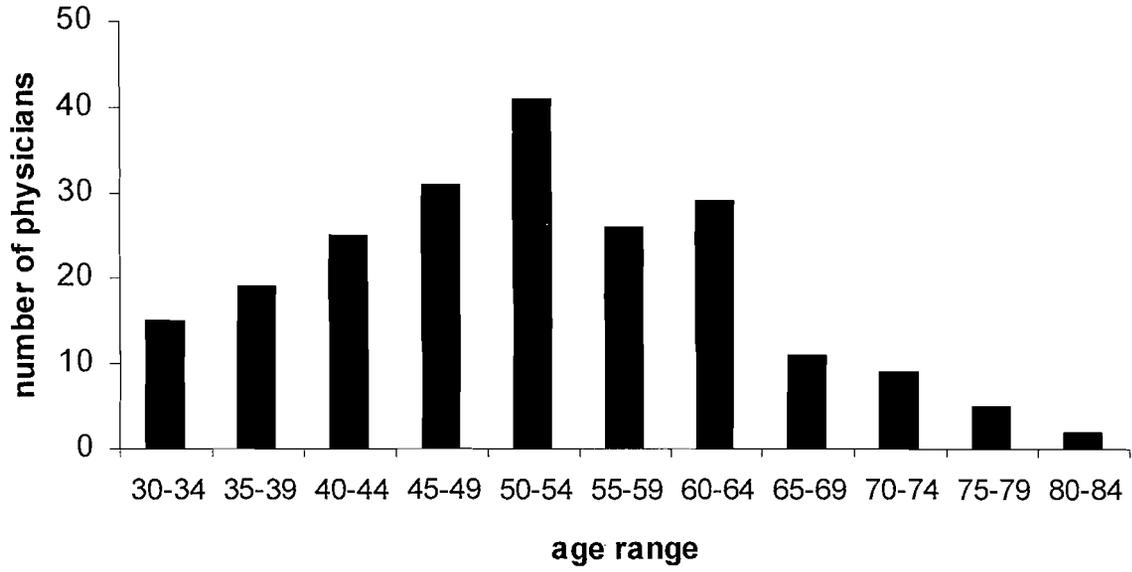
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**Supplement 2: Table 2. Addiction services provided by clinical focus of treatment center**

	Clinical focus of treatment center							
	Mental illness (N = 5)		Addictions (N = 10)		Dual diagnosis, separate (N = 10)		Dual diagnosis, integrated (N = 24)	
	N	%	N	%	N	%	N	%
<b>Addiction Services</b>								
Inpatient detoxification	0	---	3	30	6	60	11	45
Outpatient opiate maintenance	0	---	0	---	1	10	3	13
Both	0	---	0	---	0	---	2	8
Neither	5	100	7	70	3	30	8	33

**Supplement 2: Figure 1.** Age distribution of physicians who completed the Phase II survey



**Supplement 2:Table 3. Distribution of physicians with addiction certifications by clinical focus of treatment center and physician role**

	ABPN (N = 7)		ASAM (N = 11)		Either (N = 17)	
	N	%	N	%	N	%
<b>Clinical focus of treatment center (N=213)<sup>a</sup></b>						
Mental illness (n = 26)	1	4	0	---	1	4
Addictions (n = 7)	0	---	2	29	2	29
Dual diagnosis (separate) (n = 44)	0	---	2	5	2	5
Dual diagnosis (integrated) (n = 136)	6	5	7	5	12 <sup>c</sup>	9
<b>Physician's treatment role (N=212)<sup>b</sup></b>						
Mental illness (n = 134)	1	1	3	2	4	3
Addictions (n = 5)	1	20	3	60	3	60
Opiate addictions (n = 1)	0	---	1	100	1	100
Mental illness & addictions (n = 60)	5	8	2	3	7	12
Medical (n = 12)	0	---	2	17	2	17

<sup>a</sup> Missing cases excluded; two responding physicians did not report on ABPN addiction psychiatry and/or ASAM certification.

<sup>b</sup> Missing cases excluded; one responding physician did not report main treatment role and two did not report addictions certifications.

<sup>c</sup> One physician, certified in addictions by both ABPN and ASAM, worked in an integrated dual diagnosis center providing addiction treatment.

Percentages reflect the fraction of total number (n) of physicians in response category in the left column.

# The Collapsing Psychiatric Workforce In Indiana: Implications and Solutions

Presentation to Mental Health Commission, Indiana State Legislature  
Sept. 9, 2013

R. Andrew Chambers, M.D.

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IU School of Medicine

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

## Substance Use Disorders:

- 1) the #1 cause of medical illness and premature death in the United States.
- 2) are suffered by 20-30% of the general adult population and are hyper-concentrated in those with mental illness where rates range from 50-80%.

# What happens when you don't have enough professional expertise, infrastructure or training in the treatment of mental illness and addiction?

1. Higher rate of addictions across many drug types.
2. Higher expenditures for criminal justice and rates of incarceration.
3. Higher rates of neglect, abuse, and murder of children by their parents.
4. Higher rates of health care expenditure needed to treat the consequences of un-recognized and untreated addictions.
5. Higher rates of addictions caused by doctors, hospitals and emergency rooms.
6. Less state money for public secondary education and college education  
.....and a poorer and less educated population is a substrate of more mental illness and addiction.

# What's Happening in Indiana?

# 5 Ranking in nation in rates of nicotine addiction

(2002; MMWR, CDC)

#4 ranking in number of per-capita methamphetamine labs discovered (2004; National Clandestine Laboratory Database)

#1 ranking in child abuse fatalities (2005; CDC)

Indiana has higher than national averages in\*:

- Arrest rates for alcohol-related infractions
- Age adjusted mortality rate due to tobacco addiction
- Arrest rates for possession of methamphetamine
- Rates of overall prescription drug dependence, prescription opioid and tranquilizer addiction
- Rates of polysubstance dependence
- Prescription opioid sales

\* Indiana State Epidemiology and Outcomes Workgroup (IU School of Public Health)

# What's Happening in Indiana?

-2<sup>nd</sup> Largest Medical School in the U.S.

-7<sup>th</sup> lowest per-capita density of psychiatrists in the U.S.

(2000, U.S. DHHS, State Health Workforce Profiles).

(we only graduate 6 psychiatrist per year/down from 12 in the 1970's)

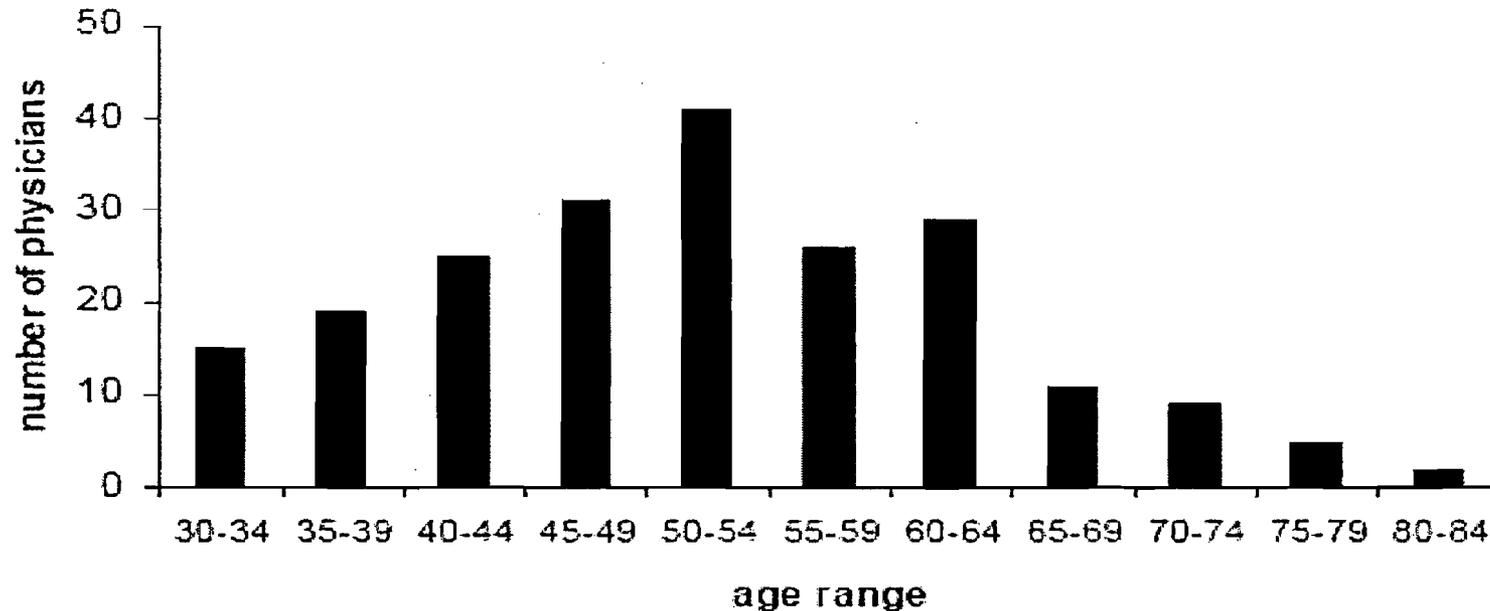
- 40% of Indiana (37 /92 counties) were designated as a Mental Health professions shortage area in 2009 (Indiana State Department of health/ UDDHHS criteria).

-The average age of psychiatrists in Indiana is 52.6.

-More than 2/3 of Indiana's psychiatrists were not trained in Indiana.

-50 counties in Indiana have no psychiatrists practicing within them.

Age histogram of Indiana Psychiatrists working at state supported hospitals (6), CMHCs (30), and Addiction centers treatment centers



In 2007, 30% of state hospital positions, 33% of addiction treatment centers and 11% of CMHC psychiatric positions were unfilled.

This means 55 positions were unfilled; compares to only 6 new psychiatrists Produced per year by IU school of medicine.

Psychiatrists aged 50-54 outnumbered those younger than 35 by 3-fold.

Nearly 4 in 10 are within a decade or beyond a retirement age of 65.

Shortages of Psychiatrists are just the tip of the iceberg:  
 Indiana's entire behavioral health workforce spanning  
 social workers and psychology is collapsing

Professional	number (% of workforce)	% by age			
		<35	35-55	55-64	65+
MA Therapists/SW	4950 (77%)	13	46	32	8
Psychologists	980 (15%)	10	48	30	13
Psychiatrists	466 (7%)	6	47	30	17

Mental health Professionals Survey Report, IN Center for Health Workforce Studies,  
 Bowen Center, 2012

## Critical Shortages of Addiction Psychiatrists are superimposed on severe shortages of general Psychiatrists

Addiction Psychiatrists are the only type of physicians that are formally trained and certified by ABMS to Understand and treat addictions and dual diagnosis

Nationwide: less than 1% of all psychiatry residents seek further sub-specialty Training in addiction psychiatry.

In Indiana (2007), only 3% of all psychiatrists working at CMHCs, State hospitals and addiction treatment centers (supported by DMHA), were certified addiction psychiatrists. (Chambers, Psy Serv, 2010)

Total Number of fully trained and ABMS-certified Addiction Psychiatrists Produced in the History of the IU School of Medicine:

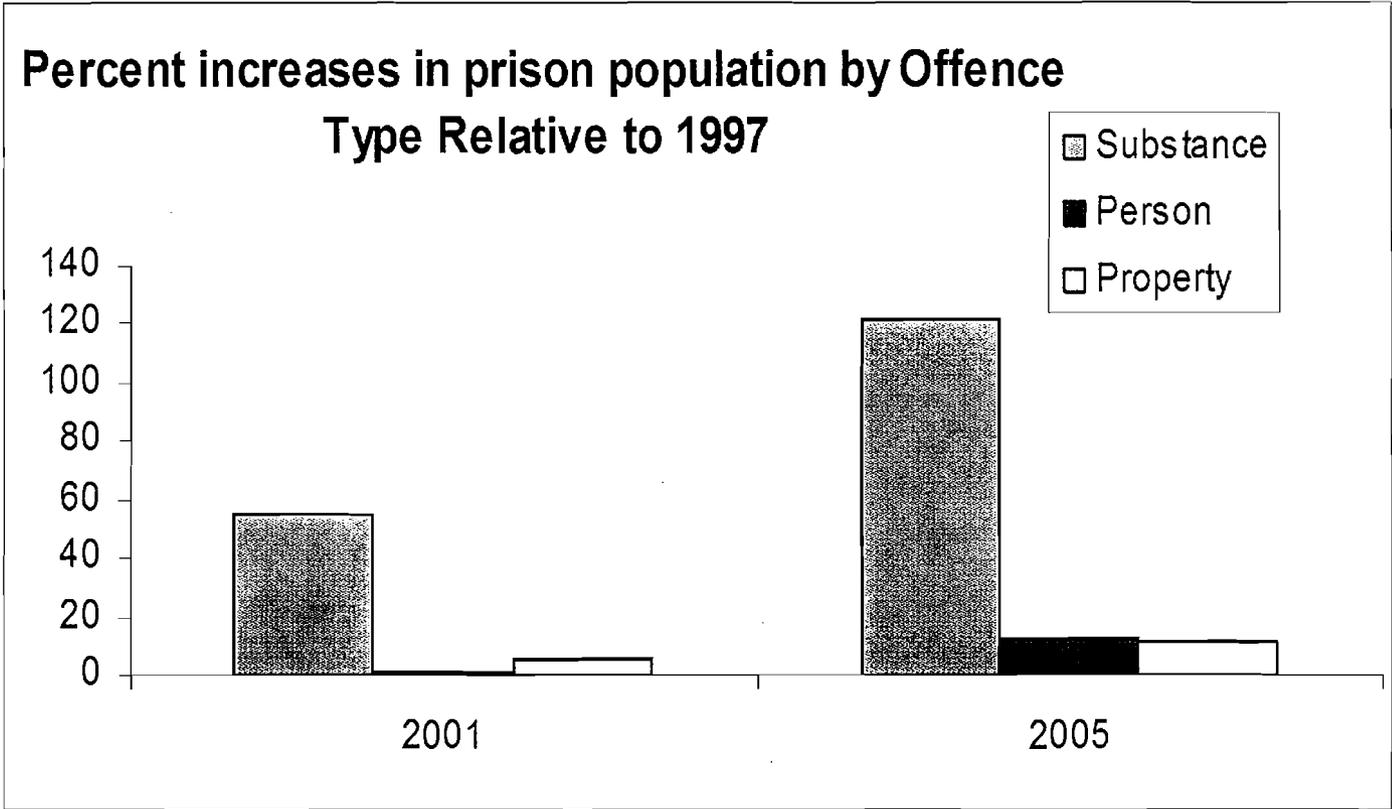
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Total number of Anesthesiologists produced per year at IU: 28.

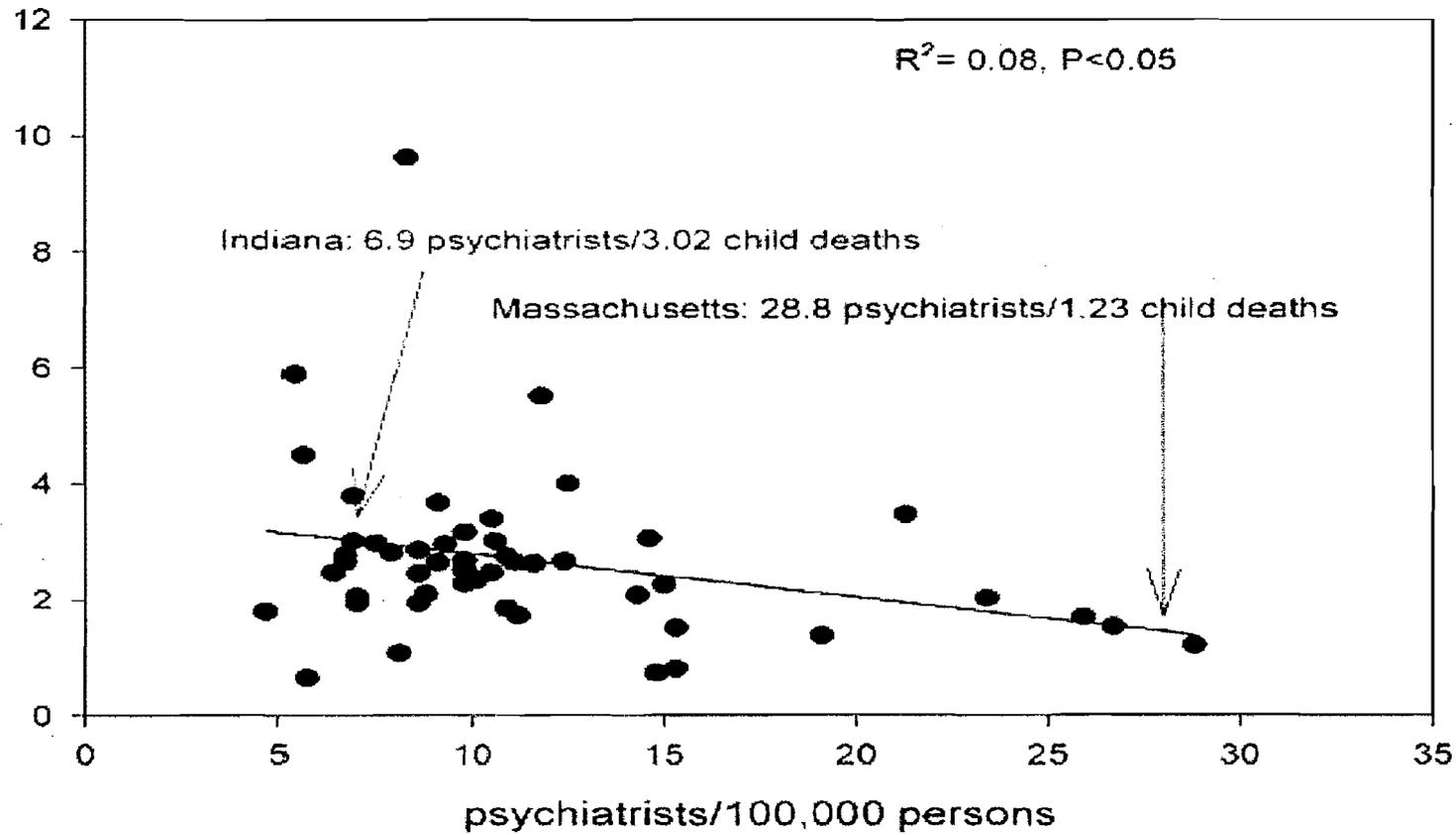
Total Number of Diagnostic Radiologists produces per year at IU: 15

Total Number of Internal medicine docs produced per year at IU: 40

Increase in Indiana Incarcerations by type of offense 1997-2005  
(IDOC data)



### Intentional Violent Death of Children ages (0-15) Per 100,000 children/ state 2004



# Extremely Low Rates of Addiction Psychiatrists is a National Crisis

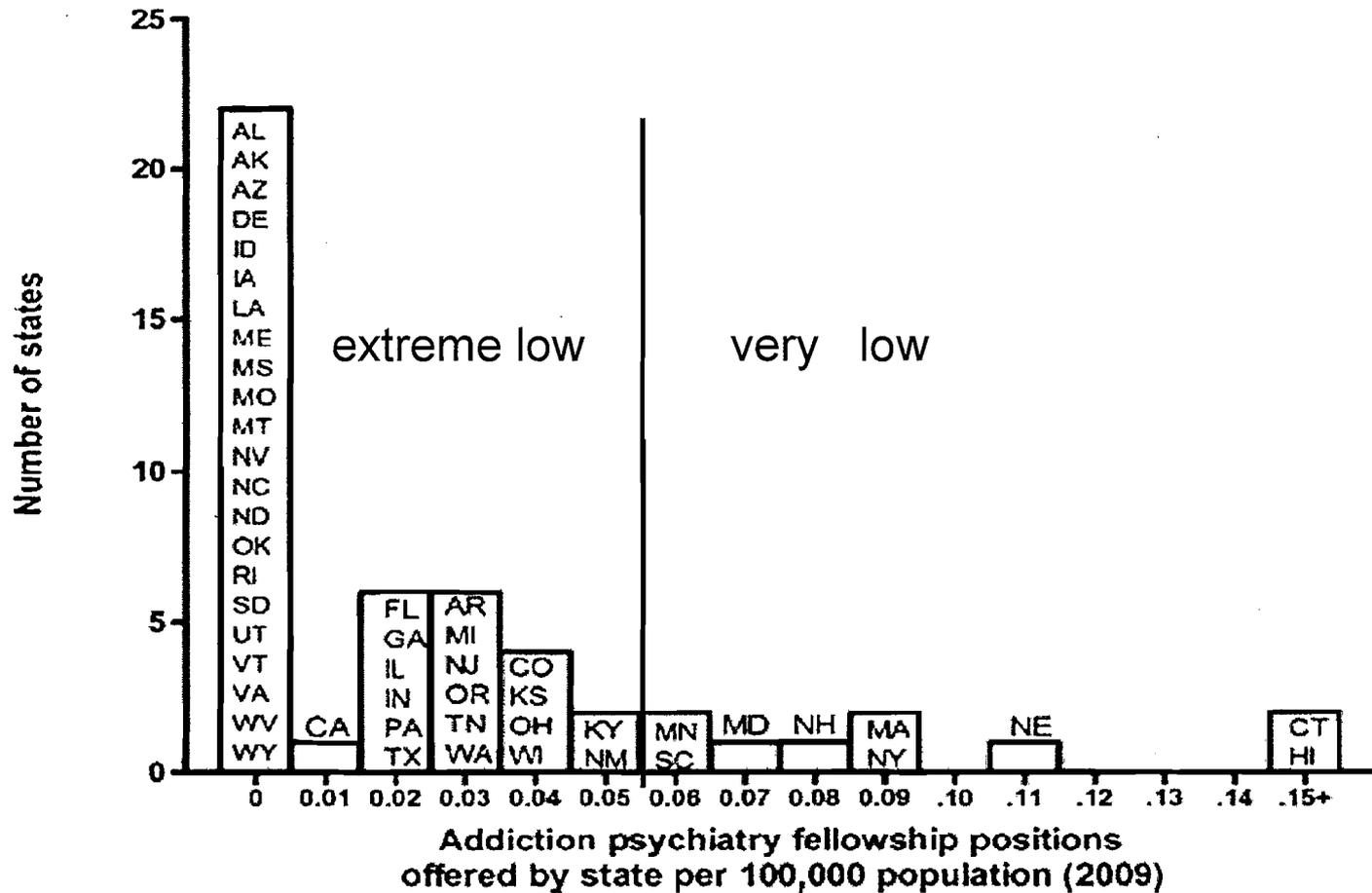
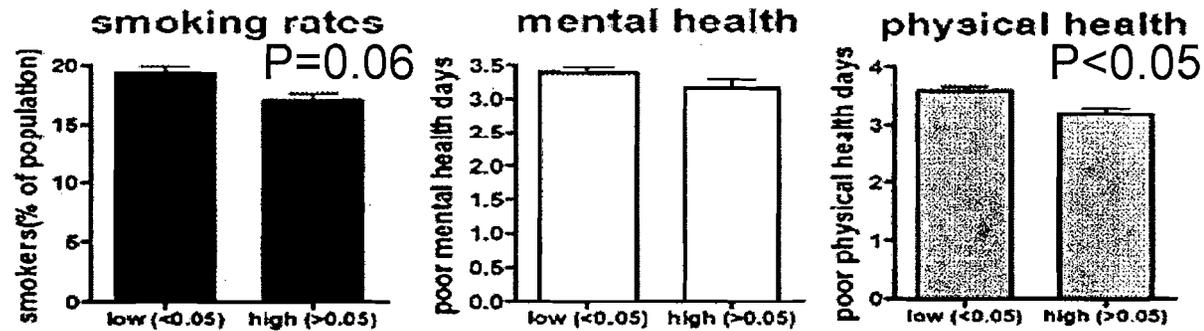


FIGURE 1 Histogram of the states grouped by numbers of addiction psychiatry fellowship positions offered by state per 100,000 population. Data in the figure were compiled from 2010 U.S. Census data (U.S. Census Bureau, 2010) and 2009 addiction fellowship census data from the Center for Medical Fellowships in Alcoholism and Drug Abuse (Galanter, 2011).

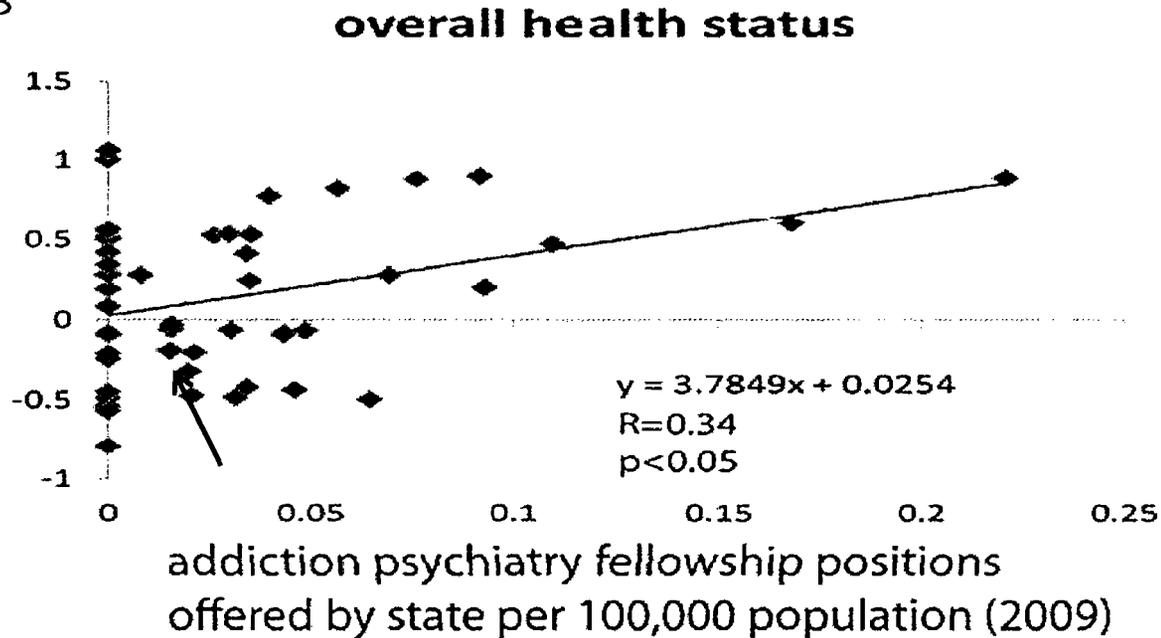
# Public health Impact of Poor Addiction Psychiatry Training Capacity

A

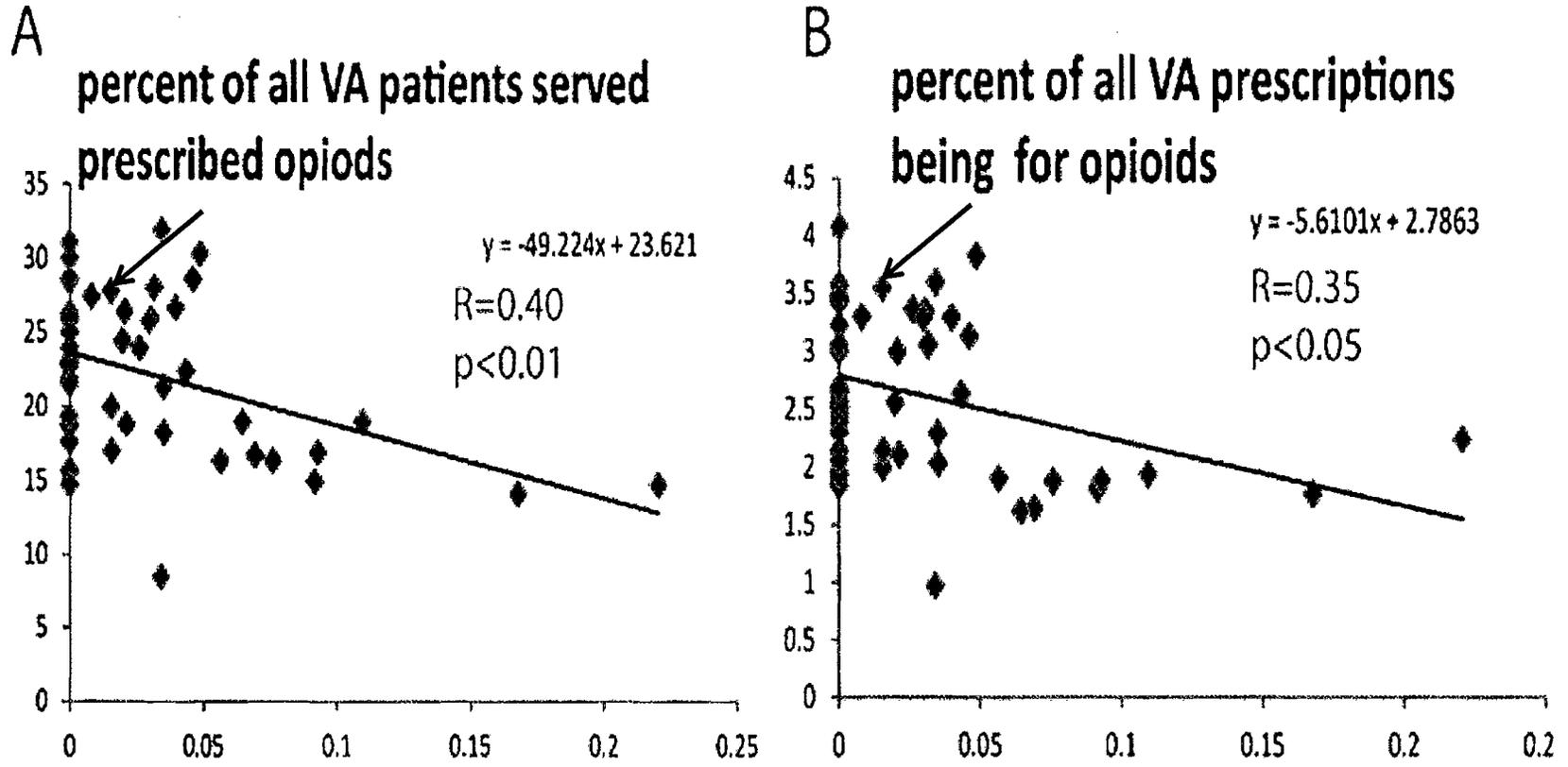


grouping of states by addiction psychiatry fellowship positions offered (per 100,000 of state population)

B



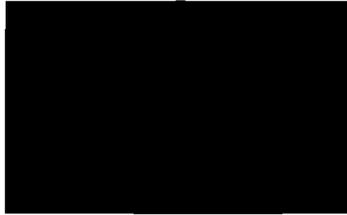
# Public health Impact of Poor Addiction Psychiatry Training Capacity



Addiction psychiatry fellowship positions offered by state per 100K population

What happens to individuals and tax payer dollars when addiction psychiatry training infrastructure, expertise and workforce are seriously deficient?

## Mr. X: A Case of Dual Diagnosis



### HPI/SUDS HX:

-i.v. Heroin since age 14; admixed with prescription opiates from many physicians and street sources over the years.

-Hx of benzodiazepine dependence (iatrogenic and street), cocaine addiction, Methamphetamine addiction and nicotine addition

### P PSY HX:

Major depression; 1 hospitalization in 2008

### MEDICAL:

-HCV positive

-2005-drank drano when intoxicated, destroyed oral cavity, and upper esophagous, resulting in multiple surgeries, 5 weeks in the hospital and weeks in ICU.

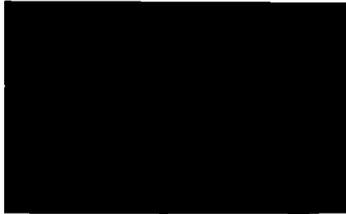
### LEGAL:

35+ episodes of prison or jail time (all drug related) Including 8 DUIs.

Mr. X. 47 year old man with 4 sons, skilled in construction, 10<sup>th</sup> grade Ed with GED.

“I want get off of drugs for good”

## Mr. X: A Case of Dual Diagnosis



History of medical Treatment in the year prior to this patient presenting to us Midtown dual diagnosis clinic:

INSPECT DATA (8/2/2010-8/2/2011):

14 prescriptions for XANAX

14 prescriptions for VALIUM

17 prescriptions for Hydrocodone

4 prescriptions for Oxycontin

49 total controlled substance prescriptions

8 different doctors

13 pharmacies

After initiating Dual Diagnosis treatment:

INSPECT (8/2/2011-1/26/12)

4 prescriptions for Suboxone

1 prescriber (us)

1 pharmacy

Mr. X. 47 year old man with 4 sons, skilled in construction, 10<sup>th</sup> grade Ed with GED.

“I want get off of drugs for good”

## Mr. Y: A Case of Dual Diagnosis

A 31 y.o. White male with a diagnosis of Bipolar Disorder

### INSPECT DATA: (11/1/2011 to 11/1/2012)

- 101 different controlled substance prescriptions
- 10 different physicians (or physician groups including IU/ Wishard)
- 4 pharmacies
  
- Meds included 9 different types of opiate, or benzodiazepine or atypical benzodiazepine like drugs.
  
- A total of 7218 doses.
- An out-of-pocket pharmacy cost of \$5745.50
- An estimated street value of \$72,180.00

## Mr. Y: A Case of Dual Diagnosis

A 31 y.o. White male with a diagnosis of Bipolar Disorder

<u>Hospitalizations (Jan to Sept 2012) (IU health):</u>	<u>Bill</u>
1. Fall. "Passing out" Head laceration. Multisystem work-up with Neuroimaging. Echocardiograms, Neurotelemetry, etc. (DC'd on opiates/BZDs)	\$24,000
2. Fall. Medication overdose. Humerus Fracture requiring open reduction Multisystem work-up with Neuroimaging. (DCd on opiates/BZDS)	\$58,000
3. Admission for Failed fixation of humerus, requiring 2 <sup>nd</sup> orthopedic surgery (DC'd on opiated/BZDs)	\$66,000
4. Altered level of consciousness. More neuroimaging (DC'd on opiates/BZDs)	\$17,000
5. Acute Alcoholic pancreatitis. More tests/imaging. (DC'd on opiates BZDs)	<u>\$6,500</u>
	\$171,500

Pt. was never diagnosed with any addiction!

Psychiatry is in the worst condition among U.S. medical specialties  
 'an unfavorable income to workforce age ratio'

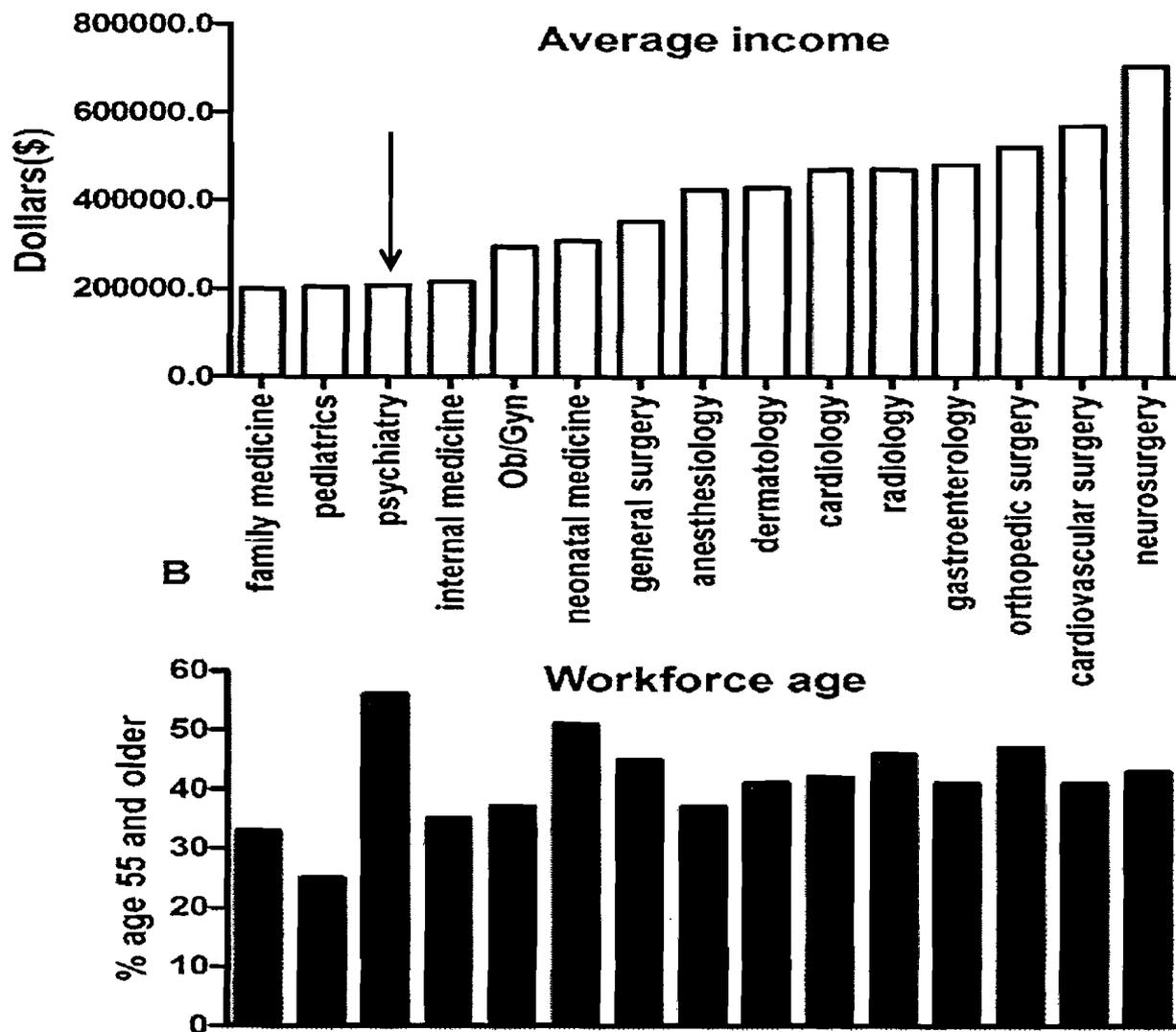


FIGURE 2 Indices of workforce vitality across major physician specialties. MGMA data from 2012 reveals psychiatry to be (a) among the lowest-reimbursed medical specialties (as with other primary care specialties) with (b) the most advanced age of workforce suggestive of a medical profession in decline.

# What does the most 'unfavorable income to workforce age ratio' signify for psychiatry in the face of high clinical demand?

-Collapsing workforce due in part to lack of reimbursement compared to other medical specialties. *But this is not about Greedy medical students!*  
Its about lack of parity of insurance reimbursement for care and:

-Explosion of Medical Student loan burdens (Jolly, 2005):

## Median Medical student loan debt:

	<u>private</u>	<u>public</u>
1985	\$22,000	\$27,000
2003	\$100,000	\$135,000

Now (undergrad + MD) \$200,000- \$250,000

-Unlike other medical specialties, psychiatrists who go on to pursue subspecialty training in Addictionology suffer a large financial penalty to do so (e.g. sacrifice another \$100,000 income to do the fellowship with no clear increase in income afterward).

-Currently Indiana's production of addiction psychiatrists is 0 with 2 unfilled positions. The last two graduates from IU addiction psychiatry and a single candidate entering in 2014 have no loan debt.

# How to address work force failures in psychiatry, Addiction psychiatry and behavioral health

## 1. Loan Repayment programs:

e.g. an addiction psychiatrist has \$20,000 of loan repayment principal paid down per year for 5 years, contingent on that physician practicing in Indiana for five years.

the unnecessary and ineffective legal and medical costs expended by the tax payers for Cases of Mr. Y and Mr. X could have supported loan repayment for 10 to 20 addiction psychiatrists in Indiana (e.g. 1 to 2 million \$).

## 2. Achieve parity of insurance reimbursement for mental health and addiction treatment services

Medicaid/Medicare and private insurance to reimburse  
Evidence-based Psychotherapies and pharmacotherapies  
For dual diagnosis conditions on par with medical care

# Thank you

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

Treatment for Opiate Pain Medicine Abuse –

Denied, Denied, Denied a word as a provider that I had a hard time getting used to when those who came in suffering from Opiate Pain Medicine Abuse that wanted to get clean and needed inpatient to do so.

Detoxification from Opiate with-drawls does not cause seizures or any life threatening physical ailments to patients who are with-drawing from opiates. Therefore Medicaid denies treatment due to them stating it is not a medical condition or does not need a safe a with-drawl.

405 IAC 5-17-5 Inpatient detoxification, rehabilitation, and aftercare for chemical dependency

Authority: IC 12-15-1-10; IC 12-15-1-15; IC 12-15-21-2

Affected: IC 12-13-7-3; IC 12-15

Sec. 5. (a) Medicaid reimbursement is available for inpatient detoxification, rehabilitation, and aftercare for chemical

Dependency when such services are prior authorized subject to this section.

(b) Admission to a general hospital floor is not indicated unless the medical services are required for life support and cannot

be rendered in a substance abuse treatment unit or facility.

(c) Prior authorization for inpatient detoxification, rehabilitation, and aftercare for chemical dependency shall include

Consideration of the following:

(1) All requests for prior authorization will be reviewed on a case-by-case basis by the contractor.

(2) The treatment, evaluation, and detoxification are based on the stated medical condition.

(3) The need for safe withdrawal from alcohol or other drugs.

(4) A history of recent convulsions or poorly controlled convulsive disorder.

(5) Reasonable evidence that detoxification and aftercare cannot be accomplished in an outpatient setting.

As a provider hearing the word denied was not as hard as it was to hear it as a sister. A sister who has a brother who at the age of 21 torn 3 lower discs from his back due to a worksite injury that allowed him to no longer work.

After many doctor appointments, surgery attempts, etc . My brother became an addict of Opiates. He could not take enough to take away his pain. When they stopped working he started using Heroin. Heroin was more affordable and easier to get. At the age of 23 my brother was a Heroin addict.

Upon moving to Indianapolis he tried Methadone to get off the pain pills and Heroin. He became a Methadone addict. My brother tried many times to get treatment but with not having many resources he was denied quite often.

18 months ago my brother was in a coma from an overdose of Opiates, cocaine, Bezos, AL and marijuana. For two weeks we wondered if he would survive and if so how. With a trach? Would he be able to talk? Would he be able to have his cognitive ability back?

My brother miraculously made it thru the overdose. When we tried to find inpatient treatment for him in the Indianapolis area, every provider said no since he had no coverage. He was discharged from the hospital on Opiates and Bezos. We were at a loss of what to do for him. Knowing that an IP setting would be the only setting that would help him.

Shortly after discharge my brother relapses again. If it wasn't for a personal favor from a wonderful treatment center in Franklin, Indiana my brother would not be 18 months sober. I wonder about those who do have favors to pull, or connections to make, those who are lost in our system because our system is set up to pay for the pills they get addicted on but not to pay to help them get off of them when enough is enough.

**Larry Humbert**  
**Executive Director**  
**Indiana Perinatal Network**  
**Testimony to the Commission on Mental Health and Addiction**  
**September, 9, 2013**

To successfully address the issue of Neonatal Abstinence Syndrome, we have to work further upstream and look at what's going on during, and ideally prior to a woman becoming pregnant.

**Recommendations:**

1. Promote universal verbal screening of **all pregnant** for alcohol, tobacco and other drug use
2. Expand provider education on how to medically manage opiate dependence during pregnancy
3. Increase the number of Ob providers certified to prescribe Buprenorphine (Suboxone / Subutex)
4. Increase communication and coordination between Methadone Clinics / Pain Management Clinics and Ob providers and birthing hospitals
5. Encourage the use of long acting reversible contraception for women of childbearing age with substance use issues. The new Medicaid family planning program implemented Jan. 1, 2013 will increase access to contraception services.
6. Shift from a punitive, shame-based approach to substance use during pregnancy to a more therapeutic, approach utilizing motivational interviewing techniques.
7. Expand access to a continuum of substance use treatment services to address the unique needs of pregnant women, especially related to child care and parenting support.

**Existing Resources shared during the testimony**

1. Current edition of the Perinatal Focus Newsletter  
[http://c.ymcdn.com/sites/www.indianaperinatal.org/resource/collection/9E7BAD9B-0CC7-4CA5-BE13-A3407BE1BCDF/PerinatalFocus2013\\_2.pdf](http://c.ymcdn.com/sites/www.indianaperinatal.org/resource/collection/9E7BAD9B-0CC7-4CA5-BE13-A3407BE1BCDF/PerinatalFocus2013_2.pdf)
2. Consumer handout for the new Medicaid Family Planning Program  
[http://c.ymcdn.com/sites/www.indianaperinatal.org/resource/resmgr/p\\_accesstocare/family\\_planning\\_handout.pdf](http://c.ymcdn.com/sites/www.indianaperinatal.org/resource/resmgr/p_accesstocare/family_planning_handout.pdf)
3. Opiate Dependence During Pregnancy: An Evidence-Based Toolkit  
Attached with e-mail
4. Buprenorphine vs. Methadone for Pregnant Women  
Results of the *Maternal Opioid Treatment: Human Experimental Research (MOTHER)* study, a multi-center rigorously designed clinical trial supported by the National Institute of Drug Abuse  
<http://www.drugabuse.gov/news-events/nida-notes/2012/07/buprenorphine-during-pregnancy-reduces-neonate-distress>
5. Integrating Screening and Treatment of Substance Use Into Prenatal Care – DVD/CD

# Perinatal FOCUS: Neonatal Abstinence Syndrome



INDIANA  
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FOR MOTHERS & BABIES*

## Inside this issue:

- 02 - Policy Update
- 03 - Spotlight: MHS
- 03 - Breastfeeding Protocol
- 04 - NAS & Delivering Hospitals

## What is NAS?

Neonatal abstinence syndrome (NAS) is a group of problems that occur in a newborn who was exposed to addictive illegal or prescription drugs while in the mother's womb.

## AAP Policy

This statement updates information about the clinical presentation of infants exposed to intrauterine drugs and the therapeutic options for treatment of withdrawal, and is expanded to include evidence-based approaches to the management of the hospitalized infant who requires weaning from analgesics or sedatives. [Click here](#) for the full policy statement.

## Special Offer! Take \$10 Off!

Comprehensive provider training DVD addresses tobacco, alcohol and other drugs during pregnancy. Features the work of James Nocon, MD JD. One of our most popular resources!

**Order online**  
with promo code  
**FOCUS2**



## What's the Problem?

### Significant increase in number of newborns affected

- While the U.S. government doesn't track the number of babies born dependent on drugs, a study last year in the Journal of the American Medical Association found that more than 13,000 U.S. infants were affected in 2009.
- Studies have shown a 5 fold increase in chronic use of narcotic prescriptions (30 days or more) from 1998 to 2008; NAS was noted in 5.6% of these infants.
- East Tennessee Children's Hospital in Knoxville expects to treat 320 children this year for NAS, up from 33 in 2008 and 283 in 2012.
- In response to surveys by IPN regarding the most significant perinatal issue they face, a large majority of providers identify NAS.

### Significant costs

- One hospital's costs to treat NAS infants born to opioid-dependent mothers who received opioid replacement therapy during pregnancy totaled more than \$4 million during a 3-year period, a new study shows.

**Lack of universal verbal screening of all pregnant women for substance use**

## IPN's Response

- In conjunction with Dr. James Nocon, IPN produced a unique DVD to train providers on how to verbally screen all pregnant women for alcohol, tobacco and other drugs. Early identification and proper medical management during pregnancy may help minimize the severity of NAS in newborns. *(see box on this page)*
- Developed a provider toolkit on how to manage the opiate dependent pregnant women. This unique document highlights clinical cases, current literature and practice experience to identify, treat and develop care plans for opioid dependent pregnant women and their infants.
- NAS has been a much sought after topic included in our regional workshop series for the past 2 years.
- NAS will be a major topic during the 4th Annual Indiana Perinatal Hospital Summit planned for Sept. 6, 2013.
- Developed a Substance Use Screening in Pregnancy Algorithm, a printable screening tool for healthcare providers.

## In the News

### Health Law Could Overwhelm Addiction Services

Millions of Americans stand to gain insurance coverage for drug addiction and alcoholism treatment when the national health overhaul takes effect next year, and some experts predict the change will help thousands of people get clean and sober. However, the new demand could swamp the current addiction treatment system before even half of the newly insured seek help, causing waiting lists of months or longer, treatment agencies say. Questions also remain about how comprehensive and affordable the new coverage will be. [Click here](#) for more.

### Genetics May Dictate Treatment in Opioid-Dependent Infants

Researchers have identified genetic variants that appear to be associated with less severe neonatal abstinence syndrome (NAS) in infants exposed to opioids in utero, a finding that could pave the way for more tailored treatments, according to a study published in the May issue of JAMA. [Click here](#) for the study.

### Neonatal Abstinence Syndrome and Associated Health Care Expenditures United States, 2000-2009

The goal of this study, published in the May issue of JAMA, was to determine the national incidence of NAS and antepartum maternal opiate use and to characterize trends in national health care expenditures associated with NAS between 2000 and 2009. In this study, state Medicaid programs were the predominant payer for mothers using opiates (60.0%) and newborns with NAS (78.1%). As a consequence, the results have specific relevance to state Medicaid budgets. Another interesting finding was that care for NAS infants delivered in hospital settings outside of the neonatal intensive care unit and outpatient management can potentially reduce length of stay and cost of stay, since NICUs are much more costly than care in a general pediatric ward. [Click here](#) for the full study.

### Breastfeeding Reduces the Need for Withdrawal Treatment in Opioid-Exposed Infants

Breastfed neonates exposed to methadone prenatally had significantly lower incidence of NAS requiring pharmacotherapy (53% versus 80%) and both the whole group of infants and the methadone-exposed neonates needed shorter pharmacological treatment of NAS than neonates who were not breastfed. [Click here](#) to view the abstract.

# Policy Update

## State Policy

Two important pieces of legislation were recently passed by the Indiana General Assembly and signed into law.

HEA 1465 – provides ongoing funding for the Indiana Scheduled Prescription Electronic Collection & Tracking Program (INSPECT), an important tool designed to address the problem of prescription drug abuse and diversion in Indiana.

### What is INSPECT?

- INSPECT is Indiana's prescription drug monitoring program (PDMP), one of 42 operational PDMPs nationally. INSPECT collects and retains in its database every controlled substance dispensed on an outpatient basis by all licensed pharmacies in Indiana. Approximately 12 million Rx records are collected annually, and over 1,700 pharmacies report to INSPECT.

SEA 246 - Requires the state board of pharmacy and other boards to adopt rules concerning clinic ownership, standards and protocols for prescribing controlled substances and requires the Commission on Mental Health and Addiction to study issues concerning treatment and recovery from prescription drug use addiction.

In September 2012, the Indiana Attorney General established the Indiana Rx Drug Abuse Task Force. Task force members include state legislators, law enforcement officials, physicians, nurses, addiction counselors, pharmacists and representatives from state and local agencies. A variety of committees have been created, included the Treatment and Recovery Committee that is addressing NAS. IPN is a member of this committee.

## National Policy

Forty-three state attorneys general, including Indiana's, are calling for new "black box" warning labels on prescription painkillers that can harm unborn children. In a letter sent in May to the FDA, the attorneys general point to an alarming spike in the number of babies born with "neonatal abstinence syndrome experienced by babies when they are cut off from the opioid drugs ingested by their mothers." [Click here](#) for the article.

## ISMA Resolution

John Ellis, MD FAAP and James Nocon, MD JD, plan to present a resolution regarding appropriate prevention, screening and treatment of pregnant women for use and abuse of substances to the Indiana State Medical Association House of Delegates in September. IPN and a number of other organizations are in support of this resolution, including the Indiana Prescription Drug Abuse Prevention Task Force and the Indianapolis Medical Society. Thank you to Dr. Ellis and Dr. Nocon for their leadership in moving this important issue forward!

## Neonatal Abstinence Syndrome Linked to Exorbitant Costs

Principal investigator Kay Roussos-Ross, MD, a psychiatrist and obstetrician specializing in addiction medicine at the University of Florida Shands Hospital, in Gainesville recommended the following ways that physicians can help decrease the incidence of neonatal abstinence syndrome:

- Use nonopioid pharmacologic management of pain in pregnant women, such as physical therapy and massage therapy.
- In pregnant women being treated for opioid dependence, use the lowest effective dose of methadone or buprenorphine to prevent cravings and withdrawal symptoms.
- Encourage long-acting contraceptive management for women of reproductive age in opioid-dependence treatment. "Half of babies born in the US are unplanned, so recommending contraceptives for these women is important." (Note: A new Medicaid Family Planning Services program is designed to make contraceptive services more affordable for women and men. [Click here](#) for more information.)
- After delivery, consider weaning women from opioid treatment in a physician-supervised setting to help protect against relapse.

[Click here](#) for the complete article.

# Spotlight: Managed Health Services

By John C. Ellis, MD FAAP – Medical Director, MHS

In June 2012, Managed Health Services produced and distributed a comprehensive clinical policy to their network providers highlighting assessment, treatment and discharge protocols for infants suffering from NAS.



In the last 2 years, the MHS census showed an increasing number of NAS babies in Indiana NICUs, a trend consistent with the experience of other health plans in Indiana and around the country. The treatment of these infants varied widely within and among NICUs, and explanations to MHS by facilities of their NAS policies were quite varied. Some NICUs had policies and followed them; some reported policies but didn't always appear to follow them; and some NICUs had no NAS policy and didn't feel the need for one. At the same time, national attention was being focused on the NAS issue.

MHS convened a group of neonatologists from across Indiana and created a draft policy based on AAP and CDC guidelines and using a framework from the Kosair policy. The policy was adopted by an MHS committee with substantial community physician involvement in June 2012. The policy was then forwarded to the Medical Directors of all nurseries in Indiana and several key cities in neighboring states with a letter explaining that MHS would be using this policy as the guideline for clinical decision-making in reviewing NICU NAS infant care.

To date, we have had no indication of dissatisfaction with the policy. In fact, the need to apply the policy has been fairly limited as NICUs seem to generally be providing care consistent with these national recommendations. I believe national attention and parallel efforts by multiple public health agencies have allowed the MHS NAS policy to fit well into clinical practice, with the ultimate result of consistent, evidence-based care for the NAS infants who continue to arrive regularly in hospitals across the state.

---

Contact John Ellis at [joellis@mhsindiana.com](mailto:joellis@mhsindiana.com). [Click here](#) to view the MHS NAS Policy and Flow Sheet.

## Breastfeeding and the Drug-Dependent Mother

Although providers may assume that a pregnant drug-dependent mother should be discouraged from breastfeeding her infant, that decision is not always so simple. Infants of drug-dependent women are often at greater risk for health and developmental complications, and therefore might benefit even more so than the average infant from breastfeeding. The choice is complicated by the lack of evidence based guidelines addressing this topic. However, the Academy of Breastfeeding Medicine has published a clinical protocol outlining the current recommended guidelines. While it is true that each mother and baby should be evaluated on a case-by-case basis, the ABM Protocol outlines several criteria that, if met, support the mother's decision to breastfeed.

Those criteria include:

- Women engaged in substance abuse treatment who have provided their consent to discuss progress in treatment and plans for postpartum treatment with substance abuse treatment counselor
- Women whose counselors endorse that she has been able to achieve and maintain sobriety prenatally; counselor approves of client's plan for breastfeeding
- Women who plan to continue in substance abuse treatment in the postpartum period
- Women who have been abstinent from illicit drug use or licit drug abuse for 90 days prior to delivery and have demonstrated the ability to maintain sobriety in an outpatient setting
- Women who have a negative maternal urine toxicology testing at delivery except for prescribed medications
- Women who received consistent prenatal care
- Women who do not have medical contraindication to breastfeeding (such as HIV)
- Women who are not taking a psychiatric medication that is contraindicated during lactation
- **Stable methadone-maintained women wishing to breastfeed should be encouraged to do so regardless of maternal methadone dose.**



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[Click here](#) to read the ABM Protocol, which also outlines situations in which a mother should be discouraged from breastfeeding.

# NAS and Delivering Hospitals: Issues to Consider

By John Wareham, MD - St. Vincent Women's Hospital, IPN Board Member

Caring for newborns at risk for the Newborn Abstinence Syndrome (NAS) has become a common and difficult problem for all hospitals with a delivery service. NAS can apply to infants withdrawing from any drug/medication that induces dependency, but primarily refers to opioids such as methadone, heroin, buprenorphine, and prescription pain relievers. Infants identified as at risk for NAS require prolonged hospitalizations even if they don't withdraw. Newborns at risk for NAS need to be observed in the hospital for 5-7 days after birth, whether they were born vaginally or by C-section. Even with a period of observation lasting 5-7 days, an occasional infant will withdraw after discharge.

Infants that develop the NAS may be treated without medication if the withdrawal is not severe by modifying the environment and the feeding routine. Irritable infants with NAS may require frequent feeding (**breastfeeding is best**) and a quiet environment with decreased stimulation. Working out a care plan that will be successful at home may further prolong the hospitalization. Should the infant require medication such as oral morphine or methadone, then the length of hospitalization becomes weeks-to-months. Having an infant in the hospital for weeks is a strain on hospitals from a staffing standpoint, as these infants are irritable and require a lot of patience and attention.

It is not unusual for infants in full blown withdrawal that requires medication to be referred to a level 3 or 4 NICU. While NICUs have a lot of experience with NAS and prolonged hospitalizations, there is a downside to such transfers. Transfer usually takes the infant out of the county whose Child Protective Service office is responsible for the mother and infant, usually knows the family best and may already have some familiarity with the situation. The geographic separation makes visitation by the parents harder, and bonding may already be an issue in a family with limited resources and social issues. Finally, breastfeeding may buffer withdrawal, and that is much harder to do with geographic separation, especially a separation that may last for weeks to months.

Infants suffering from NAS are a problem that is not going away any time soon. The upsurge in abuse of oral narcotic pain relievers has made the situation worse. To the extent possible with limited resources, these at risk infants need to be followed and treated at their birth hospital. When resource limitations or the severity of withdrawal mandate a transfer to an NICU, the hospitalizations will often be long and the social stresses increased due to geographic separation of the infant from the parents.

Contact John Wareham at [JAWareha@stvincent.org](mailto:JAWareha@stvincent.org).

## Stay Tuned!

IPN will be hosting a Spring 2014 conference on NAS and Substance Use During Pregnancy.

More details coming soon!

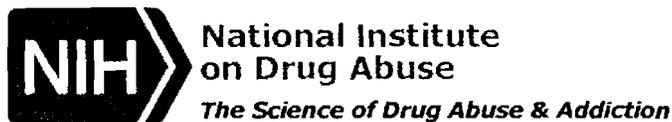


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## Buprenorphine During Pregnancy Reduces Neonate Distress

[Print](#)

### **A multisite clinical trial lays groundwork for improving care for mothers and babies affected by opioid dependence.**

**July 06, 2012**

*Lori Whitten, NIDA Notes Staff Writer*

A NIDA-supported clinical trial, the Maternal Opioid Treatment: Human Experimental Research (MOTHER) study, has found [buprenorphine](#) to be a safe and effective alternative to [methadone](#) for treating opioid dependence during pregnancy. Women who received either medication experienced similar rates of pregnancy complications and gave birth to infants who were comparable on key indicators of neonatal health and development. Moreover, the infants born to women who received buprenorphine had milder symptoms of neonatal opioid withdrawal than those born to women who received methadone.

Methadone and buprenorphine maintenance therapy are both widely used to help individuals with opioid dependence achieve and sustain abstinence. Methadone has been the standard of care for the past 40 years for opioid-dependent pregnant women. However, interest is growing in the possible use of buprenorphine, a more recently approved medication, as another option for the treatment of opioid addiction during pregnancy.

"Our findings suggest that buprenorphine treatment during pregnancy has some advantages for infants compared with methadone and is equally safe," says [Dr. Hendrée Jones](#), who led the [multicenter study](#) while at the Johns Hopkins University School of Medicine and is now at RTI International.

### **A Rigorous Trial Design**

Methadone maintenance therapy (MMT) enhances an opioid-dependent woman's chances for a trouble-free pregnancy and a healthy baby. Compared with continued opioid abuse, MMT lowers her risk of developing infectious diseases, including hepatitis and HIV; of experiencing pregnancy complications, including spontaneous abortion and miscarriages; and of having a child with challenges including low birth weight and neurobehavioral problems.

Along with these benefits, MMT may also produce a serious adverse effect. Like most drugs, methadone enters fetal circulation via the placenta. The fetus becomes dependent on the medication during gestation and typically experiences withdrawal when it separates from the placental circulation at birth. The symptoms of withdrawal, known as neonatal abstinence syndrome (NAS) include hypersensitivity and hyperirritability, tremors, vomiting, respiratory difficulties, poor sleep, and low-grade fevers. Newborns with NAS often require hospitalization and treatment, during which they receive medication (often morphine) in tapering doses to relieve their symptoms while their bodies adapt to becoming opioid-free.

The MOTHER researchers hypothesized that buprenorphine maintenance could yield methadone's advantages for pregnant women with less neonatal distress. Buprenorphine, like methadone, reduces opioid craving and alleviates withdrawal symptoms without the safety and health risks related to acquiring and abusing drugs. Therapeutic dosing with buprenorphine, as with methadone, avoids the extreme fluctuations in opioid blood concentrations that occur in opioid abuse and place physiological stress on both the mother and the fetus. However, unlike methadone, buprenorphine is a partial rather than full opioid and so might cause less severe fetal opioid dependence than methadone therapy.

The MOTHER study recruited women as they sought treatment for opioid dependence at six treatment centers in the United States and one in Austria. All the women were 6 to 30 weeks pregnant. The research team initiated treatment with morphine for each woman, stabilized her dose, and then followed with the daily administration of buprenorphine therapy or MMT for the remainder of her pregnancy. Throughout the trial, the team increased each woman's medication dosage as needed to ease withdrawal symptoms.

The study incorporated design features to ensure that its findings would be valid. Among the most notable were measures taken to prevent biases that might arise if staff and participants knew which medication a woman was getting.

To treat the participants without knowing which medication each woman was receiving, the study physicians wrote all prescriptions in pairs, one for each medication, in equivalent strengths. Study pharmacists matched the patient's name and ID number to her medication group and filled only the prescription for the medication she was taking.

Each day, participants dissolved seven tablets under their tongues and then swallowed a syrup. If a woman was in the buprenorphine group, one or more of her tablets contained that medication, depending on her prescribed dosage, while the rest of the tablets and the syrup were placebos. If a woman was in the methadone group, the syrup contained that medication in her prescribed strength and the tablets all were placebos. In this way, each woman's complement of medications appeared identical to that of every other participant. The placebo tablets and syrup were crafted to look, taste, and smell like the active medications.

## As Good For Mothers, Better for Infants

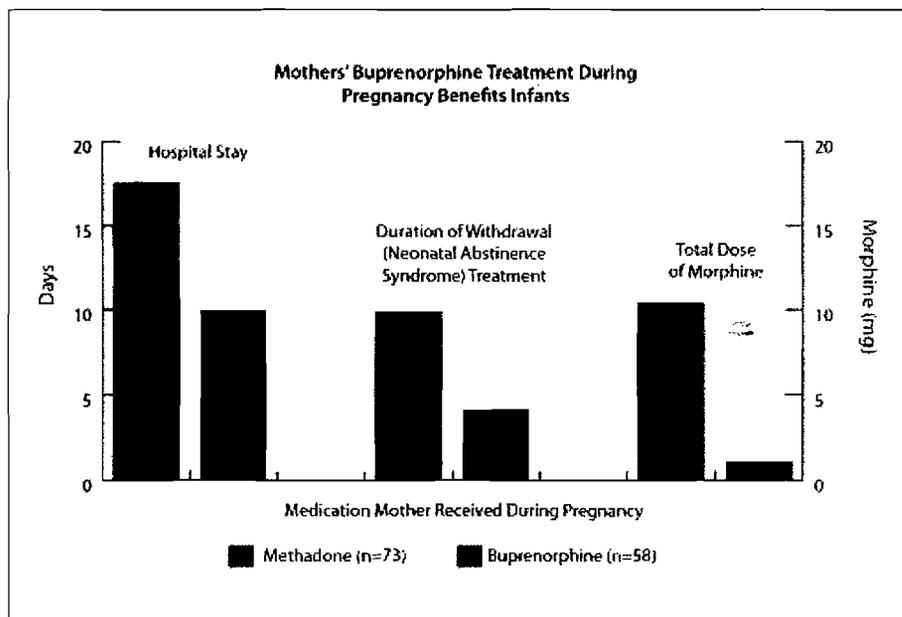
Of 175 women who started a study medication, 131 continued until they gave birth. Those who received MMT and those given buprenorphine experienced similar pregnancy courses and outcomes. The two groups of women did not differ significantly in maternal weight gain, positive drug screens at birth,

percentage of abnormal fetal presentations or need for Cesarean section, need for analgesia during delivery, or serious medical complications at delivery.

As the MOTHER researchers had hypothesized, the infants whose mothers were treated with buprenorphine experienced milder NAS than those infants exposed to methadone (see [graph](#)). Whereas most infants in both groups required morphine to control NAS, the buprenorphine group, on average, needed only 11 percent as much, finished its taper in less than half the time, and remained in the hospital roughly half as long as the infants exposed to methadone.

At Dr. Gabriele Fischer’s Medical University of Vienna site in Austria, three women became pregnant for a second time during the time MOTHER was enrolling participants. This development allowed researchers to compare the two medications’ relative safety and efficacy in individual women as well as across groups. During her second pregnancy, each of the three women took the alternative medication to the one she took in her first pregnancy. In each instance, the child born following buprenorphine treatment exhibited milder NAS symptoms than the one born following methadone treatment. This result suggests that differences in the effects of the two medications, rather than women’s individual differences in physiology, underlie the group findings.

“Buprenorphine may be a good option for pregnant women, particularly those who are new to treatment or who become pregnant while on this medication,” says Dr. Jones. “If a patient is on methadone maintenance and stable, however, she should remain on methadone.”



### Next Questions

MOTHER researchers observed that although the women in their buprenorphine and methadone groups benefited equally from treatment, the drop-out rate was higher in the buprenorphine group (33 vs. 18 percent). This difference was not statistically significant. The researchers speculate that if it is meaningful, it may be owing to factors other than different responses to the two medications. They surmise that the

experimental treatment protocols may have moved patients from morphine to buprenorphine too rapidly, causing discomfort, or that buprenorphine may have been easier than methadone to discontinue when women decided to become abstinent.

The MOTHER study did not include women with some substance use disorders that are commonly comorbid with opioid abuse. "Future studies should compare neonatal abstinence syndrome, birth outcomes, and maternal outcomes of these two medications for pregnant women who also abuse alcohol and benzodiazepines," Dr. Jones says.

"The field also needs data on neonatal outcomes when pregnant women are treated with buprenorphine combined with naloxone, the current first-line form of buprenorphine therapy for opioid dependence," Dr. Jones notes. The MOTHER study administered buprenorphine without naloxone to avoid exposing the fetus to a second medication with potential adverse effects.

"Research challenges remaining after this brilliant study are to determine the factors that resulted in the differential drop-out rates between the two medications," says Dr. Loretta P. Finnegan, who did pioneering work in the assessment and treatment of NAS. "Additionally, researchers need to conduct followup research on these children to determine the longer term significance of the differences in newborn withdrawal symptoms." Dr. Finnegan, now president of Finnegan Consulting, was formerly the medical advisor to the director of the Office of Research on Women's Health at the National Institutes of Health.

"Neonatal abstinence syndrome is a terrible experience for infants, and there is a great need to improve care for this condition," says Dr. Jamie Biswas of [NIDA's Division of Pharmacotherapies and Medical Consequences of Drug Abuse](#). "Dr. Jones' study is a superb contribution to this area of clinical research, and the robust results should provide more treatment options for a syndrome that affects thousands of infants each year."

#### Sources:

Unger, A., et al. Randomized controlled trials in pregnancy: Scientific and ethical aspects. Exposure to different opioid medications during pregnancy in an intra-individual comparison. *Addiction* 106(7):1355-1362, 2011. [Full Text](#)

Jones, H.E., et al. Neonatal abstinence syndrome after methadone or buprenorphine exposure. *New England Journal of Medicine* 363(24):2320-2331, 2010. [Full Text](#)

## MOTHER Collaborators

Following is a list of collaborators on the Maternal Opioid Treatment: Human Experimental Research (MOTHER) Study and their university affiliations:

Dr. Hendrée Jones (study leader), Johns Hopkins University School of Medicine; Dr. Amelia Arria, University of Maryland, College Park; Dr. Mara Coyle, Warrant Alpert Medical School of Brown University; Dr. Gabriele Fischer, Medical University of Vienna; Dr. Sarah Heil, University of Vermont; Dr. Karol Kaltenbach, Jefferson Medical College; Dr. Peter Martin, Vanderbilt University School of Medicine; Dr. Peter Selby, University of Toronto; and Dr. Susan Stine, Wayne State University School of Medicine.

*This page was last updated July 2012*



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# OPIOID DEPENDENCE IN PREGNANCY: AN EVIDENCE-BASED TOOLKIT

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OBSTETRICS AND GYNECOLOGY

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*Supported in part by the Indiana State Department of Health, Division of Maternal and Child Health.*

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# MODULE 1: INTRODUCTION

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## Purpose

- The Toolkit should serve as basic resource for non-addiction providers
  - Obstetricians; Family physicians, pediatricians; residents and medical students.
  - Midwives; Prenatal and Labor Nurses; nursing students
  - Anesthesiologists
  - Emergency physicians
  - Paramedics; EMTs
  - Anyone providing obstetrical and primary care.
- The Toolkit applies to pregnant patients and focuses on opioid dependence in pregnancy.

## Toolkit Format

- Allows for rapid identification of detection, treatment and management plans.
- Clinical cases highlight the contents of the chapter and key issues for the provider.
- Includes substantial references from the literature and data from the treatment of over 500 patients in the Prenatal Recovery Program at Wishard Memorial Hospital, Indianapolis, Indiana. (Wishard Data)
  - Wishard is a public hospital for Indianapolis and a major teaching hospital for the Indiana University School of Medicine.
  - Demographics include approximately 3000 deliveries per year of Black (35%), White (25%) and Hispanic (40%) patients.
  - About 95% are Medicaid funded.
- Comments will be in italics.

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### Case 1

A 32 year old presents to the labor suite in preterm labor at 32 weeks. She complains of painful contractions for two days while yawning constantly, and appears sleepy and complains of hot flashes.

Attempts to stop the preterm labor fail and she delivered a 2000-gram male with Apgar scores of 7 and 9.

In the nursery, the baby shows all the signs of opioid withdrawal and drug testing reveals opioids, specifically oxycodone. The newborn was treated and did well while spending 62 days in the NICU.

The mother was questioned about prior drug use and revealed an "Oxy" (oxycodone) addiction using up to 160 mg per day.

In retrospect, she presented in acute opioid withdrawal.

She was started on buprenorphine/naloxone (Suboxone) with a good response and agreed to addiction treatment. Six months later, she remained opioid free on Suboxone maintenance and attends an addiction treatment program.

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**THIS CASE IDENTIFIES THE MOST SIGNIFICANT PROBLEM IN TREATING SUBSTANCE USE IN PREGNANCY - FAILURE TO IDENTIFY THE SUBSTANCE-USING PATIENT.**

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**Opioid Use, especially among women, is skyrocketing in the United States.<sup>1</sup>**

Percent of pregnant patients dependent on opioids referred to the Wishard Program:

2002-2007: 69/287 patients: 24%

2008: 69.3%

2009: 79.1%

2010: 75.5%

This study includes patients with opioid addictions, opioid dependent chronic pain patients, opioid poly-substance users, and methadone and buprenorphine maintenance.

**Opioid Use carries high morbidity and mortality for both fetus and mother<sup>2</sup>**

- Over 2,000 deaths per week have been attributed to opioid abuse.
- Most of the fatalities are due to Oxycontin
- Maternal treatment with opioid analgesics increases the risk of birth defects.
- Opioid withdrawal carries substantial Risks:<sup>3</sup>
  - High rate of preterm labor - 41%
  - Increased abruption - 13%
  - High rate of low birth weight – 27%

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**THE RISK OF ADVERSE EVENTS FROM OPIOID WITHDRAWAL APPEARS TO BE FAR GREATER THAN FROM THE TREATMENT OF NEONATAL ABSTINENCE**

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**Pregnancy makes a difference in long-term recovery<sup>4</sup>**

After one year of treatment:

65.7% of women who entered treatment while pregnant used no drugs, while,

Only 27.7% of non-pregnant women remained drug free. (p<0.0005)

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<sup>1</sup> [http://www.foodconsumer.org/newsite/Politics/32/opioid\\_abuse\\_skyrockets\\_061820100141.html](http://www.foodconsumer.org/newsite/Politics/32/opioid_abuse_skyrockets_061820100141.html)

<sup>2</sup> [http://www.ajog.org/article/S0002-9378\(10\)02524-X/abstract](http://www.ajog.org/article/S0002-9378(10)02524-X/abstract)

<sup>3</sup> Lam SK, To WK, Duthie SJ, Ma HK. Narcotic addiction in pregnancy with adverse maternal and perinatal outcome. Aust N Z J Obstet Gynaecol 1992 Aug;32(3):216-21.

<sup>4</sup> Peles E, Adelson M. Gender Differences and Pregnant Women in a Methadone Maintenance Treatment (MMT) Clinic. *J Addictive Diseases* 2006; 25: 39-45.

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# MODULE 2: SUBSTANCE USE TERMINOLOGY

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## Case 2

A 26 year old at 16 weeks of pregnancy was in a motor vehicle accident with multiple soft tissue injuries. Ultrasound revealed an intact fetus. She received hydrocodone 5/acetaminophen 325 for pain and alprazolam 0.5 mg for anxiety.

She requested refills at two weeks and at 6 weeks from the accident, the doctor refused to refill her prescriptions due to her “drug seeking behavior.”

She was able to “score” drugs from her friends and presented for her first prenatal visit at 24 weeks with an opioid and benzodiazepine addictions.

*This case illustrates one of the most common etiologic factors in opioid use amongst young women, that is, treatment with opioids and benzodiazepines for injuries sustained in a motor vehicle accident.*

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## Addiction

- Commonly used term meaning the aberrant use of a specific psychoactive substance or a behavior in a manner characterized by
  - Loss of control,
  - Compulsive use,
  - Preoccupation, and
  - Continued use despite harm.
- *In reality, this can be an extremely difficult illness to define and the general consensus among addiction counselors is, “I know it when I see it.”*

## Relationship View of Addiction

- If the behavior keeps the patient from being physically and emotionally present for those she loves and those who love her.
- Then she has a problem with the behavior.
- May be alcohol, tobacco or other drugs (ATOD)
- May be eating, sex, gambling, being a workaholic, etc.

## Substance Use Disorder

- “Substance Use Disorder” (SUD) replaced the pejorative term “addiction” in the American Psychiatric Association (DSM-IV-TR).<sup>5</sup>
- The DSM-IV-TR distinguishes between:
  - Substance Dependence *and* Substance Abuse

See Appendix A: Substance Use Terminology.<sup>6</sup>

### **Dependence**

- **Psychological dependence:** A need for a specific psychoactive substance either for its positive effects or to avoid negative psychological or physical effects associated with its withdrawal.
- **Physical dependence:** A physiologic state of adaptation to a specific psychoactive substance characterized by the emergence of a withdrawal syndrome during abstinence, which may be relieved in total or in part by re-administration of the substance.

### **Withdrawal**

- The onset of a predictable constellation of signs and symptoms after the abrupt discontinuation of or a rapid decrease in dosage of a psychoactive substance.
- In the adult, classic signs of opiate withdrawal include:
  - Early Signs: (8-12 hrs.): Diaphoresis, nausea, yawning, excessive crying, tremor, runny nose, irritability, dilated pupils, resp. rate, pulse>90
  - Severe Signs: (12-48 hrs.): Insomnia, elevated T, P, R & BP, nausea, vomiting, abdominal cramps, chills, diarrhea, muscle twitching and dilated pupils.<sup>7</sup>
- Newborn withdrawal is called Neonatal Abstinence Syndrome (NAS).<sup>8</sup>

### **Tolerance**

- Increased dosage of a substance is needed to produce a desired effect.
- Increased frequency of use to achieve desired effect.

### **Cross Tolerance**

- Induced by repeated administration of one substance that is manifested toward another substance to which the individual has not been recently exposed.
- Clinical Examples:
  - High tolerance to amphetamines may exhibit high tolerance to methamphetamines
  - Cigarette smokers have a lower sensitivity to caffeine

### **Diversion**

- The use of prescription drugs for recreational or other purposes.
- Clinical examples:
  - Chronic pain patient sells some of her oxycodone to her friends.
  - Patient's mother gives daughter some of her alprazolam (Xanax) for "panic attacks."
  - Buprenorphine/naloxone (Suboxone) is sold on the street to methadone patients so they do not have to go to a methadone clinic for their maintenance.

### **Dependence versus Addiction - Clinical Examples**

- A well-managed chronic pain patient using oxycodone for pain relief is dependent on opioids.
  - She will go through withdrawal if the opioids are discontinued.
  - She is NOT considered an addict.
- A patient takes "oxy" (Oxycontin) obtained from "street" dealers:
  - She is dependent.

- She will go through withdrawal if drug is discontinued.
- By definition, this is substance abuse because of the illegal nature in which she obtains her drugs.
- She could be considered an “addict.”

### Polysubstance Use

- Concomitant use of two or more psychoactive substances, in quantities and frequencies that cause individually significant distress or impairment.
- The Wishard data shows that 107/287 or 37.2% of pregnant women presented for prenatal care with polysubstance use.
- Opiates are a common component along with alcohol and tobacco.
- As are Alcohol and Tobacco
- Common conditions with polysubstance use:
  - Chronic pain conditions
  - Fibromyalgia
  - Bipolar
  - Anxiety disorders

### Recovery Terminology

- **Recovery:** A process of overcoming both physical and psychological dependence on a psychoactive substance with a commitment to sobriety.
- **Abstinence:** Non-use of any psychoactive substance.
- **Maintenance:** Prevention of craving behavior and withdrawal symptoms of opioids by long-acting opioids (e.g. methadone, buprenorphine).
- **Harm Reduction:** a gradual process of change that eventually leads to recovery – viewed by some as controversial.

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<sup>5</sup> Mitra S. & Sinatra R. S. Perioperative management of acute pain in the opioid-dependent patient. *Anesthesiology*, 2004;101:212-227.

<sup>6</sup> American Psychiatric Association (2000). *Diagnostic and statistical manual of mental disorders* (Revised 4th ed.). Washington, DC: Author.

<sup>7</sup> Handelsman L, Cochrane KJ, Aronson MJ, et al. Two new rating scales for opiate withdrawal. *Am J Drug Alcohol Abuse* 1987;13(3)293-308

<sup>8</sup> Ebner N. Management of neonatal abstinence syndrome in neonates born to opioid maintained women. *Drug Alcohol Depend*, 2007;87:131-138

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# MODULE 3: ETHICAL AND PSYCHOSOCIAL DIMENSIONS OF THE PHYSICIAN-PATIENT RELATIONSHIP

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## **Role of Physician treating patients with substance use:**

- The physician is the patient's advocate, not adversary.
- Mandatory reporting laws obligate the physician to follow the law or suffer severe penalties including felony prosecution.
- Difficult situations make difficult laws and they risk turning the physician into an adversary, thus driving the patients from care.<sup>9</sup>
- Evidence indicates physician attitudes are more punitive than supportive.<sup>10</sup>
- Obstetrical nurses noted to be judgmental and punitive.<sup>11</sup>

## **Physician-Patient Relationship: Informed Consent**

- The provider is in a superior position to the patient with respect to knowledge, expertise and skills.
- This is called a "fiduciary" relationship.
- The physician-patient relationship creates a duty for the physician to inform the patient of the risks and benefits of the planned care, procedure, tests, medications, etc.
- The validity test for informed consent is whether the patient has been adequately informed to exercise her right to refuse the planned care.
- Rarely do issues of informed consent lead to liability.

## **Three Important Tools for success in treating substance use**

- Attitude: Non Judgmental
- Attitude: Supportive
- Attitude: Be specific about every detail of care.

## **Legal and Ethical Issues in Urine Testing<sup>12</sup>**

- There is no uniform policy on maternal or newborn drug testing.
- It is well established that patients may refuse even lifesaving care.<sup>13</sup>
- When it comes to childbearing, the most prominent issue places the mother's right to autonomy against a fetus' right to physical integrity.
- This is especially true for issues such as court ordered cesarean delivery, abortion, employment in the toxic workplace and criminalization of maternal drug use.<sup>14</sup>

## **Current opinions indicate two lines of thought about drug testing**

### Focus on autonomy

- A specific and informed consent needs to be obtained for maternal or newborn testing.
- Such consent must also inform the patient that positive results may be reported to Child Protective Services or may be used for legal action if the state enacts criminal penalties for drug use in pregnancy.

- Patient must be informed that she may “opt out” of any test.
- If she “opts out” of the drug test, she must be informed that the pediatrician is able to test the baby’s meconium without her consent.

Focus on Beneficence and Justice

- In contrast, the other opinion holds that the signed consent for prenatal and obstetrical care covers all tests necessary for medical diagnosis and treatment.
- Implied in this opinion is that all information acquired by the physician remains “privileged” and confidential between the patient and physician.

**Legal Issues**

- It is clear that state laws that criminalize maternal conduct (i.e. that make illegal substance use a felony) do not resolve the issue of drug use in pregnancy.
- The greatest risk is that such laws create an adversarial situation and drive patients away from prenatal care.
- Thus, it is most important to identify alcohol and drug use within the “privileged” and confidential clinical setting and this appears to be best achieved by universal verbal screening for all pregnant women.

**Ferguson v. City of Charleston**

- South Carolina enacted a law that makes the use of an illegal or illicit substance during pregnancy a Class D felony.
- Two issues became clear as a result of this law and they were noted in a United States Supreme Court decision, *Ferguson v. City of Charleston*.<sup>15</sup>
- The case noted that 40 out of 41 women arrested as a result of postpartum drug testing for cocaine were African-American.
- In contrast, when tests were positive for heroin or methamphetamine, more often used by white women, patients were more likely referred to social services.
- The second issue in this case involved a point of law.
- The Court held that if the drug test was obtained without the patient’s consent, then the patient cannot be subject to criminal prosecution because it constitutes an unlawful search under the Fourth Amendment.

*This Supreme Court decision is, in fact, the law of the land.*

<sup>9</sup> Poland ML, Dombrowski MP, Ager JW, Sokol RJ. Punishing pregnant drug users: enhancing the flight from care. *Drug Alcohol Depend* 1993;31:199-203.

<sup>10</sup> Abel EL, Kruger M. Physician attitudes concerning legal coercion of pregnant alcohol and drug abusers. *Am J Obstet Gynecol* 2002;186:768-72.

<sup>11</sup> Selleck CS, Redding BA. Knowledge and attitudes of registered nurses toward perinatal substance abuse. *J Obstet Gynecol Neonatal Nurs* 1998;27:70-7.

<sup>12</sup> Indiana Perinatal Network. Substance use disorders in pregnancy: consensus statement. September 2006, [www.indianaperinatal.org](http://www.indianaperinatal.org).

<sup>13</sup> *Cruzan v. Director, Missouri Dept. of Health*, 110 S. CT. 2841 (1990).

<sup>14</sup> Nocon JJ, Physicians and Maternal-Fetal Conflicts: Duties, Rights, and Responsibilities, *Journal of Law and Health, Cleveland-Marshall College of Law Review* 1991;5:1.

<sup>15</sup> *Ferguson v. City of Charleston*, 532 U.S. 67 (2001)

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## MODULE 4: WHAT PROVIDERS NEED TO KNOW ABOUT OPIOIDS

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### Case 3

A 30 year-old former heroin addict is in her third pregnancy at 32 weeks. She has been stable for the last two years on a methadone maintenance program taking 70 mg. per day.

She presents with a complaint of insomnia due to hot flashes and night sweats. These symptoms started about two weeks ago. Typically they start about 5 AM and the symptoms were mild. Now they start about 2 AM and they are more severe. She now has “stomach cramps” when she awakens.

She stated this occurred in her prior labors and she went into premature labor both times.

In consultation with the methadone clinic physician, we agreed that the pregnancy was increasing the methadone metabolism and she was going into withdrawal before her customary treatment time of 7 AM.

Her methadone dose was increased by 5 mg. daily until the symptoms stopped

She had good relief at a dose of 95 mg., continued to term and delivered a 2900-gram boy at 38 weeks.

Her dose was modified downward during the next 3 months.

*Frequent communication with the methadone clinic physician is necessary to insure the patient is adequately monitored during the pregnancy.*

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### **Opioids are metabolized faster in pregnancy.**

- Methadone, hydrocodone and oxycodone are metabolized at a more rapid rate in pregnancy.
- Thus, the requirement for a maintenance dose will increase.
- In the Wishard data, 32/92 (35%) of the methadone maintenance patients required an increase of 30% to over 50% over their initial dose to prevent withdrawal.

### **The rate of excretion is faster than withdrawal**

- Morphine is excreted within 72 hours while the withdrawal is 3-6 days.
- Methadone can be excreted in 4-5 days but withdrawal is prolonged to 10-20 days.
- The clinical relevance is that a patient in withdrawal may have a negative urine drug screen (UDS).

## Effects on Pregnancy

**The major maternal risk of opioid use is respiratory depression and death.**

- Many opioid users also use benzodiazepines, which greatly increase the risk of death.
- In the Wishard data, 19 of 45 (42.2%) opioid chronic pain patients tested positive for benzodiazepines at their first prenatal visit.
- In addition, about two thirds of the patients use tobacco.
- The Wishard data also reveals that opioid users have a higher incidence of low birth weight and preterm labor.

**Maternal treatment of opioid addiction involves:**

- Managing acute overdose,
- Treating withdrawal,
- Maintenance and
- Detoxification.

*All too often, the patient presents in acute withdrawal. After she is stabilized, most are managed by maintenance with methadone or buprenorphine and only occasionally does a patient choose detoxification.*

## Changes in Approach to Opioid Dependent Patient

There has been a major shift in the approach to opiate treatment from detoxification and abstinence to maintenance. A number of factors have contributed to this shift.

- Relapse in this population is high.
- Maintenance helps prevent relapse and diseases attributed to IV drug use.
- Most important is that opiate withdrawal significantly increases the risk for abortion and preterm labor.
- However, in selected patients, detoxification has been accomplished with relative safety.<sup>16</sup>
- In one retrospective study of gradual methadone detoxification, there was no increased risk of preterm delivery.<sup>17</sup>
- However, the relapse rate in one study was 56% after detoxification.<sup>18</sup>

## General Notes

- **Opiates** are alkaloids derived from the opium poppy and include morphine, codeine and thebaine.
- **Opioids** include all opiates plus the semi-synthetics, which are derived from the alkaloids (thebaine): hydrocodone, oxycodone, and heroin, plus the synthetics: methadone, fentanyl, Nubian, and buprenorphine.
- Many physicians use the terms “opiate” and “opioid,” interchangeably.

## Pharmacology

**Opioids bind to neuroreceptors specifically:**

- Mu: analgesia; euphoria, respiratory depression, constipation, sedation, miosis
- Kappa: dysphoria, sedation, and psychotomimetic
- Delta: unknown

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<sup>16</sup> Dashe JS, Jackson GL, Olscher DA, Zane EH, Wendel GD, Jr. Opioid detoxification in pregnancy. *Obstet Gynecol* 1998;92:854-8.

<sup>17</sup> Luty J, Nikolaou V, Bearn J. Is opiate detoxification unsafe in pregnancy? *Journal of Substance Abuse Treatment* 2003;24(4):363-367.

<sup>18</sup> Maas U, Kattner E, Weingart-Jesse B, et al. Infrequent neonatal opioid withdrawal following maternal methadone detoxification during pregnancy. *J Perinat Med.* 1990;18:111–118.

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# MODULE 5: OPIOID OVERDOSE

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## Case 4

An 18 year old women presents to the emergency room comatose and barely breathing. She appears to be pregnant at term. Fetal heart rate is 180 BPM. There is some froth to her breath.

This is a classic presentation for opioid overdose. An airway was established, parenteral fluids started and naloxone was administered. One hour after Naloxone, her breathing slows again. Overdose most likely due to long acting opioid – methadone. Repeat naloxone counteracted the opioid.

She was restarted on methadone for stabilization and delivered a healthy 2800-gram female shortly thereafter. The infant was treated for NAS for 30 days in the NICU.

*This case illustrates an all too common experience for emergency department physicians. Rapid identification and treatment is lifesaving.*

---

### Overdose is increasingly more common

- Opioid prescription abuse is the fastest rising addiction and public health problem in the United States.
- Over 2,000 deaths per week have been attributed to opioid abuse.
- Most of the fatalities are due to Oxycontin
- Comparison of Mortality rates in the U.S., 2009<sup>19</sup>
  - MVA 36,284
  - Drugs 37,485
  - Firearms 30,694

### Opioid Overdose Management

- Characterized by pinpoint pupils, respiratory depression, coma, and pulmonary edema.
- Establish airway.
- Start parenteral fluids, e.g., Lactated Ringer's solution.
- **Avoid fluid overload – many patients with overdose are in subclinical or overt pulmonary edema.**
- Inject Naloxone – repeat if long acting opiate present, e.g., methadone.
- Naloxone will not harm fetus.
- **Check acetaminophen levels in patients using opiate/acetaminophen compounds.**

### Treatment will precipitate a severe withdrawal

- Will need to restart and modify an opioid dose to prevent further withdrawal
- May use oxycodone 10 mg. every 2-4 hours until stable.
- Patients on IV Morphine pumps typically use over 100 mg. in 24 hours to stop the withdrawal symptoms.

### **Symptomatic relief during transition to maintenance**

- Withdrawal affects four major systems:
  - CNS
  - GI
  - Cardiovascular
  - Autonomic Nervous System
- Phenergan 25 mg q 4-6 H for withdrawal symptoms – best for nausea, vomiting and GI symptoms
- Phenobarbital, 30 mg TID for neurological withdrawal symptoms.
  - A long acting barbiturate.
  - Anti-seizure medication
  - A vasodilator
- Clonidine 0.1 mg TID – vascular withdrawal symptoms.<sup>20</sup>
- **Avoid benzodiazepines.**

### **Convert to maintenance: use Methadone or Buprenorphine**

- Methadone: start at 20 mg BID and increase 5-10 mg per day until stable.
- Buprenorphine/naloxone (Suboxone): start at 2 – 4 mg; increase by 2-4 mg every 6 hours until withdrawal is abated.
- Typical Suboxone doses for maintenance are from 8-16 mg.
- Naloxone carries no recognizable harm to the fetus.

### **Evaluate for psychiatric co-morbidity**

Some co-morbid psychiatric problems are more common in women:<sup>21</sup>

- Bipolar disorders
- Panic Disorder
- PTSD
- Cluster B Personality Disorders
- Bulimia
- Depression

### **Psychiatric evaluations should include at least**

- Depression scale at first and subsequent prenatal visits if at risk.
- Independent evaluations by psychiatric trained providers.
- Care coordination of psychiatric problems.

<sup>19</sup> Kochanek KD, Xu J, Murphy SL, Miniño AM, Kung H, Deaths: preliminary data 2009. National Vital Statistics Reports 2011; 59(4).

<sup>20</sup> Horvath JS, Phippard A, Korda A, Henderson-Smart DJ, Child A, Tiller DJ. Clonidine hydrochloride--a safe and effective antihypertensive agent in pregnancy. *Obstet Gynecol* 1985;66:634-8

<sup>21</sup> Miles DR, Kulstad JL, Haller DL. "Severity of substance abuse and psychiatric problems among perinatal drug-dependent women." *J Psychoactive Drugs*. 2002;34(4): 339-346.

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# MODULE 6: OPIOID WITHDRAWAL

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## Case 5

A 26 year-old chronic pain patient, in good control with hydrocodone 10 mg. acetaminophen 325 mg. four times daily. She also takes amitriptyline 50 mg. before sleep. She suffered a gunshot wound to her leg with resulting femoral nerve neuropathy.

At 28 weeks, she visited her pregnant sister who was about to deliver. She ran out of meds and could not get refills in the other state.

She presented to the E.D with hot flashes, abdominal cramps, diarrhea, irritability and rapid pulse.

She was diagnosed with “stomach flu” and told to maintain hydration and was given a prescription for Phenergan, 25 mg. every six hours.

She returned home shortly thereafter in florid opioid withdrawal and fortunately, refills of her prescriptions resolved the problem.

*Opioid withdrawal can be subtle in its onset and often missed as a diagnosis.*

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## CURRENT RECOMMENDATION IS TO AVOID WITHDRAWAL DURING PREGNANCY

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### Opioid Withdrawal: Affects Major Systems

- CNS – tremors, seizures
- Metabolic – sweating; yawning
- Vascular – hot flashes and chills
- Respiratory – increased rate; respiratory alkalosis
- GI – cramps, nausea, vomiting, diarrhea
- Drug specific effects – methadone has a prolonged withdrawal: 10 – 20 days.
- Restart and modify opioid dose.
- **Avoid benzodiazepines; potentiates CNS and respiratory depression.**

### Opioid Withdrawal Treatment

- Initiate methadone or buprenorphine to stabilize withdrawal:
  - May use oxycodone 10 mg q 4-6h for up to 72 hours to stabilize patient a
  - Then switch to methadone or buprenorphine.
- Phenergan 25 mg q 4-6 H for withdrawal symptoms – best for nausea, vomiting and GI symptoms
- Phenobarbital, 30 mg TID for neurological withdrawal symptoms.

- Clonidine 0.1 mg TID – vascular withdrawal symptoms.<sup>22</sup>
- Check acetaminophen levels in patients using opiate/acetaminophen compounds.

### **Opioid Detoxification**

- Must be closely controlled. Benefits rarely outweigh risks.
- Gradual reduction to minimize withdrawal but preterm labor remains high.
- Relapse rates in detoxification plans are also high – over 50%.

### **Preterm labor remains a major risk in overdose, withdrawal and detoxification**

- Pharmacologic treatments for preterm labor, such as magnesium sulfate, may potentiate respiratory depression in the mother and neonate.
- Fetal monitoring is significantly affected by opioids with reduced fetal activity most common.<sup>23</sup>
- Methadone will cause a higher incidence of non-reactive non stress tests (NST), especially if given 1-3 hours before the NST.<sup>24</sup>
- The biophysical profile is the appropriate follow up tool for a non-reactive NST.<sup>25</sup>

### **Intrauterine growth restriction (IUGR) is another common problem in opioid dependent women and monitoring with ultrasound is essential to determine prenatal management.**

- If IUGR is identified, the degree of placental dysfunction is thought to be associated with changes in diastolic blood flow through the umbilical cord.
- Increasing resistance of diastolic flow and reduction of amniotic fluid are markers indicating closer surveillance and earlier intervention.
- Typically, opioid dependent patients with fetal growth less than the tenth percentile are delivered after 37 completed weeks.

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**IT IS ESSENTIAL TO RESTART THE PATIENT'S MAINTENANCE PROGRAM AFTER AN EPISODE OF WITHDRAWAL. THIS MAY REQUIRE A HIGHER DOSE OF OPIOIDS.**

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<sup>22</sup> Horvath JS, Phippard A, Korda A, Henderson-Smart DJ, Child A, Tiller DJ. Clonidine hydrochloride--a safe and effective antihypertensive agent in pregnancy. *Obstet Gynecol* 1985;66:634-8

<sup>23</sup> Cejtin HE, Mills A, Swift EL. Effect of methadone on the biophysical profile. *J Reprod Med* 1996;41:819-22.

<sup>24</sup> Archie CL, Lee MI, Sokol RJ, Norman G. The effects of methadone treatment on the reactivity of the nonstress test. *Obstet Gynecol* 1989;74:254-5.

<sup>25</sup> Levine AB, Rebarber A. Methadone maintenance treatment and the nonstress test. *J Perinatol* 1995;15:229-31.

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# MODULE 7: OPIOID MAINTENANCE STRATEGIES - METHADONE

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## Case 6

A 30 year–old former “oxy” addict, single mom, was stabilized on methadone, 90 mg. daily.

She is in her second pregnancy at 28 weeks and doing well.

She works in the laundry department at the hospital and her shift runs from 7 AM. To 3 PM.

Thus, she must attend the methadone clinic before work to receive her dose – the clinic is open from 5 AM to 1 PM.

She almost always suffers adverse effects of the methadone, especially nausea for the first 2 hours after receiving her dose.

She has received numerous warnings that she appears “drugged” at work and is at risk for losing her job.

She cannot work another shift due to her need to attend to her first child, who returns from school at 3:30 PM

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**Methadone maintenance** has been the model for maintenance of opioid dependent pregnant patients for many years.

- Contrary to popular belief, it has never been approved to treat opioid dependency in pregnancy.
- Methadone maintenance is highly regulated and can only be dispensed for opioid dependence treatment in a federally certified clinic.
- Thus, the patient must arrive early in the morning, receive her dose and its attendant side effects and then carry on through her day.

## **Methadone Maintenance**

Early reports found substantial benefits from maintenance therapy, especially reduction of infectious disease and stillbirth.<sup>26</sup>

- Originally, the dosing regimen for methadone followed the practice of using the lowest possible dose to reduce the risk of NAS.
- Dose of less than 20-40 mg often failed to achieve a blocking effect and led to increased preterm labor, low birth weight and relapse.<sup>27</sup>
- Thus, it is most prudent to adjust the dose of methadone based on withdrawal symptoms and cravings.
- Up to 35% of patients will require an increase in methadone, typically in the late second

and early third trimesters.

- Although the evidence does not support an advantage to divided doses of methadone, many patients report better tolerance and less nausea, which improves compliance with treatment and prenatal care.<sup>28</sup>
- If the patient experiences the typical post-partum diuresis, it is recommended to reduce the methadone dose by 20-40% shortly after delivery.

#### **Opioid Maintenance - Methadone**

- Encourage patient to remain on methadone during pregnancy.
- Expect dose to increase up to 50% during pregnancy in about 35% of patients.
- Doses range from 50-150 mg. per day.
- Higher doses **ARE NOT** associated with the severity of NAS and have been shown to improve maternal compliance with prenatal care.<sup>29</sup>
- Patient should be encouraged to breast feed.<sup>30</sup>

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<sup>26</sup> Newman RG, Bashkow S, Calko D. Results of 313 consecutive live births of infants delivered to patients in the New York City Methadone Maintenance Treatment Program. *Am J Obstet Gynecol* 1975;121:233-7.

<sup>27</sup> Kashiwagi M, Arlettaz R, Lauper U, Zimmermann R, Hebisch G. Methadone maintenance program in a Swiss perinatal center: (I): Management and outcome of 89 pregnancies. *Acta Obstet Gynecol Scand* 2005;84:140-4.

<sup>28</sup> DePetrillo PB, Rice JM. Methadone dosing and pregnancy: impact on program compliance. *Int J Addict.* 1995;30:207-217.

<sup>29</sup> McCarthy JJ, Leamon MH, Parr MS, Anania B. High-dose methadone maintenance in pregnancy: maternal and neonatal outcomes. *Am J Obstet Gynecol* 2005;193:606-10.

<sup>30</sup> Philipp BL, Merewood A, O'Brien S. Methadone and breastfeeding: new horizons. *Pediatrics* 2003;111:1429-30.

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## MODULE 8: OPIOID MAINTENANCE - BUPRENORPHINE

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### Case 7

A 22 year-old presents at 12 weeks with her second pregnancy.

She states she was a former “pain patient” and is maintained on Suboxone 8 mg/2mg. daily and wanted to wean down so she could test negative at delivery.

She also did not want her parents or partner to know she was on Suboxone.

She was given feedback about the risks of weaning and also reassured that her information was confidential

A very gradual reduction of Suboxone to 2 mg. per day was achieved at 32 weeks gestation.

She stopped her Suboxone at 38 weeks and delivered a healthy male two weeks later.

Her drug screen on admission was negative and as well as the baby’s meconium screen.

She resumed her 8 mg./2 mg. Suboxone dose by the 4 week postpartum visit.

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**Buprenorphine maintenance** was first registered to treat opiate dependence in France in 1996, and practitioners were allowed to dispense buprenorphine by prescription enabling easy access to treatment.<sup>31</sup>

- Thousands of patients underwent buprenorphine treatment, including among them an increasing number of pregnant women.
- An initial striking observation was that in the majority of newborns, the neonatal abstinence syndrome (NAS) was either absent or mild enough to not require treatment.
- A prospective French study of 34 buprenorphine treated pregnancies revealed that only 13 had NAS, nine of which were confounded by other psychoactive drugs (benzodiazepines, opiates and cannabis).<sup>32</sup>

Buprenorphine was approved for use in the United States in 2002 by an amendment to the Drug Treatment Act of 2000.<sup>33</sup> (DATA)

- DATA enables QUALIFYING PHYSICIANS to receive a WAIVER from the special registration requirements in the Controlled Substances Act for the provision of medication-assisted opioid therapy.

- This waiver allows qualifying physicians to practice medication-assisted opioid addiction therapy with Schedule III, IV, or V narcotic medications specifically approved by the Food and Drug Administration (FDA).
- On October 8, 2002 Subutex® (buprenorphine hydrochloride) and Suboxone® tablets (buprenorphine hydrochloride and naloxone hydrochloride) received FDA approval for the treatment of opioid addiction.
- Such medications may be prescribed and dispensed by waived physicians in treatment settings other than the traditional Opioid Treatment Program (methadone clinic) setting.
- The first United States survey of a registry of over 300 mothers treated with buprenorphine reveals that buprenorphine is safe and effective for mothers and newborns with a qualitatively and quantitatively diminished NAS compared to methadone.<sup>34</sup>
- A comparative study between methadone and buprenorphine confirmed improved maternal and neonatal outcomes on buprenorphine.<sup>35</sup>

**How to get certified as a Buprenorphine Provider:**

- **For complete details about qualifications, see <http://buprenorphine.samhsa.gov/pls/bwns/training>**
- **DATA-qualifying training events are available both in-person and on the Web.**
- **Web Based Trainings:**
  - American Academy of Addiction Psychiatry (AAAP)**
  - American Osteopathic Academy of Addiction Medicine (AOAAM)**
  - American Psychiatric Association (APA)**
  - American Society of Addiction Medicine (ASAM)**

**Pharmacology of Buprenorphine**

- Buprenorphine is an agonist/antagonist with a high binding affinity for the Mu receptor.
- Thus, if the patient uses another opiate while on buprenorphine, she will have a minimal euphoric experience.
- This effect significantly reduces the abuse potential.<sup>36</sup>
- It is metabolized by placental aromatase to nor-buprenorphine resulting in low placental transfer.
- This may account for limited fetal exposure and its lower incidence of NAS.<sup>37</sup>

**Buprenorphine is marketed in the United States in two forms, buprenorphine (Subutex) and buprenorphine combined with naloxone (Suboxone)**

- Initially, there was some concern that the buprenorphine/naloxone combination might cause an intrauterine withdrawal in the fetus.
- Hence, only Subutex was initially recommended for use in pregnancy.
- The evidence clearly indicates that the dose of naloxone has little to no effect on the fetus.<sup>38</sup>
- Moreover, sublingual buprenorphine has been found to be safe and effective in treating NAS.<sup>39</sup>
- Small amounts of buprenorphine are found in the breast milk. However, it has little, if any effect on the newborn with no evidence of neonatal withdrawal when breastfeeding is discontinued.<sup>40</sup>

## Opioid Maintenance: Buprenorphine

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**PATIENT MUST BE IN OPIOID WITHDRAWAL TO START BUPRENORPHINE TREATMENT.  
IF NOT IN WITHDRAWAL, THE ANTAGONISTIC EFFECTS OF BUPRENORPHINE WILL  
INITIATE A RAPID AND SEVERE WITHDRAWAL**

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- Inpatient: some recommend initiating treatment with buprenorphine, 2-4 mg sublingual by either tablet or film.
- Increase dose by 2-4 mg every 6 hours to stop withdrawal symptoms.

### Convert to buprenorphine/naloxone for outpatient use.

- Target doses range from 4 to 24 mg per day
- Most pregnant patients are stable at 8-16 mg per day in divided doses.

### Analgesia and Anesthesia for Methadone and Buprenorphine managed patients

#### Labor and Delivery

- Inform the patient to continue her maintenance dose of buprenorphine or methadone on the day of admission for labor.
- Restart maintenance after delivery as soon as oral intake is tolerated.
- Epidural anesthesia for labor, vaginal delivery and cesarean delivery is the standard.
- Typically, postpartum analgesia for a vaginal delivery is to start Ibuprofen 800 mg, every 8 hours alternating with oxycodone 10 mg, every six hours.
- Most patients will be able to wean off the additional opioid analgesic in 4-7 days

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**IT IS IMPERATIVE TO INFORM THE PATIENT TO CONTINUE HER MAINTENANCE DOSE  
ON THE DAY OF ADMISSION AND TO RESTART MAINTENANCE AS SOON AS ORAL  
INTAKE IS TOLERATED.**

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#### Cesarean Delivery

- Continue maintenance dose of methadone or buprenorphine on day of admission for elective cesarean delivery
- Restart maintenance as soon as oral intake is tolerated.
- Epidural or Spinal anesthesia preferred for cesarean delivery.
- General anesthesia if indicated.
- Typically, postpartum analgesia for a cesarean delivery is to use an opioid pump with 50-100% more opioid than for the non-opioid dependent patient.
- Start Ibuprofen 800 mg, every 8 hours alternating with oxycodone 10-20 mg, every four to six hours weaning off the additional opioid analgesic in 7-10 days.

In addition to the maintenance dose of methadone or buprenorphine:

- Methadone-maintained women have similar analgesic needs and response during labor, but require 70% more opiate analgesic after cesarean delivery.<sup>41</sup>
- Likewise, Buprenorphine maintained women have similar intrapartum pain and analgesic needs during labor, but experience more postpartum pain and require 47% more opioid analgesic following cesarean delivery.<sup>42</sup>
- Morphine is the best tolerated opioid analgesic by the largest group of patients.
- Dilaudid appears to also be well tolerated

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<sup>31</sup> Auriacombe M, Fatseas M, Dubernet J, Daulouede JP, Tignol J. French field experience with buprenorphine. *Am J Addict* 2004;13 Suppl 1:S17-28.

<sup>32</sup> Lacroix I, Berrebi A, Chaumerliac C, Lapeyre-Mestre M, Montastruc JL, Damase-Michel C. Buprenorphine in pregnant opioid-dependent women: first results of a prospective study. *Addiction* 2004;99:209-14.

<sup>33</sup> Drug Treatment Act of 2000.: 21 U.S.C., Section 823 (g)(2)(B), Nov. 8, 2002.

<sup>34</sup> Johnson RE, Jones HE, Fischer G. Use of buprenorphine in pregnancy: patient management and effects on the neonate. *Drug Alcohol Depend* 2003 May 21;70(2 Suppl):S87-101.

<sup>35</sup> Kakko J, Heilig M, Sarman I. Buprenorphine and methadone treatment of opiate dependence during pregnancy: comparison of fetal growth and neonatal outcomes in two consecutive case series. *Drug Alcohol Depend* 2008;96:69-78

<sup>36</sup> Bridge TP, Fudala PJ, Herbert S, Leiderman DB. Safety and health policy considerations related to the use of buprenorphine/naloxone as an office-based treatment for opiate dependence. *Drug Alcohol Depend* 2003;70:S79-85.

<sup>37</sup> Deshmukh SV, Nanovskaya TN, Ahmed MS. Aromatase is the major enzyme metabolizing buprenorphine in human placenta. *J Pharmacol Exp Ther.* 2003;306:1099–1105.

<sup>38</sup> Coles LD, Lee IJ, Hassan HE, Eddington ND. Distribution of saquinavir, methadone, and buprenorphine in maternal brain, placenta, and fetus during two different gestational stages of pregnancy in mice. *J Pharm Sci* 2008 Dec 30.

<sup>39</sup> Kraft WK, Gibson E, Dysart K, et al. Sublingual Buprenorphine for Treatment of Neonatal Abstinence Syndrome: A Randomized Trial. *Pediatrics* 2008;122:e601-607

<sup>40</sup> 128. Marquet P, Chevrel J, Lavignasse P, et al. Buprenorphine withdrawal syndrome in a newborn. *Clin Pharmacol Ther.* 1997;62:569–571.

<sup>41</sup> Meyer M, Wagner K, Benvenuto A, Plante D, Howard D. Intrapartum and Postpartum Analgesia for Women Maintained on Methadone During Pregnancy. *Obstet Gynecol* 2007;110:261-262.

<sup>42</sup> Meyer M, Paranya G, Keefer Norris A, Howard D. Intrapartum and postpartum analgesia for women maintained on buprenorphine during pregnancy. *Eur J Pain.* 2010 Oct;14(9):939-43. Epub 2010 May 4.

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# MODULE 9: OPIOID DEPENDENT PATIENTS: A COMPARISON OF MATERNAL AND NEONATAL OUTCOMES

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## Case 8

A 30 year-old takes two Oxycodone 10 mg. acetaminophen 325 mg. tablets four times a day for relief of chronic back pain. In addition, she attends physical therapy twice weekly. She has had three operations on her back for severe scoliosis and herniated discs.

The patient is employed as a graphics designer.

She delivered a healthy 3700-gram male vaginally at 40 weeks. The baby showed minimal signs of withdrawal, relieved by comfort measures.

She was discharged on the second post-partum day with her baby.

She continued to breast feed for six months and on weaning, the baby had no signs of withdrawal.

*In an analysis of chronic pain patients in the Wishard Program on opioid alone for pain relief, 30 of 31 newborns were discharged on day two or three with no signs of withdrawal requiring treatment.*

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### **The Wishard data reflects a long-term observational study of opioid dependent patients**

- The study includes data from the Prenatal Recovery Clinic starting in 2002 through 2010, and includes 90 patients treated with methadone compared to 46 patients treated with buprenorphine and buprenorphine/naloxone.
- In addition, there is data from two other groups of opioid dependent chronic pain patients.
  - One group (n=31) consists of patients whose urine drug screens revealed only opiate and opiate/acetaminophen combinations for pain control
  - Another group (n=45) had urine drug screens that revealed multiple licit and illicit substances including benzodiazepines, cocaine, and marijuana (designated Opioid P for poly-substance use)

### **Methadone treated Patients**

- Had significantly higher preterm deliveries, more low birth weight babies and longer length of stay (LOS) for withdrawal when compared to the buprenorphine group.
- Interestingly, opioid dependent chronic pain patients who used only opioids for pain

- relief had the lowest maternal and neonatal morbidity.
- Doses of hydrocodone and oxycodone in the latter group varied from 40 to 80 mg per day.
  - Only 9 babies of methadone treated mothers tested positive for illicit drugs in their meconium. In a prior study in the same institution in 1999, 85% of methadone patients tested positive for an illicit substance (predominantly cocaine) in the 30 days prior to delivery.<sup>43</sup>
  - It appears that a significant change in the treatment approach addressing illicit drugs resulted in substantially lower use

### Methadone vs. Buprenorphine: Major Pregnancy Outcomes

	Bup. (46) <sup>1</sup>	Meth (90) <sup>2</sup>	p
Preterm Delivery	5 (10.9 %)	27 (30%)	0.001
Low Birth Weight (<2500g)	4	26	0.01
Mean Birth Weight	3079 g	2718 g	0.005
Positive Meconium	3 (6.9%)	9 (10.8%)	NS
Neonatal Abstinence (NAS)	8	89	0.001
NAS Treated	6 <sup>3</sup>	80	0.001
Mean Length of Stay (days)	6.78	30.3	0.001
Failed to return PP	13 (28.8%)	28 (31.1%)	NS
PP UDS "negative "	29 (63%)	59 (65.5%)	NS
Tobacco use (>05.ppd)	29 (63%)	51 (56.6%)	NS

<sup>1</sup> In the buprenorphine group there were 12 patients treated with buprenorphine and 34 treated with buprenorphine/naloxone with no differences within the groups.

<sup>2</sup> In the methadone group there were 92 babies (two sets of twins).

<sup>3</sup> Three of the NAS treated had concomitant use of benzodiazepines.

PP = postpartum

## Comparison of Opioid Dependent Chronic Pain Patients

	Opioid (31)	Opioid P (45)*	p
Preterm Delivery	4 (12.9 %)	8 (17.7%)	NS
Low Birth Weight (<2500g)	3	8	NS
Mean Birth Weight	3085 g	2879g	NS
Positive Meconium	0	12 (26.6%)	0.001
NAS Treated	1	5	NS
Mean Length of Stay	3.3	7.8	0.01
Failed to return PP	3	13	0.01
PP UDS "negative"	23 (74.2%)	25 (55.5%)	NS
Tobacco use (>05.ppd)	21 (67.7%)	30 (66.6%)	NS

\* Opioid P = polysubstance use including benzodiazepines, cocaine, and marijuana.  
PP = postpartum

*Opioid dependent patients treated with buprenorphine and opioid-only treated chronic pain patients had the lowest incidence of maternal and neonatal morbidity. In both groups, preterm delivery and birth weights were within the norm for non-opioid dependent patients.*

*The findings strongly suggest new strategies for managing opioid dependent patients in pregnancy. One recommendation is to start opioid dependent patients presenting in withdrawal on buprenorphine rather than methadone.<sup>44</sup>*

**Another recommendation is to maintain the opioid-only patient on her current regimen as follows:**

### Opioid Only Dependent Chronic Pain Patient

- Maintain current opiate regimen – avoid withdrawal (both legal to do and meets standard of care)
  - Hydrocodone 5/325 or 10/325 (up to 2 tabs q 6h)
  - Oxycodone 5/325 or 10/325 (up to 2 tabs q 6h)
- Low rate of NAS noted with these doses
- Requirement of opiate may increase
- Pain moderators may be helpful
  - Amitriptyline 50-100 mg h.s. (also good for insomnia)
  - Gabapentin 300 mg TID
- Physical Therapy – maintain mobility

<sup>43</sup> Brown HL, Britton KA, Mahaffey D, Brizendine E, Hiatt AK, Turnquest MA. Methadone maintenance in pregnancy: a reappraisal. *Am J Obstet Gynecol* 1998;179:459-63.

<sup>44</sup> Nocon JJ. Buprenorphine in pregnancy: the advantages. *Addiction* 2006;101:608.

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# MODULE 10: NEONATAL ABSTINENCE SYNDROME (NAS)

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## Case 9

A 35 year-old with a twin pregnancy presents in preterm labor at 35 weeks.

She currently takes 100 mg. of methadone daily for a chronic back pain condition caused by a herniated disc at L4-L5.

She has been complaining of night sweats, hot flashes and contractions for three days.

A spontaneous vaginal delivery of vertex/vertex male twins resulted after attempts to prolong pregnancy failed. The newborns were 2400 and 2235 grams respectively.

By day 4, neither newborn displayed evidence of NAS but both were under the “bili-lights” for physiologic jaundice.

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## Neonatal Abstinence Syndrome NAS<sup>45</sup>

- A complex disorder of behavioral and physiological signs and symptoms.
- Similar manifestations from a large variety of drugs, i.e. opioids, benzodiazepines, barbiturates, anti-depressants.<sup>46</sup>
- Prenatal NAS – due to maternal use of substances
- Postnatal NAS – from pain therapy in newborn.

## Neonatal abstinence syndrome (NAS) is the most common effect on the fetus/neonate

- The incidence is as high as 90% in methadone maintenance users and varies with each opioid used, the daily dose, length of use, and concomitant use of other drugs, especially benzodiazepines.<sup>47</sup>
- In NAS, the neonate is in acute withdrawal with an onset of hours to about 4 days.
- Common symptoms include irritable cry, increased tone, tachypnea, sleeplessness and tremor and treatment is based on scores from observations of psychomotor behavior.<sup>48</sup>
- Treatment consists of stabilizing the withdrawal, usually with morphine drops and then gradually decreasing the dose to detoxify the baby.<sup>49</sup>
- Pharmacologic treatment of NAS may also use clonidine, an alpha agonist used to stabilize the cardiovascular system and phenobarbital to reduce brain activity and seizures.

**There are readily observable neurobehavioral effects in newborns of opioid treated mothers.**

- The most common observations include decreased head circumference, developmental delays, and poor fine motor coordination.<sup>50</sup>
- However, long-term effects of opioid treatment appear to be more dependent on home environment.<sup>51</sup>
- Not surprising is that methadone-exposed infants that had delayed mental development were also raised in poor environmental conditions<sup>52</sup>.

**Dose of Methadone and NAS is Inconsistent**

- The incidence of preterm labor, NAS and short versus long term neonatal LOS does not follow a typical dose-response curve within a dose range of 50-120 mg.<sup>53</sup>
- These observations have significant impact on maternal treatment.
- **Thus, attempting to lower the typical maternal dose will gain little for the newborn while increasing the likelihood of maternal withdrawal that can precipitate preterm labor and/or abruption.**
- This is thought to be due to a higher elimination rate of methadone as pregnancy progresses.<sup>54</sup>
- In addition, patients on higher dose methadone have a greater compliance with prenatal care than those on low dose.<sup>55</sup>
- One study found that the incidence of NAS was less only in very low doses: when comparing women who received less than 20 mg per day, 20-39 mg per day, and at least 40 mg per day of methadone, the treatment for withdrawal occurred in 12%, 44%, and 90% of infants, respectively ( $P < 0.02$ ).<sup>56</sup>

**NAS: A Multisystem Disorder: Four Key Neurobehavioral Signs**

- CNS signs:
  - Irritability, excessive crying; voracious appetite
  - Seizures
- GI signs: vomiting; diarrhea
- Respiratory signs: tachypnea; hyperpnoea
- ANS signs: sneezing, yawning, tearing
- Finnegan Scale for assessment of symptoms and treatment.<sup>57</sup>
- Highly subjective variability in assessment of NAS; Lipsitz Scale.<sup>58</sup>

**NAS Withdrawal a Function of the Drug's Half-life**

- Hydrocodone babies rarely have NAS
- Morphine: Heroin – acute, severe but rapid – over in 72 hours
- Methadone – prolonged – 14-28 days with 6-8 weeks not uncommon
- Buprenorphine – mild and often not requiring treatment.
- Benzodiazepines: delayed withdrawal – may not start until week 2.<sup>59</sup>

**Current Treatment for NAS<sup>60</sup>**

- Combination therapy
  - Oral clonidine; phenobarbital
  - Dilute morphine drops<sup>61</sup>
- Increase morphine dose until signs of withdrawal controlled

- Maintain controlling dose for 2 days
- Wean morphine dose every 1-2 days

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## BREASTFEEDING ASSISTS NAS RECOVERY

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### NAS Morbidity and Mortality

- All Opiates cause some depression but significant depression and death is rare.
- Most complications result from prematurity, infection and severe perinatal asphyxia.
- Risk for SIDS is significantly higher.

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<sup>45</sup> Jansson LM. Neonatal abstinence syndrome. *Acta Paediatr* 2008;97:1321-3.

<sup>46</sup> Levinson-Castiel R, Merlob P, Linder N, Sirota L, Klinger G. Neonatal abstinence syndrome after in utero exposure to selective serotonin reuptake inhibitors in term infants. *Arch Pediatr Adolesc Med* 2006;160:173-6.

<sup>47</sup> Serane VT, Kurian O. Neonatal abstinence syndrome. *Indian J Pediatr* 2008;75:911-4.

<sup>48</sup> Finnegan, L.p., Kron, R.E., Connaughton, J.F., & Emich, J.P. Assessment and treatment of abstinence in the infant of the drug dependent mother. *International Journal of Clinical Pharmacology and Biopharmacy* 1975;12 (1-2):19-32.

<sup>49</sup> Ebner N, Rohrmeister K, Winklbaur B, et al. Management of neonatal abstinence syndrome in neonates born to opioid maintained women. *Drug Alcohol Depend* 2007;87:131-8.

<sup>50</sup> Rosen TS, Johnson HL. Children of methadone-maintained mothers: follow-up to 18 months of age. *J Pediatr*. 1982;101:192-196.

<sup>51</sup> Lifschitz MH, Wilson GS, Smith EO, et al. Factors affecting head growth and intellectual function in children of drug addicts. *Pediatrics* 1985;75:269-274.

<sup>52</sup> Hans SL. Developmental consequences of prenatal exposure to methadone. *Ann N Y Acad Sci*. 1989;562:195-207.

<sup>53</sup> Berghella V, Lim PJ, Hill MK, Cherpes J, Chennat J, Kaltenbach K. Maternal methadone dose and neonatal withdrawal. *Am J Obstet Gynecol* 2003 Aug;189(2):312-7.

<sup>54</sup> Jarvis MA, Wu-Pong S, Kniseley JS, Schnoll SH. Alterations in methadone metabolism during late pregnancy. *J Addict Dis* 1999;18(4):51-61.

<sup>55</sup> McCarthy JJ, Leamon MH, Parr MS, Anania B. High-dose methadone maintenance in pregnancy: maternal and neonatal outcomes. *Am J Obstet Gynecol* 2005 Sep;193(3 Pt 1):606-10.

<sup>56</sup> Dashe JS, Sheffield JS, Olscher DA, Todd SJ, Jackson GL, Wendel GD. Relationship between maternal methadone dosage and neonatal withdrawal. *Obstet Gynecol* 2002 Dec;100(6):1244-9.

<sup>57</sup> Finnegan and Kaltenbach (1992) in Hoekelman (ed) *Primary Pediatric Care*. St. Louis; CV Mosby 1367-1378

<sup>58</sup> Crocetti MT, Amin DD, Jansson LM. Variability in the evaluation and management of opiate-exposed newborns in Maryland. *Clin Pediatr (Phila)* 2007;46:632-5.

<sup>59</sup> Couvee JE, Zitman FG. The Benzodiazepine Withdrawal Symptom Questionnaire: psychometric evaluation during a discontinuation program in depressed chronic benzodiazepine users in general practice. *Addiction* 2002;97:337-45.

<sup>60</sup> AAP Committee on Drugs. Neonatal Drug Withdrawal. *Pediatrics* 1998; 101: 1079-1088

<sup>61</sup> Coyle MG, Ferguson A, Lagasse L, Oh W, Lester B. Diluted tincture of opium (DTO) and phenobarbital versus DTO alone for neonatal opiate withdrawal in term infants. *J Pediatr* 2002;140:561-4.

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# MODULE 11: OBSTETRICAL CARE GUIDELINES

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## Case 10

An 18 year-old with one prior pregnancy presents for her annual exam to have her IUD removed. She stated she has a new boyfriend and wants to have another baby.

She successfully quit smoking in her first pregnancy but was back to a pack a day habit.

Her urine drug screen was negative.

She was counseled about her decision to attempt another pregnancy and she was also referred to a smoking cessation program.

A few months later she presented for prenatal care at 10 weeks.

She did stop smoking cigarettes.

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## Pre-Conception Counseling<sup>62</sup>

- Evaluates existing medical problems, especially diabetes and hypertension.<sup>63</sup>
- May reveal previously undetected diseases.
- Allows for a discussion of risks for the mother and fetus of substance use.<sup>64</sup>
- Especially helpful for the older mother to discuss genetic risks.<sup>65</sup>
- Allows for optimal diet and exercise counseling.
- May allow for a modification of opioid maintenance prior to pregnancy.
- Allows for consultation with mental health providers for management of coexisting psychiatric co-morbidity.<sup>66</sup>
- It's unusual to prevent a substance use problem prior to pregnancy.

## Prenatal Care

- Routine obstetrical care is modified for the substance user.
- Thorough evaluation of drug use history and plans for modifying substance use are established.
- Perform all routine screening tests.
- Generally, prenatal visits occur every two weeks until 36 weeks, then weekly.
- Urine drug screen at every prenatal visit – enhances recovery.<sup>67</sup>
- Care coordination for psychiatric co-morbidity.
- Encourage other forms of support: therapy, AA, etc.
- Arrange to see social service consultant frequently.
- Dietician review at each visit.
- Growth restriction is common, especially in methadone maintenance patients.

- Follow with non-stress tests, biophysical profiles and ultrasounds for growth restriction.
- Encourage breast-feeding, especially in methadone patients
- Create a delivery plan.

### **Labor and Delivery**

- Decision for delivery based on obstetrical reasons.
- Stress of last few weeks of pregnancy places patient at risk for relapse.
- Induction of labor based on obstetrical reasons.
- Early induction for IUGR in methadone patients.
- Have detailed reports of drug use and maintenance medications available for nursing staff and anesthesiologists.
- Instruct methadone and buprenorphine patients to take their maintenance dose on day of delivery or arrange for patient to receive maintenance dose at appropriate time after admission.

### **Analgesia and anesthesia for labor, delivery and Cesarean delivery**

- Epidural anesthesia for labor, delivery and cesarean delivery is the standard.
- Spinal anesthesia for cesarean delivery.
- Intrathecal opioids very effective for acute pain relief.<sup>68</sup>
- For acute postoperative pain, methadone and buprenorphine patients will gain relief with doses of opiates 70 to 100% over usual doses.
- Morphine analgesia is well tolerated by the majority of patients
- Hydromorphone (Dilaudid) also well tolerated
- Typically, postpartum analgesia is to:
  - Start Ibuprofen 800 mg. every 8 hours
  - Alternating with oxycodone 10 mg, every six hours.
  - This regimen is effective for about 90% of patients.<sup>69</sup>
- It is imperative to inform the patient to continue her maintenance dose on the day of admission and to restart maintenance as soon as oral intake is tolerated.

### **Post-partum Care**

- Recommend at least three postpartum visits:
  - Two weeks: stabilize all medications and maintenance doses.
  - Four weeks: Routine testing: Pap, STD, etc.
  - Six weeks: Social service consultation with focus on continued therapy, support and maintenance.
- Urine drug screen at each visit.
- Breast feeding support at each visit
- Family planning discussion at each visit.

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<sup>62</sup> Summers L, Price RA. "Preconception care. An opportunity to maximize health in pregnancy". *Journal of Nurse-midwifery* 1993;38 (4): 188–98.

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- <sup>63</sup> McElvy SS, Miodovnik M, Rosenn B et al.. "A focused preconceptional and early pregnancy program in women with type 1 diabetes reduces perinatal mortality and malformation rates to general population levels". *The Journal of Maternal-fetal Medicine* 2000;9 (1): 14–20.
- <sup>64</sup> Swan LL, Apgar BS. "Preconceptual obstetric risk assessment and health promotion". *American Family Physician* 1995;51 (8): 1875–85, 1888–90.
- <sup>65</sup> McGregor S, Parker E. "Family matters: taking a genetic history". *The Practising Midwife* 2003;6 (10): 26–8
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- <sup>69</sup> Ismail S, Shahzad K, Shafiq F. Observational study to assess the effectiveness of postoperative pain management of patients undergoing elective cesarean section. *J Anaesthesiol Clin Pharmacol* 2012;28:36-40.

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# MODULE 12: EFFECTS OF SPECIFIC DRUGS ON BREASTFEEDING

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## Case 11

A 24 year-old at term with her second pregnancy plans to breast feed.

She is on methadone maintenance at 150 mg. per day.

In her previous pregnancy (also on 150 mg.) she was told by a neonatal fellow that her dose was too high to breast feed and that the baby would probably spend 4-6 weeks in the nursery, thus making it difficult for her to pump her breasts and supply adequate quantities of milk.

She underwent a cesarean delivery for breech presentation and insisted on breast-feeding shortly after delivery.

She was coached by the “lactation team” of nurses and did well in her immediate post-partum recovery.

The baby was discharged on day 14 after a short and mild NAS.

She weaned at 4 months without any withdrawal in the baby.

*NAS in newborns of methadone treated mothers is unpredictable with respect to dose of methadone. Breast-feeding has been associated with shorter withdrawal in the newborns.<sup>70</sup>*

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## Factors in Assessing the Risk of Drugs on the Breast-fed Infant<sup>71</sup>

- Drug concentration in breast milk.
- Drug clearance.
- Therapeutic dose – clinical effect on infant.
- Levels of exposure - the exposure index
- Effects of drugs on production of breast milk.
- Effects of drugs on the breast-feeding patient.

## Drug Transfer into Breast Milk:<sup>72</sup>

- Transcellular diffusion
  - Small molecules, ethanol
  - Rapid transfer
- Intercellular diffusion
  - Occurs during colostrum phase
  - Alveolar cells spaced wide apart
- Passive diffusion - most drugs.

### Factors Affecting Transfer of Drugs into Breast Milk<sup>73</sup>

- Lipid Solubility - benzodiazepines
- Protein binding – free and unbound
- Half-Life – fluoxetine
- Molecular size - ethanol
- Infant Factors
  - Gastric pH; transit time
  - Less plasma proteins = more unbound drugs

### Clinical Pearls: Drug Concentration into Breast Milk<sup>74</sup>

- Milk to plasma ratio - varies over time.
- When the amount of drug ingested from the milk, per unit of time, is less than the therapeutic dose (clinical effect),
- The level of exposure is low.
- Regardless of the milk to plasma ratio.

### Rate of Drug Clearance

- If the rate of drug clearance is high,
- Then even a high milk-to-plasma level will not result in a clinical effect.
- However, long acting drugs like fluoxetine may accumulate over time and create a clinical effect.

### Level of Breast Milk Exposure: The Exposure Index

- Amount of drug in breast milk is expressed as a percentage of the therapeutic dose (clinical effect) for the infant.
- Arbitrary “safe value” is 10% of the therapeutic dose.
- *If the exposure index is less than 10, then the effect is not clinically important.*

### Methadone<sup>75</sup>

- Long half life
- BUT, transfer to milk is minimal.
- Maternal dose of 80 mg. per day (typical) yields infant dose about 2.8% of maternal.<sup>76</sup>
- Some studies indicate concentrations in breast milk unrelated to maternal methadone dose.<sup>77</sup>
- Appears to have mitigating effect on NAS – shorter LOS of breast-fed infants.<sup>78</sup>

### Buprenorphine: Subutex and Suboxone

- Suboxone: buprenorphine and naloxone.
- Oral Rx for opiate dependent maintenance.
- Substantially reduced NAS.
- Minimal to no effect on breastfeeding.
- Most recent literature indicates using buprenorphine to treat NAS in newborn: improved efficacy and shortened LOS.<sup>79</sup>

### **Opioid Dependent Chronic Pain Patients**

- Hydrocodone, oxycodone and fentanyl.
- Usual doses for pain relief appear to have minimal to no effect on infant.
- However, many of these patients also use pain moderators which may depress infant:
  - Benzodiazepines: Xanax; Klonopin
  - Gabapentin: Neurontin
  - Amitriptyline: Elavil (generally safe)
  - Cyclobenzaprine: Flexoril
- High rate of tobacco use.

### **Antidepressant Drugs**

- Most tricyclic antidepressants and SSRI's have an exposure index less than 10.
- Exceptions: Use with caution:
  - Fluoxetine – long acting; may accumulate; colic.<sup>80</sup>
  - Doxepin - sedation
  - Lithium – hypothermia, hypotonia; contraindicated
- Sertraline – no adverse effects noted.

### **Alcohol Use and Breast Feeding<sup>81</sup>**

- Level of alcohol dehydrogenase in first year is 50% of that in adults: rapid absorption into infant's bloodstream.
  - May impair neurologic development.
  - Decreases time spent in active sleep
  - Beer drinking may reduce milk intake by 20%
- Dose-response effect – takes about 2 hours for one drink to be eliminated from mother
- If breast-feeding every 2-3 hours, then should not consume more than one drink between feedings.
- Or, instruct patient to drink just AFTER breastfeeding.
- Or, "Pump and dump."

### **An Old Wife's Tale Refuted**

- A bit o' brandy before breastfeeding can help let-down – NOT TRUE!
- Evidence does not support that alcohol has any benefit to any aspect of breastfeeding.
- If a woman cannot stop or limit her drinking to one drink a day after breastfeeding, than one may correctly assume she has a problem.
- In this case, AA may be more important than breastfeeding.

### **Nicotine and Breast-Feeding<sup>82</sup>**

- Depends on the amount she smokes.
- 60-90 minutes to eliminate 50% of nicotine
- Nicotine induced toxicity reported in breast-fed infants.
  - Decreased Milk volume
  - Early weaning from breast-feeding
  - Decreased weight gain in infant - controversial
- Secondhand smoke may be far more dangerous.
  - SIDS

- Asthma
- Women who breastfeed and continue to smoke have infants with lower incidence of acute respiratory illness compared with bottle-fed infants of women who smoke.
- If she can't stop smoking, there is still a benefit to breastfeeding.

#### **Recovery, Relapse and Breast-feeding**

- Does breastfeeding enhance or detract from ongoing recovery in the postpartum patient?
- The most common cause of relapse is stress, and it does not take much to trigger a relapse
- If breastfeeding is not going well and the patient is experiencing significant stress, she is ripe for relapse.
- Plays into low self-esteem - "I'm a failure"
- Baby always crying – "I need some peace and quiet."
- Despair – using drugs to "numb out."

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### EVALUATION

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Please help us to assess the effectiveness of this toolkit by [clicking here](#) to complete a **brief follow-up survey**. We greatly appreciate your feedback!

<sup>70</sup> Ballard JL. Treatment of neonatal abstinence syndrome with breast milk containing methadone. *J Perinat Neonatal Nurs* 2002;15:76-85.

<sup>71</sup> Ito S. Drug therapy for breast-feeding women. *NEJM* 2000;343:118-127

<sup>72</sup> American Academy of Pediatrics, Committee on Drugs. The transfer of drugs and other chemicals into breast milk. *PEDIATRICS* 2001;108:776-89.

<sup>73</sup> Ressel G. AAP updates statement for transfer of drugs and other chemicals into breast milk. *American Academy of Pediatrics. Am Fam Physician* 2002;65:979-80.

<sup>74</sup> Briggs GG FR, YaffeSJ. *Drugs in pregnancy and lactation: a reference guide to fetal and neonatal risk*. 7th ed. ed. Philadelphia: Lippincott Williams and Wilkins; 2005.

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<sup>76</sup> McCarthy JJ, Posey BL. Methadone levels in human milk. *J Hum Lact* 2000;16:115-20.

<sup>77</sup> Jansson LM, Choo RE, Harrow C, et al. Concentrations of methadone in breast milk and plasma in the immediate perinatal period. *J Hum Lact* 2007;23:184-90.

<sup>78</sup> Phillip BL, Merewood A, O'Brien S. Methadone and breastfeeding; new horizons. *Pediatrics* 2003;111:1429-1430.

<sup>79</sup> Kraft WK, et al. Sublingual buprenorphine for treatment of neonatal abstinence syndrome: a randomized trial. *Pediatrics*; published online August 11, 2008

<sup>80</sup> Lester BM, Cucca J, Andreozzi L, Flanagan P, Oh W: Possible association between fluoxetine hydrochloride and colic in an infant. *J Am Acad Child Adolesc Psychiatry* 1993; 32: 1253-1255.

<sup>81</sup> Giglia RC, Binns CW, Alfonso HS, Scott JA, Oddy WH. The effect of alcohol intake on breastfeeding duration in Australian women. *Acta Paediatr* 2008;97:624-9.

<sup>82</sup> Vio F, Salazar G, Infante C. Smoking during pregnancy and lactation and its effects on breast-milk volume. *Am J Clin Nutr* 1991;54:1011-6.

## APPENDIX A      SUBSTANCE USE TERMINOLOGY

---

The term “addiction” has been replaced by “substance dependence” and “substance abuse.”

The DSM-IV distinguishes between Substance Dependence and Substance Abuse as follows.<sup>83</sup>

**Substance Dependence** is a pattern of substance use, leading to clinically significant impairment or distress, with **three or more** of the following, occurring at any time in the same 12 month period:

- Tolerance
- Withdrawal
- The substance is taken in larger amounts over a longer period than was intended.
- A persistent desire or unsuccessful efforts to cut down or control use.
- Inordinate time spent in acquiring the substance, use of the substance, or recover from its effects
- Important social, occupational or recreational activities are given up or reduced.
- The substance is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.

**Substance Abuse** is a separate diagnosis from substance dependence. It is a maladaptive pattern of substance use with **one or more** of the following criteria over a 1-year period:

- Repeated substance use that results in an inability to fulfill obligations at home, school or work.
- Repeated substance when it could be dangerous (driving a car).
- Repeated substance-related legal problems, such as arrests.
- Continued substance use despite interpersonal or social problems that are caused or made worse by use.

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<sup>83</sup> American Psychiatric Association (2000). Diagnostic and statistical manual of mental disorders (Revised 4th ed.). Washington, DC: Author.

## APPENDIX B CONTROLLED SUBSTANCES ACT

---

### Controlled Substances Act 1970<sup>84</sup>

- Set various schedules to regulate specific substances.
- Based on potential for abuse.
- Most commonly used drugs listed.

#### Schedule I. High potential for abuse; no currently accepted therapeutic use:

- Heroin,
- Gamma hydroxybutyric acid,
- Khat,
- MDMA (Ecstasy),
- LSD; mescaline, psilocin, and
- Marijuana\*

*\*Medicinal Marijuana: legal to use for medical purposes if certified by a physician licensed to practice in a state that has legalized its use for these purposes. As of March 1, 2012, 17 states plus the District of Columbia have statutes regulating the use of marijuana for medical purposes. An additional 17 states have legislation pending to approve the use of medical marijuana.*

#### Schedule II. High potential for abuse but accepted therapeutic use. Requires a written prescription with physician's DEA number for outpatient use.

- Codeine; fentanyl; hydromorphone; oxycodone; morphine; methadone
- Pentobarbital; secobarbital;
- Amphetamines; PCP

#### Schedule III: Moderate abuse potential: Outpatient prescriptions may be telephoned to the pharmacy:

- Buprenorphine; codeine and hydrocodone combinations: Vicodin; Lortab; Fiorinal;
- Anabolic steroids,
- Ketamine.

#### Schedule IV: Low abuse potential – but some drugs are often combined with a drug with a higher abuse potential:

- Butorphanol (Stadol); propoxyphene;
- Benzodiazepines;
- Phenobarbital;
- Phentermine.

#### Schedule V: Lowest potential for abuse:

- Codeine preparations: (a favorite drug of abuse among pre adolescents);
- Lomotil

---

<sup>84</sup> Comprehensive Drug Abuse Prevention and CONTROL ACT of 1970 (21. U.S.C. 801 et seq.

## APPENDIX C      ADDICTION IS A DISEASE OF THE BRAIN

---

- Continuous use of drugs changes the anatomy and physiology of brain cells, particularly in the lateral tegmental area and the nucleus accumbens.<sup>85</sup>
- PET/MRI scans have mapped the location in the brain where drugs and behaviors have their effects.
- Addiction depletes dopamine and the altered brain cannot manufacture sufficient dopamine to function in a normal manner.<sup>86</sup>
- This process occurs in all addictive drugs and many patterns of behavior
- Just as alcohol, tobacco, and **drugs** activate the pleasure circuit in the brain, so do many **behaviors** such as sexual activity, winning a contest, gambling, and being praised and working very hard.

### Dopamine “Reward System”

- What drugs and many behaviors have in common is the release of various neurotransmitters in nucleus accumbens in the brain, primarily dopamine:
  - Dopamine – creates the “buzz.”
  - Serotonin – sense of well-being.
  - Endorphins – euphoria.
  - GABA (gamma amino butyric acid) – satiety and somnolence (sleepy after a big meal or sexual activity).
- There comes a point when the affected person becomes an addict, as if a switch in the brain is flipped, and the person no longer has the ability to make free choices about the continued use of the drug.<sup>87</sup>

### The Addicted Brain Can Recover

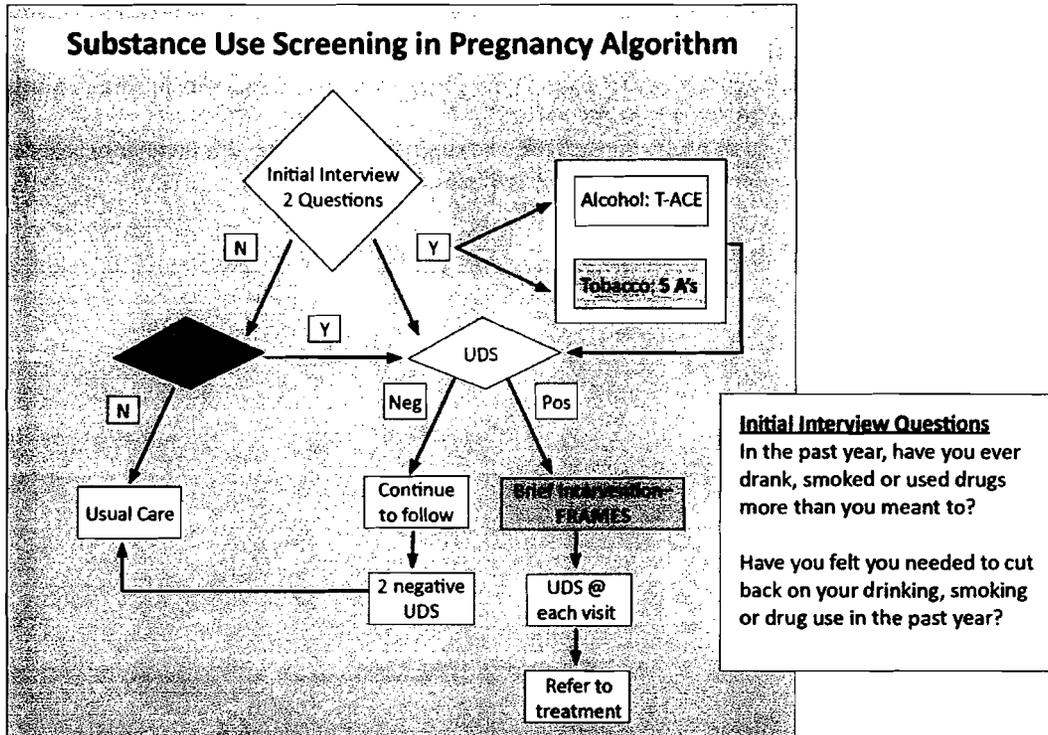
Current research indicates that recovery in the brain is mediated by adult stem cells, a large source of which is located by the nucleus accumbens.<sup>88</sup> The stem cells can migrate relatively large distances and appear to rebuild damaged circuitry.

*Factors stimulating stem cells include:*

- Nutrition and exercise stimulates stem cells to rebuild circuitry
- Reading is critical to rebuilding new circuitry: “Don’t drink, eat well, go to meetings and read the Big Book.”
- Folic acid is important.
- Folic acid supplements are able to prevent neural tube defects and thereby repair other structural damage.<sup>89</sup>
- Thus, folic acid supplementation may become a new pharmacologic strategy to enhance recovery from addiction.

- 
- <sup>85</sup> McCann UD, Szabo Z, Scheffel U, Dannals RF, Ricaurte GA. Positron emission tomographic evidence of toxic effect of MDMA ("Ecstasy") on brain serotonin neurons in human beings. *Lancet* 1998 Oct 31;352(9138):1433-7.
- <sup>86</sup> Wise RA. Addictive drugs and brain stimulation reward. *Ann Rev Neuroscience* 1996;19:319-340.
- <sup>87</sup> Leshner AI. *Addiction is a brain disease, and it matters*. *Science* 1997;278:45-47
- <sup>88</sup> Nixon K. Alcohol and adult neurogenesis: Roles in neurodegeneration and recovery in chronic alcoholism. *Hippocampus*. 2006 Volume 16, Issue 3, pages 287–295.
- <sup>89</sup> Milunsky A, Jick H, Jick SS, et al. Multivitamin/folic acid supplementation in early pregnancy reduces the prevalence of neural tube defects. *JAMA* 1989;262:2847-2852.

## APPENDIX D



### **T-ACE for alcohol screening**

- Tolerance:** How many drinks does it take you to feel high? (*More than 2 = 1 point*)
  - Annoyed:** Have people annoyed you by criticizing your drinking? (*Yes = 1 point*)
  - Cut Down:** Have you ever felt you ought to cut down on your drinking? (*Yes = 1 point*)
  - Eye Opener:** Have you ever had a drink first thing in the morning to steady your nerves or get rid of a hangover? (*Yes = 1 point*)
- 2 or more points is a positive screen*

### **5 A's: Tobacco Intervention**

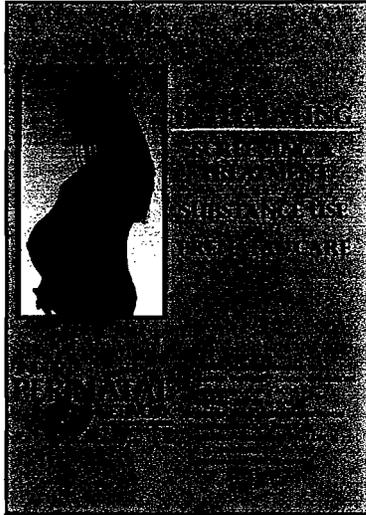
- 1) **Ask**—Identify and document tobacco status for every visit.
- 2) **Advise**—In a clear, strong and personalized manner, urge every smoker to quit.
- 3) **Assess**—Willingness to quit.
- 4) **Assist**—Refer to smoking cessation program or quit line and use patch or gum.
- 5) **Arrange**—Schedule follow-up contact in 1 week after quit date.

### **Brief Intervention—FRAMES**

Feedback about adverse effects  
 Responsibility for change in behavior  
 Advise to reduce or stop  
 Menu of options to help  
 Empathy  
 Self empowerment

APPENDIX E

**INDIANA PERINATAL NETWORK RESOURCE ORDER FORM**



**Integrating Screening and Treatment of Substance Use into Prenatal Care**

This comprehensive, online provider training program addresses tobacco, alcohol and other drug use during pregnancy.

The online training features:

- Practical role-play scenarios with clinical and research-based material and interventions. Featuring the work of Dr. James Nocon, Professor Emeritus, IU School of Medicine and former Director of the Prenatal Recovery Clinic at Wishard Memorial Hospital.
- Additional materials and PowerPoint presentations on related clinical topics, referral resources, and information on how to obtain reimbursement for screening and intervention services.
- Training is approved for CME for physicians, CEU for nurses and continuing education hours for social workers.
- Order online at [www.indianaperinatal.org](http://www.indianaperinatal.org).

TITLE/DESCRIPTION	MEMBER PRICE	QUANTITY	NON-MEMBER PRICE	QUANTITY
<b>Integrating Screening and Treatment of Substance Use into Prenatal Care - Online Training (90 Day Access)</b>	\$30		\$ 50	
			<b>TOTAL</b>	

**PAYMENT METHOD**

- Check payable to IPN enclosed     Mastercard     Visa

**SHIPPING INFORMATION**

Name \_\_\_\_\_ Credentials (i.e. "R.N.") \_\_\_\_\_

Job Title \_\_\_\_\_

Organization \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

Phone \_\_\_\_\_ Fax \_\_\_\_\_

E-mail Address (Important: Training access code will be sent to this address)

**CREDIT CARD BILLING ADDRESS**

Name on card \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

Credit Card No. \_\_\_\_\_ Exp. \_\_\_\_\_

Email Address (if different than at left)



RETURN WITH YOUR PAYMENT TO IPN

1991 East 56th St, Indianapolis, IN 46220 ipn@indianaperinatal.org P 317.924.0825 F 317.924.0831

Jim Ryser was born in 1965 with Spina Bifida Myelomeningocele and expected to live a poor quality and short life. His parents were encouraged to let him die after day one. They chose otherwise. Here is his brief story and a plea for awareness and education.

I begin today with these words...“ I know we are all struggling with how to approach this issue, and the right thing to do is to work together. I do, however, want you to know the damage, the disease, and the magnitude of the issue from my own personal experience.” First, a bit of history.

“Jim Ryser played Madison Square Garden as a solo violinist when he was 9, but it was picking up the guitar at 14 that took him down the musical path of rock and roll dreams. A record deal with Arista Records in 1988 was next under music legend Clive Davis. "Same Old Look," the first single released in 1990, reached #6 on the Billboard chart and sent Jim on a summer tour with The Moody Blues, Henry Lee Summer, REO Speedwagon, and John Mellencamp. He has played on several albums with Mellencamp, Hall and Oates, Tracy Chapman, and others."

This past paragraph is part of the bio on my musical website. Here's the non fluff real. In 1983 I had Percocet prescribed to me for kidney pain. I hated the way they made me feel. I hated how any drug made me feel. I tried a few things to fit in with friends but I ultimately became “the guy in the band who didn't do drugs.” More pain, more surgeries. More prescriptions. I was finding doctors who told me that I would have to be on some sort of pain medication for the rest of my life. I had multiple medical issues and eventually multiple doctors prescribing for me, continuing to believe that if something is prescribed it can't be dangerous. I began to limit what I took. Suddenly, I realized that taking my two prescribed Percocet at the end of my shows were my reason to live. I reached out for help after 13 years of being on chronic opioids. How could I have a problem if I had a successful career, a perceived good life, and a pilot's license (with the FAA's knowledge that I was on chronic opioids – I just had to be off of them for 72 hours prior to flying)?

I went through a pain program at the Cleveland Clinic and was able to learn new ways to deal with pain which inspired my undergraduate college degree. My addiction, however, lay hidden and by the time I graduated Indiana University Summa Cum Laude, I was prescribed some of the same drugs that led to Michael Jackson's demise, using up to 500 mg of IV Demerol and taking 10-20 percocet pills a day. I hit bottom when I started drinking in 1997, and had I not started drinking I never would have gotten help. The people who treated pain were under a false belief that one can't get addicted while treating chronic pain. I hold no ill will toward doctors as I believe that the pharmaceutical industry was part of a large problem that sold us a bill of goods.

I am here to tell you that addiction can happen when treating chronic non cancer pain with opioid pain medications. When I went through chronic pain rehab in 1990, I was taking 6 percocet 5/325 daily. It was considered excessive at the time. I learned lifeskills that did not include

mood altering medication management. I went through the same program again in 1999 as I had gotten back on many of those prior medications and eventually added the alcohol. I had lost my coping skills. I was initially confused because two of the top addictionists at the Cleveland Clinic were unsure as to how addicted I had become or whether or not I even had the disease. Some of this was my own denial and some was the standard of care with regard to opioid treatment of the time. The heroin addicts I was surrounded by called me "lucky" because I had access to large amounts of prescribed opioids, and my entire daily dose from 1990 would have been considered a moderate breakthrough dose by 1999. We already know of the fines some pharmaceutical companies have had to pay for their marketing strategies, which have compounded the problem. September 11, 1999 was my first day off of opioids, alcohol, and tobacco, and it has been this way ever since. My pain is the same, but I am not. I know peace.

I changed careers completely as a result of the help I finally received. Someone knew what was wrong and what to do and placed me in the place to get well. I was an addict. I had chronic pain. I was an addict that developed the illness due to the treatment of my pain. Fortunately, I had an addiction and pain doctor that stopped chemically coddling me after all of the years of being "poor little Jimmy with spina bifida and 55 surgeries." I was offered an abstinence based program. I was offered to get out from under the heavy hand of the perpetually sick. I got life.

There seems to remain a stigma about iatrogenic addiction, and even more importantly iatrogenic relapse, as we try to combine apples and oranges into the same bag. Acute pain, Cancer pain and Chronic pain are not equals. None of these pains should be treated the same way, legislation or not. I asked people whom I am currently treating who have chronic pain and addiction to help me with the most important message to give to everyone in this room today. They said, "Please, offer alternatives, and if you think we have a problem, we do. Don't sugar coat it. Send us to the right kind of help – we will absolutely resist and threaten you, but the truth is what we need."

While I believe that something has to be done, I believe that education is the most important thing we can provide for everyone. I also know that addiction, especially in the setting of pain, is not something anyone appears to want to look at. It's messy and ugly. We can't ignore it. I have been working with others in chronic pain and acute pain and of every combination in between for the past decade and it is tough.

My fear with legislation is that doctors will drop patients and they will turn to other self-medicating ways to treat pain. My fear without legislation is that we iatrogenic addicts will continue to be hidden under the guise that "if it's prescribed it must be safe." I do not see an easy solution here. I see people every single day who were not properly assessed and ended up iatrogenically relapsed. Or perhaps they were properly assessed and lied as they once again manipulated another doctor due to untreated addiction. I see too many people just get dropped by their pain doctors for being an addict and it's absolutely unethical and in fact perpetuates the problem. My hope is that we see education for treating pain with better alternatives, treating addiction when it occurs, and if one does not know how to land, just don't take off.

**Prescription Drug Abuse**

Martha (Marty) Cangany, MSN, RN, ACNS-BC  
317-538-0285  
[mcangany@sbcglobal.net](mailto:mcangany@sbcglobal.net)  
4207 Dartmoor Drive Greenwood, Indiana 46143

A Opening Issue or Problem Statement:

Prescription drug abuse is the Nation's fastest-growing drug problem. Health Agency leadership is identifying perspectives on how prescription drug overdose has emerged as a national public health problem. Data from the National Survey on Drug Use and Health (NSDUH) show that nearly one-third of people aged 12 and over whom used drugs for the first time in 2009 began by using a prescription drug non-medically (CDC, 2010). The same survey found that over 70 percent of people who abused prescription pain relievers got them from friends or relatives, while approximately 5 percent got them from a drug dealer or from the Internet (CDC, 2012). Indiana ranks 16<sup>th</sup> nationally in opioid drug deaths per 100,000 population with a rate increase that is accelerating above the pace of the national average (CDC, 2010). Indiana is only one of two states with no opioid prescribing regulations. There are four main components that need to be addressed related to the issue:

- Prescribing Regulations Related to Accessibility of Prescription Painkillers.
- Healthcare Provider Accountability
- Patient Review and Restriction Program
- Better Access To Substance Abuse Treatment

As a constituent, a healthcare provider, and a mom who has experienced losing my son Jarrod from an accidental methadone overdose I am requesting that there be stricter prescribing practices for prescription painkillers as well as addressing the other significant three needs listed above. We must

start somewhere to stop the senseless deaths from prescription drug abuse and decrease the accessibility of these drugs to those who are selling them illegally.

### References

Centers for Disease Control and Prevention. CDC Grand Rounds: Prescription Drug Overdoses — a U.S. Epidemic. MMWR 2012; 61(01):10-13

This report from the CDC identifies in 2007 there were 27,000 unintentional drug overdose deaths in the United States, one every 19 minutes. Prescription drug abuse is the fastest growing drug problem in the United States. This is being driven by the increase in the use of prescription drugs called opioid analgesics. More overdoses from opioids have occurred than from heroin and cocaine combined.

Unintentional Drug Poisoning in the United States, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, July 2010.

This document describes the unintentional drug poisonings in the U.S. and gives some statistics related to why and what is occurring related to poisonings which is mainly from drugs both illegal and legal.

SAMHSA (2010). Results from the 2009 National Survey on Drug Use and Health (NSDUH): National Findings.

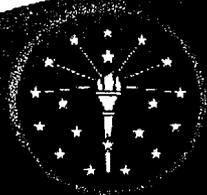
In these national findings there were many summaries for drug use in 8 different states. What each state was doing to address the issue and optional opportunities for improvement.



# The Indiana Family and Social Services Administration

## *Addiction Prevention and Treatment Commission on Mental Health and Addiction*

*September 9, 2013*





## **FSSA's Division of Mental Health and Addiction (DMHA)**

### **Responsibilities Include:**

- Certify all community mental health centers, addiction treatment services, and contracted care providers.
- Administer federal funds for substance abuse prevention projects.
- Provide funding support for mental health and addiction services to target populations with financial need through a network of providers.



# Addiction Prevention and Treatment

	<b>Federal Funds</b>	<b>State Funds</b>	<b>Total Funds</b>
Prevention	7,500,000	500,000	8,000,000
Treatment	31,000,000	9,000,000	40,000,000
Total Funds	38,500,000	9,500,000	48,000,000

\*\*estimated state fiscal year 2014



# Certified Addiction Providers

	<b>Number</b>
Community Mental Health Centers	25
Opioid Treatment Providers	13
Addiction Outpatient Service Providers	139
Detoxification Providers	41
Total	218



## Funded Addiction Prevention & Treatment Allocation

	Community Mental Health Center	Addiction Provider	Total
Outpatient / IOP	25	8	33
Detoxification	3	2	5
Residential	4	3	7
Women's Residential	2	4	6
Opioid Treatment	3	0	3





## Persons Served with Substance Use / Abuse Diagnosis

	Total	Total Served – Any Diagnosis	Percentage with SU/SA Diagnosis
Seriously Mentally Ill	22,263	72,610	31%
Seriously Emotionally Disturbed	2,474	48,618	5%
Chronic Abuse	27,269	27,740	98%
Total Served with a Substance Abuse Diagnosis	52,006	148,968	35%

\*\*data is state fiscal year 2013



## Persons Served with Substance Use / Abuse Diagnosis (cont')

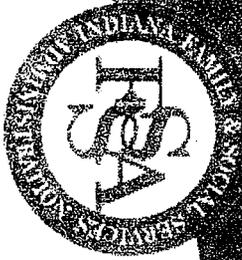
	0 to 18	18 to 64	Over 64
Percent Served by Age Group	7%	92%	1%

\*\*data is state fiscal year 2013



## Medicaid Health Coverage and Persons with Addiction

- Primary criteria for Medicaid Eligibility:
  - Income/Family Size
  - Age
  - Resources / Assets
  - Medical Needs
- Addiction is not a disability under Medicaid regulations.
- Children up to age 19 may be eligible based on family income, foster care placement, or adoption.



# Questions?



# The Indiana Family and Social Services Administration

*Addiction Prevention and Treatment*  
*Commission on Mental Health and Addiction*  
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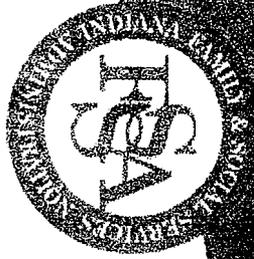
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# Questions?

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# OPIOID DEPENDENCE IN PREGNANCY: AN EVIDENCE-BASED TOOLKIT

---

JAMES J. NOCON, M.D., J.D.

PROFESSOR EMERITUS

INDIANA UNIVERSITY SCHOOL OF MEDICINE

OBSTETRICS AND GYNECOLOGY

AUGUST 2012



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# MODULE 1: INTRODUCTION

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## Purpose

- The Toolkit should serve as basic resource for non-addiction providers
  - Obstetricians; Family physicians, pediatricians; residents and medical students.
  - Midwives; Prenatal and Labor Nurses; nursing students
  - Anesthesiologists
  - Emergency physicians
  - Paramedics; EMTs
  - Anyone providing obstetrical and primary care.
- The Toolkit applies to pregnant patients and focuses on opioid dependence in pregnancy.

## Toolkit Format

- Allows for rapid identification of detection, treatment and management plans.
- Clinical cases highlight the contents of the chapter and key issues for the provider.
- Includes substantial references from the literature and data from the treatment of over 500 patients in the Prenatal Recovery Program at Wishard Memorial Hospital, Indianapolis, Indiana. (Wishard Data)
  - Wishard is a public hospital for Indianapolis and a major teaching hospital for the Indiana University School of Medicine.
  - Demographics include approximately 3000 deliveries per year of Black (35%), White (25%) and Hispanic (40%) patients.
  - About 95% are Medicaid funded.
- Comments will be in italics.

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### Case 1

A 32 year old presents to the labor suite in preterm labor at 32 weeks. She complains of painful contractions for two days while yawning constantly, and appears sleepy and complains of hot flashes.

Attempts to stop the preterm labor fail and she delivered a 2000-gram male with Apgar scores of 7 and 9.

In the nursery, the baby shows all the signs of opioid withdrawal and drug testing reveals opioids, specifically oxycodone. The newborn was treated and did well while spending 62 days in the NICU.

The mother was questioned about prior drug use and revealed an "Oxy" (oxycodone) addiction using up to 160 mg per day.

In retrospect, she presented in acute opioid withdrawal.

She was started on buprenorphine/naloxone (Suboxone) with a good response and agreed to addiction treatment. Six months later, she remained opioid free on Suboxone maintenance and attends an addiction treatment program.

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**THIS CASE IDENTIFIES THE MOST SIGNIFICANT PROBLEM IN TREATING SUBSTANCE USE  
IN PREGNANCY - FAILURE TO IDENTIFY THE SUBSTANCE-USING PATIENT.**

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**Opioid Use, especially among women, is skyrocketing in the United States.<sup>1</sup>**

Percent of pregnant patients dependent on opioids referred to the Wishard Program:

2002-2007: 69/287 patients: 24%

2008: 69.3%

2009: 79.1%

2010: 75.5%

This study includes patients with opioid addictions, opioid dependent chronic pain patients, opioid poly-substance users, and methadone and buprenorphine maintenance.

**Opioid Use carries high morbidity and mortality for both fetus and mother<sup>2</sup>**

- Over 2,000 deaths per week have been attributed to opioid abuse.
- Most of the fatalities are due to Oxycontin
- Maternal treatment with opioid analgesics increases the risk of birth defects.
- Opioid withdrawal carries substantial Risks:<sup>3</sup>
  - High rate of preterm labor - 41%
  - Increased abruption - 13%
  - High rate of low birth weight – 27%

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**THE RISK OF ADVERSE EVENTS FROM OPIOID WITHDRAWAL APPEARS TO BE FAR  
GREATER THAN FROM THE TREATMENT OF NEONATAL ABSTINENCE**

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**Pregnancy makes a difference in long-term recovery<sup>4</sup>**

After one year of treatment:

65.7% of women who entered treatment while pregnant used no drugs, while,

Only 27.7% of non-pregnant women remained drug free. (p<0.0005)

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<sup>1</sup> [http://www.foodconsumer.org/newsite/Politics/32/opioid\\_abuse\\_skyrockets\\_061820100141.html](http://www.foodconsumer.org/newsite/Politics/32/opioid_abuse_skyrockets_061820100141.html)

<sup>2</sup> [http://www.ajog.org/article/S0002-9378\(10\)02524-X/abstract](http://www.ajog.org/article/S0002-9378(10)02524-X/abstract)

<sup>3</sup> Lam SK, To WK, Duthie SJ, Ma HK. Narcotic addiction in pregnancy with adverse maternal and perinatal outcome. Aust N Z J Obstet Gynaecol 1992 Aug;32(3):216-21.

<sup>4</sup> Peles E, Adelson M. Gender Differences and Pregnant Women in a Methadone Maintenance Treatment (MMT) Clinic. *J Addictive Diseases* 2006; 25: 39-45.

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# MODULE 2: SUBSTANCE USE TERMINOLOGY

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## Case 2

A 26 year old at 16 weeks of pregnancy was in a motor vehicle accident with multiple soft tissue injuries. Ultrasound revealed an intact fetus. She received hydrocodone 5/acetaminophen 325 for pain and alprazolam 0.5 mg for anxiety.

She requested refills at two weeks and at 6 weeks from the accident, the doctor refused to refill her prescriptions due to her “drug seeking behavior.”

She was able to “score” drugs from her friends and presented for her first prenatal visit at 24 weeks with an opioid and benzodiazepine addictions.

*This case illustrates one of the most common etiologic factors in opioid use amongst young women, that is, treatment with opioids and benzodiazepines for injuries sustained in a motor vehicle accident.*

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## Addiction

- Commonly used term meaning the aberrant use of a specific psychoactive substance or a behavior in a manner characterized by
  - Loss of control,
  - Compulsive use,
  - Preoccupation, and
  - Continued use despite harm.
- *In reality, this can be an extremely difficult illness to define and the general consensus among addiction counselors is, “I know it when I see it.”*

## Relationship View of Addiction

- If the behavior keeps the patient from being physically and emotionally present for those she loves and those who love her.
- Then she has a problem with the behavior.
- May be alcohol, tobacco or other drugs (ATOD)
- May be eating, sex, gambling, being a workaholic, etc.

## Substance Use Disorder

- “Substance Use Disorder” (SUD) replaced the pejorative term “addiction” in the American Psychiatric Association (DSM-IV-TR).<sup>5</sup>
- The DSM-IV-TR distinguishes between:
  - Substance Dependence *and* Substance Abuse

See Appendix A: Substance Use Terminology.<sup>6</sup>

### **Dependence**

- **Psychological dependence:** A need for a specific psychoactive substance either for its positive effects or to avoid negative psychological or physical effects associated with its withdrawal.
- **Physical dependence:** A physiologic state of adaptation to a specific psychoactive substance characterized by the emergence of a withdrawal syndrome during abstinence, which may be relieved in total or in part by re-administration of the substance.

### **Withdrawal**

- The onset of a predictable constellation of signs and symptoms after the abrupt discontinuation of or a rapid decrease in dosage of a psychoactive substance.
- In the adult, classic signs of opiate withdrawal include:
  - Early Signs: (8-12 hrs.): Diaphoresis, nausea, yawning, excessive crying, tremor, runny nose, irritability, dilated pupils, resp. rate, pulse>90
  - Severe Signs: (12-48 hrs.): Insomnia, elevated T, P, R & BP, nausea, vomiting, abdominal cramps, chills, diarrhea, muscle twitching and dilated pupils.<sup>7</sup>
- Newborn withdrawal is called Neonatal Abstinence Syndrome (NAS).<sup>8</sup>

### **Tolerance**

- Increased dosage of a substance is needed to produce a desired effect.
- Increased frequency of use to achieve desired effect.

### **Cross Tolerance**

- Induced by repeated administration of one substance that is manifested toward another substance to which the individual has not been recently exposed.
- Clinical Examples:
  - High tolerance to amphetamines may exhibit high tolerance to methamphetamines
  - Cigarette smokers have a lower sensitivity to caffeine

### **Diversion**

- The use of prescription drugs for recreational or other purposes.
- Clinical examples:
  - Chronic pain patient sells some of her oxycodone to her friends.
  - Patient's mother gives daughter some of her alprazolam (Xanax) for "panic attacks."
  - Buprenorphine/naloxone (Suboxone) is sold on the street to methadone patients so they do not have to go to a methadone clinic for their maintenance.

### **Dependence versus Addiction - Clinical Examples**

- A well-managed chronic pain patient using oxycodone for pain relief is dependent on opioids.
  - She will go through withdrawal if the opioids are discontinued.
  - She is NOT considered an addict.
- A patient takes "oxy" (Oxycontin) obtained from "street" dealers:
  - She is dependent.

- She will go through withdrawal if drug is discontinued.
- By definition, this is substance abuse because of the illegal nature in which she obtains her drugs.
- She could be considered an “addict.”

### Polysubstance Use

- Concomitant use of two or more psychoactive substances, in quantities and frequencies that cause individually significant distress or impairment.
- The Wishard data shows that 107/287 or 37.2% of pregnant women presented for prenatal care with polysubstance use.
- Opiates are a common component along with alcohol and tobacco.
- As are Alcohol and Tobacco
- Common conditions with polysubstance use:
  - Chronic pain conditions
  - Fibromyalgia
  - Bipolar
  - Anxiety disorders

### Recovery Terminology

- **Recovery:** A process of overcoming both physical and psychological dependence on a psychoactive substance with a commitment to sobriety.
- **Abstinence:** Non-use of any psychoactive substance.
- **Maintenance:** Prevention of craving behavior and withdrawal symptoms of opioids by long-acting opioids (e.g. methadone, buprenorphine).
- **Harm Reduction:** a gradual process of change that eventually leads to recovery – viewed by some as controversial.

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<sup>5</sup> Mitra S. & Sinatra R. S. Perioperative management of acute pain in the opioid-dependent patient. *Anesthesiology*, 2004;101:212-227.

<sup>6</sup> American Psychiatric Association (2000). *Diagnostic and statistical manual of mental disorders (Revised 4th ed.)*. Washington, DC: Author.

<sup>7</sup> Handelsman L, Cochrane KJ, Aronson MJ, et al. Two new rating scales for opiate withdrawal. *Am J Drug Alcohol Abuse* 1987;13(3)293-308

<sup>8</sup> Ebner N. Management of neonatal abstinence syndrome in neonates born to opioid maintained women. *Drug Alcohol Depend*, 2007;87:131-138

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# MODULE 3: ETHICAL AND PSYCHOSOCIAL DIMENSIONS OF THE PHYSICIAN-PATIENT RELATIONSHIP

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## **Role of Physician treating patients with substance use:**

- The physician is the patient's advocate, not adversary.
- Mandatory reporting laws obligate the physician to follow the law or suffer severe penalties including felony prosecution.
- Difficult situations make difficult laws and they risk turning the physician into an adversary, thus driving the patients from care.<sup>9</sup>
- Evidence indicates physician attitudes are more punitive than supportive.<sup>10</sup>
- Obstetrical nurses noted to be judgmental and punitive.<sup>11</sup>

## **Physician-Patient Relationship: Informed Consent**

- The provider is in a superior position to the patient with respect to knowledge, expertise and skills.
- This is called a "fiduciary" relationship.
- The physician-patient relationship creates a duty for the physician to inform the patient of the risks and benefits of the planned care, procedure, tests, medications, etc.
- The validity test for informed consent is whether the patient has been adequately informed to exercise her right to refuse the planned care.
- Rarely do issues of informed consent lead to liability.

## **Three Important Tools for success in treating substance use**

- Attitude: Non Judgmental
- Attitude: Supportive
- Attitude: Be specific about every detail of care.

## **Legal and Ethical Issues in Urine Testing<sup>12</sup>**

- There is no uniform policy on maternal or newborn drug testing.
- It is well established that patients may refuse even lifesaving care.<sup>13</sup>
- When it comes to childbearing, the most prominent issue places the mother's right to autonomy against a fetus' right to physical integrity.
- This is especially true for issues such as court ordered cesarean delivery, abortion, employment in the toxic workplace and criminalization of maternal drug use.<sup>14</sup>

## **Current opinions indicate two lines of thought about drug testing**

### Focus on autonomy

- A specific and informed consent needs to be obtained for maternal or newborn testing.
- Such consent must also inform the patient that positive results may be reported to Child Protective Services or may be used for legal action if the state enacts criminal penalties for drug use in pregnancy.

- Patient must be informed that she may “opt out” of any test.
- If she “opts out” of the drug test, she must be informed that the pediatrician is able to test the baby’s meconium without her consent.

#### Focus on Beneficence and Justice

- In contrast, the other opinion holds that the signed consent for prenatal and obstetrical care covers all tests necessary for medical diagnosis and treatment.
- Implied in this opinion is that all information acquired by the physician remains “privileged” and confidential between the patient and physician.

#### **Legal Issues**

- It is clear that state laws that criminalize maternal conduct (i.e. that make illegal substance use a felony) do not resolve the issue of drug use in pregnancy.
- The greatest risk is that such laws create an adversarial situation and drive patients away from prenatal care.
- Thus, it is most important to identify alcohol and drug use within the “privileged” and confidential clinical setting and this appears to be best achieved by universal verbal screening for all pregnant women.

#### **Ferguson v. City of Charleston**

- South Carolina enacted a law that makes the use of an illegal or illicit substance during pregnancy a Class D felony.
- Two issues became clear as a result of this law and they were noted in a United States Supreme Court decision, Ferguson v. City of Charleston.<sup>15</sup>
- The case noted that 40 out of 41 women arrested as a result of postpartum drug testing for cocaine were African-American.
- In contrast, when tests were positive for heroin or methamphetamine, more often used by white women, patients were more likely referred to social services.
- The second issue in this case involved a point of law.
- The Court held that if the drug test was obtained without the patient’s consent, then the patient cannot be subject to criminal prosecution because it constitutes an unlawful search under the Fourth Amendment.

*This Supreme Court decision is, in fact, the law of the land.*

<sup>9</sup> Poland ML, Dombrowski MP, Ager JW, Sokol RJ. Punishing pregnant drug users: enhancing the flight from care. *Drug Alcohol Depend* 1993;31:199-203.

<sup>10</sup> Abel EL, Kruger M. Physician attitudes concerning legal coercion of pregnant alcohol and drug abusers. *Am J Obstet Gynecol* 2002;186:768-72.

<sup>11</sup> Selleck CS, Redding BA. Knowledge and attitudes of registered nurses toward perinatal substance abuse. *J Obstet Gynecol Neonatal Nurs* 1998;27:70-7.

<sup>12</sup> Indiana Perinatal Network. Substance use disorders in pregnancy: consensus statement. September 2006, [www.indianaperinatal.org](http://www.indianaperinatal.org).

<sup>13</sup> Cruzan v. Director, Missouri Dept. of Health, 110 S. Ct. 2841 (1990).

<sup>14</sup> Nocon JJ, Physicians and Maternal-Fetal Conflicts: Duties, Rights, and Responsibilities, *Journal of Law and Health, Cleveland-Marshall College of Law Review* 1991;5:1.

<sup>15</sup> Ferguson v. City of Charleston, 532 U.S. 67 (2001)

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# MODULE 4: WHAT PROVIDERS NEED TO KNOW ABOUT OPIOIDS

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## Case 3

A 30 year-old former heroin addict is in her third pregnancy at 32 weeks. She has been stable for the last two years on a methadone maintenance program taking 70 mg. per day.

She presents with a complaint of insomnia due to hot flashes and night sweats. These symptoms started about two weeks ago. Typically they start about 5 AM and the symptoms were mild. Now they start about 2 AM and they are more severe. She now has “stomach cramps” when she awakens.

She stated this occurred in her prior labors and she went into premature labor both times.

In consultation with the methadone clinic physician, we agreed that the pregnancy was increasing the methadone metabolism and she was going into withdrawal before her customary treatment time of 7 AM.

Her methadone dose was increased by 5 mg. daily until the symptoms stopped

She had good relief at a dose of 95 mg., continued to term and delivered a 2900-gram boy at 38 weeks.

Her dose was modified downward during the next 3 months.

*Frequent communication with the methadone clinic physician is necessary to insure the patient is adequately monitored during the pregnancy.*

---

### **Opioids are metabolized faster in pregnancy.**

- Methadone, hydrocodone and oxycodone are metabolized at a more rapid rate in pregnancy.
- Thus, the requirement for a maintenance dose will increase.
- In the Wishard data, 32/92 (35%) of the methadone maintenance patients required an increase of 30% to over 50% over their initial dose to prevent withdrawal.

### **The rate of excretion is faster than withdrawal**

- Morphine is excreted within 72 hours while the withdrawal is 3-6 days.
- Methadone can be excreted in 4-5 days but withdrawal is prolonged to 10-20 days.
- The clinical relevance is that a patient in withdrawal may have a negative urine drug screen (UDS).

## Effects on Pregnancy

**The major maternal risk of opioid use is respiratory depression and death.**

- Many opioid users also use benzodiazepines, which greatly increase the risk of death.
- In the Wishard data, 19 of 45 (42.2%) opioid chronic pain patients tested positive for benzodiazepines at their first prenatal visit.
- In addition, about two thirds of the patients use tobacco.
- The Wishard data also reveals that opioid users have a higher incidence of low birth weight and preterm labor.

**Maternal treatment of opioid addiction involves:**

- Managing acute overdose,
- Treating withdrawal,
- Maintenance and
- Detoxification.

*All too often, the patient presents in acute withdrawal. After she is stabilized, most are managed by maintenance with methadone or buprenorphine and only occasionally does a patient choose detoxification.*

## Changes in Approach to Opioid Dependent Patient

There has been a major shift in the approach to opiate treatment from detoxification and abstinence to maintenance. A number of factors have contributed to this shift.

- Relapse in this population is high.
- Maintenance helps prevent relapse and diseases attributed to IV drug use.
- Most important is that opiate withdrawal significantly increases the risk for abortion and preterm labor.
- However, in selected patients, detoxification has been accomplished with relative safety.<sup>16</sup>
- In one retrospective study of gradual methadone detoxification, there was no increased risk of preterm delivery.<sup>17</sup>
- However, the relapse rate in one study was 56% after detoxification.<sup>18</sup>

## General Notes

- **Opiates** are alkaloids derived from the opium poppy and include morphine, codeine and thebaine.
- **Opioids** include all opiates plus the semi-synthetics, which are derived from the alkaloids (thebaine): hydrocodone, oxycodone, and heroin, plus the synthetics: methadone, fentanyl, Nubian, and buprenorphine.
- Many physicians use the terms “opiate” and “opioid,” interchangeably.

## Pharmacology

**Opioids bind to neuroreceptors specifically:**

- Mu: analgesia; euphoria, respiratory depression, constipation, sedation, miosis
- Kappa: dysphoria, sedation, and psychotomimetic
- Delta: unknown

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<sup>16</sup> Dashe JS, Jackson GL, Olscher DA, Zane EH, Wendel GD, Jr. Opioid detoxification in pregnancy. *Obstet Gynecol* 1998;92:854-8.

<sup>17</sup> Luty J, Nikolaou V, Bearn J. Is opiate detoxification unsafe in pregnancy? *Journal of Substance Abuse Treatment* 2003;24(4):363-367.

<sup>18</sup> Maas U, Kattner E, Weingart-Jesse B, et al. Infrequent neonatal opioid withdrawal following maternal methadone detoxification during pregnancy. *J Perinat Med.* 1990;18:111–118.

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# MODULE 5: OPIOID OVERDOSE

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## Case 4

An 18 year old women presents to the emergency room comatose and barely breathing. She appears to be pregnant at term. Fetal heart rate is 180 BPM. There is some froth to her breath.

This is a classic presentation for opioid overdose. An airway was established, parenteral fluids started and naloxone was administered. One hour after Naloxone, her breathing slows again. Overdose most likely due to long acting opioid – methadone. Repeat naloxone counteracted the opioid.

She was restarted on methadone for stabilization and delivered a healthy 2800-gram female shortly thereafter. The infant was treated for NAS for 30 days in the NICU.

*This case illustrates an all too common experience for emergency department physicians. Rapid identification and treatment is lifesaving.*

---

## Overdose is increasingly more common

- Opioid prescription abuse is the fastest rising addiction and public health problem in the United States.
- Over 2,000 deaths per week have been attributed to opioid abuse.
- Most of the fatalities are due to Oxycontin
- Comparison of Mortality rates in the U.S., 2009<sup>19</sup>
  - MVA 36,284
  - Drugs 37,485
  - Firearms 30,694

## Opioid Overdose Management

- Characterized by pinpoint pupils, respiratory depression, coma, and pulmonary edema.
- Establish airway.
- Start parenteral fluids, e.g., Lactated Ringer's solution.
- **Avoid fluid overload – many patients with overdose are in subclinical or overt pulmonary edema.**
- Inject Naloxone – repeat if long acting opiate present, e.g., methadone.
- Naloxone will not harm fetus.
- **Check acetaminophen levels in patients using opiate/acetaminophen compounds.**

## Treatment will precipitate a severe withdrawal

- Will need to restart and modify an opioid dose to prevent further withdrawal
- May use oxycodone 10 mg. every 2-4 hours until stable.
- Patients on IV Morphine pumps typically use over 100 mg. in 24 hours to stop the withdrawal symptoms.

### **Symptomatic relief during transition to maintenance**

- Withdrawal affects four major systems:
  - CNS
  - GI
  - Cardiovascular
  - Autonomic Nervous System
- Phenergan 25 mg q 4-6 H for withdrawal symptoms – best for nausea, vomiting and GI symptoms
- Phenobarbital, 30 mg TID for neurological withdrawal symptoms.
  - A long acting barbiturate.
  - Anti-seizure medication
  - A vasodilator
- Clonidine 0.1 mg TID – vascular withdrawal symptoms.<sup>20</sup>
- **Avoid benzodiazepines.**

### **Convert to maintenance: use Methadone or Buprenorphine**

- Methadone: start at 20 mg BID and increase 5-10 mg per day until stable.
- Buprenorphine/naloxone (Suboxone): start at 2 – 4 mg; increase by 2-4 mg every 6 hours until withdrawal is abated.
- Typical Suboxone doses for maintenance are from 8-16 mg.
- Naloxone carries no recognizable harm to the fetus.

### **Evaluate for psychiatric co-morbidity**

Some co-morbid psychiatric problems are more common in women:<sup>21</sup>

- Bipolar disorders
- Panic Disorder
- PTSD
- Cluster B Personality Disorders
- Bulimia
- Depression

### **Psychiatric evaluations should include at least**

- Depression scale at first and subsequent prenatal visits if at risk.
- Independent evaluations by psychiatric trained providers.
- Care coordination of psychiatric problems.

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<sup>19</sup> Kochanek KD, Xu J, Murphy, SL, Miniño AM, Kung H, Deaths: preliminary data 2009. National Vital Statistics Reports 2011; 59(4).

<sup>20</sup> Horvath JS, Phippard A, Korda A, Henderson-Smart DJ, Child A, Tiller DJ. Clonidine hydrochloride--a safe and effective antihypertensive agent in pregnancy. *Obstet Gynecol* 1985;66:634-8

<sup>21</sup> Miles DR, Kulstad JL, Haller DL. "Severity of substance abuse and psychiatric problems among perinatal drug-dependent women." *J Psychoactive Drugs*. 2002;34(4): 339-346.

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# MODULE 6: OPIOID WITHDRAWAL

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## Case 5

A 26 year-old chronic pain patient, in good control with hydrocodone 10 mg. acetaminophen 325 mg. four times daily. She also takes amitriptyline 50 mg. before sleep. She suffered a gunshot wound to her leg with resulting femoral nerve neuropathy.

At 28 weeks, she visited her pregnant sister who was about to deliver. She ran out of meds and could not get refills in the other state.

She presented to the E.D with hot flashes, abdominal cramps, diarrhea, irritability and rapid pulse.

She was diagnosed with “stomach flu” and told to maintain hydration and was given a prescription for Phenergan, 25 mg. every six hours.

She returned home shortly thereafter in florid opioid withdrawal and fortunately, refills of her prescriptions resolved the problem.

*Opioid withdrawal can be subtle in its onset and often missed as a diagnosis.*

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## CURRENT RECOMMENDATION IS TO AVOID WITHDRAWAL DURING PREGNANCY

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### Opioid Withdrawal: Affects Major Systems

- CNS – tremors, seizures
- Metabolic – sweating; yawning
- Vascular – hot flashes and chills
- Respiratory – increased rate; respiratory alkalosis
- GI – cramps, nausea, vomiting, diarrhea
- Drug specific effects – methadone has a prolonged withdrawal: 10 – 20 days.
- Restart and modify opioid dose.
- **Avoid benzodiazepines; potentiates CNS and respiratory depression.**

### Opioid Withdrawal Treatment

- Initiate methadone or buprenorphine to stabilize withdrawal:
  - May use oxycodone 10 mg q 4-6h for up to 72 hours to stabilize patient a
  - Then switch to methadone or buprenorphine.
- Phenergan 25 mg q 4-6 H for withdrawal symptoms – best for nausea, vomiting and GI symptoms
- Phenobarbital, 30 mg TID for neurological withdrawal symptoms.

- Clonidine 0.1 mg TID – vascular withdrawal symptoms.<sup>22</sup>
- Check acetaminophen levels in patients using opiate/acetaminophen compounds.

#### **Opioid Detoxification**

- Must be closely controlled. Benefits rarely outweigh risks.
- Gradual reduction to minimize withdrawal but preterm labor remains high.
- Relapse rates in detoxification plans are also high – over 50%.

#### **Preterm labor remains a major risk in overdose, withdrawal and detoxification**

- Pharmacologic treatments for preterm labor, such as magnesium sulfate, may potentiate respiratory depression in the mother and neonate.
- Fetal monitoring is significantly affected by opioids with reduced fetal activity most common.<sup>23</sup>
- Methadone will cause a higher incidence of non-reactive non stress tests (NST), especially if given 1-3 hours before the NST.<sup>24</sup>
- The biophysical profile is the appropriate follow up tool for a non-reactive NST.<sup>25</sup>

#### **Intrauterine growth restriction (IUGR) is another common problem in opioid dependent women and monitoring with ultrasound is essential to determine prenatal management.**

- If IUGR is identified, the degree of placental dysfunction is thought to be associated with changes in diastolic blood flow through the umbilical cord.
- Increasing resistance of diastolic flow and reduction of amniotic fluid are markers indicating closer surveillance and earlier intervention.
- Typically, opioid dependent patients with fetal growth less than the tenth percentile are delivered after 37 completed weeks.

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**IT IS ESSENTIAL TO RESTART THE PATIENT’S MAINTENANCE PROGRAM AFTER AN EPISODE OF WITHDRAWAL. THIS MAY REQUIRE A HIGHER DOSE OF OPIOIDS.**

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<sup>22</sup> Horvath JS, Phippard A, Korda A, Henderson-Smart DJ, Child A, Tiller DJ. Clonidine hydrochloride--a safe and effective antihypertensive agent in pregnancy. *Obstet Gynecol* 1985;66:634-8

<sup>23</sup> Cejtin HE, Mills A, Swift EL. Effect of methadone on the biophysical profile. *J Reprod Med* 1996;41:819-22.

<sup>24</sup> Archie CL, Lee MI, Sokol RJ, Norman G. The effects of methadone treatment on the reactivity of the nonstress test. *Obstet Gynecol* 1989;74:254-5.

<sup>25</sup> Levine AB, Rebarber A. Methadone maintenance treatment and the nonstress test. *J Perinatol* 1995;15:229-31.

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# MODULE 7: OPIOID MAINTENANCE STRATEGIES - METHADONE

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## Case 6

A 30 year–old former “oxy” addict, single mom, was stabilized on methadone, 90 mg. daily.

She is in her second pregnancy at 28 weeks and doing well.

She works in the laundry department at the hospital and her shift runs from 7 AM. To 3 PM.

Thus, she must attend the methadone clinic before work to receive her dose – the clinic is open from 5 AM to 1 PM.

She almost always suffers adverse effects of the methadone, especially nausea for the first 2 hours after receiving her dose.

She has received numerous warnings that she appears “drugged” at work and is at risk for losing her job.

She cannot work another shift due to her need to attend to her first child, who returns from school at 3:30 PM

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**Methadone maintenance** has been the model for maintenance of opioid dependent pregnant patients for many years.

- Contrary to popular belief, it has never been approved to treat opioid dependency in pregnancy.
- Methadone maintenance is highly regulated and can only be dispensed for opioid dependence treatment in a federally certified clinic.
- Thus, the patient must arrive early in the morning, receive her dose and its attendant side effects and then carry on through her day.

## Methadone Maintenance

Early reports found substantial benefits from maintenance therapy, especially reduction of infectious disease and stillbirth.<sup>26</sup>

- Originally, the dosing regimen for methadone followed the practice of using the lowest possible dose to reduce the risk of NAS.
- Dose of less than 20-40 mg often failed to achieve a blocking effect and led to increased preterm labor, low birth weight and relapse.<sup>27</sup>
- Thus, it is most prudent to adjust the dose of methadone based on withdrawal symptoms and cravings.
- Up to 35% of patients will require an increase in methadone, typically in the late second

and early third trimesters.

- Although the evidence does not support an advantage to divided doses of methadone, many patients report better tolerance and less nausea, which improves compliance with treatment and prenatal care.<sup>28</sup>
- If the patient experiences the typical post-partum diuresis, it is recommended to reduce the methadone dose by 20-40% shortly after delivery.

#### **Opioid Maintenance - Methadone**

- Encourage patient to remain on methadone during pregnancy.
- Expect dose to increase up to 50% during pregnancy in about 35% of patients.
- Doses range from 50-150 mg. per day.
- Higher doses **ARE NOT** associated with the severity of NAS and have been shown to improve maternal compliance with prenatal care.<sup>29</sup>
- Patient should be encouraged to breast feed.<sup>30</sup>

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<sup>26</sup> Newman RG, Bashkow S, Calko D. Results of 313 consecutive live births of infants delivered to patients in the New York City Methadone Maintenance Treatment Program. *Am J Obstet Gynecol* 1975;121:233-7.

<sup>27</sup> Kashiwagi M, Arlettaz R, Lauper U, Zimmermann R, Hebisch G. Methadone maintenance program in a Swiss perinatal center: (I): Management and outcome of 89 pregnancies. *Acta Obstet Gynecol Scand* 2005;84:140-4.

<sup>28</sup> DePetrillo PB, Rice JM. Methadone dosing and pregnancy: impact on program compliance. *Int J Addict.* 1995;30:207-217.

<sup>29</sup> McCarthy JJ, Leamon MH, Parr MS, Anania B. High-dose methadone maintenance in pregnancy: maternal and neonatal outcomes. *Am J Obstet Gynecol* 2005;193:606-10.

<sup>30</sup> Philipp BL, Merewood A, O'Brien S. Methadone and breastfeeding: new horizons. *Pediatrics* 2003;111:1429-30.

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## MODULE 8: OPIOID MAINTENANCE - BUPRENORPHINE

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### Case 7

A 22 year-old presents at 12 weeks with her second pregnancy.

She states she was a former “pain patient” and is maintained on Suboxone 8 mg/2mg. daily and wanted to wean down so she could test negative at delivery.

She also did not want her parents or partner to know she was on Suboxone.

She was given feedback about the risks of weaning and also reassured that her information was confidential

A very gradual reduction of Suboxone to 2 mg. per day was achieved at 32 weeks gestation.

She stopped her Suboxone at 38 weeks and delivered a healthy male two weeks later.

Her drug screen on admission was negative and as well as the baby’s meconium screen.

She resumed her 8 mg./2 mg. Suboxone dose by the 4 week postpartum visit.

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**Buprenorphine maintenance** was first registered to treat opiate dependence in France in 1996, and practitioners were allowed to dispense buprenorphine by prescription enabling easy access to treatment.<sup>31</sup>

- Thousands of patients underwent buprenorphine treatment, including among them an increasing number of pregnant women.
- An initial striking observation was that in the majority of newborns, the neonatal abstinence syndrome (NAS) was either absent or mild enough to not require treatment.
- A prospective French study of 34 buprenorphine treated pregnancies revealed that only 13 had NAS, nine of which were confounded by other psychoactive drugs (benzodiazepines, opiates and cannabis).<sup>32</sup>

Buprenorphine was approved for use in the United States in 2002 by an amendment to the Drug Treatment Act of 2000.<sup>33</sup> (DATA)

- DATA enables QUALIFYING PHYSICIANS to receive a WAIVER from the special registration requirements in the Controlled Substances Act for the provision of medication-assisted opioid therapy.

- This waiver allows qualifying physicians to practice medication-assisted opioid addiction therapy with Schedule III, IV, or V narcotic medications specifically approved by the Food and Drug Administration (FDA).
- On October 8, 2002 Subutex® (buprenorphine hydrochloride) and Suboxone® tablets (buprenorphine hydrochloride and naloxone hydrochloride) received FDA approval for the treatment of opioid addiction.
- Such medications may be prescribed and dispensed by waived physicians in treatment settings other than the traditional Opioid Treatment Program (methadone clinic) setting.
- The first United States survey of a registry of over 300 mothers treated with buprenorphine reveals that buprenorphine is safe and effective for mothers and newborns with a qualitatively and quantitatively diminished NAS compared to methadone.<sup>34</sup>
- A comparative study between methadone and buprenorphine confirmed improved maternal and neonatal outcomes on buprenorphine.<sup>35</sup>

**How to get certified as a Buprenorphine Provider:**

- For complete details about qualifications, see <http://buprenorphine.samhsa.gov/pls/bwns/training>
- DATA-qualifying training events are available both in-person and on the Web.
- Web Based Trainings:
  - American Academy of Addiction Psychiatry (AAAP)**
  - American Osteopathic Academy of Addiction Medicine (AOAAM)**
  - American Psychiatric Association (APA)**
  - American Society of Addiction Medicine (ASAM)**

**Pharmacology of Buprenorphine**

- Buprenorphine is an agonist/antagonist with a high binding affinity for the Mu receptor.
- Thus, if the patient uses another opiate while on buprenorphine, she will have a minimal euphoric experience.
- This effect significantly reduces the abuse potential.<sup>36</sup>
- It is metabolized by placental aromatase to nor-buprenorphine resulting in low placental transfer.
- This may account for limited fetal exposure and its lower incidence of NAS.<sup>37</sup>

**Buprenorphine is marketed in the United States in two forms, buprenorphine (Subutex) and buprenorphine combined with naloxone (Suboxone)**

- Initially, there was some concern that the buprenorphine/naloxone combination might cause an intrauterine withdrawal in the fetus.
- Hence, only Subutex was initially recommended for use in pregnancy.
- The evidence clearly indicates that the dose of naloxone has little to no effect on the fetus.<sup>38</sup>
- Moreover, sublingual buprenorphine has been found to be safe and effective in treating NAS.<sup>39</sup>
- Small amounts of buprenorphine are found in the breast milk. However, it has little, if any effect on the newborn with no evidence of neonatal withdrawal when breastfeeding is discontinued.<sup>40</sup>

## Opioid Maintenance: Buprenorphine

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**PATIENT MUST BE IN OPIOID WITHDRAWAL TO START BUPRENORPHINE TREATMENT.  
IF NOT IN WITHDRAWAL, THE ANTAGONISTIC EFFECTS OF BUPRENORPHINE WILL  
INITIATE A RAPID AND SEVERE WITHDRAWAL**

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- Inpatient: some recommend initiating treatment with buprenorphine, 2-4 mg sublingual by either tablet or film.
- Increase dose by 2-4 mg every 6 hours to stop withdrawal symptoms.

### Convert to buprenorphine/naloxone for outpatient use.

- Target doses range from 4 to 24 mg per day
- Most pregnant patients are stable at 8-16 mg per day in divided doses.

### Analgesia and Anesthesia for Methadone and Buprenorphine managed patients

#### Labor and Delivery

- Inform the patient to continue her maintenance dose of buprenorphine or methadone on the day of admission for labor.
- Restart maintenance after delivery as soon as oral intake is tolerated.
- Epidural anesthesia for labor, vaginal delivery and cesarean delivery is the standard.
- Typically, postpartum analgesia for a vaginal delivery is to start Ibuprofen 800 mg. every 8 hours alternating with oxycodone 10 mg, every six hours.
- Most patients will be able to wean off the additional opioid analgesic in 4-7 days

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**IT IS IMPERATIVE TO INFORM THE PATIENT TO CONTINUE HER MAINTENANCE DOSE  
ON THE DAY OF ADMISSION AND TO RESTART MAINTENANCE AS SOON AS ORAL  
INTAKE IS TOLERATED.**

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#### Cesarean Delivery

- Continue maintenance dose of methadone or buprenorphine on day of admission for elective cesarean delivery
- Restart maintenance as soon as oral intake is tolerated.
- Epidural or Spinal anesthesia preferred for cesarean delivery.
- General anesthesia if indicated.
- Typically, postpartum analgesia for a cesarean delivery is to use an opioid pump with 50-100% more opioid than for the non-opioid dependent patient.
- Start Ibuprofen 800 mg. every 8 hours alternating with oxycodone 10-20 mg, every four to six hours weaning off the additional opioid analgesic in 7-10 days.

In addition to the maintenance dose of methadone or buprenorphine:

- Methadone-maintained women have similar analgesic needs and response during labor, but require 70% more opiate analgesic after cesarean delivery.<sup>41</sup>
- Likewise, Buprenorphine maintained women have similar intrapartum pain and analgesic needs during labor, but experience more postpartum pain and require 47% more opioid analgesic following cesarean delivery.<sup>42</sup>
- Morphine is the best tolerated opioid analgesic by the largest group of patients.
- Dilauded appears to also be well tolerated

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<sup>31</sup> Auriacombe M, Fatseas M, Dubernet J, Daulouede JP, Tignol J. French field experience with buprenorphine. *Am J Addict* 2004;13 Suppl 1:S17-28.

<sup>32</sup> Lacroix I, Berrebi A, Chaumerliac C, Lapeyre-Mestre M, Montastruc JL, Damase-Michel C. Buprenorphine in pregnant opioid-dependent women: first results of a prospective study. *Addiction* 2004;99:209-14.

<sup>33</sup> Drug Treatment Act of 2000.: 21 U.S.C., Section 823 (g)(2)(B), Nov. 8, 2002.

<sup>34</sup> Johnson RE, Jones HE, Fischer G. Use of buprenorphine in pregnancy: patient management and effects on the neonate. *Drug Alcohol Depend* 2003 May 21;70(2 Suppl):S87-101.

<sup>35</sup> Kakko J, Heilig M, Sarman I. Buprenorphine and methadone treatment of opiate dependence during pregnancy: comparison of fetal growth and neonatal outcomes in two consecutive case series. *Drug Alcohol Depend* 2008;96:69-78

<sup>36</sup> Bridge TP, Fudala PJ, Herbert S, Leiderman DB. Safety and health policy considerations related to the use of buprenorphine/naloxone as an office-based treatment for opiate dependence. *Drug Alcohol Depend* 2003;70:S79-85.

<sup>37</sup> Deshmukh SV, Nanovskaya TN, Ahmed MS. Aromatase is the major enzyme metabolizing buprenorphine in human placenta. *J Pharmacol Exp Ther*. 2003;306:1099-1105.

<sup>38</sup> Coles LD, Lee IJ, Hassan HE, Eddington ND. Distribution of saquinavir, methadone, and buprenorphine in maternal brain, placenta, and fetus during two different gestational stages of pregnancy in mice. *J Pharm Sci* 2008 Dec 30.

<sup>39</sup> Kraft WK, Gibson E, Dysart K, et al. Sublingual Buprenorphine for Treatment of Neonatal Abstinence Syndrome: A Randomized Trial. *Pediatrics* 2008;122:e601-607

<sup>40</sup> 128. Marquet P, Chevrel J, Lavignasse P, et al. Buprenorphine withdrawal syndrome in a newborn. *Clin Pharmacol Ther*. 1997;62:569-571.

<sup>41</sup> Meyer M, Wagner K, Benvenuto A, Plante D, Howard D. Intrapartum and Postpartum Analgesia for Women Maintained on Methadone During Pregnancy. *Obstet Gynecol* 2007;110:261-262.

<sup>42</sup> Meyer M, Paranya G, Keefer Norris A, Howard D. Intrapartum and postpartum analgesia for women maintained on buprenorphine during pregnancy. *Eur J Pain*. 2010 Oct;14(9):939-43. Epub 2010 May 4.

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# MODULE 9: OPIOID DEPENDENT PATIENTS: A COMPARISON OF MATERNAL AND NEONATAL OUTCOMES

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## Case 8

A 30 year-old takes two Oxycodone 10 mg. acetaminophen 325 mg. tablets four times a day for relief of chronic back pain. In addition, she attends physical therapy twice weekly. She has had three operations on her back for severe scoliosis and herniated discs.

The patient is employed as a graphics designer.

She delivered a healthy 3700-gram male vaginally at 40 weeks. The baby showed minimal signs of withdrawal, relieved by comfort measures.

She was discharged on the second post-partum day with her baby.

She continued to breast feed for six months and on weaning, the baby had no signs of withdrawal.

*In an analysis of chronic pain patients in the Wishard Program on opioid alone for pain relief, 30 of 31 newborns were discharged on day two or three with no signs of withdrawal requiring treatment.*

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### **The Wishard data reflects a long-term observational study of opioid dependent patients**

- The study includes data from the Prenatal Recovery Clinic starting in 2002 through 2010, and includes 90 patients treated with methadone compared to 46 patients treated with buprenorphine and buprenorphine/naloxone.
- In addition, there is data from two other groups of opioid dependent chronic pain patients.
  - One group (n=31) consists of patients whose urine drug screens revealed only opiate and opiate/acetaminophen combinations for pain control
  - Another group (n=45) had urine drug screens that revealed multiple licit and illicit substances including benzodiazepines, cocaine, and marijuana (designated Opioid P for poly-substance use)

### **Methadone treated Patients**

- Had significantly higher preterm deliveries, more low birth weight babies and longer length of stay (LOS) for withdrawal when compared to the buprenorphine group.
- Interestingly, opioid dependent chronic pain patients who used only opioids for pain

relief had the lowest maternal and neonatal morbidity.

- Doses of hydrocodone and oxycodone in the latter group varied from 40 to 80 mg per day.
- Only 9 babies of methadone treated mothers tested positive for illicit drugs in their meconium. In a prior study in the same institution in 1999, 85% of methadone patients tested positive for an illicit substance (predominantly cocaine) in the 30 days prior to delivery.<sup>43</sup>
- It appears that a significant change in the treatment approach addressing illicit drugs resulted in substantially lower use

### Methadone vs. Buprenorphine: Major Pregnancy Outcomes

	Bup. (46) <sup>1</sup>	Meth (90) <sup>2</sup>	p
Preterm Delivery	5 (10.9%)	27 (30%)	0.001
Low Birth Weight (<2500g)	4	26	0.01
Mean Birth Weight	3079 g	2718 g	0.005
Positive Meconium	3 (6.9%)	9 (10.8%)	NS
Neonatal Abstinence (NAS)	8	89	0.001
NAS Treated	6 <sup>3</sup>	80	0.001
Mean Length of Stay (days)	6.78	30.3	0.001
Failed to return PP	13 (28.8%)	28 (31.1%)	NS
PP UDS "negative "	29 (63%)	59 (65.5%)	NS
Tobacco use (>05.ppd)	29 (63%)	51 (56.6%)	NS

<sup>1</sup> In the buprenorphine group there were 12 patients treated with buprenorphine and 34 treated with buprenorphine/naloxone with no differences within the groups.

<sup>2</sup> In the methadone group there were 92 babies (two sets of twins).

<sup>3</sup> Three of the NAS treated had concomitant use of benzodiazepines.

PP = postpartum

## Comparison of Opioid Dependent Chronic Pain Patients

	Opioid (31)	Opioid P (45)*	p
Preterm Delivery	4 (12.9 %)	8 (17.7%)	NS
Low Birth Weight (<2500g)	3	8	NS
Mean Birth Weight	3085 g	2879g	NS
Positive Meconium	0	12 (26.6%)	0.001
NAS Treated	1	5	NS
Mean Length of Stay	3.3	7.8	0.01
Failed to return PP	3	13	0.01
PP UDS "negative"	23 (74.2%)	25 (55.5%)	NS
Tobacco use (>05.ppd)	21 (67.7%)	30 (66.6%)	NS

\* Opioid P = polysubstance use including benzodiazepines, cocaine, and marijuana.

PP = postpartum

*Opioid dependent patients treated with buprenorphine and opioid-only treated chronic pain patients had the lowest incidence of maternal and neonatal morbidity. In both groups, preterm delivery and birth weights were within the norm for non-opioid dependent patients.*

*The findings strongly suggest new strategies for managing opioid dependent patients in pregnancy. One recommendation is to start opioid dependent patients presenting in withdrawal on buprenorphine rather than methadone.<sup>44</sup>*

**Another recommendation is to maintain the opioid-only patient on her current regimen as follows:**

### Opioid Only Dependent Chronic Pain Patient

- Maintain current opiate regimen – avoid withdrawal (both legal to do and meets standard of care)
  - Hydrocodone 5/325 or 10/325 (up to 2 tabs q 6h)
  - Oxycodone 5/325 or 10/325 (up to 2 tabs q 6h)
- Low rate of NAS noted with these doses
- Requirement of opiate may increase
- Pain moderators may be helpful
  - Amitriptyline 50-100 mg h.s. (also good for insomnia)
  - Gabapentin 300 mg TID
- Physical Therapy – maintain mobility

<sup>43</sup> Brown HL, Britton KA, Mahaffey D, Brizendine E, Hiatt AK, Turnquest MA. Methadone maintenance in pregnancy: a reappraisal. Am J Obstet Gynecol 1998;179:459-63.

<sup>44</sup> Nocon JJ. Buprenorphine in pregnancy: the advantages. Addiction 2006;101:608.

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# MODULE 10: NEONATAL ABSTINENCE SYNDROME (NAS)

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## Case 9

A 35 year-old with a twin pregnancy presents in preterm labor at 35 weeks.

She currently takes 100 mg. of methadone daily for a chronic back pain condition caused by a herniated disc at L4-L5.

She has been complaining of night sweats, hot flashes and contractions for three days.

A spontaneous vaginal delivery of vertex/vertex male twins resulted after attempts to prolong pregnancy failed. The newborns were 2400 and 2235 grams respectively.

By day 4, neither newborn displayed evidence of NAS but both were under the “bili-lights” for physiologic jaundice.

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## Neonatal Abstinence Syndrome NAS<sup>45</sup>

- A complex disorder of behavioral and physiological signs and symptoms.
- Similar manifestations from a large variety of drugs, i.e. opioids, benzodiazepines, barbiturates, anti-depressants.<sup>46</sup>
- Prenatal NAS – due to maternal use of substances
- Postnatal NAS – from pain therapy in newborn.

## Neonatal abstinence syndrome (NAS) is the most common effect on the fetus/neonate

- The incidence is as high as 90% in methadone maintenance users and varies with each opioid used, the daily dose, length of use, and concomitant use of other drugs, especially benzodiazepines.<sup>47</sup>
- In NAS, the neonate is in acute withdrawal with an onset of hours to about 4 days.
- Common symptoms include irritable cry, increased tone, tachypnea, sleeplessness and tremor and treatment is based on scores from observations of psychomotor behavior.<sup>48</sup>
- Treatment consists of stabilizing the withdrawal, usually with morphine drops and then gradually decreasing the dose to detoxify the baby.<sup>49</sup>
- Pharmacologic treatment of NAS may also use clonidine, an alpha agonist used to stabilize the cardiovascular system and phenobarbital to reduce brain activity and seizures.

**There are readily observable neurobehavioral effects in newborns of opioid treated mothers.**

- The most common observations include decreased head circumference, developmental delays, and poor fine motor coordination.<sup>50</sup>
- However, long-term effects of opioid treatment appear to be more dependent on home environment.<sup>51</sup>
- Not surprising is that methadone-exposed infants that had delayed mental development were also raised in poor environmental conditions<sup>52</sup>.

**Dose of Methadone and NAS is Inconsistent**

- The incidence of preterm labor, NAS and short versus long term neonatal LOS does not follow a typical dose-response curve within a dose range of 50-120 mg.<sup>53</sup>
- These observations have significant impact on maternal treatment.
- **Thus, attempting to lower the typical maternal dose will gain little for the newborn while increasing the likelihood of maternal withdrawal that can precipitate preterm labor and/or abruption.**
- This is thought to be due to a higher elimination rate of methadone as pregnancy progresses.<sup>54</sup>
- In addition, patients on higher dose methadone have a greater compliance with prenatal care than those on low dose.<sup>55</sup>
- One study found that the incidence of NAS was less only in very low doses: when comparing women who received less than 20 mg per day, 20-39 mg per day, and at least 40 mg per day of methadone, the treatment for withdrawal occurred in 12%, 44%, and 90% of infants, respectively (P < 0.02).<sup>56</sup>

**NAS: A Multisystem Disorder: Four Key Neurobehavioral Signs**

- CNS signs:
  - Irritability, excessive crying; voracious appetite
  - Seizures
- GI signs: vomiting; diarrhea
- Respiratory signs: tachypnea; hyperpnoea
- ANS signs: sneezing, yawning, tearing
- Finnegan Scale for assessment of symptoms and treatment.<sup>57</sup>
- Highly subjective variability in assessment of NAS; Lipsitz Scale.<sup>58\*</sup>

**NAS Withdrawal a Function of the Drug's Half-life**

- Hydrocodone babies rarely have NAS
- Morphine: Heroin – acute, severe but rapid – over in 72 hours
- Methadone – prolonged – 14-28 days with 6-8 weeks not uncommon
- Buprenorphine – mild and often not requiring treatment.
- Benzodiazepines: delayed withdrawal – may not start until week 2.<sup>59</sup>

**Current Treatment for NAS<sup>60</sup>**

- Combination therapy
  - Oral clonidine; phenobarbital
  - Dilute morphine drops<sup>61</sup>
- Increase morphine dose until signs of withdrawal controlled

- Maintain controlling dose for 2 days
- Wean morphine dose every 1-2 days

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## BREASTFEEDING ASSISTS NAS RECOVERY

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### NAS Morbidity and Mortality

- All Opiates cause some depression but significant depression and death is rare.
- Most complications result from prematurity, infection and severe perinatal asphyxia.
- Risk for SIDS is significantly higher.

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<sup>45</sup> Jansson LM. Neonatal abstinence syndrome. *Acta Paediatr* 2008;97:1321-3.

<sup>46</sup> Levinson-Castiel R, Merlob P, Linder N, Sirota L, Klinger G. Neonatal abstinence syndrome after in utero exposure to selective serotonin reuptake inhibitors in term infants. *Arch Pediatr Adolesc Med* 2006;160:173-6.

<sup>47</sup> Serane VT, Kurian O. Neonatal abstinence syndrome. *Indian J Pediatr* 2008;75:911-4.

<sup>48</sup> Finnegan, L.p., Kron, R.E., Connaughton, J.F., & Emich, J.P. Assessment and treatment of abstinence in the infant of the drug dependent mother. *International Journal of Clinical Pharmacology and Biopharmacy* 1975;12 (1-2):19-32.

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<sup>50</sup> Rosen TS, Johnson HL. Children of methadone-maintained mothers: follow-up to 18 months of age. *J Pediatr*. 1982;101:192-196.

<sup>51</sup> Lifschitz MH, Wilson GS, Smith EO, et al. Factors affecting head growth and intellectual function in children of drug addicts. *Pediatrics* 1985;75:269-274.

<sup>52</sup> Hans SL. Developmental consequences of prenatal exposure to methadone. *Ann N Y Acad Sci*. 1989;562:195-207.

<sup>53</sup> Berghella V, Lim PJ, Hill MK, Cherpes J, Chennat J, Kaltenbach K. Maternal methadone dose and neonatal withdrawal. *Am J Obstet Gynecol* 2003 Aug;189(2):312-7.

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<sup>55</sup> McCarthy JJ, Leamon MH, Parr MS, Anania B. High-dose methadone maintenance in pregnancy: maternal and neonatal outcomes. *Am J Obstet Gynecol* 2005 Sep;193(3 Pt 1):606-10.

<sup>56</sup> Dashe JS, Sheffield JS, Olscher DA, Todd SJ, Jackson GL, Wendel GD. Relationship between maternal methadone dosage and neonatal withdrawal. *Obstet Gynecol* 2002 Dec;100(6):1244-9.

<sup>57</sup> Finnegan and Kaltenbach (1992) in Hoekelman (ed) *Primary Pediatric Care*. St. Louis; CV Mosby 1367-1378

<sup>58</sup> Crocetti MT, Amin DD, Jansson LM. Variability in the evaluation and management of opiate-exposed newborns in Maryland. *Clin Pediatr (Phila)* 2007;46:632-5.

<sup>59</sup> Couvee JE, Zitman FG. The Benzodiazepine Withdrawal Symptom Questionnaire: psychometric evaluation during a discontinuation program in depressed chronic benzodiazepine users in general practice. *Addiction* 2002;97:337-45.

<sup>60</sup> AAP Committee on Drugs. Neonatal Drug Withdrawal. *Pediatrics* 1998; 101: 1079-1088

<sup>61</sup> Coyle MG, Ferguson A, Lagasse L, Oh W, Lester B. Diluted tincture of opium (DTO) and phenobarbital versus DTO alone for neonatal opiate withdrawal in term infants. *J Pediatr* 2002;140:561-4.

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# MODULE 11: OBSTETRICAL CARE GUIDELINES

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## Case 10

An 18 year-old with one prior pregnancy presents for her annual exam to have her IUD removed. She stated she has a new boyfriend and wants to have another baby.

She successfully quit smoking in her first pregnancy but was back to a pack a day habit.

Her urine drug screen was negative.

She was counseled about her decision to attempt another pregnancy and she was also referred to a smoking cessation program.

A few months later she presented for prenatal care at 10 weeks.

She did stop smoking cigarettes.

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## Pre-Conception Counseling<sup>62</sup>

- Evaluates existing medical problems, especially diabetes and hypertension.<sup>63</sup>
- May reveal previously undetected diseases.
- Allows for a discussion of risks for the mother and fetus of substance use.<sup>64</sup>
- Especially helpful for the older mother to discuss genetic risks.<sup>65</sup>
- Allows for optimal diet and exercise counseling.
- May allow for a modification of opioid maintenance prior to pregnancy.
- Allows for consultation with mental health providers for management of coexisting psychiatric co-morbidity.<sup>66</sup>
- It's unusual to prevent a substance use problem prior to pregnancy.

## Prenatal Care

- Routine obstetrical care is modified for the substance user.
- Thorough evaluation of drug use history and plans for modifying substance use are established.
- Perform all routine screening tests.
- Generally, prenatal visits occur every two weeks until 36 weeks, then weekly.
- Urine drug screen at every prenatal visit – enhances recovery.<sup>67</sup>
- Care coordination for psychiatric co-morbidity.
- Encourage other forms of support: therapy, AA, etc.
- Arrange to see social service consultant frequently.
- Dietician review at each visit.
- Growth restriction is common, especially in methadone maintenance patients.

- Follow with non-stress tests, biophysical profiles and ultrasounds for growth restriction.
- Encourage breast-feeding, especially in methadone patients
- Create a delivery plan.

### **Labor and Delivery**

- Decision for delivery based on obstetrical reasons.
- Stress of last few weeks of pregnancy places patient at risk for relapse.
- Induction of labor based on obstetrical reasons.
- Early induction for IUGR in methadone patients.
- Have detailed reports of drug use and maintenance medications available for nursing staff and anesthesiologists.
- Instruct methadone and buprenorphine patients to take their maintenance dose on day of delivery or arrange for patient to receive maintenance dose at appropriate time after admission.

### **Analgesia and anesthesia for labor, delivery and Cesarean delivery**

- Epidural anesthesia for labor, delivery and cesarean delivery is the standard.
- Spinal anesthesia for cesarean delivery.
- Intrathecal opioids very effective for acute pain relief.<sup>68</sup>
- For acute postoperative pain, methadone and buprenorphine patients will gain relief with doses of opiates 70 to 100% over usual doses.
- Morphine analgesia is well tolerated by the majority of patients
- Hydromorphone (Dilaudid) also well tolerated
- Typically, postpartum analgesia is to:
  - Start Ibuprofen 800 mg. every 8 hours
  - Alternating with oxycodone 10 mg, every six hours.
  - This regimen is effective for about 90% of patients.<sup>69</sup>
- It is imperative to inform the patient to continue her maintenance dose on the day of admission and to restart maintenance as soon as oral intake is tolerated.

### **Post-partum Care**

- Recommend at least three postpartum visits:
  - Two weeks: stabilize all medications and maintenance doses.
  - Four weeks: Routine testing: Pap, STD, etc.
  - Six weeks: Social service consultation with focus on continued therapy, support and maintenance.
- Urine drug screen at each visit.
- Breast feeding support at each visit
- Family planning discussion at each visit.

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- <sup>63</sup> McElvy SS, Miodovnik M, Rosenn B et al.. "A focused preconceptional and early pregnancy program in women with type 1 diabetes reduces perinatal mortality and malformation rates to general population levels". *The Journal of Maternal-fetal Medicine* 2000;9 (1): 14–20.
- <sup>64</sup> Swan LL, Apgar BS. "Preconceptual obstetric risk assessment and health promotion". *American Family Physician* 1995;51 (8): 1875–85, 1888–90.
- <sup>65</sup> McGregor S, Parker E. "Family matters: taking a genetic history". *The Practising Midwife* 2003;6 (10): 26–8
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## MODULE 12: EFFECTS OF SPECIFIC DRUGS ON BREASTFEEDING

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### Case 11

A 24 year-old at term with her second pregnancy plans to breast feed.

She is on methadone maintenance at 150 mg. per day.

In her previous pregnancy (also on 150 mg.) she was told by a neonatal fellow that her dose was too high to breast feed and that the baby would probably spend 4-6 weeks in the nursery, thus making it difficult for her to pump her breasts and supply adequate quantities of milk.

She underwent a cesarean delivery for breech presentation and insisted on breast-feeding shortly after delivery.

She was coached by the “lactation team” of nurses and did well in her immediate post-partum recovery.

The baby was discharged on day 14 after a short and mild NAS.

She weaned at 4 months without any withdrawal in the baby.

*NAS in newborns of methadone treated mothers is unpredictable with respect to dose of methadone. Breast-feeding has been associated with shorter withdrawal in the newborns.<sup>70</sup>*

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### Factors in Assessing the Risk of Drugs on the Breast-fed Infant<sup>71</sup>

- Drug concentration in breast milk.
- Drug clearance.
- Therapeutic dose – clinical effect on infant.
- Levels of exposure - the exposure index
- Effects of drugs on production of breast milk.
- Effects of drugs on the breast-feeding patient.

### Drug Transfer into Breast Milk:<sup>72</sup>

- Transcellular diffusion
  - Small molecules, ethanol
  - Rapid transfer
- Intercellular diffusion
  - Occurs during colostrum phase
  - Alveolar cells spaced wide apart
- Passive diffusion - most drugs.

### **Factors Affecting Transfer of Drugs into Breast Milk<sup>73</sup>**

- Lipid Solubility - benzodiazepines
- Protein binding – free and unbound
- Half-Life – fluoxetine
- Molecular size - ethanol
- Infant Factors
  - Gastric pH; transit time
  - Less plasma proteins = more unbound drugs

### **Clinical Pearls: Drug Concentration into Breast Milk<sup>74</sup>**

- Milk to plasma ratio - varies over time.
- When the amount of drug ingested from the milk, per unit of time, is less than the therapeutic dose (clinical effect),
- The level of exposure is low.
- Regardless of the milk to plasma ratio.

### **Rate of Drug Clearance**

- If the rate of drug clearance is high,
- Then even a high milk-to-plasma level will not result in a clinical effect.
- However, long acting drugs like fluoxetine may accumulate over time and create a clinical effect.

### **Level of Breast Milk Exposure: The Exposure Index**

- Amount of drug in breast milk is expressed as a percentage of the therapeutic dose (clinical effect) for the infant.
- Arbitrary “safe value” is 10% of the therapeutic dose.
- *If the exposure index is less than 10, then the effect is not clinically important.*

### **Methadone<sup>75</sup>**

- Long half life
- BUT, transfer to milk is minimal.
- Maternal dose of 80 mg. per day (typical) yields infant dose about 2.8% of maternal.<sup>76</sup>
- Some studies indicate concentrations in breast milk unrelated to maternal methadone dose.<sup>77</sup>
- Appears to have mitigating effect on NAS – shorter LOS of breast-fed infants.<sup>78</sup>

### **Buprenorphine: Subutex and Suboxone**

- Suboxone: buprenorphine and naloxone.
- Oral Rx for opiate dependent maintenance.
- Substantially reduced NAS.
- Minimal to no effect on breastfeeding.
- Most recent literature indicates using buprenorphine to treat NAS in newborn: improved efficacy and shortened LOS.<sup>79</sup>

### **Opioid Dependent Chronic Pain Patients**

- Hydrocodone, oxycodone and fentanyl.
- Usual doses for pain relief appear to have minimal to no effect on infant.
- However, many of these patients also use pain moderators which may depress infant:
  - Benzodiazepines: Xanax; Klonopin
  - Gabapentin: Neurontin
  - Amitriptyline: Elavil (generally safe)
  - Cyclobenzaprine: Flexoril
- High rate of tobacco use.

### **Antidepressant Drugs**

- Most tricyclic antidepressants and SSRI's have an exposure index less than 10.
- Exceptions: Use with caution:
  - Fluoxetine – long acting; may accumulate; colic.<sup>80</sup>
  - Doxepin - sedation
  - Lithium – hypothermia, hypotonia; contraindicated
- Sertraline – no adverse effects noted.

### **Alcohol Use and Breast Feeding<sup>81</sup>**

- Level of alcohol dehydrogenase in first year is 50% of that in adults: rapid absorption into infant's bloodstream.
  - May impair neurologic development.
  - Decreases time spent in active sleep
  - Beer drinking may reduce milk intake by 20%
- Dose-response effect – takes about 2 hours for one drink to be eliminated from mother
- If breast-feeding every 2-3 hours, then should not consume more than one drink between feedings.
- Or, instruct patient to drink just AFTER breastfeeding.
- Or, "Pump and dump."

### **An Old Wife's Tale Refuted**

- A bit o' brandy before breastfeeding can help let-down – NOT TRUE!
- Evidence does not support that alcohol has any benefit to any aspect of breastfeeding.
- If a woman cannot stop or limit her drinking to one drink a day after breastfeeding, than one may correctly assume she has a problem.
- In this case, AA may be more important than breastfeeding.

### **Nicotine and Breast-Feeding<sup>82</sup>**

- Depends on the amount she smokes.
- 60-90 minutes to eliminate 50% of nicotine
- Nicotine induced toxicity reported in breast-fed infants.
  - Decreased Milk volume
  - Early weaning from breast-feeding
  - Decreased weight gain in infant - controversial
- Secondhand smoke may be far more dangerous.
  - SIDS

- Asthma
- Women who breastfeed and continue to smoke have infants with lower incidence of acute respiratory illness compared with bottle-fed infants of women who smoke.
- If she can't stop smoking, there is still a benefit to breastfeeding.

#### **Recovery, Relapse and Breast-feeding**

- Does breastfeeding enhance or detract from ongoing recovery in the postpartum patient?
- The most common cause of relapse is stress, and it does not take much to trigger a relapse
- If breastfeeding is not going well and the patient is experiencing significant stress, she is ripe for relapse.
- Plays into low self-esteem - "I'm a failure"
- Baby always crying – "I need some peace and quiet."
- Despair – using drugs to "numb out."

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### EVALUATION

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Please help us to assess the effectiveness of this toolkit by [clicking here](#) to complete a **brief follow-up survey**. We greatly appreciate your feedback!

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## APPENDIX A      SUBSTANCE USE TERMINOLOGY

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The term “addiction” has been replaced by “substance dependence” and “substance abuse.”

The DSM-IV distinguishes between Substance Dependence and Substance Abuse as follows:<sup>83</sup>

**Substance Dependence** is a pattern of substance use, leading to clinically significant impairment or distress, with **three or more** of the following, occurring at any time in the same 12 month period:

- Tolerance
- Withdrawal
- The substance is taken in larger amounts over a longer period than was intended.
- A persistent desire or unsuccessful efforts to cut down or control use.
- Inordinate time spent in acquiring the substance, use of the substance, or recover from its effects
- Important social, occupational or recreational activities are given up or reduced.
- The substance is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.

**Substance Abuse** is a separate diagnosis from substance dependence. It is a maladaptive pattern of substance use with **one or more** of the following criteria over a 1-year period:

- Repeated substance use that results in an inability to fulfill obligations at home, school or work.
- Repeated substance when it could be dangerous (driving a car).
- Repeated substance-related legal problems, such as arrests.
- Continued substance use despite interpersonal or social problems that are caused or made worse by use.

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<sup>83</sup> American Psychiatric Association (2000). Diagnostic and statistical manual of mental disorders (Revised 4th ed.). Washington, DC: Author.

## APPENDIX B CONTROLLED SUBSTANCES ACT

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### Controlled Substances Act 1970<sup>84</sup>

- Set various schedules to regulate specific substances.
- Based on potential for abuse.
- Most commonly used drugs listed.

#### Schedule I. High potential for abuse; no currently accepted therapeutic use:

- Heroin,
- Gamma hydroxybutyric acid,
- Khat,
- MDMA (Ecstasy),
- LSD; mescaline, psilocin, and
- Marijuana\*

*\*Medicinal Marijuana: legal to use for medical purposes if certified by a physician licensed to practice in a state that has legalized its use for these purposes. As of March 1, 2012, 17 states plus the District of Columbia have statutes regulating the use of marijuana for medical purposes. An additional 17 states have legislation pending to approve the use of medical marijuana.*

#### Schedule II. High potential for abuse but accepted therapeutic use. Requires a written prescription with physician's DEA number for outpatient use.

- Codeine; fentanyl; hydromorphone; oxycodone; morphine; methadone
- Pentobarbital; secobarbital;
- Amphetamines; PCP

#### Schedule III: Moderate abuse potential: Outpatient prescriptions may be telephoned to the pharmacy:

- Buprenorphine; codeine and hydrocodone combinations: Vicodin; Lortab; Fiorinal;
- Anabolic steroids,
- Ketamine.

#### Schedule IV: Low abuse potential – but some drugs are often combined with a drug with a higher abuse potential:

- Butorphanol (Stadol); propoxyphene;
- Benzodiazepines;
- Phenobarbital;
- Phentermine.

#### Schedule V: Lowest potential for abuse:

- Codeine preparations: (a favorite drug of abuse among pre adolescents);
- Lomotil

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<sup>84</sup> Comprehensive Drug Abuse Prevention and CONTROL ACT of 1970 (21. U.S.C. 801 et seq.

## APPENDIX C      ADDICTION IS A DISEASE OF THE BRAIN

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- Continuous use of drugs changes the anatomy and physiology of brain cells, particularly in the lateral tegmental area and the nucleus accumbens.<sup>85</sup>
- PET/MRI scans have mapped the location in the brain where drugs and behaviors have their effects.
- Addiction depletes dopamine and the altered brain cannot manufacture sufficient dopamine to function in a normal manner.<sup>86</sup>
- This process occurs in all addictive drugs and many patterns of behavior
- Just as alcohol, tobacco, and **drugs** activate the pleasure circuit in the brain, so do many **behaviors** such as sexual activity, winning a contest, gambling, and being praised and working very hard.

### Dopamine “Reward System”

- What drugs and many behaviors have in common is the release of various neurotransmitters in nucleus accumbens in the brain, primarily dopamine:
  - Dopamine – creates the “buzz.”
  - Serotonin – sense of well-being.
  - Endorphins – euphoria.
  - GABA (gamma amino butyric acid) – satiety and somnolence (sleepy after a big meal or sexual activity).
- There comes a point when the affected person becomes an addict, as if a switch in the brain is flipped, and the person no longer has the ability to make free choices about the continued use of the drug.<sup>87</sup>

### The Addicted Brain Can Recover

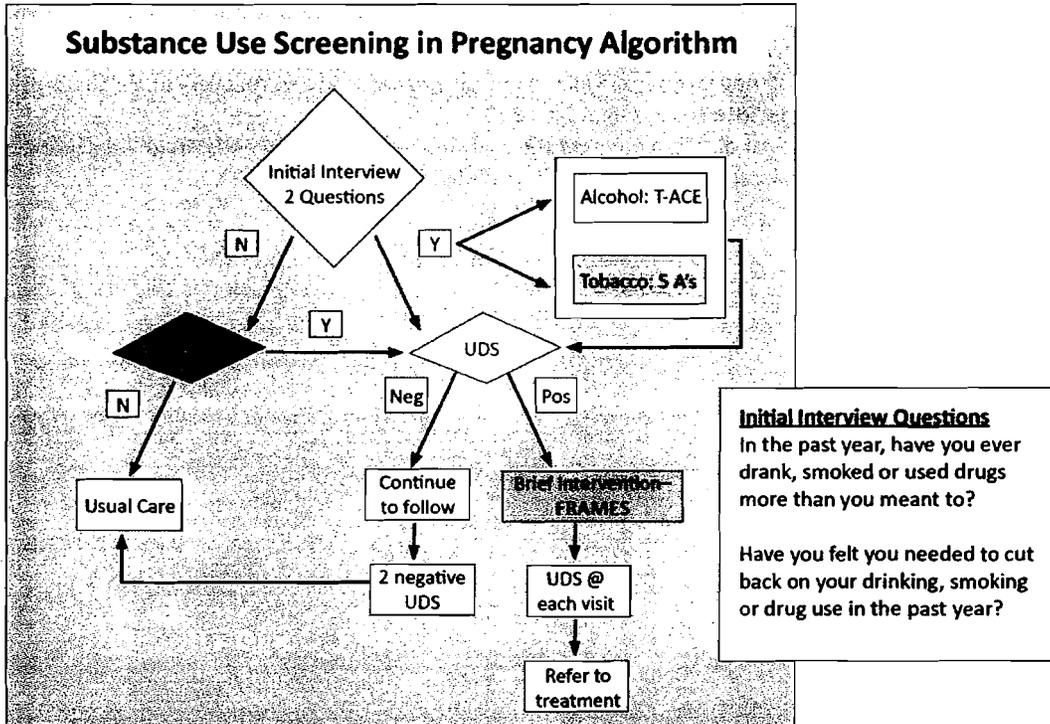
Current research indicates that recovery in the brain is mediated by adult stem cells, a large source of which is located by the nucleus accumbens.<sup>88</sup> The stem cells can migrate relatively large distances and appear to rebuild damaged circuitry.

*Factors stimulating stem cells include:*

- Nutrition and exercise stimulates stem cells to rebuild circuitry
- Reading is critical to rebuilding new circuitry: “Don’t drink, eat well, go to meetings and read the Big Book.”
- Folic acid is important.
- Folic acid supplements are able to prevent neural tube defects and thereby repair other structural damage.<sup>89</sup>
- Thus, folic acid supplementation may become a new pharmacologic strategy to enhance recovery from addiction.

- 
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## APPENDIX D



### T-ACE for alcohol screening

- Tolerance:** How many drinks does it take you to feel high? *(More than 2 = 1 point)*
  - Annoyed:** Have people annoyed you by criticizing your drinking? *(Yes = 1 point)*
  - Cut Down:** Have you ever felt you ought to cut down on your drinking? *(Yes = 1 point)*
  - Eye Opener:** Have you ever had a drink first thing in the morning to steady your nerves or get rid of a hangover? *(Yes = 1 point)*
- 2 or more points is a positive screen*

### 5 A's Tobacco Intervention

- 1) **Ask** – Identify and document tobacco status for every visit.
- 2) **Advise** – In a clear, strong and personalized manner, urge every smoker to quit.
- 3) **Assess** – Willingness to quit.
- 4) **Assist** – Refer to smoking cessation program or quit line and use patch or gum.
- 5) **Arrange** – Schedule follow-up contact in 1 Week after quit date.

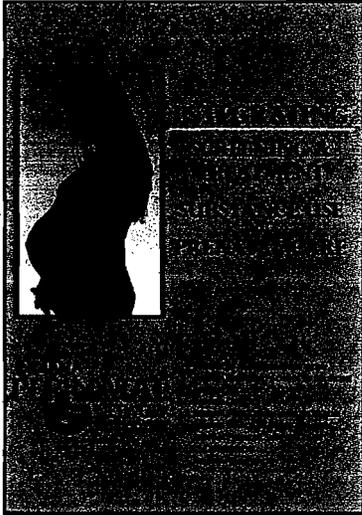
### Brief Intervention - FRAMES

Feedback about adverse effects  
 Responsibility for change in behavior  
 Advise to reduce or stop  
 Menu of options to help  
 Empathy  
 Self empowerment

APPENDIX E

**INDIANA PERINATAL NETWORK RESOURCE ORDER FORM**

**Integrating Screening and Treatment of Substance Use into Prenatal Care**



This comprehensive, online provider training program addresses tobacco, alcohol and other drug use during pregnancy.

The online training features:

- Practical role-play scenarios with clinical and research-based material and interventions. Featuring the work of Dr. James Nocon, Professor Emeritus, IU School of Medicine and former Director of the Prenatal Recovery Clinic at Wishard Memorial Hospital.
- Additional materials and PowerPoint presentations on related clinical topics, referral resources, and information on how to obtain reimbursement for screening and intervention services.
- Training is approved for CME for physicians, CEU for nurses and continuing education hours for social workers.
- Order online at [www.indianaperinatal.org](http://www.indianaperinatal.org).

TITLE/DESCRIPTION	MEMBER PRICE	QUANTITY	NON-MEMBER PRICE	QUANTITY
<b>Integrating Screening and Treatment of Substance Use into Prenatal Care - Online Training (90 Day Access)</b>	\$30		\$ 50	
			<b>TOTAL</b>	

**PAYMENT METHOD**

- Check payable to IPN enclosed     Mastercard     Visa

**SHIPPING INFORMATION**

Name \_\_\_\_\_ Credentials (i.e. "R.N.") \_\_\_\_\_

Job Title \_\_\_\_\_

Organization \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

Phone \_\_\_\_\_ Fax \_\_\_\_\_

**CREDIT CARD BILLING ADDRESS**

Name on card \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

Credit Card No. \_\_\_\_\_ Exp. \_\_\_\_\_

Email Address (if different than at left) \_\_\_\_\_

E-mail Address (Important: Training access code will be sent to this address)



RETURN WITH YOUR PAYMENT TO IPN

1991 East 56th St, Indianapolis, IN 46220 ipn@indianaperinatal.org P 317.924.0825 F 317.924.0831



# Perinatal FOCUS: Neonatal Abstinence Syndrome



## Inside this issue:

- 02 - Policy Update
- 03 - Spotlight: MHS
- 03 - Breastfeeding Protocol
- 04 - NAS & Delivering Hospitals

## What is NAS?

Neonatal abstinence syndrome (NAS) is a group of problems that occur in a newborn who was exposed to addictive illegal or prescription drugs while in the mother's womb.

## AAP Policy

This statement updates information about the clinical presentation of infants exposed to intrauterine drugs and the therapeutic options for treatment of withdrawal, and is expanded to include evidence-based approaches to the management of the hospitalized infant who requires weaning from analgesics or sedatives. [Click here](#) for the full policy statement.

## Special Offer! Take \$10 Off!

Comprehensive provider training DVD addresses tobacco, alcohol and other drugs during pregnancy. Features the work of James Nocon, MD JD. One of our most popular resources!



**Order online**  
with promo code  
**FOCUS2**

## What's the Problem?

### Significant increase in number of newborns affected

- While the U.S. government doesn't track the number of babies born dependent on drugs, a study last year in the Journal of the American Medical Association found that more than 13,000 U.S. infants were affected in 2009.
- Studies have shown a 5 fold increase in chronic use of narcotic prescriptions (30 days or more) from 1998 to 2008; NAS was noted in 5.6% of these infants.
- East Tennessee Children's Hospital in Knoxville expects to treat 320 children this year for NAS, up from 33 in 2008 and 283 in 2012.
- In response to surveys by IPN regarding the most significant perinatal issue they face, a large majority of providers identify NAS.

### Significant costs

- One hospital's costs to treat NAS infants born to opioid-dependent mothers who received opioid replacement therapy during pregnancy totaled more than \$4 million during a 3-year period, a new study shows.

*Lack of universal verbal screening of all pregnant women for substance use*

## IPN's Response

- In conjunction with Dr. James Nocon, IPN produced a unique DVD to train providers on how to verbally screen all pregnant women for alcohol, tobacco and other drugs. Early identification and proper medical management during pregnancy may help minimize the severity of NAS in newborns. *(see box on this page)*
- Developed a provider toolkit on how to manage the opiate dependent pregnant women. This unique document highlights clinical cases, current literature and practice experience to identify, treat and develop care plans for opioid dependent pregnant women and their infants.
- NAS has been a much sought after topic included in our regional workshop series for the past 2 years.
- NAS will be a major topic during the 4th Annual Indiana Perinatal Hospital Summit planned for Sept. 6, 2013.
- Developed a Substance Use Screening in Pregnancy Algorithm, a printable screening tool for healthcare providers.

## In the News

### Health Law Could Overwhelm Addiction Services

Millions of Americans stand to gain insurance coverage for drug addiction and alcoholism treatment when the national health overhaul takes effect next year, and some experts predict the change will help thousands of people get clean and sober. However, the new demand could swamp the current addiction treatment system before even half of the newly insured seek help, causing waiting lists of months or longer, treatment agencies say. Questions also remain about how comprehensive and affordable the new coverage will be. [Click here](#) for more.

### Genetics May Dictate Treatment in Opioid-Dependent Infants

Researchers have identified genetic variants that appear to be associated with less severe neonatal abstinence syndrome (NAS) in infants exposed to opioids in utero, a finding that could pave the way for more tailored treatments, according to a study published in the May issue of JAMA. [Click here](#) for the study.

### Neonatal Abstinence Syndrome and Associated Health Care Expenditures United States, 2000-2009

The goal of this study, published in the May issue of JAMA, was to determine the national incidence of NAS and antepartum maternal opiate use and to characterize trends in national health care expenditures associated with NAS between 2000 and 2009. In this study, state Medicaid programs were the predominant payer for mothers using opiates (60.3%) and newborns with NAS (78.1%). As a consequence, the results have specific relevance to state Medicaid budgets. Another interesting finding was that care for NAS infants delivered in hospital settings outside of the neonatal intensive care unit and outpatient management can potentially reduce length of stay and cost of stay, since NICUs are much more costly than care in a general pediatric ward. [Click here](#) for the full study.

### Breastfeeding Reduces the Need for Withdrawal Treatment in Opioid-Exposed Infants

Breastfed neonates exposed to methadone prenatally had significantly lower incidence of NAS requiring pharmacotherapy (53% versus 80%) and both the whole group of infants and the methadone-exposed neonates needed shorter pharmacological treatment of NAS than neonates who were not breastfed. [Click here](#) to view the abstract.

# Policy Update

## State Policy

Two important pieces of legislation were recently passed by the Indiana General Assembly and signed into law.

HEA 1465 – provides ongoing funding for the Indiana Scheduled Prescription Electronic Collection & Tracking Program (INSPECT), an important tool designed to address the problem of prescription drug abuse and diversion in Indiana.

#### What is INSPECT?

- INSPECT is Indiana's prescription drug monitoring program (PDMP), one of 42 operational PDMPs nationally. INSPECT collects and retains in its database every controlled substance dispensed on an outpatient basis by all licensed pharmacies in Indiana. Approximately 12 million Rx records are collected annually, and over 1,700 pharmacies report to INSPECT.

SEA 246 - Requires the state board of pharmacy and other boards to adopt rules concerning clinic ownership, standards and protocols for prescribing controlled substances and requires the Commission on Mental Health and Addiction to study issues concerning treatment and recovery from prescription drug use addiction.

In September 2012, the Indiana Attorney General established the Indiana Rx Drug Abuse Task Force. Task force members include state legislators, law enforcement officials, physicians, nurses, addiction counselors, pharmacists and representatives from state and local agencies. A variety of committees have been created, included the Treatment and Recovery Committee that is addressing NAS. IPN is a member of this committee.

## National Policy

Forty-three state attorneys general, including Indiana's, are calling for new "black box" warning labels on prescription painkillers that can harm unborn children. In a letter sent in May to the FDA, the attorneys general point to an alarming spike in the number of babies born with "neonatal abstinence syndrome experienced by babies when they are cut off from the opioid drugs ingested by their mothers." [Click here](#) for the article.

## ISMA Resolution

John Ellis, MD FAAP and James Nocon, MD JD, plan to present a resolution regarding appropriate prevention, screening and treatment of pregnant women for use and abuse of substances to the Indiana State Medical Association House of Delegates in September. IPN and a number of other organizations are in support of this resolution, including the Indiana Prescription Drug Abuse Prevention Task Force and the Indianapolis Medical Society. Thank you to Dr. Ellis and Dr. Nocon for their leadership in moving this important issue forward!

## Neonatal Abstinence Syndrome Linked to Exorbitant Costs

Principal investigator Kay Roussos-Ross, MD, a psychiatrist and obstetrician specializing in addiction medicine at the University of Florida Shands Hospital, in Gainesville recommended the following ways that physicians can help decrease the incidence of neonatal abstinence syndrome:

- Use nonopioid pharmacologic management of pain in pregnant women, such as physical therapy and massage therapy.
- In pregnant women being treated for opioid dependence, use the lowest effective dose of methadone or buprenorphine to prevent cravings and withdrawal symptoms.
- Encourage long-acting contraceptive management for women of reproductive age in opioid-dependence treatment. "Half of babies born in the US are unplanned, so recommending contraceptives for these women is important." (Note: A new Medicaid Family Planning Services program is designed to make contraceptive services more affordable for women and men. [Click here](#) for more information.)
- After delivery, consider weaning women from opioid treatment in a physician-supervised setting to help protect against relapse.

[Click here](#) for the complete article.

# Spotlight: Managed Health Services

By John C. Ellis, MD FAAP – Medical Director, MHS

In June 2012, Managed Health Services produced and distributed a comprehensive clinical policy to their network providers highlighting assessment, treatment and discharge protocols for infants suffering from NAS.



In the last 2 years, the MHS census showed an increasing number of NAS babies in Indiana NICUs, a trend consistent with the experience of other health plans in Indiana and around the country. The treatment of these infants varied widely within and among NICUs, and explanations to MHS by facilities of their NAS policies were quite varied. Some NICUs had policies and followed them; some reported policies but didn't always appear to follow them; and some NICUs had no NAS policy and didn't feel the need for one. At the same time, national attention was being focused on the NAS issue.

MHS convened a group of neonatologists from across Indiana and created a draft policy based on AAP and CDC guidelines and using a framework from the Kosair policy. The policy was adopted by an MHS committee with substantial community physician involvement in June 2012. The policy was then forwarded to the Medical Directors of all nurseries in Indiana and several key cities in neighboring states with a letter explaining that MHS would be using this policy as the guideline for clinical decision-making in reviewing NICU NAS infant care.

To date, we have had no indication of dissatisfaction with the policy. In fact, the need to apply the policy has been fairly limited as NICUs seem to generally be providing care consistent with these national recommendations. I believe national attention and parallel efforts by multiple public health agencies have allowed the MHS NAS policy to fit well into clinical practice, with the ultimate result of consistent, evidence-based care for the NAS infants who continue to arrive regularly in hospitals across the state.

Contact John Ellis at [joellis@mhsindiana.com](mailto:joellis@mhsindiana.com). [Click here to view the MHS NAS Policy and Flow Sheet.](#)

## Breastfeeding and the Drug-Dependent Mother

Although providers may assume that a pregnant drug-dependent mother should be discouraged from breastfeeding her infant, that decision is not always so simple. Infants of drug-dependent women are often at greater risk for health and developmental complications, and therefore might benefit even more so than the average infant from breastfeeding. The choice is complicated by the lack of evidence based guidelines addressing this topic. However, the Academy of Breastfeeding Medicine has published a clinical protocol outlining the current recommended guidelines. While it is true that each mother and baby should be evaluated on a case-by-case basis, the ABM Protocol outlines several criteria that, if met, support the mother's decision to breastfeed.

Those criteria include:

- Women engaged in substance abuse treatment who have provided their consent to discuss progress in treatment and plans for postpartum treatment with substance abuse treatment counselor
- Women whose counselors endorse that she has been able to achieve and maintain sobriety prenatally; counselor approves of client's plan for breastfeeding
- Women who plan to continue in substance abuse treatment in the postpartum period
- Women who have been abstinent from illicit drug use or licit drug abuse for 90 days prior to delivery and have demonstrated the ability to maintain sobriety in an outpatient setting
- Women who have a negative maternal urine toxicology testing at delivery except for prescribed medications
- Women who received consistent prenatal care
- Women who do not have medical contraindication to breastfeeding (such as HIV)
- Women who are not taking a psychiatric medication that is contraindicated during lactation.
- **Stable methadone-maintained women wishing to breastfeed should be encouraged to do so regardless of maternal methadone dose.**



[Click here](#) to read the ABM Protocol, which also outlines situations in which a mother should be discouraged from breastfeeding.

# NAS and Delivering Hospitals:

## Issues to Consider

By John Wareham, MD - St. Vincent Women's Hospital, IPN Board Member

Caring for newborns at risk for the Newborn Abstinence Syndrome (NAS) has become a common and difficult problem for all hospitals with a delivery service. NAS can apply to infants withdrawing from any drug/medication that induces dependency, but primarily refers to opioids such as methadone, heroin, buprenorphine, and prescription pain relievers. Infants identified as at risk for NAS require prolonged hospitalizations even if they don't withdraw. Newborns at risk for NAS need to be observed in the hospital for 5-7 days after birth, whether they were born vaginally or by C-section. Even with a period of observation lasting 5-7 days, an occasional infant will withdraw after discharge.

Infants that develop the NAS may be treated without medication if the withdrawal is not severe by modifying the environment and the feeding routine. Irritable infants with NAS may require frequent feeding (**breastfeeding is best**) and a quiet environment with decreased stimulation. Working out a care plan that will be successful at home may further prolong the hospitalization. Should the infant require medication such as oral morphine or methadone, then the length of hospitalization becomes weeks-to-months. Having an infant in the hospital for weeks is a strain on hospitals from a staffing standpoint, as these infants are irritable and require a lot of patience and attention.

It is not unusual for infants in full blown withdrawal that requires medication to be referred to a level 3 or 4 NICU. While NICUs have a lot of experience with NAS and prolonged hospitalizations, there is a downside to such transfers. Transfer usually takes the infant out of the county whose Child Protective Service office is responsible for the mother and infant, usually knows the family best and may already have some familiarity with the situation. The geographic separation makes visitation by the parents harder, and bonding may already be an issue in a family with limited resources and social issues. Finally, breastfeeding may buffer withdrawal, and that is much harder to do with geographic separation, especially a separation that may last for weeks to months.

Infants suffering from NAS are a problem that is not going away any time soon. The upsurge in abuse of oral narcotic pain relievers has made the situation worse. To the extent possible with limited resources, these at risk infants need to be followed and treated at their birth hospital. When resource limitations or the severity of withdrawal mandate a transfer to an NICU, the hospitalizations will often be long and the social stresses increased due to geographic separation of the infant from the parents.

Contact John Wareham at [JAWareha@stvincent.org](mailto:JAWareha@stvincent.org).

## Stay Tuned!

IPN will be hosting a Spring 2014 conference on NAS and Substance Use During Pregnancy.

More details coming soon!



Methodist Hospital



University Hospital





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## Buprenorphine During Pregnancy Reduces Neonate Distress

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### **A multisite clinical trial lays groundwork for improving care for mothers and babies affected by opioid dependence.**

**July 06, 2012**

*Lori Whitten, NIDA Notes Staff Writer*

A NIDA-supported clinical trial, the Maternal Opioid Treatment: Human Experimental Research (MOTHER) study, has found [buprenorphine](#) to be a safe and effective alternative to [methadone](#) for treating opioid dependence during pregnancy. Women who received either medication experienced similar rates of pregnancy complications and gave birth to infants who were comparable on key indicators of neonatal health and development. Moreover, the infants born to women who received buprenorphine had milder symptoms of neonatal opioid withdrawal than those born to women who received methadone.

Methadone and buprenorphine maintenance therapy are both widely used to help individuals with opioid dependence achieve and sustain abstinence. Methadone has been the standard of care for the past 40 years for opioid-dependent pregnant women. However, interest is growing in the possible use of buprenorphine, a more recently approved medication, as another option for the treatment of opioid addiction during pregnancy.

"Our findings suggest that buprenorphine treatment during pregnancy has some advantages for infants compared with methadone and is equally safe," says [Dr. Hendrée Jones](#), who led the [multicenter study](#) while at the Johns Hopkins University School of Medicine and is now at RTI International.

### **A Rigorous Trial Design**

Methadone maintenance therapy (MMT) enhances an opioid-dependent woman's chances for a trouble-free pregnancy and a healthy baby. Compared with continued opioid abuse, MMT lowers her risk of developing infectious diseases, including hepatitis and HIV; of experiencing pregnancy complications, including spontaneous abortion and miscarriages; and of having a child with challenges including low birth weight and neurobehavioral problems.

Along with these benefits, MMT may also produce a serious adverse effect. Like most drugs, methadone enters fetal circulation via the placenta. The fetus becomes dependent on the medication during gestation and typically experiences withdrawal when it separates from the placental circulation at birth. The symptoms of withdrawal, known as neonatal abstinence syndrome (NAS) include hypersensitivity and hyperirritability, tremors, vomiting, respiratory difficulties, poor sleep, and low-grade fevers. Newborns with NAS often require hospitalization and treatment, during which they receive medication (often morphine) in tapering doses to relieve their symptoms while their bodies adapt to becoming opioid-free.

The MOTHER researchers hypothesized that buprenorphine maintenance could yield methadone's advantages for pregnant women with less neonatal distress. Buprenorphine, like methadone, reduces opioid craving and alleviates withdrawal symptoms without the safety and health risks related to acquiring and abusing drugs. Therapeutic dosing with buprenorphine, as with methadone, avoids the extreme fluctuations in opioid blood concentrations that occur in opioid abuse and place physiological stress on both the mother and the fetus. However, unlike methadone, buprenorphine is a partial rather than full opioid and so might cause less severe fetal opioid dependence than methadone therapy.

The MOTHER study recruited women as they sought treatment for opioid dependence at six treatment centers in the United States and one in Austria. All the women were 6 to 30 weeks pregnant. The research team initiated treatment with morphine for each woman, stabilized her dose, and then followed with the daily administration of buprenorphine therapy or MMT for the remainder of her pregnancy. Throughout the trial, the team increased each woman's medication dosage as needed to ease withdrawal symptoms.

The study incorporated design features to ensure that its findings would be valid. Among the most notable were measures taken to prevent biases that might arise if staff and participants knew which medication a woman was getting.

To treat the participants without knowing which medication each woman was receiving, the study physicians wrote all prescriptions in pairs, one for each medication, in equivalent strengths. Study pharmacists matched the patient's name and ID number to her medication group and filled only the prescription for the medication she was taking.

Each day, participants dissolved seven tablets under their tongues and then swallowed a syrup. If a woman was in the buprenorphine group, one or more of her tablets contained that medication, depending on her prescribed dosage, while the rest of the tablets and the syrup were placebos. If a woman was in the methadone group, the syrup contained that medication in her prescribed strength and the tablets all were placebos. In this way, each woman's complement of medications appeared identical to that of every other participant. The placebo tablets and syrup were crafted to look, taste, and smell like the active medications.

## As Good For Mothers, Better for Infants

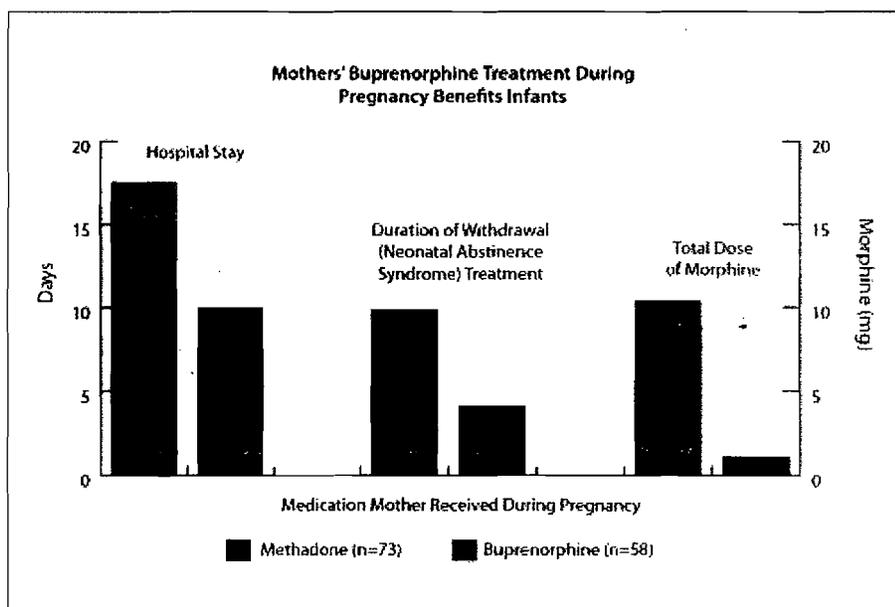
Of 175 women who started a study medication, 131 continued until they gave birth. Those who received MMT and those given buprenorphine experienced similar pregnancy courses and outcomes. The two groups of women did not differ significantly in maternal weight gain, positive drug screens at birth,

percentage of abnormal fetal presentations or need for Cesarean section, need for analgesia during delivery, or serious medical complications at delivery.

As the MOTHER researchers had hypothesized, the infants whose mothers were treated with buprenorphine experienced milder NAS than those infants exposed to methadone (see [graph](#)). Whereas most infants in both groups required morphine to control NAS, the buprenorphine group, on average, needed only 11 percent as much, finished its taper in less than half the time, and remained in the hospital roughly half as long as the infants exposed to methadone.

At Dr. Gabriele Fischer's Medical University of Vienna site in Austria, three women became pregnant for a second time during the time MOTHER was enrolling participants. This development allowed researchers to compare the two medications' relative safety and efficacy in individual women as well as across groups. During her second pregnancy, each of the three women took the alternative medication to the one she took in her first pregnancy. In each instance, the child born following buprenorphine treatment exhibited milder NAS symptoms than the one born following methadone treatment. This result suggests that differences in the effects of the two medications, rather than women's individual differences in physiology, underlie the group findings.

"Buprenorphine may be a good option for pregnant women, particularly those who are new to treatment or who become pregnant while on this medication," says Dr. Jones. "If a patient is on methadone maintenance and stable, however, she should remain on methadone."



## Next Questions

MOTHER researchers observed that although the women in their buprenorphine and methadone groups benefited equally from treatment, the drop-out rate was higher in the buprenorphine group (33 vs. 18 percent). This difference was not statistically significant. The researchers speculate that if it is meaningful, it may be owing to factors other than different responses to the two medications. They surmise that the

experimental treatment protocols may have moved patients from morphine to buprenorphine too rapidly, causing discomfort, or that buprenorphine may have been easier than methadone to discontinue when women decided to become abstinent.

The MOTHER study did not include women with some substance use disorders that are commonly comorbid with opioid abuse. "Future studies should compare neonatal abstinence syndrome, birth outcomes, and maternal outcomes of these two medications for pregnant women who also abuse alcohol and benzodiazepines," Dr. Jones says.

"The field also needs data on neonatal outcomes when pregnant women are treated with buprenorphine combined with naloxone, the current first-line form of buprenorphine therapy for opioid dependence," Dr. Jones notes. The MOTHER study administered buprenorphine without naloxone to avoid exposing the fetus to a second medication with potential adverse effects.

"Research challenges remaining after this brilliant study are to determine the factors that resulted in the differential drop-out rates between the two medications," says Dr. Loretta P. Finnegan, who did pioneering work in the assessment and treatment of NAS. "Additionally, researchers need to conduct followup research on these children to determine the longer term significance of the differences in newborn withdrawal symptoms." Dr. Finnegan, now president of Finnegan Consulting, was formerly the medical advisor to the director of the Office of Research on Women's Health at the National Institutes of Health.

"Neonatal abstinence syndrome is a terrible experience for infants, and there is a great need to improve care for this condition," says Dr. Jamie Biswas of [NIDA's Division of Pharmacotherapies and Medical Consequences of Drug Abuse](#). "Dr. Jones' study is a superb contribution to this area of clinical research, and the robust results should provide more treatment options for a syndrome that affects thousands of infants each year."

#### Sources:

Unger, A., et al. Randomized controlled trials in pregnancy: Scientific and ethical aspects. Exposure to different opioid medications during pregnancy in an intra-individual comparison. *Addiction* 106(7):1355-1362, 2011. [Full Text](#)

Jones, H.E., et al. Neonatal abstinence syndrome after methadone or buprenorphine exposure. *New England Journal of Medicine* 363(24):2320-2331, 2010. [Full Text](#)

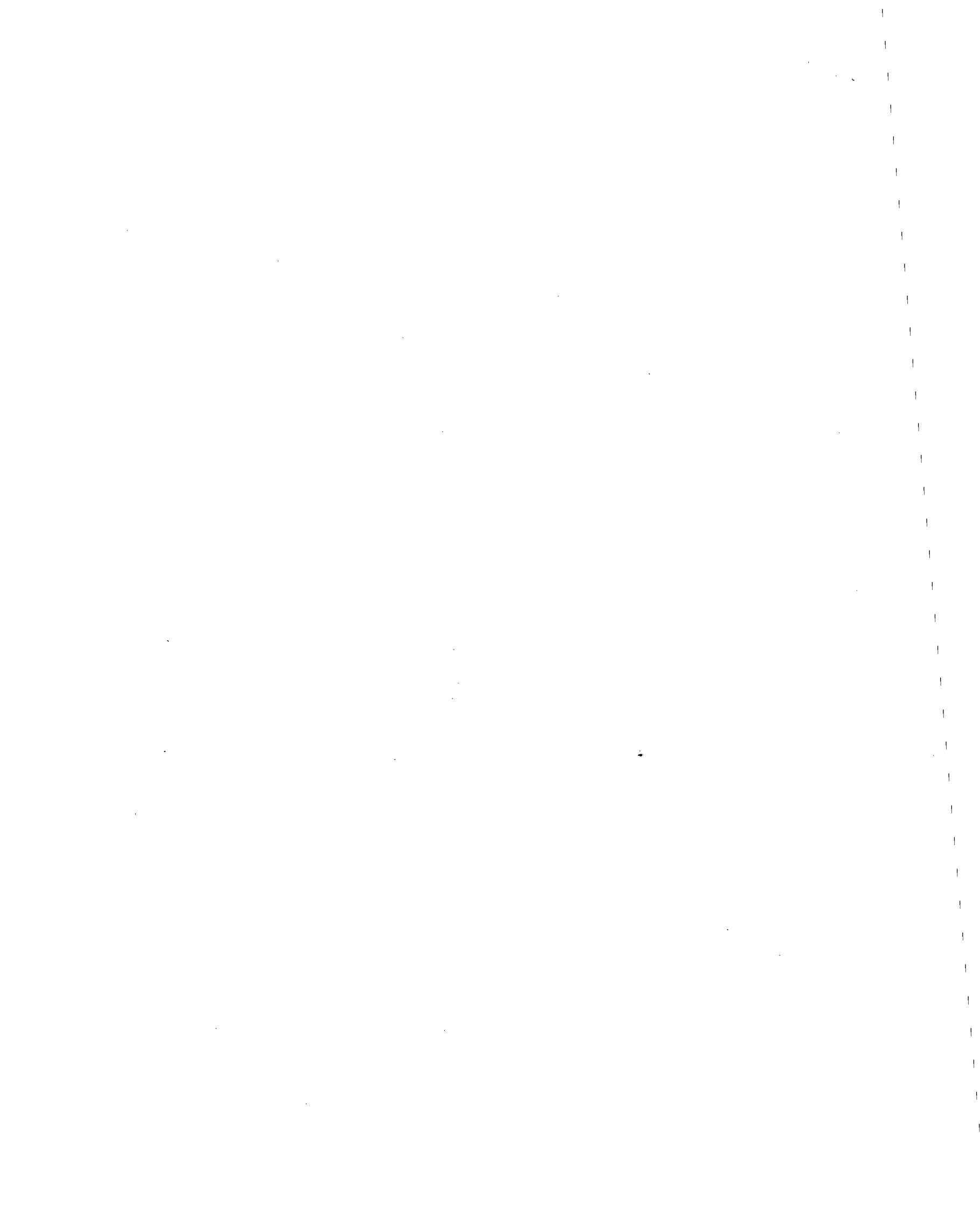
## MOTHER Collaborators

Following is a list of collaborators on the Maternal Opioid Treatment: Human Experimental Research (MOTHER) Study and their university affiliations.

Dr. Hendrée Jones (study leader), Johns Hopkins University School of Medicine; Dr. Amelia Arria, University of Maryland, College Park; Dr. Mara Coyle, Warrant Alpert Medical School of Brown University; Dr. Gabriele Fischer, Medical University of Vienna; Dr. Sarah Heil, University of Vermont; Dr. Karol Kaltenbach, Jefferson Medical College; Dr. Peter Martin, Vanderbilt University School of Medicine; Dr. Peter Selby, University of Toronto; and Dr. Susan Stine, Wayne State University School of Medicine.

*This page was last updated July 2012*





**Indiana Commission on Mental Health and Addiction  
Remarks by Indiana Attorney General Greg Zoeller  
Sept. 9, 2013**

**GOOD MORNING. THANK YOU CHAIRWOMAN MILLER AND THE MEMBERS OF THE COMMISSION FOR INVITING ME TO SPEAK AT YOUR HEARING TODAY ABOUT INDIANA'S PRESCRIPTION DRUG ABUSE EPIDEMIC.**

**WHILE PRESCRIPTION DRUGS PROVIDE RELIEF TO MILLIONS OF PEOPLE EVERY YEAR WHEN USED APPROPRIATELY, THE ABUSE OF THESE ADDICTIVE AND SOMETIMES DEADLY DRUGS HAS BECOME ONE OF THE GRAVEST ISSUES FACING OUR STATE. THAT'S WHY LAST SEPTEMBER I LAUNCHED INDIANA'S FIRST AND ONLY STATEWIDE PRESCRIPTION DRUG ABUSE TASK FORCE. AS CHAIRMAN, I FELT IT WAS CRITICAL TO ENSURE THE TASK FORCE INCLUDED EVERY FACET OF ASSISTANCE. OUR TASK FORCE INCLUDES STATE LEGISLATORS, LAW ENFORCEMENT, HEALTH OFFICIALS, MEMBERS OF THE MEDICAL COMMUNITY, PHARMACISTS, STATE AND LOCAL AGENCIES AND EDUCATION PROVIDERS.**

**WE MODELED THE TASK FORCE AFTER THE WHITE HOUSE OFFICE OF NATIONAL DRUG CONTROL POLICY OF 2011 -- WITH ONE DISTINCT DIFFERENCE. BOTH MODELS INCLUDE EDUCATION, ENFORCEMENT, PRESCRIPTION DRUG MONITORING PROGRAMS AND SAFE DISPOSAL. INDIANA'S TASK FORCE OFFERS A FIFTH, AND VERY CRITICAL, COMMITTEE-- FOCUSED ON TREATMENT AND RECOVERY TO ADDRESS WAYS TO INCREASE ACCESS TO TREATMENT FOR THOSE ADDICTED TO PRESCRIPTION DRUGS. OUR COMMITTEE MEMBERS WHICH YOU WILL HEAR FROM TODAY HAVE BEEN WORKING TO IDENTIFY POSSIBLE SOLUTIONS TO BARRIERS THAT PREVENT HOOSIERS ADDICTED TO OPIATES TO SEEK TREATMENT.**

**THEY HAVE ALSO EXPANDED THEIR EFFORTS TO TACKLE THE ISSUE OF NEONATAL ABSTINENCE SYNDROME, MORE COMMONLY KNOWN AS N-A-S. THESE EXPERTS WILL BE SHARING THEIR KNOWLEDGE AND EXPERTISE ON THE PROBLEM OF N-A-S.**

**ACCORDING TO THE NATIONAL INSTITUTE ON DRUG ABUSE, 7 MILLION AMERICANS CURRENTLY ABUSE PRESCRIPTION DRUGS – THAT’S MORE THAN THE NUMBER USING COCAINE, HEROIN, HALLUCINOGENS AND INHALENTS COMBINED.**

**IN 2011, 718 HOOSIERS DIED FROM ACCIDENTAL DRUG OVERDOSES, ACCORDING TO THE INDIANA STATE DEPARTMENT OF HEALTH. THIS EPIDEMIC EXTENDS FAR BEYOND THE NUMBER OF OVERDOSE DEATHS. FOR EVERY ONE DEATH, THERE ARE 10 TREATMENT ADMISSIONS FOR ABUSE, 32 EMERGENCY ROOM VISITS FOR ABUSE, 130 PEOPLE WHO ABUSE OR ARE DEPENDENT, AND 825 NON-MEDICAL USERS – INCLUDING OUR YOUTH.**

**THE 2011 YOUTH RISK BEHAVIOR SURVEY RESULTS SHOWED THAT MORE THAN ONE OUT OF FIVE INDIANA HIGH SCHOOL STUDENTS HAVE TAKEN PRESCRIPTION MEDICATIONS PRESCRIBED TO SOMEONE ELSE FOR NON-MEDICAL REASONS. IN FACT, OUR YOUTH RANKED FIFTH HIGHEST NATIONALLY – THAT’S NOT A STATISTIC THAT WE SHOULD BE PROUD OF.**

**ALSO NATIONALLY, SOMEONE IN THE U.S. DIES EVERY 25 MINUTES FROM A PRESCRIPTION DRUG OVERDOSE. AND EVERY HOUR, A BABY IS BORN SUFFERING FROM OPIOID WITHDRAWAL.**

**A LOCAL NEONATOLOGIST AND GUEST SPEAKER OF MY PRESCRIPTION DRUG ABUSE SYMPOSIUM LAST YEAR, DR. PAUL WINCHESTER, SAID THAT IN 2001, HE WOULD SEE AN AVERAGE OF ONE BABY PER YEAR BORN WITH N-A-S...NOW HE SEES AT LEAST ONE PER WEEK. IN 2010, IT WAS ESTIMATED THAT INDIANA HOSPITAL CHARGES FOR N-A-S CASES TOTALED NEARLY \$30 MILLION. CURRENTLY, N-A-S IS NOT A DISEASE THAT IS REQUIRED TO BE REPORTED TO OUR STATE DEPARTMENT OF HEALTH.**

**TENNESSEE AND FLORIDIA HAVE ENACTED LEGISLATION REQUIRING N-A-S TO BE REPORTED TO THE STATE DEPARTMENT OF HEALTH. I WOULD SUGGEST THAT MORE CONSISTENT AND ACCURATE DATA NEEDS TO BE COLLECTED ON THIS DISEASE SO WE MAY COME UP WITH BETTER SOLUTIONS TO COMBAT IT.**

**IN INDIANA, OBSTATRICIANS ARE NOT REQUIRED TO SCREEN PREGNANT MOTHERS FOR ADDICTION OF CONTROLLED SUBSTANCES. YET IDENTIFICATION AND APPROPRIATE MANAGEMENT MAY SUBSTANTIALLY REDUCE THE POTENTIAL RISK TO THE MOTHER AND THE FETUS.**

**OUR TASK FORCE SUPPORTS RECOMMENDATIONS TO PUT CRITICAL CHANGES IN PLACE TO COMBAT N-A-S. THESE ARE SMALL STEPS TOWARDS A HUGE PROBLEM, BUT WE RECOGNIZE WE NEED TO START SOMEWHERE.**

**OPIATE ADDICTION IS A BRAIN DISEASE. ADDICTION TREATMENT PROFESSIONALS UNDERSTAND THIS DISEASE AND HAVE THE EXPERTISE TO TREAT IT. UNFORTUNATELY INDIANA HAS AN EXTREME SHORTAGE OF THESE PROFESSIONALS. WE MUST MAKE IT A PRIORITY TO TRAIN AND RETAIN MORE ADDICTION PROFESSIONALS IN OUR STATE TO MEET THE EVER-MOUNTING NUMBER OF OPIATE ADDICTED HOOSIERS, INCLUDING PREGNANT WOMEN, TO TREAT THIS BRAIN DISEASE.**

**WE ARE FACING A COMPLEX PROBLEM THAT REQUIRES ALL STAKEHOLDERS WITH VARIOUS EXPERTISES TO COLLABORATE AND TARGET COMPREHENSIVE SOLUTIONS. THAT'S WHY THE PRESCRIPTION DRUG ABUSE TASK FORCE ENCOURAGES THE INDIANA GENERAL ASSEMBLY TO SUPPORT THE EFFORTS OF THE TREATMENT AND RECOVERY COMMITTEE TO WORK TOWARD THE COMMON GOAL OF HELPING FAMILIES AFFECTED BY THIS EPIDEMIC AND TO SAVE HOOSIER LIVES BEFORE IT'S TOO LATE.**

**THANKS AGAIN FOR ALLOWING FOR ME TO SPEAK BEFORE YOUR COMMITTEE TODAY. I WOULD LIKE TO REQUEST THAT YOU HOLD YOUR QUESTIONS UNTIL YOU HEAR MORE INFORMATION FROM MY VERY CAPABLE TASK FORCE MEMBERS AS THEY ARE THE REAL SUBJECT MATTER EXPERTS ON THESE ADDICTION ISSUES.**



Treatment for Opiate Pain Medicine Abuse –

Denied, Denied, Denied a word as a provider that I had a hard time getting used to when those who came in suffering from Opiate Pain Medicine Abuse that wanted to get clean and needed inpatient to do so.

Detoxification from Opiate with-drawls does not cause seizures or any life threatening physical ailments to patients who are with-drawing from opiates. Therefore Medicaid denies treatment due to them stating it is not a medical condition or does not need a safe a with-drawl.

405 IAC 5-17-5 Inpatient detoxification, rehabilitation, and aftercare for chemical dependency

Authority: IC 12-15-1-10; IC 12-15-1-15; IC 12-15-21-2

Affected: IC 12-13-7-3; IC 12-15

Sec. 5. (a) Medicaid reimbursement is available for inpatient detoxification, rehabilitation, and aftercare for chemical

Dependency when such services are prior authorized subject to this section.

(b) Admission to a general hospital floor is not indicated unless the medical services are required for life support and cannot

be rendered in a substance abuse treatment unit or facility.

(c) Prior authorization for inpatient detoxification, rehabilitation, and aftercare for chemical dependency shall include

Consideration of the following:

(1) All requests for prior authorization will be reviewed on a case-by-case basis by the contractor.

(2) The treatment, evaluation, and detoxification are based on the stated medical condition.

(3) The need for safe withdrawal from alcohol or other drugs.

(4) A history of recent convulsions or poorly controlled convulsive disorder.

(5) Reasonable evidence that detoxification and aftercare cannot be accomplished in an outpatient setting.

As a provider hearing the word denied was not as hard as it was to hear it as a sister. A sister who has a brother who at the age of 21 torn 3 lower discs from his back due to a worksite injury that allowed him to no longer work.

After many doctor appointments, surgery attempts, etc . My brother became an addict of Opiates. He could not take enough to take away his pain. When they stopped working he started using Heroin. Heroin was more affordable and easier to get. At the age of 23 my brother was a Heroin addict.

Upon moving to Indianapolis he tried Methadone to get off the pain pills and Heroin. He became a Methadone addict. My brother tried many times to get treatment but with not having many resources he was denied quite often.

18 months ago my brother was in a coma from an overdose of Opiates, cocaine, Bezos, AL and marijuana. For two weeks we wondered if he would survive and if so how. With a trach? Would he be able to talk? Would he be able to have his cognitive ability back?

My brother miraculously made it thru the overdose. When we tried to find inpatient treatment for him in the Indianapolis area, every provider said no since he had no coverage. He was discharged from the hospital on Opiates and Bezos. We were at a loss of what to do for him. Knowing that an IP setting would be the only setting that would help him.

Shortly after discharge my brother relapses again. If it wasn't for a personal favor from a wonderful treatment center in Franklin, Indiana my brother would not be 18 months sober. I wonder about those who do have favors to pull, or connections to make, those who are lost in our system because our system is set up to pay for the pills they get addicted on but not to pay to help them get off of them when enough is enough.