A Hidden Epidemic: Neonatal Abstinence Syndrome

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East TN Children’s Hospital
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Dr. Thomas Freiden  
Director of the Centers for Disease Control

“When I was in medical school…. I was told…if you give opiates to a patient who's in pain, they will not get addicted. Completely wrong… A generation of us grew up being trained that these drugs aren't risky. In fact, they are risky”
Addiction is a disease of the brain, NOT a moral failure.
ABUSE

- Intentional, Recreational, Unintentional
- Use of a substance that does not conform to social norms
- Can lead to addiction

Tolerance – Dependence – Addiction

Tolerance
- Our body develops tolerance to a drug’s effect so that an increased amount of drug is required to produce effect.

Dependence
- If the supply of the drug is removed then the person will exhibit “withdrawal symptoms”.

Addiction
- The continuing, compulsive nature of the drug use despite physical and/or psychological harm to the user and society. **BEHAVIORAL**
DOPAMINE

- Catecholamine
- Chemical neurotransmitter
- Sends signals to nerve cells
- Produced in several areas of the brain
- Responsible for reward-driven learning
  - Allows body to sense pleasure

The Dopamine Pathway

- The brain contains a natural reward system (limbic system)

- This increases temporary levels of dopamine
  - Natural triggers
    - Food
    - Exercise
    - Sex
    - Nurturing children
Why is this important?

Drugs activate the same system activated by natural rewards

BUT...drugs activate the system stronger and longer

Drugs “hijack” the brain's dopamine system and the brain becomes dependent on the drug

Natural rewards no longer produce the desired dopamine levels which result in a feeling of pleasure

EVOLUTION OF ADDICTION

After a while, use of a drug leads to an adaptation in the brain.

Brain expects higher levels of dopamine.

The deficit in dopamine causes an inability to feel pleasure, except through drug use.

Effects of Drugs on Dopamine Release

Amphetamine

Cocaine

Nicotine

Morphine

Di Chiara and Imperato, PNAS, 1988
Epidemiology

• NIDA estimates $600 billion is spent annually on costs associated with substance abuse in U.S.
  • American Diabetes Association estimates annual costs associated with diabetes is $174 billion in 2007.
  • National Cancer Institute estimates $125 billion in annual costs for cancer care in 2010.
  • Projected 220 billion gym

• 2009 National Survey on Drug Use and Health:
  • 4.5 percent of pregnant women aged 15 to 44 have used illicit drugs in the past month.
    • In 2008 there were 9430 babies born in Knox County according to Knox County hospitals birth records: Estimated 424 babies born annually in Knox County whose mother used illicit drugs in the past month.

• 2009 Key Birth Stats from CDC report 4,131,019 births in U.S.
  • Approximately 186,000 babies born to mothers who used illicit drugs in past month

Drug-induced deaths exceed MVA deaths

Figure 1. Motor vehicle traffic, poisoning, and drug poisoning death rates: United States, 1980–2008

NOTE: In 1999, the International Classification of Diseases, Tenth Revision (ICD–10) replaced the previous revision of the ICD (ICD–9). This resulted in approximately 5% fewer deaths being classified as motor-vehicle traffic–related deaths and 2% more deaths being classified as poisoning-related deaths. Therefore, death rates for 1998 and earlier are not directly comparable with those computed after 1998. Access data table for Figure 1 at http://www.cdc.gov/nchs/data/databriefs/db81_tables.pdf#1.


1999 Veterans Health Admin. Initiative: “Pain as the 5th Vital Sign”
JCAHO institute pain standards in 2001

Source: Centers for Disease Control and Prevention. *Unintentional Drug Poisoning in the United States (July 2010).*
Pain the 5\textsuperscript{th} Vital Sign

1980s: Dr. Russell Portenoy lead drive to expand use of opioids

Risk of addiction felt to be less than 1%

1886 paper 38 cases supported safety of opioids outside end of life care

American Pain Society campaign “Pain as the 5\textsuperscript{th} Vital Sign”

1998 Federation of State Medical Boards removes regulations on amount of narcotics physicians can prescribe

2004 Federation makes under treatment of pain “punishable”

Joint commission: is no evidence that addiction is a significant issue when persons are given opioids for pain control
Dr. Portenoy and others claimed that the risk of addiction to opioids use to treat chronic pain was less than 1%, this figure was based on virtually no scientific evidence.

In a frequently cited 1986 paper — based on just 38 cases — Portenoy and Foley concluded that "opioid maintenance therapy can be a safe, salutary and more humane alternative to the options of surgery or no treatment in those patients with intractable non-malignant pain and no history of drug abuse".

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building consensus now is that there is little if any evidence that opioids provide safe and effective treatment for chronic non-cancer pain, and that paradoxical, under-appreciated conditions such as opioid-induced hyperalgesia and narcotic bowel syndrome can complicate long-term treatment. -

See more at: http://www.thepoisonreview.com/2012/12/16/the-money-and-influence-behind-pain-as-a-fifth-vital-sign/#sthash.qtbKs3s7.dpuf
THE PRESIDENT'S PLAN TO Reform Drug Policy

1) PREVENT drug use before it ever begins through education

2) EXPAND access to treatment for Americans struggling with addiction

3) REFORM our criminal justice system to break the cycle of drug use, crime, and incarceration while protecting public safety

4) SUPPORT Americans in recovery by lifting the stigma associated with those suffering or in recovery from substance use disorders

Drug policy is a public health issue, not just a criminal justice issue.

SPREAD THE WORD

Prescription Nation: Addressing America’s Prescription Drug Epidemic Report from the National Safety Council, October 14, 2013

Prescription Nation: Addressing America’s Prescription Drug Epidemic
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* Scales differ for deaths and emergency department visits.

Substance Use Treatment among Women of Childbearing Age

6.3 Million Women Aged 18 to 49 Needed Substance Use Treatment in the Past Year

## Narcotics and Contraceptive Use: TennCare Women, CY2011

<table>
<thead>
<tr>
<th>Demographics</th>
<th>TennCare Women</th>
<th>Women Prescribed Narcotics (&gt;30 days supplied)</th>
<th>Narcotic Users Rate per 1,000</th>
<th>Women Prescribed Contraceptives and Narcotics</th>
<th>% of Women on Narcotics and Contraceptives</th>
<th>Women Prescribed Narcotics without Contraceptives</th>
<th>% of Women on Narcotics Not on Contraceptives</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Women</td>
<td>299,989</td>
<td>45,774</td>
<td>152.6</td>
<td>8,400</td>
<td>18%</td>
<td>37,374</td>
<td>82%</td>
</tr>
<tr>
<td>15 - 20</td>
<td>88,668</td>
<td>3,450</td>
<td>38.9</td>
<td>1,663</td>
<td>48%</td>
<td>1,787</td>
<td>52%</td>
</tr>
<tr>
<td>21 - 24</td>
<td>44,877</td>
<td>5,244</td>
<td>116.9</td>
<td>1,758</td>
<td>34%</td>
<td>3,486</td>
<td>66%</td>
</tr>
<tr>
<td>25 - 29</td>
<td>53,583</td>
<td>9,883</td>
<td>184.4</td>
<td>2,368</td>
<td>24%</td>
<td>7,515</td>
<td>76%</td>
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<tr>
<td>30 - 34</td>
<td>48,173</td>
<td>10,504</td>
<td>218.0</td>
<td>1,501</td>
<td>14%</td>
<td>9,003</td>
<td>86%</td>
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<tr>
<td>35 - 39</td>
<td>37,194</td>
<td>9,398</td>
<td>252.7</td>
<td>746</td>
<td>8%</td>
<td>8,652</td>
<td>92%</td>
</tr>
<tr>
<td>40 - 44</td>
<td>27,494</td>
<td>7,295</td>
<td>265.3</td>
<td>364</td>
<td>5%</td>
<td>6,931</td>
<td>95%</td>
</tr>
</tbody>
</table>

Data source: Division of Health Care Finance and Administration, Bureau of TennCare.
Unintended Pregnancy Among All Women & Opioid Abusers

- General Population: 49.9%
- Opioid-Abusing Women: 86.3%

Unintended Pregnancy Among All Women & Opioid Abusers

In TN, women with unintended pregnancy:
- More likely to have no preconception counseling (77.7% vs. 55.4%)
- More likely to have short interpregnancy interval (45.0% vs. 15.6%)
- More likely to have late or no prenatal care (28.1% vs. 10.9%)
- More likely to not take folic acid daily (82.6% vs. 64.7%)

National sample of opioid-abusing women
- Women with unintended pregnancy 60% more likely to have used cocaine within past 30 days compared to women with intended pregnancy

Prenatal Care is Vital

“Adequate prenatal care often defines the difference between routine and high-risk pregnancy and between good and bad pregnancy outcomes.

- Timely initiation of prenatal care remains a problem nationwide, and it is overrepresented among women with substance use disorders. In part, the threat of legal consequences for using during pregnancy and limited substance abuse treatment facilities (only 14 percent) that offer special programs for pregnant women (SAMHSA 2007) are key obstacles to care.”

Early Intervention

• Window of opportunity
  • “Brief interventions can provide an opening to engage women in a process that may lead toward treatment and wellness.”

• Pregnancy creates a sense of urgency to
  • Enter treatment
  • Become abstinent
  • Eliminate high-risk behaviors

Potential Benefit of a Perinatal Substance Abuse Program (Early Start)

- Purpose: cost-benefit analysis of an integrated prenatal intervention program for stopping substance abuse in pregnancy.
- Retrospective study of 49,261 women
- Kaiser Permanente Northern California
- Completed questionnaires at OB clinics and had urine screening
- Costs included: maternal health care (prenatal through 1 year postpartum), neonatal birth hospitalization care, and pediatric health care through 1 year
  - Adjusted to 2009 dollars and mean costs adjusted for age, race, education, income, marital status, and amount of prenatal care.

Early Start

- **Mission:**
  - “to provide women with access to services and support to have an alcohol, tobacco, and drug free pregnancy, allowing the delivery of a healthy baby.”

- **Goal: Complete abstinence**

- **Interventions**
  - Universal screening of all pregnant women
  - Co-location of a licensed mental health professional in the Department of Obstetrics and Gynecology
  - Linking Early Start appointments with routine prenatal care appointments
  - Educating all women and clinicians

Potential Benefit of a Perinatal Substance Abuse Program (Early Start)

<table>
<thead>
<tr>
<th></th>
<th>SAF</th>
<th>SA</th>
<th>S</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal</td>
<td>$9,430</td>
<td>$9,230</td>
<td>$10,869</td>
<td>$8,282</td>
</tr>
<tr>
<td>Infant</td>
<td>$11,214</td>
<td>$11,304</td>
<td>$16,943</td>
<td>10,416</td>
</tr>
<tr>
<td>Total</td>
<td>$20,644</td>
<td>$20,534</td>
<td>$27,812</td>
<td>$18,698</td>
</tr>
</tbody>
</table>

- Compared SAF and SA to S
- Net cost-benefit averaged $5,946,741 per year

Is MAT cost-effective?

- For every $1 spent on addiction treatment programs
  - $4 to $7 saved in reduced drug-related crime, criminal justice, and theft
  - Including health-care costs, up to $12 saved.

- Other considerations
  - Neonatal abstinence syndrome might be reduced
  - More productive citizens
Substance Abuse Reporting and Pregnancy: The Role of the Obstetrician–Gynecologist

Abstract: Drug enforcement policies that deter women from seeking prenatal care are contrary to the welfare of the mother and fetus. Incarceration and the threat of incarceration have proved to be ineffective in reducing the incidence of alcohol or drug abuse. Obstetrician–gynecologists should be aware of the reporting requirements related to alcohol and drug abuse within their states. They are encouraged to work with state legislators to retract legislation that punishes women for substance abuse during pregnancy.
Highlights of HB277 Dunn/SB459 Yager, the Safe Harbor Act:

- This bill provides a safe harbor if
  - A woman seeks prenatal care before the 20th week; and
  - If determined to be misusing prescription drugs, initiates appropriate drug treatment expeditiously;
  - Maintains compliance with both prenatal and drug treatment regimens throughout the term of the pregnancy, then
- DCS would not seek to initiate actions to take the baby solely because of the prescription drug misuse.
- Pregnant women would be established as a priority for drug treatment at publicly-funded treatment facilities.
- The law specifically permits DCS to take action if other factors exist that could be harmful to the newborn.
- Provides liability protection for health care providers and facilities who provide services pursuant to the provisions of the legislation.
Neonatal Abstinence Syndrome (NAS)

- Constellation of withdrawal symptoms
  - **CNS**
    - Inconsolability, high-pitched crying, skin excoriation, hyperactive reflexes, tremors, seizures
  - **GI**
    - Poor feeding, excessive sucking, feeding intolerance, loose or watery stools
  - **Autonomic/metabolic**
    - Sweating, nasal stuffiness, sneezing, fever, tachypnea, mottling
Incidence of Maternal Opiate Use and NAS

Maternal Opiate Use increased x 5

NAS Incidence tripled

Patrick, S. W. et al. JAMA 2012;307:1934-1940
NAS Incidence in the U.S.

Every hour, 1 BABY is born suffering from opiate withdrawal.

- Average length or cost of hospital stay:
  - Newborns with NAS: 16.4 days, $53,400
  - Newborns w/o NAS: 3.3 days, $9,500

Patrick, S. W. et al. JAMA 2012;307:1934-1940
NAS in TN: 1999-2010

Data sources: Tennessee Department of Health; Office of Health Statistics; Hospital Discharge Data System (HDDS) and Birth Statistical System. Analysis includes inpatient hospitalizations with age less than 1 and any diagnosis of drug withdrawal syndrome of newborn (ICD-9-CM 779.5). HDDS records may contain up to 18 diagnoses. Infants were included if any of these diagnosis fields were coded 779.5. Note that these are discharge-level data and not unique patient data.
Current TennCare Costs

- Healthy Newborn: $4,237
- NAS Newborn: $66,973

PREVENTABLE

Tennessee DOH Media Release October 7, 2013
American Academy of Pediatrics (AAP) Guidelines

- “Reported rates of illicit drug use…underestimate true rates…”
- 55 to 94% of neonates exposed to opioids in utero will develop withdrawal signs.
- Each nursery that cares for infants should develop protocol for screening for maternal substance abuse
- Screening is best accomplished by using multiple methods
  - Maternal history
  - Maternal urine testing
  - Testing of newborn urine/meconium
  - May consider umbilical cord samples

# Drug Testing

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<tr>
<th>Types of UDTs</th>
<th>Results</th>
</tr>
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<tbody>
<tr>
<td><strong>In-Office</strong></td>
<td><em>Immunoassays</em></td>
</tr>
<tr>
<td></td>
<td>Identifies drug class – a few specific drugs</td>
</tr>
<tr>
<td><strong>GC/MS</strong></td>
<td><em>Gas chromatography-mass spectrometry</em></td>
</tr>
<tr>
<td></td>
<td>Identifies specific drugs and metabolites</td>
</tr>
<tr>
<td><strong>LC-MS/MS</strong></td>
<td><em>Liquid chromatography tandem mass spectrometry</em></td>
</tr>
<tr>
<td></td>
<td>Identifies specific drugs and metabolites</td>
</tr>
</tbody>
</table>

- Meconium
- Umbilical Cord
AAP Guidelines - Newborn Observation

Risk Factors

• No prenatal care
• Limited prenatal care
• History of substance use or abuse
• Any positive screen during pregnancy
• Positive UDS on admission

Recommendation

• Observe in the hospital for 4 to 7 days
• Early outpatient followup
  • Reinforce caregiver education about late withdrawal signs

Pharmacologic interventions include:

- Oral morphine solution, or methadone as primary therapy
- Increasing evidence for clonidine as primary or adjunctive therapy
- Buprenorphine use as primary or adjunctive therapy is also increasing
- Treatment for polysubstance exposure may include opioid, phenobarbital, and clonidine in combination.
NAS TREATMENT OPTIONS

INPATIENT
No standardized evidence based “Best Practice”
Lengthy
Unique challenges for staff and institution,
Physical and emotional challenges
Multidisciplinary needs
Staff education on Science of Addiction
Interacting with the substance abusing parent
Listen to front line staff
Must be ORGANIZED STANDARDIZED and MULTIDISCIPLINARY

OUTPATIENT
Compliance
Physicians and pharmacies
Custodial changes
Caregiver bias
DIVERSION
Requires: contracts, incentives for compliance,
accountability for non-compliance
ETCH Haslam Neonatal Intensive Care Unit

- 152 beds / Level III NICU – 60 beds
  - About 30% of our NICU admissions primarily for NAS treatment
- 135 admissions for 2011
- 283 admissions for 2012
- Highest daily census: 37 in September, 2012

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<td></td>
<td>1st Quarter (JAN-MAR)</td>
</tr>
<tr>
<td>2011</td>
<td>8</td>
</tr>
<tr>
<td>2012</td>
<td>29</td>
</tr>
<tr>
<td>2013</td>
<td>28</td>
</tr>
</tbody>
</table>
Typical course of treatment

- 70% of NAS babies
  - Wean in 20 days
  - No adjunctive meds
  - LOS 24 days

- 30% of NAS babies
  - Wean in 60 days
  - Require adjunctive meds
    - Phenobarbital (27%)
    - Phenobarbital + Clonidine (7%)
  - LOS 68 days
    - (longest LOS = 155 days)
### Project Statistics

- **Project start date:** 22 NOV 2010; 1052 days; (35 months)
- **Projected annual admissions:** 257 (based on CY 2013 admissions to date: 198)

<table>
<thead>
<tr>
<th>Admissions</th>
<th>Discharges</th>
<th>NAS diagnosis at D/C</th>
<th>≥ 35 weeks</th>
<th>&lt; 35 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>631</td>
<td>606</td>
<td>325 (53.6%)</td>
<td>593</td>
</tr>
<tr>
<td>2010</td>
<td>11</td>
<td>11</td>
<td>0 (%)</td>
<td>10</td>
</tr>
<tr>
<td>2011</td>
<td>139</td>
<td>139</td>
<td>0 (%)</td>
<td>122</td>
</tr>
<tr>
<td>2012</td>
<td>283</td>
<td>283</td>
<td>172 (99.4%)</td>
<td>193</td>
</tr>
<tr>
<td>2013</td>
<td>198</td>
<td>173</td>
<td>172 (99.4%)</td>
<td>193</td>
</tr>
</tbody>
</table>

### LOS Statistics

- **Average LOS pre-7 NOV 2011:** 40
- **Average LOS post-7 NOV 2011:** 33

#### Number of Patients

<table>
<thead>
<tr>
<th>Average LOS</th>
</tr>
</thead>
<tbody>
<tr>
<td>606</td>
</tr>
<tr>
<td>552 (91.1%)</td>
</tr>
<tr>
<td>429 (70.8%)</td>
</tr>
<tr>
<td>313 (51.7%)</td>
</tr>
</tbody>
</table>

#### Number Weaned

- **Number:** 429 patients, (70.8%); 177 patients, (29.2%)

#### Weaning Statistics (Morphine)

<table>
<thead>
<tr>
<th>Overall</th>
<th>≥ 35 wk</th>
<th>&lt; 35 wk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number Weaned:</td>
<td>607</td>
<td>567</td>
</tr>
<tr>
<td>Average wean:</td>
<td>37 days</td>
<td>27 days</td>
</tr>
<tr>
<td>Average wean post NICU-III opening:</td>
<td>26 days</td>
<td></td>
</tr>
<tr>
<td>Inpatient days post-wean (average)</td>
<td>7</td>
<td></td>
</tr>
</tbody>
</table>

**Overall Longest wean:** 155 days  **Shortest wean:** 7 days.

### Pharmacotherapy

- **Most common initial dose:** 40 mcg; **Highest Initial Dose:** 500 mcg; **Highest overall dose:** 540 mcg

- **No Adjunct Rx:** 417 (66.1%)
- **Phenobarbital:** 170 (26.9%)
- **Phenobarb + Clonidine:** 42 (6.7%)
- **Clonidine:** 2 (0.3%)
- **Nystatin:** 127 (20.1%)

### Referral Source

- **FS Regional:** 364 (58%)
- **Oak Ridge Methodist:** 69 (11%)
- **Morristown Hamblen:** 65 (10%)
- **Leconte:** 41 (6%)
- **Cumberland Med Center:** 33 (5%)
- **Lakeway Medical Center:** 17 (3%)
- **FS ParkWest:** 17 (3%)
- **Jellico:** 6 (1%)
- **Sweetwater:** 4 (1%)

### Census

- **Current Census:** 25 **Jul-2012:** 24
- **Last 7 days percent NAS in NICU:** 50% **Aug-2012:** 33
- **Overall NAS Ratio:** 46% **Sep-2012:** 22
- **Highest Census:** 37 **Oct-2012:** 27
- **Average Overall Census:** 21 **Nov-2012:** 24
- **6 month Average Census (JAN-JUN) 2013:** 22 **Dec-2012:** 23

### Quarterly Average Census

<table>
<thead>
<tr>
<th>Quarter</th>
<th>2013</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st quarter (JAN-MAR)</td>
<td>29</td>
<td>25</td>
</tr>
<tr>
<td>2nd quarter (APR-JUN)</td>
<td>29</td>
<td>25</td>
</tr>
<tr>
<td>3rd quarter (JUL-SEP)</td>
<td>19</td>
<td>11</td>
</tr>
<tr>
<td>4th quarter (OCT-DEC)</td>
<td>19</td>
<td>11</td>
</tr>
</tbody>
</table>

### LOS Statistics

<table>
<thead>
<tr>
<th>LOS ≤ 40 days</th>
<th>LOS &gt; 40 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>429 patients, (70.8%); 177 patients, (29.2%)</td>
</tr>
</tbody>
</table>

### Daily Census - 01 APR 2012 through Current

- **Daily Census (NAS):** 30-day Moving Average Trendline with 60-day projection Median Census

### NAS Project Summary Report

10/9/2013

---

East Tennessee Children’s Hospital Confidential
Prevalence of Substance Use Among Drug Using Pregnant Women (%)
Why do expectant mothers use drugs?

- Prior injury / chronic pain
- Medical need for pain management
  - Appropriately managed
  - Inappropriately managed
- In a substance abuse treatment program (MAT)
- Confusion between symptoms of withdrawal and early pregnancy.
- Family/social environment
Why do MDs continue to prescribe?

- ACOG Guidelines and SAMSHA Guidelines recommend to continue MRT (methadone or buprenorphine)
- “Lesser of two evils”
  - Risky drug-seeking behaviors
  - Goals of quelling cravings
  - Prevent mini-withdrawals
  - Ceiling effect of being in treatment
    - Methadone, suboxone, subutex
      - Reveal danger of I.V. suboxone
“Standard of care for pregnant women with opioid dependence: referral for opioid-assisted therapy

- Abrupt d/c of opioids can result in preterm labor, fetal distress, or fetal demise

- During intrapartum/postpartum period, special considerations are needed...ensure appropriate pain management, prevent postpartum relapse, prevent risk of overdose, ensure adequate contraception.
Intrauterine Drug Exposure

The presence or absence of NAS does not indicate the severity of intrauterine drug exposure or abuse.
The Newborn with Intrauterine Drug Exposue

- Low birth weight
- Small Head Circumference
- Abnormal EEG pattern / Seizures
- Signs of physical dependency – withdrawal
  - Signs of effects may last for months
    - Hypertonic
    - Tremors
  - Periods of irritability
Opioid Intra-Uterine Drug Exposure

OPIATES or OPIOIDS
  Morphine
  Heroin
  Codeine

Semi-synthetic and synthetic opioids
  Oxycodone
  Hydrocodone
  Methadone
  Buprenorphine
  Tramadol
Drug source may be legal or illegal (diverted)
Used as directed, misused, or abused...

*The baby doesn’t know the difference*

They will affect brain development
Effects dependent on stage of gestation of the fetus had drug exposure
Fetal Brain Development

Majority of development occurs in first 12 weeks

2wks: Brain is first organ to develop

4wks: cerebral hemispheres appear

5-6wks Cranial nerves identifiable

6-7wks Brain wave activity begins

7-8wks Brain represents 43% of embryo

8-9wk Begin to experience light sense of touch

13wks Most of body has sensation to touch

19wks Daily cycles of biological rhythms

26-38wks Brain increases in weight by 400-500%
Behavior Teratology Framework: Agents that are relatively harmless to the mother could still have a harmful effect or consequences to the fetus

- Based on 2 principles (Vorhees CV in Hutchins DE, Editor. Prenatal abuse of licit and illicit drugs NYAS 1989, p31–41.)
  - Vulnerability of the CNS to injury extends beyond fetal, neonatal, and infancy stage
  - Most frequent manifestations of CNS injury: not grossly malformed brain but in functional abnormalities that may not be detected at birth, but later in childhood, adolescence, or adulthood.

Related to Barker hypothesis: Any perturbation during fetal development may have enduring effects on later behavior.
Brain Development

Neuroimaging showed physiological brain changes in drug-exposed infants vs. non-exposed infants

Temporal/frontal lobe changes

Permanent, can not be “fixed”

Nurturing and environment can mitigate damages
MRI: Brain Volumes

Term
No opiate exposure

Term
Lortab use during pregnancy
LONG-TERM EFFECTS

- BRAIN DEVELOPMENT
- SIDS
- SLEEP
- NEURODEVELOPMENTAL DELAYS
- BEHAVIOR REGULATION
- SENSORY PROCESSING
- COGNITIVE/LEARNING DELAYS
- PSYCHOSOCIAL IMPLICATIONS
Intra-Uterine Exposure to Other Drugs

Marijuana
- Decreased problem-solving skills
- Decreased attention
- Impulsivity
- Decreased memory, memory processing, even at 18 Y

Methamphetamines
- Memory
- Impulse control
- Decreased goal setting
- Decreased flexibility
- Increase in ADHD
“The focus has turned to the long-term developmental outcome of children with prenatal drug exposure, especially as they reach adolescence.”

-Henrietta Bada, MD, MPH

The Hidden Epidemic:
Living with Neonatal Abstinence Syndrome (NAS) and What the Future Holds
September 13, 2013
“Addiction is a developmental disorder of adolescence”

Dr. Nora Volkow,
Director, National Institute on Drug Abuse
What we see is often only a fractional part of what it's reality is.
Public Health Issues

• NICU beds taken by infants whose only need is withdrawal treatment
• Behavioral issues in childhood
  • Schools – teacher retraining
• Potential long-term public health issue
  • Generational addiction problems
  • 2nd and 3rd generational behaviors sustained
    • Genetic predisposition?
    • Does intrauterine exposure activate gene in utero?
    • Does NAS treatment complicate addictive tendencies?
TIPQC
Tennessee Initiative for Perinatal Quality Care

State wide recognition of NAS as a growing problem Spring 2011

Elected as statewide quality improvement initiative

Toolkit Development:
Menu of Potentially Better Practices for the care of the NAS infant
RedCap Data collection
Grant for participation
## The Levels of Prevention

<table>
<thead>
<tr>
<th></th>
<th>PRIMARY Prevention</th>
<th>SECONDARY Prevention</th>
<th>TERTIARY Prevention</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>An intervention implemented before there is evidence of a disease or injury</td>
<td>An intervention implemented after a disease has begun, but before it is symptomatic.</td>
<td>An intervention implemented after a disease or injury is established</td>
</tr>
<tr>
<td><strong>Intent</strong></td>
<td>Reduce or eliminate causative risk factors (risk reduction)</td>
<td>Early identification (through screening) and treatment</td>
<td>Prevent sequelae (stop bad things from getting worse)</td>
</tr>
<tr>
<td><strong>NAS Example</strong></td>
<td>Prevent addiction from occurring</td>
<td>Screen pregnant women for substance use during prenatal visits and refer for treatment</td>
<td>Treat addicted women</td>
</tr>
<tr>
<td></td>
<td>Prevent pregnancy</td>
<td></td>
<td>Treat babies with NAS</td>
</tr>
</tbody>
</table>

Adapted from: Centers for Disease Control and Prevention. A Framework for Assessing the Effectiveness of Disease and Injury Prevention. MMWR. 1992; 41(RR-3); 001. Available at: [http://www.cdc.gov/mmwr/preview/mmwrhtml/00016403.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/00016403.htm)

Doctors and other prescribers need clear guidelines to determine the appropriate amount of painkillers needed.

**Washington: responsible prescribing**

In 2007, the state of Washington issued voluntary prescribing guidelines. Passed into law in 2010, the guidelines reversed a decade-long trend of increasing fatal prescription opioid overdoses.

![Bar chart showing number of deaths from 1995 to 2011 with 23% reduction in deaths.](http://www.nsc.org/safety_home/PrescriptionDrugOverdoses/Documents/Prescription%20Nation%20Report.pdf)

DOH NAS Efforts in TN

• Spring 2012
  • “Prescription Safety Act” required prescribers to register with Controlled Substances Monitoring Database (CSMD)
  • Growing awareness of increasing NAS incidence among neonatal providers
  • Initial discussions between public health (TN Department of Health) and Medicaid (TennCare)
NAS Subcabinet Working Group

• Convened in late Spring 2012
• Committed to meeting every 3-4 weeks
• Cabinet-level representation from Departments:
  – Public Health (TDH)
  – Children’s Services (DCS)
  – Human Services (DHS)
  – Mental Health and Substance Abuse Services (DMHSAS)
  – Medicaid (TennCare)
  – Children’s Cabinet
NAS Subcabinet Working Group

• Working principles:
  • Multi-pronged approach
  • Best strategy is primary prevention but clearly must address secondary and tertiary prevention
  • Each department progresses independently, keep group informed of efforts
  • Supportive rather than punitive approach
Opioid Prescribing Guidelines Task Force

- Pain and addiction treatment specialists
- Primary care physicians
- Pharmacists
- Perinatal Specialists
- Midwifery
- Neonatology
- Legal
- State medicaid
- Charged by commissioner to “Be bold” in approach
- Implementation Goal: Jan 1st, 2014
NAS Research Steering Committee

- Board identified Spring 2013
- Monthly conference calls
- Invitations sent to experts from across the state for September 25\textsuperscript{th} 2013
- Goal: Identify 3-5 potentially answerable research questions surrounding NAS
- Identify groups to begin to look at developing research framework for each question
NAS—Primary Prevention

• Prevent addiction from occurring
  – Letter to FDA encouraging black box warning
  – Provider education
    • Letter to providers to increase awareness
    • Possibly add to “responsible prescribing” CME
  – TennCare limitations on opioid availability
    • Requirement for counseling as part of prior authorization
    • Limitations on available quantity
November 1, 2012

Margaret Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

We write out of grave concern for the health, developmental and life course consequences for babies whose antenatal environment includes substantial opioid analgesic exposure. We believe that a “black box warning” for these medications would help assure that women of childbearing age and their health care providers are aware of the serious risks associated with narcotic use during pregnancy. Possible content for the warning may be as follows:

**WARNING: USE OF NARCOTIC ANALGESICS IN WOMEN OF CHILD BEARING AGE MAY CAUSE NEONATAL ABSTINENCE SYNDROME**

This message would also promote a critical dialog between the patient and provider regarding considerations in planning for pregnancy or prevention of unintended pregnancy for women who are benefiting therapeutically from these powerful medications or who may be at risk for abusing them. This
The FDA is also requiring a new boxed warning on ER/LA opioid analgesics to caution that chronic maternal use of these products during pregnancy can result in neonatal opioid withdrawal syndrome (NOWS), which may be life-threatening and require management according to protocols developed by neonatology experts. NOWS can occur in a newborn exposed to opioid drugs while in the mother’s womb. Symptoms may include poor feeding, rapid breathing, trembling, and excessive or high-pitched crying.
## TennCare Prior Authorization Form

**Prior Authorization Form**

**Long Acting Narcotics**

***All PA forms may be found by accessing https://tnm.providerportal.sxc.com/rxclaim/TNM/PAs.htm.***

If the following information is not complete, correct, or legible the PA process can be delayed. Use one form per record.

### Member Information

<table>
<thead>
<tr>
<th>Member Information</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Last Name</td>
<td></td>
</tr>
<tr>
<td>First Name</td>
<td></td>
</tr>
<tr>
<td>ID Number</td>
<td>Date of Birth</td>
</tr>
</tbody>
</table>

### Prescriber Information

For female patients between the ages of 18 & 45, please complete questions 10-12

10. The use of opioid analgesics during pregnancy has been associated with neonatal abstinence syndrome. Has this patient been counseled regarding the risks of becoming pregnant while receiving this medication, including the risk of neonatal abstinence syndrome? □ Yes □ No

11. Is this patient currently utilizing a form of contraception? □ Yes □ No

12. Has access to contraceptive services been offered to this patient? □ Yes □ No

Form available at: [https://tnm.providerportal.sxc.com/rxclaim/TNM/TC%20PA%20Request%20Form%20(Long%20Acting%20Narcotics).pdf](https://tnm.providerportal.sxc.com/rxclaim/TNM/TC%20PA%20Request%20Form%20(Long%20Acting%20Narcotics).pdf)
NAS—Primary Prevention

• Prevent pregnancy from occurring
  – Provider education
    • Counseling by providers at initial prescription
    • Promotion of contraceptives, particularly long-acting reversible contraceptives (LARCs)
  – Work with non-traditional partners to promote counseling re: addition during pregnancy and contraceptives
    • A&D
    • Pain clinics
    • Drug courts
NAS—Secondary Prevention

• Identify pregnant women who may be opioid addicted
  – Identify reproductive-aged women via CSMD whose fill patterns suggest risk of dependence
  – Referral to TennCare managed care organization case management programs
  – Screen women for drug use
    • Consent of patient
    • Supportive rather than punitive approach
NAS—Tertiary Prevention

• Minimize complications for women who are addicted (and their neonates)
  – Can addicted pregnant women be weaned?
  – What are best strategies for treating NAS infants?
NAS—Reportable Disease

• Previous estimates of NAS incidence came from:
  – Hospital discharge data (all payers but ~18 month lag)
  – Medicaid claims data (only ~9 month lag but only includes Medicaid)

• Need more real-time estimation of incidence in order to drive policy and program efforts
NAS—Reportable Disease

• Health Commissioner has authority to add diseases to Reportable Disease list
  – **Reportable disease**—Any disease which is communicable, contagious, subject to isolation or quarantine, or epidemic…
  – **Event**—An occurrence of public health significance and required by the Commissioner to be reported in the List.

• Add NAS to state’s Reportable Disease list
  – Effective January 1, 2013

NAS—Reportable Disease

• Identified stakeholders:
  – Birthing hospitals
    • Hospital associations
  – Providers and professional groups
    • Obstetricians, neonatologists/pediatricians
  – Department of Children’s Services (DCS)
  – State Public Health Epidemiologists
  – Addressed Concerns
NAS—Reportable Disease

• Approach to Stakeholder Concerns:
  – Transparency, transparency, transparency
  – Listen and incorporate feedback into design of reporting tool
  – Joint messaging with DCS re: intent and inter-agency data sharing
  – Engage end-users in piloting system (test cases with subsequent revisions)
NAS—Reportable Disease

• Reporting hospitals/providers submit electronic report (SurveyMonkey)
• Reporting Elements
  – Case Information
  – Diagnostic Information
  – Source of Maternal Exposure
Drug Dependent Newborns (Neonatal Abstinence Syndrome) Surveillance Summary For the Week of October 6-October 12, 2013 (Week 41)

Reporting Summary (Year-to-date)
Cases Reported: 660
   Male: 383
   Female: 277
Unique Hospitals Reporting: 49

<table>
<thead>
<tr>
<th>Maternal County of Residence (By Health Department Region)</th>
<th># Cases</th>
<th>% Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Davidson</td>
<td>33</td>
<td>5.0%</td>
</tr>
<tr>
<td>East</td>
<td>181</td>
<td>27.4%</td>
</tr>
<tr>
<td>Hamilton</td>
<td>11</td>
<td>1.7%</td>
</tr>
<tr>
<td>Jackson/Madison</td>
<td>1</td>
<td>0.2%</td>
</tr>
<tr>
<td>Knox</td>
<td>71</td>
<td>10.8%</td>
</tr>
<tr>
<td>Mid-Cumberland</td>
<td>46</td>
<td>7.0%</td>
</tr>
<tr>
<td>North East</td>
<td>100</td>
<td>15.2%</td>
</tr>
<tr>
<td>Shelby</td>
<td>14</td>
<td>2.1%</td>
</tr>
<tr>
<td>South Central</td>
<td>22</td>
<td>3.3%</td>
</tr>
<tr>
<td>South East</td>
<td>10</td>
<td>1.5%</td>
</tr>
<tr>
<td>Sullivan</td>
<td>67</td>
<td>10.2%</td>
</tr>
<tr>
<td>Upper Cumberland</td>
<td>85</td>
<td>12.9%</td>
</tr>
<tr>
<td>West</td>
<td>19</td>
<td>2.9%</td>
</tr>
<tr>
<td>Total</td>
<td>660</td>
<td>100%</td>
</tr>
</tbody>
</table>

Cumulative Cases NAS Reported
- 2013 Cases:
- Estimated 2011:

<table>
<thead>
<tr>
<th>Source of Maternal Substance (if known)</th>
<th># Cases</th>
<th>% Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supervised replacement therapy</td>
<td>292</td>
<td>44.2%</td>
</tr>
<tr>
<td>Supervised pain therapy</td>
<td>134</td>
<td>20.3%</td>
</tr>
<tr>
<td>Therapy for psychiatric or neurological condition</td>
<td>51</td>
<td>7.7%</td>
</tr>
<tr>
<td>Prescription substance obtained WITHOUT a prescription</td>
<td>262</td>
<td>39.7%</td>
</tr>
<tr>
<td>Non-prescription substance</td>
<td>185</td>
<td>26.0%</td>
</tr>
<tr>
<td>No known exposure but clinical signs consistent with NAS</td>
<td>11</td>
<td>1.7%</td>
</tr>
<tr>
<td>No response</td>
<td>15</td>
<td>2.3%</td>
</tr>
</tbody>
</table>

1. Summary reports are archived weekly at: http://health.tn.gov/MCH/NAS/NAS_Summary_Archive.shtml
2. Multiple maternal substances may be reported; therefore the total number of cases in this table may not match the total number of cases reported.
Key Points

- The impact of NAS does not end in the NICU.
- Long-term impact to both the healthcare system and society is significant.
- Prevention of unintended pregnancy is crucial.
- Prenatal care with supervised replacement therapy is critical.
- We must do all we can to promote prenatal care and substance abuse treatment/counseling in this high-risk population.
- Incentives to seek help may allow more opportunities for the woman to receive successful treatment with lifelong benefits.
- RX Substance abuse prevention and complete rehabilitation

Preventable
WE CANNOT SOLVE OUR PROBLEMS WITH THE SAME THINKING WE USED WHEN WE CREATED THEM

-Albert Einstein
Innovation—any new idea—by definition will not be accepted at first. It takes repeated attempts, endless demonstrations, monotonous rehearsals before innovation can be accepted and internalized by an organization. This requires *courageous patience.*" — Warren Bennis
Contact:
csaunders@etch.com