Care Process Model

Perinatal Substance Exposure (PSE) in Newborns
What is Multidisciplinary Care?
Multidisciplinary care is agreed upon, interdisciplinary, patient-centered, disease-focused, care delivery systems that are informed by a series of evidence-based care process models. Multidisciplinary care supports the achievement of the BIG(GER) Aim systematically across the continuum of care.

What is a Care Process Model (CPM)?
Care process models ensure that all care delivered by a hospital and its caregivers is medically necessary, the leading edge in medical science and the appropriate treatment intensity. Put into effect, these models will systemize treatment processes across all hospitals and practices, improving consistency as well as effectiveness. This CPM summarizes Mission Health’s multidisciplinary care in regards to Perinatal Substance Exposure (PSE) in newborns.

What are the benefits of a CPM?
- Reduces variation
- Utilizes the best practice from literature and expert opinion
- Improves care delivery process
- More readily exposes errors
- Variation study informs revisions to CPMs
Why Focus on “Perinatal Substance Exposure (PSE) in Newborns”?

Infants exposed in utero to substances of use/abuse are known to be at risk for problems, including medical conditions, growth issues, developmental delays, and child abuse and neglect. The overall incidence of NAS in the US has increased almost 300% during 1999-2013, from 1.5 to 6 cases per 1,000 hospital births, which does not account for babies exposed to substances other than opioids. In the U.S., nearly 90% of drug-abusing women are of reproductive age. As opioid and other substance use has grown nationally and locally, Mission data suggests that there has been a 400% increase from 2010 – 2014 infants pharmacologically treated for neonatal withdrawal syndrome. Currently toxicology is performed only on the infants with a risk factor. Our current toxicology results demonstrate that 9.5% of infants born in the Mission Health System have experienced perinatal substance exposure.

Executive Summary

Newborn withdrawal refers to a group of symptoms that are seen in a baby whose mother has taken certain drugs or medications during her pregnancy. Symptoms occur as the baby’s body tries to adjust to life outside of the womb without the substance. When a baby is withdrawing from opioids (e.g., methadone, buprenorphine, heroin) it is called Neonatal Abstinence Syndrome (NAS). Some babies begin to experience withdrawal within a few hours after birth, while others may not develop symptoms until a few weeks later. The symptoms each baby may experience are affected by the way his/her body processes the drug. Guidelines have been developed to give care providers a community standard approach to the testing and management of newborns exposed to a variety of substances in utero.

Examples of substances a newborn may be exposed to prenatally:
- Prescribed substances (opioids) that cause withdrawal in the infant
  - 20% of women fill a prescription during pregnancy for pain medicine
- Medication Assisted Therapy for Addiction
  - Common substances include methadone or buprenorphine
  - The American College of Obstetrics and Gynecology recommends continuing opioids if the pregnant women entered pregnancy on opioids
- Illicit Use of Substances (Heroin, Amphetamines, Methamphetamines)
- Alcohol
- Herbal substances
- Smoking/Nicotine
- Caffeine
Key Interventions: Recommendations for Management of Infants with Perinatal Substance Exposure

Identification:
- Timely detection of in utero drug exposure is critical for effective management of withdrawal syndromes, and long-term needs (social and medical) for exposed neonates. The actual time window for detecting exposure is unknown and is drug dependent, but is thought to represent approximately the last trimester.
- Detection of drugs depends on:
  - Extent of maternal drug use
  - Drug stability
  - Deposition of drug metabolites in umbilical cord tissue
  - Analytical method
- Umbilical cord tissue testing may be preferable to meconium due to:
  - Ease of collection of a larger volume of specimen
  - Relatively fast turnaround time if specimen is sent to the laboratory on the day of birth
  - Reflex/confirmation testing typically not required⁶

Identification of Infants with Perinatal Substance Exposure will be performed via the following:
- Maternal universal history-taking screen
- Maternal UDS of women with Risk Factors:
  - A urine drug screen (UDS) will be collected on all women with a risk factor as outlined by Policy 1PC.WC.0011
- Infant Cord toxicology (standard means of identification):
  - Cord Toxicology will be ordered on all infants that meet criteria per Policy 1PC.WC.0011
  - For those infants without risk factors, the umbilical cord tissue will be held for 14 days for future testing if indicated
- Parent Education:
  - A prenatal plan preparing the mother for parenting, breastfeeding, and substance abuse treatment should be formulated through individualized, patient-centered discussions with each woman. This care plan should include instruction in the consequences of relapse to drug or excessive alcohol use during lactation, as well as teaching regarding potential for donor milk, formula preparation, and bottle handling and cleaning should breastfeeding be or become contraindicated. Education should begin in the prenatal setting with mother and continue throughout hospital stay with what to expect during hospitalization and transition to home.⁶
Interventions and Treatment:

- The infant’s attending of record will be notified if a maternal urine toxicology screen is ordered for a mother based upon risk factor criteria in Policy 1PC.WC.0011. The Perinatal Substance Exposure (PSE) Order Set will be initiated by the attending of record.

- This order set includes but is not limited to:
  - Expert consultation by our Perinatal Substance Exposure (PSE) Team if exposure is an opioid, benzodiazepine, cocaine, methamphetamine, or other substance which may lead to withdrawal in the infant
    - Finnegan scoring when indicated
    - Non-pharmacologic interventions
    - Multidisciplinary interventions from Occupational Therapy (OT), Physical Therapy (PT), Speech and Language Pathology (SLP), Lactation, Nutrition, Case Management and Social Work

- Infants should be monitored as inpatients for a length of time based on specific opioid exposure:
  - Short-acting opioids (heroin, prescription) – monitor minimally for 48-72 hours
  - Methadone – monitor for 4-6 days
  - Buprenorphine - monitor for 5-7 days
  - Providers must recognize that the symptoms of withdrawal from opioids may not present until 4-6 weeks of life

- Infants exposed to non-opioid substances will receive monitoring and non-pharmacologic interventions.

- Recommendations for infants exposed to marijuana exclusively
  - Mother will be advised not to breastfeed as described on “Breastfeeding Statement” information sheet
  - Provider will make determination when cord toxicology is ordered

- Note: pharmacologic interventions are not indicated in all areas of neonatal abstinence. It will be at the discretion of the Perinatal Substance Exposure Team or attending Licensed Infant Provider (LIP) to initiate pharmacologic therapy. Caution must be exercised when ordering pharmacologic intervention for polysubstance exposure.

- Onset of withdrawal depends on the half-life of the drug, duration of the exposure, and time of last maternal dose prior to delivery
### Drug Approximate time to onset of withdrawal symptoms

<table>
<thead>
<tr>
<th>Drug</th>
<th>Time to Onset of Withdrawal Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barbiturates *</td>
<td>4-7 days but can range from 1-14 days</td>
</tr>
<tr>
<td>Cocaine *</td>
<td>Usually no withdrawal signs but sometimes neurobehavioral abnormalities (decreased arousal and physiologic stress) occurs at 48-60 hours</td>
</tr>
<tr>
<td>Alcohol</td>
<td>3-12 hours</td>
</tr>
<tr>
<td>Caffeine</td>
<td>At birth</td>
</tr>
<tr>
<td>Heroin</td>
<td>Within 24 hours</td>
</tr>
<tr>
<td>Marijuana *</td>
<td>Usually no clinical withdrawal signs</td>
</tr>
<tr>
<td>Methadone</td>
<td>3 days but up to 5-7 days; Timing and severity of withdrawal does not correlate with maternal dose</td>
</tr>
<tr>
<td>Subutex / Suboxone</td>
<td>5 days but up to 7-14 days</td>
</tr>
<tr>
<td>Methamphetamines *</td>
<td>Usually no withdrawal signs but sometimes neurobehavioral abnormalities (decreased arousal, increased physiologic stress, and poor quality of movement) occur at 48-60 hours</td>
</tr>
<tr>
<td>Opioids</td>
<td>24-36 hours but can be up to 5-7 days</td>
</tr>
<tr>
<td>Sedatives</td>
<td>1-3 days</td>
</tr>
<tr>
<td>SSRIs</td>
<td>Several hours to several days – withdrawal linked with 3rd trimester use</td>
</tr>
</tbody>
</table>

* Babies of mothers who use some addictive drugs (nicotine, amphetamines, barbiturates, cocaine, and marijuana) may have long-term problems such as birth defects, premature birth, sudden infant death syndrome and problems with development and behavior. However, there is no clear evidence of a neonatal abstinence syndrome for these drugs.  

- Non-pharmacologic interventions will include the following:
  - Swaddling the baby in a sleep slack
  - Non-nutritive sucking (pacifier)
  - Touch and movement techniques (examples)
    - Skin-to-skin
    - Rhythmically pat baby’s bottom or back
    - Provide boundaries when lying in crib
  - Non-stimulating environment to include dim lights, low noise, clustering of care
  - Nutrition (breast vs. formula) education
    - Parent education regarding contraindications in breastfeeding
    - Parent education on implications of abruptly stop breastfeeding / notify infant LIP
  - Safe infant sleep implemented and modeled during hospital stay
Finnegan Newborn Screening Tool (FNAST) for opioid exposed infants:

Should be the standard screening tool used to help identify newborns experiencing withdrawal symptoms associated with exposure to opioids. This tool has been validated and accepted as the recommended screening tool by the American Academy of Pediatrics. Screens should be initiated at 4 to 6 hours of age and continued at least every 4 hours, mid-feed.9

Pharmacologic interventions (if appropriate): The Perinatal Substance Exposure (PSE) Consult Team or Infant Provider will determine when pharmacologic therapy is needed. If the infant does not respond to non-pharmacologic measures additional pharmacologic interventions will be added when indicated. If difficult to capture with methadone alone, adjunct medications including, but not limited to, clonidine, phenobarbital or gabapentin may be added. Administration of these adjunct medications should only occur in the NICU setting.

Workflow for Initiation of Methadone and Subsequent Weaning Protocol when Indicated

- Consider initiation of methadone 0.1mg/kg PO q12 when 3 consecutive Finnegan scores greater than 8 or 2 consecutive Finnegan scores greater than 12
  - Cardiorespiratory monitoring is required if pharmacological treatment started
  - May advance to 0.1mg/kg PO q8 to capture
- If Finnegan scores are 0-1 or newborn is over-sedated (excessive sleepiness, not waking to feed, etc.), decrease dose by 20% and continue to monitor
- Once captured for 24-48 hours, methadone will be weaned either:
  - at home. For those patients that meet home discharge criteria (see below) with adequate family environment, social risk factors, and barriers to follow-up care, the weaning schedule may be determined using the Cerner Weaning Calculator
  - in hospital. For patients who do not meet these criteria, the weaning schedule will be at the discretion of the neonatologist/NPN (see Inpatient Weaning Protocol). AAP recommends stopping methadone when the total daily dose is less than 0.03 mg/kg per day
  - The smallest measurable dose that the pediatric pharmacy safely recommends is 0.1 ml which equals 0.1 mg. Methadone may be stopped at this point even if mg/kg dose is not less than 0.03mg/kg per day. May consider once daily dosing for one week.10

Transition to Home

- Discharge Criteria for Infants on Methadone:
  - Discharge may happen once the infant is stable on current methadone dosing and if the following criteria are met:
    - The infant is not receiving adjunct pharmacologic therapy for abstinence other than methadone (clonidine, phenobarbital, etc.)
    - No changes have been made in methadone dosing for at least the previous 48 hours
    - The current dosing schedule is q12 hours
    - Finnegan scores have been less than 8 for the previous 48 hours period
Providers involved in the delivery and care of infants born with and identified as being affected by substance abuse, withdrawal symptoms resulting from prenatal drug exposure, or FASD must notify Child Protective Services of the occurrence.

In North Carolina, the notification to the county child welfare agency must occur upon identification of the infant as a “substance affected infant,” as defined by DHHS.

All infants discharged home on methadone AND those infants that meet criteria for being at risk for NAS but are not currently receiving pharmacologic therapy will also receive:

- Primary care Follow-up
  - Recommended outpatient provider follow-up within 24-48 hours after discharge, then weekly for 9 weeks with weight check and withdrawal assessment
- A Home Health referral for in-home services with the following schedule:
  - 2 times a week for the first 2 weeks, then weekly for 7 additional weeks
    - Indications are weight checks, withdrawal assessment and medication administration
  - For infants on a weaning protocol that are being considered for discharge to a county without Pediatric Home Health Services for Neonatal Abstinence Syndrome, it is recommended that the infant receive inpatient pharmacologic weaning, unless the interagency/interdisciplinary team develops a community care plan that addresses the clinical follow-up and special needs of the infant and family.
- An Early Intervention referral
- A follow-up appointment at the Neonatal–Toddler Follow-up (NDFP) Clinic at Mission Children’s Specialists
- Extensive education regarding breast feeding (and the cessation of breast feeding) with the mother (See Breastfeeding Policy for details)
- Extensive education on soothing and caring for an infant withdrawing from opioids including safety prior to discharge
Algorithms

Mission Health – Perinatal Substance Exposure in Newborns

**Labor and Delivery**

- **Mother negative substance use Hx**
- **Meets risk criteria?**
  - Yes: Maternal UDS taken
  - No: Mother Baby Unit

- **Mother positive substance use Hx**
- **Meets risk criteria?**
  - Yes: Peds LIP initiates appropriate PSE subplan
  - No: *NNP will not be called for consult for marijuana only exposure

- **Maternal UDS taken**
  - Yes: Peds LIP to initiate PSE plan, send cord Tox
  - No: Peds LIP initiates appropriate PSE subplan

- **Mother Baby Unit**

- **Finnegan Scoring**
  - **Opiate?**
    - Yes: Finnegan Score Elevated?
    - No: Infant Stable?
      - Yes: Discharge when D/C criteria met
      - No: Stay on MOMB

- **Finnegan Score Elevated?**
  - Yes: Begin Pharm Intervention
  - No: No Pharm

- **Infant Stable?**
  - Yes: Discharge when D/C criteria met
  - No: Stay on MOMB

- **NNP Evaluates Need For Pharm**
  - Yes: DC with Meds?
    - Yes: Discharge home with meds when D/C criteria met
    - No: Discharge when D/C criteria met
  - No: No Pharm

**NICU**

- **Begin Pharm Intervention**
  - Yes: DC with Meds?
    - Yes: Discharge home with meds when D/C criteria met
    - No: Discharge when D/C criteria met
  - No: Discharge when D/C criteria met

**Discharge Criteria**

* HH: Home Health arranged
* PCP: PCP follow up appointment scheduled and in Depart
* Call: Phone call to PCP if not attending of record on the infant
* NDFP: Neonatal Development Follow up scheduled and in Depart
* EI: Early Intervention referral made
* SAFETY: Safety Plan and DSS arrangements made, if applicable
* FEEDS: Feeding plan and education provided to family
* CONTACT: Contact information in Patient Info and Case Manager form reviewed and updated
* MED: Prescriptions filled with detailed education and teach back from family on appropriate administration
* EDUCATION: Parent education on Perinatal Substance Exposure given

**Methadone wean 0.1mg/kg**
**Q8-Q12 hours**
(Q8 hours if difficult to capture, Q12 hours is standard)
**Care Process Model**

**McDowell Hospital – Perinatal Substance Exposure in Newborns**

**Labor and Delivery**
- Mother negative substance use Hx
  - Meets risk criteria? Yes
    - Maternal UDS taken
    - Notify Pediatrician of Exposure
  - No
    - Peds LIP to initiate plan and appropriate subplan
    - Send Cord Tox
    - Lab holds cord for 14-days
- Mother positive substance use Hx
  - Birthing Center

**McDowell Birthing Center**
- Finnegan Scoring
  - Opiate?
    - Yes
      - Finnegan Scores Elevated?
        - Yes
          - Pharmacologic Interventions
        - No
          - Infant Stable?
            - Yes
              - Discharge when D/C criteria met
            - No
              - Non-Pharmacologic interventions
            - No Pharm
  - No

**Monitored Baby Care**
- Begin Pharmacologic Intervention with Cardiorespiratory Monitoring
- DC with Meds?
  - Yes
    - Discharge home with meds when D/C criteria met
  - No

**Discharge Criteria**

* HH: Home Health arranged
* PCP: PCP follow up appointment scheduled and in Depart
* CALL: Phone call to PCP if not attending of record on the infant
* NDFP: Neonatal Development Follow up scheduled and in Depart
* EI: Early Intervention referral made
* SAFETY: Safety Plan and DSS arrangements made, if applicable
* FEEDS: Feeding plan and education provided to family
* CONTACT: Contact Information in Patient Info and Case Manager form reviewed and updated
* MED: Prescriptions filled with detailed education and teach back from family on appropriate administration
* EDUCATION: Parent education on Perinatal Substance Exposure given

Methadone wean 0.1mg/kg Q12 hours. Transfer to NICU if difficult to capture.
Mission Health Neonatal Intensive Care Unit – Perinatal Substance Exposure in Newborns

Infant with Perinatal Substance Exposure (PSE) to Opioids

Maximize non-Pharm comfort measures, initiate PSE order set and Finnegan scoring

Scores >=8x3 or >=12x2

Scores >=8x3 or >=12x2

No

Yes

Start methadone 0.1 mg/kg Q12 hours

Continue to monitor Finnegan scores

Increase dose to Q6-8 hour x24 hours to capture, then return to Q12 hour dosing Scores 8-12: Q8 Scores >12: Q6

D/C home on 10%/week wean after 24-48 hours of observation, home health arranged, DSS approval

Initiate Inpatient Weaning Protocol* 

*See Inpatient Weaning Protocol Table

Yes

Yes

No

D/C home after appropriate interval based on exposure

Short acting: 48-72 hrs

Methadone: 4-6 days

Buprenorphine: 5-7 days

Finnegan scores 0-1 or oversedated?

Avg Finnegan score <8x24-48 hours on Q12 dose

No

No

Yes

Decrease dose by 20%

D/C home after 48-72 hours of observation, home health arranged, DSS approval

Wean Complete?

Average Finnegan for 24 hrs

<8

=8-12

>12

Wean to next step

Do not wean

Consider extra dose of methadone or return to previous step

D/C home after 24-48 hours to capture, then return to Q12 hour dosing Scores 8-12: Q8 Scores >12: Q6

*Inpatient Weaning Protocol Table

Wean Complete?

Wean to next step

D/C home after appropriate interval based on exposure

Short acting: 48-72 hrs

Methadone: 4-6 days

Buprenorphine: 5-7 days

Avg Finnegan score <8x24-48 hours on Q12 dose
**Inpatient Weaning Protocol Table**

<table>
<thead>
<tr>
<th>Step</th>
<th>Methadone Dose</th>
<th>Dosing Interval</th>
<th>Number of Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1</td>
<td>0.1 mg/kg</td>
<td>q12 hours</td>
<td>4</td>
</tr>
<tr>
<td>Step 2</td>
<td>0.07 mg/kg</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Step 3</td>
<td>0.05 mg/kg</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Step 4</td>
<td>0.04 mg/kg</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Step 5</td>
<td>0.03 mg/kg</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Step 6</td>
<td>0.02 mg/kg</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Step 7</td>
<td>0.01 mg/kg</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Step 8</td>
<td>0.01 mg/kg</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Step 9</td>
<td>Wean Complete</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Metrics

These metrics are to serve as important elements in the creation of the templates in the electronic medical record and will be collected and reported as they become available in our information systems.

The following metrics will be used by Mission Health as a measure of the quality care we provide. These measures are based on national standards of care and signal critical points in the care of perinatal substance exposed newborns.

Average Length of Stay (LOS)
Average Cost per Case
Readmission Rate
Maternal UDS Result
Infant Cord Toxicology
Reason for Cord Toxicology
Gestational Age
Finnegan Score at Time of Pharm Intervention
Highest Finnegan
Comfort Measures
Pharmacological Interventions
Discharge Rate with Pharm
Rate of Home Health Referral
Rate of Care Management Consult
Type of Feeding
DSS Referral Rate
NICU Admission Rate
PowerPlan Adherence

Resources


MotherToBaby Hotline: (866) 626.6847 or mother-to-baby.org/fact-sheets-parent/

Breastfeeding Statement
References


References continued


References continued


National Survey of Drug Use and Health (Substance Abuse and Mental Health Services Administration). 2012.


Notes
Achieving the BIG(GER) Aim
To get every person to their desired outcome, first without harm, also without waste and always with an exceptional experience for each person, family and team member.

About Mission Health
Mission Health, based in Asheville, North Carolina, is the state’s sixth-largest health system and was recognized as one of the nation’s Top 15 Health Systems from 2012-2015 by Truven Health Analytics, formerly Thomson Reuters, becoming the only health system in North Carolina to achieve this recognition. Mission Health operates six hospitals, numerous outpatient and surgery centers, post-acute care provider CarePartners, long-term acute care provider Asheville Specialty Hospital, and the region’s only dedicated Level II trauma center. With approximately 10,700 employees and 2,000 volunteers, Mission Health is dedicated to improving the health and wellness of the people of western North Carolina. For more information, please visit mission-health.org or @MissionHealthNC.