Your line has been placed on mute. The webinar will begin shortly.

August 13, 2019
2:00-3:00pm
EFFECTS OF IN-UTERO EXPOSURE TO OPIOIDS/DRUGS OF ABUSE

August 13th, 2019

Deepa Ranganathan, MD, MPH
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Division of Neonatology
Emory University School of Medicine
Atlanta, GA
Timeline of Neonatal Abstinence Syndrome (NAS)

1804: Morphine isolated
1817: Marketed as analgesic
1827: Commercial production

1845: Hypodermic needle developed
1874: Heroin synthesized
1898: Commercial production

1875: First reported case of neonatal withdrawal
1903: Morphine treatment for neonates reported
1921: Methadone withdrawal in 5 neonates

1902: Series of 12 infants, 9 died. Paregoric was tried
1967: Buprenorphine developed
1996: Buprenorphine use in France
2002: FDA approval for opioid dependence

Opioid analgesic medications:
- Vicodin (1984)
- Oxycontin (1989)
- Percocet (1999)

2002: First reported case of NAS due to oxycodone
2012: Epidemic of NAS
1997: First reported case of buprenorphine withdrawal
2001: Series of buprenorphine withdrawal in 13 infants
Drug Withdrawal Spectrum Over Time

- Before 1970 – Secondary to morphine or heroin
- Today - Morphine, heroin, methadone, buprenorphine, prescription opioid analgesics, antidepressants, anxiolytics, and/or other substances
- Also contributing - Medication-Assisted Therapy with methadone, buprenorphine
- More common and complex - Increased use of opioids, simultaneous use of multiple opioids, concurrent use of multiple other licit and illicit substances.
- Additional social, economic, and health care costs on society
Placental Drug Transfer

**Mechanisms of placental drug transfer** -
A: Simple diffusion
B: Facilitated diffusion using a carrier
C: active transport using ATP
D: Pinocytosis

**Factors affecting drug transfer across the placenta** -
Physical
Pharmacological

BM, basal membrane of the syncytiotrophoblast; MVM, microvillous membrane of the syncytiotrophoblast (adapted from a diagram in Desforges and Sibley with kind permission from the International Journal of Developmental Biology)
Opiates and Placental Transfer

- Low molecular weight, water soluble, lipophilic - Easily transfer across the placenta to the fetus
- Transmission increases as gestation increases
- Synthetic opiates cross more easily than semisynthetic
- Combination of cocaine or heroin with methadone - further increases permeability of methadone
- Ease of transfer across the bloodbrain barrier of the fetus + prolonged half-life in the fetus – worsens withdrawal in infants
- Sudden discontinuation of prolonged fetal exposure to opioids- Neonatal abstinence syndrome (NAS)/ Neonatal Opioid Withdrawal Syndrome (NOWS)
NAS/(NOWS)- Pathophysiology(1)

- More complex in neonates - immature neurologic development, impaired neurologic processing, and complex materno-feto-placental pharmacokinetics
- Opioids act through opioid receptors (G protein–coupled receptors, m, k, and d)- extensively distributed across the CNS
- Also located within the PNS, GI system, and various other systems.
- The density and affinity of m-receptors in neonates are as good as those in adults
- Opioid receptors in chronically stimulated state + lack of opioids - increases activity in the opioid receptors
- Leads to increased adenyl cyclase activity and cellular ionic imbalance - causes production and release of various neurotransmitters
NAS/NOWS – Clinical Signs/Symptoms

- Tremors, irritability, excessive crying, and diarrhea at presentation; sometimes seizures
- CNS signs – first irritability, jitteriness, tremors, and excessive crying
- Hallmark Hyperirritability - can lead to agitation, difficulty sleeping, and inconsolable crying
- High-pitched, uncontrollable excessive crying - requires immediate attention
- Tremors, exaggerated Moro reflex, hypertonia, and myoclonic jerks - commoner with methadone
- Can mimic seizures – may need EEG for confirmation
- Seizures in 2% to 11% - serious, should be treated immediately
- Dysregulation/instability of ANS – Impaired physiologic responses to stimuli, abnormalities of heart rate, respiratory rate, muscle tone; temperature instability, sweating, sneezing, mottling
- May persist for months, or even longer, especially with maternal buprenorphine
NAS/NOWS – Clinical Signs/Symptoms (cont.)

- Chemical odor - neonates born to mothers who abuse inhalants
- Tachypnea, nasal flaring, and nasal stuffiness - misinterpreted as respiratory distress
- Hyperthermia, although rarely higher than 102°F - misdiagnosis as sepsis
- Poor feeding, excessive motor activity, regurgitation, vomiting, and diarrhea - poor weight gain
- Severe diarrhea, leading to dehydration and electrolyte imbalance – especially for heroin
- Non-CNS causes of increased irritability and agitation - perianal skin excoriation secondary to excessive loose stools; unattended skin excoriation over the face and body, secondary to excessive motor movements
- Hyperphagia widely recognized - may require intake of more than 150 calories per kilogram per day
Preterm Infant

- Incidence and severity of withdrawal less extensive in preterm neonates
- Various factors:
  - Decreased cumulative exposure
  - Decreased transmission across the placenta during early gestation
  - Decreased morphine clearance
  - Decreased excretion because of immaturity of the kidneys and liver
  - Decreased fatty tissues in preterm infants (methadone is accumulated in fatty tissue)
  - Decreased receptor development
  - Decreased receptor sensitivity
Withdrawal presentation differs by exposure, so monitoring of infants for signs and symptoms of withdrawal should be commensurate (e.x. a methadone exposed infant may need a longer period of monitoring)

### TABLE 1 Onset, Duration, and Frequency of NAS Caused by Various Substances

<table>
<thead>
<tr>
<th>Drug</th>
<th>Onset, h</th>
<th>Frequency, %</th>
<th>Duration, d</th>
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<tbody>
<tr>
<td><strong>Opioids</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heroin</td>
<td>24–48</td>
<td>40–80&lt;sup&gt;27&lt;/sup&gt;</td>
<td>8–10</td>
</tr>
<tr>
<td>Methadone</td>
<td>48–72</td>
<td>13–94&lt;sup&gt;37&lt;/sup&gt;</td>
<td>Up to 30 or more</td>
</tr>
<tr>
<td>Buprenorphine</td>
<td>36–60</td>
<td>22–67&lt;sup&gt;46,48&lt;/sup&gt;</td>
<td>Up to 28 or more</td>
</tr>
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<td>Prescription opioid medications</td>
<td>36–72</td>
<td>5–20&lt;sup&gt;56,60&lt;/sup&gt;</td>
<td>10–30</td>
</tr>
<tr>
<td><strong>Nonopioids</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SSRIs</td>
<td>24–48</td>
<td>20–30&lt;sup&gt;64&lt;/sup&gt;</td>
<td>2–6</td>
</tr>
<tr>
<td>TCAs</td>
<td>24–48</td>
<td>20–50&lt;sup&gt;64&lt;/sup&gt;</td>
<td>2–6</td>
</tr>
<tr>
<td>Methamphetamine</td>
<td>24</td>
<td>2–49&lt;sup&gt;101&lt;/sup&gt;</td>
<td>7–10</td>
</tr>
<tr>
<td>Inhalants</td>
<td>24–48</td>
<td>48&lt;sup&gt;70&lt;/sup&gt;</td>
<td>2–7</td>
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</table>
Course – Severity and Intensity

• Initial phase - short but intense, with tremors, seizures, irritability, feeding problems, vomiting, diarrhea, hyperthermia, and other systemic signs lasting for 1 to 2 weeks
• Long chronic and relapsing course - hyperirritability, sleep disturbances, hyperphagia, and other neurologic and autonomic signs, lasting for a few weeks to a few months
Non-Opiate Withdrawal

- SSRI intake by mothers - withdrawal symptoms from excess serotonin and noradrenaline.
- Tricyclic antidepressants – withdrawal is cholinergic rebound phenomenon
- Benzodiazepines – withdrawal from increased release of g-amino butyric acid
- Methamphetamine - withdrawal from decrease in dopamine, serotonin, and other monoamines
- Inhalant - withdrawal through dopamine, glutamate, and g-amino butyric acid pathways
Effects of Fetal Exposures to Various Substances

- Neonatal abstinence syndrome
- Preterm birth and obstetric complications
- Attenuated myelination in infants
- Respiratory insufficiency
- Heart defects
- Reduced growth
- Deficits in cognitive and motor ability
- Attention deficit hyperactivity disorder
- Lower IQ
- Behavioral problems

- Decreased growth
- Deficits in attention
- Increased impulsivity
- Long-term deficits in executive function
- Depression diagnosis
- Future substance use

- Increased risk of growth restriction and prematurity (at high levels)
- Possible decrease in executive function at school age

- Preterm labor
- Short- and long-term growth deficits
- Cardiac and cardiovascular anomalies
- Cranial and brain abnormalities
- Behavior problems
- Emotional and social effects
- Deficits in attention, memory and motivation
- Anxious/depressed behaviors and symptoms
- Aggression and delinquent behavior

- Prematurity and spontaneous abortion
- Limb and facial development
- Reduced growth
- Cognitive delays and impairments
- Reduced brain volumes
- Abnormalities in the corpus callosum
- Deficits in attention, memory, verbal fluency, executive functioning, reaction times, and motor learning

Cannabinoids

Opiates

Tobacco

Alcohol

Psychostimulants

Caffeine
Indirect Effects of Fetal Drug Exposure

- Polypharmacy exposure (alcohol, tobacco, marijuana)
- Prenatal substance use
- Additional risk markers (maternal and paternal age, education, stressors)

Mental state:
- Anxiety
- Depression
- Insomnia
- Memory loss
- Hallucinations
- Abnormal behavior

Lungs:
- Pulmonary edema
- Breathing problems

Breastfeeding:
- Continued exposure
- Decreased prolactin release and supply

Amniotic fluid:
- Possible accumulation of intact drugs

Umbilical cord:
- Drugs are passed directly to fetus
- Tissue can be used to detect drugs

Increased risk:
- Blood, heart, and skin infections
- Arrhythmias
- Infectious diseases
- Seizures
- Stroke
- Hypothermia

Mother’s blood:
- Increased levels of CO₂, CO, and blood pressure
- Anemia
- Pre-eclampsia

Placenta:
- Vasoconstriction
- Placental insufficiency
- Placental abruption

Uterus:
- Premature birth
- Contractions
VON Day Audit
GaPQC Results
VON Day Audit Participation

- 38 hospitals participated
  - 80% of the Collaborative
- 16 hospitals audited 34 infants
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<td></td>
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<td>17</td>
<td>35</td>
<td>(48.6)</td>
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<tr>
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<td>20</td>
<td>35</td>
<td>(57.1)</td>
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<tr>
<td>Lipsitz</td>
<td>1</td>
<td>35</td>
<td>(2.9)</td>
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<tr>
<td>Fir Square checklist</td>
<td>0</td>
<td>35</td>
<td>(0.0)</td>
</tr>
<tr>
<td>Locally Developed Instrument</td>
<td>0</td>
<td>35</td>
<td>(0.0)</td>
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### Demographics

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<th>Cases</th>
<th>N</th>
<th>(%)</th>
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<tr>
<td>&lt;1501g</td>
<td>0</td>
<td>34</td>
<td>(0.0)</td>
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<td>1501 to 2500g</td>
<td>5</td>
<td>34</td>
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<tr>
<th>Gestational age</th>
<th>Cases</th>
<th>N</th>
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<td>&lt;35 weeks</td>
<td>3</td>
<td>34</td>
<td>(8.8)</td>
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<td>35 to 37 weeks</td>
<td>14</td>
<td>34</td>
<td>(41.2)</td>
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## Non-Pharmacologic Care

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Total Duration of Pharmacologic Treatment

- Max: 75
- Q3: 23
- Median: 13
- Q1: 9
- Min: 2
Total Length of NICU Stay

- Max: 77
- Q3: 24
- Median: 18
- Q1: 10
- Min: 2
Total Length of Hospital Stay

- Max: 77
- Q3: 32
- Median: 22
- Q1: 15
- Min: 7
VON Day Audit

GaPQC Results
VON Day Audit Participation

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## Policies and Guidelines

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</tbody>
</table>
Total Duration of Pharmacologic Treatment

- Max: 75
- Q3: 23
- Median: 13
- Q1: 9
- Min: 2
Total Length of NICU Stay

- Max: 77
- Q3: 24
- Median: 18
- Q1: 10
- Min: 2
Total Length of Hospital Stay

- Max: 77
- Q3: 32
- Median: 22
- Q1: 15
- Min: 7
The Model for Improvement

- What are we trying to accomplish?  
  AIM STATEMENT
- How will we know that a change is an improvement?  
  MEASURE
- What changes will result in an improvement  
  PROCESS IMPROVEMENT TOOLS
- Tests of change  
  Plan-Do-Study-Act (PDSA)

The Model for Improvement is recommended by the Institute for Healthcare Improvement and was originally developed by API (http://www.apiweb.org/)
SMART AIM statement template

We will increase/decrease
______________________ (what) among
______________________ (population) from
__X__(baseline) to __Y__ (goal) by
______________________ (date)
Example of a SMART AIM

We will increase the percentage of drug screens obtained on infants born to at-risk mothers from 85% to 95% by July of 2021
Specific, Measurable, Achievable

We will increase the percentage of drug screens obtained on infants born to at-risk mothers from 85% to 95% by July of 2021
Relevant - Defined population

We will increase the percentage of drug screens obtained on infants born to at-risk mothers from 85% to 95% by July of 2021.
We will increase the percentage of drug screens obtained on infants born to at-risk mothers from 85% to 95% by July of 2021.
Steps – Model for Improvement

1. Form a team
2. Make an AIM statement
3. Establish measures
4. Identify and select changes to test using process improvement tools
5. Test changes using PDSA cycles
6. Implement changes that work
7. Spread changes to other locations
QI - Measurement in Healthcare

- Maxim - “You can't manage what you don't measure”
- Goal - Understand a process quantitatively and provide interventions to improve performance
- Apply interventions - Use a metric to determine the effect of the intervention
- Monitor the measure over time and track the performance trend

The Donabedian model

- Structure
  - Infrastructure
  - Demographics
  - Technology
  - Education
  - Facilities

- Process
  - Diagnosis
  - Treatment
  - Appropriateness
  - Process of care
  - Resource requirements

- Outcomes
  - Mortality
  - Morbidity
  - Cost
  - Factors creating cost
  - Quality of life
QI – IMPROVEMENT MEASURES

- Measurement strategy - Important for data to determine whether your changes are, in fact, leading to improvement

- Types of measures
  - Structure measures: All factors that affect the context in which care is delivered – Infrastructure, demographics, technology, facilities etc.
  - Process measures: Related to the processes you are working on as part of the improvement effort – Diagnosis, treatment, process of care, appropriateness etc.
  - Outcome measures: Tied to the overall aim of the project- Mortality, morbidity, cost, LOS, etc. Can take a long time
  - Balancing measures: Help ensure that you’re not improving one part of the system at the expense of another

Example- For reducing patients' length of stay in the hospital: Make sure readmission rates are not increasing
We will increase the percentage of drug screens obtained on infants born to at-risk mothers from 85% to 95% by July of 2021
Urine drug screens obtained

Process

Identification of newborns at risk for drug withdrawal

Outcome

Balancing

False-positive/negative drug screens

Patient-family centered measure:

Infant discharged to mother’s care
Measures: Process Measures

- Is the process happening as planned

- Must find a way to track and document whether process is happening as defined in your measure

- Example: Tracking UDS in at risk infants i.e born to mothers with a history and/or positive UDS
Outcome Measures

- Is the intervention having the desired effect on the target population (e.g. increased testing helping to identify at newborns at risk for withdrawal)
- Clinically relevant, concrete data is best
- Example: Length of stay

- Most QI projects should have at least one outcome measure, although for some projects this may be difficult to define
Balancing Measures

- Are there untoward consequences of your specified intervention?

- Example:
  - Process: Urine drug screens obtained
  - Outcome: Identification of newborns at risk for drug withdrawal
  - Balancing: False-positive drug screens

- Try to anticipate possible outcomes, but be open for unexpected ones
Family-centered measure

- If none of your measures capture the patient-family experience, think about if you can incorporate a measure related to this.

- This is often difficult to measure, so most QI projects do not have this.

- Example: mother providing skin-to-skin care/mother providing own breastmilk.
Examples of team SMART aims

- Ex 1: we aim to decrease the length of treatment time among infants diagnosed with NAS who are treated with pharmacotherapy from xxx to xx by April 2021

  What type of measure is involved?

- Ex 2: we will educate at least 85% of the staff taking care of newborns by having them complete the VON NAS Universal Training Program

  What type of measure is involved?
Housekeeping Items

• Watch VON Micro-Lesson #2 this month
• You will receive reports on your micro-lesson progress soon
• Thank you for sending in your SMART Aim!!
Please watch the following VON Micro-lessons this month (August 2019): Lesson #2

**Key Driver Diagram for VONNAS initiative**

**Primary drivers**
- Improve identification of mothers and infants at risk
- Increase reliability of scoring for symptoms of NAS
- Increase non-pharmacologic treatment
- Provide family-centered care / avoid mother-infant separation
- Reduce pharmacologic treatment
- Reduce variation in treatment of infants with NAS
- Improve transition to home, engaging parents

**Interventions**
- Develop standard screening guidelines
- Educate staff on scoring
- Assess inter-rater reliability of scoring
- Use Eat, Sleep, Console
- Increase breastfeeding
- Use non-pharmacologic bundles of care
- Use a standard opioid treatment protocol
- Back-transfer infants stabilized on treatment
- Collaborate with support organizations/agencies
- Provider education to reduce stigma

**SMART Aim**
We aim to decrease length of stay among newborns diagnosed with NAS in participating GaPQC hospitals from 11.2 days to 10.1 days by 9/30/2021

**Global Aim**
Improve care for babies and mothers impacted by NAS

**VON Vermont Oxford Network**
Micro-lessons
- Lesson 1: Improved Family-Centered Care at Lower Cost: Improvement Story: Using Standardization to Create a High Reliability
- Lesson 2: The Prescription Opioid Epidemic and Neonatal Abstinence Syndromes: A Public Health Approach
- Lesson 3: Virtual Video Visit Chapter 1: Linking Attitudes with Outcomes
- Lesson 4: Substance Use 101: Myths and Misunderstandings
- Lesson 5: Virtual Video Visit Chapter 2: The Face of Trauma
- Lesson 6: Substance Use 101: Frequency and Neonatal Impact by Agent
- Lesson 7: Standardizing Care to Improve Outcomes
- Lesson 8: Screening and Obtaining a Complete Drug History for Substance Use in Pregnancy
- Lesson 9: Presentation and Typical Course
- Lesson 10: Non-Pharmacologic Strategies for Symptom Management
- Lesson 11: Virtual Video Visit Chapter 3: The Birth Story
- Lesson 12: Scoring and Reducing Risks
- Lesson 13: Scoring: Cases, Controversies
- Lesson 14: Withdrawal, Toxidromes, and Confounders
- Lesson 15: Lactation and the Substance-Exposed Mother-Infant Dyad
- Lesson 16: Engaging Families in Feeding and Nutritional Support
- Lesson 17: Developmental Outcomes of Substance-Exposed Infants
- Lesson 18: Virtual Video Visit: Two Stories of Recovery and the Long Road Home