Updates from

THE
University of Vermont
Children's Hospital

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Disclosures

- I receive funding from the IDEA States Network to provide training in use of the ESC Care Tool for the ACT NOW Eat, Sleep, Console Clinical Trial
- I have no other relevant financial relationships to disclose or conflicts of interest to resolve

Changes to the Model of Care - 2018

Traditional Approach

- Finnegan Score
- Staff direct care and assessment
- Treatment with scheduled medication that is weaned slowly
- NICU

Eating, Sleeping, Consoling

- ESC Assessment
- Plan of care always includes family
- Treatment with optimized non-pharmacologic care before considering pharmacologic treatment
- Room in with parents

Refining Use of the Eat, Sleep, Console (ESC) Care Tool

EAT, SLEEP, CONSOLE (ESC) CARE TOOL

ESC 3rd edition 11.14.19

- **Review ESC behaviors, signs of withdrawal present,** and **Non-Pharm Care Interventions (NPIs)** with parent(s)/caregiver **every 2-4 hours** (using **Newborn Care Diary**), ***clustering care with infant's wakings and feedings.*** With each assessment, **reinforce NPIs** that parents/caregivers are implementing well (**"R"**), *and* **educate ("E") / coach parents** in ways that **other NPIs can be increased further ("I").**
- If **Yes** for any **ESC** item *or* **3** for **Consoling Support Needed:** Perform a **Formal Parent/Caregiver Huddle** to ***formally*** **review NPIs that can be optimized further to help with infant's current ESC difficulties** and **continue to monitor infant closely.**
- If **2nd Yes in a row** for **any single ESC** item (***or*** **2nd "3"** for **Consoling Support Needed)** despite **maximal non-pharm care** *OR* ***other significant concerns*** are present *(e.g., seizures, apnea)*: Perform a **Full Care Team Huddle** with **parent/caregiver, infant RN** *and* **physician or associate provider** to 1) **consider all potential etiologies** for symptoms, 2) **re-assess if NPIs** are **maximized** to fullest extent possible in infant's clinical setting, and 3) **determine if Neonatal Opioid Withdrawal Syndrome (NOWS)/Neonatal Abstinence Syndrome (NAS) medication treatment is needed. Continue** to **maximize all NPIs and monitor infant closely.**

Perform assessment of ESC behaviors, signs of withdrawal, and NPIs for time period since last ESC assessment *– note date/time:*	
NOWS/NAS ASSESSMENT	
Are signs of withdrawal present? (e.g., hyperactive moro, tremors/jitteriness, increased tone, excessive/disorganized suck) Yes / No	
If Yes, is timing of withdrawal consistent with known opioid exposure? Yes / No / Unsure	
Are co-exposures present that may be contributing to signs of withdrawal? Yes / No / Unsure (please list co-exposures)	
Are NPIs maximized to fullest extent possible in infant's clinical setting? Yes / No / Unsure	
EATING	
Takes > 10 min to coordinate feeding *or* **breastfeeds < 10 min** *or* **feeds < 10 mL** (*or* other age-appropriate duration/volume) **due to NOWS/NAS?** Yes / No	
SLEEPING	
Sleeps < 1 hr due to NOWS/NAS? Yes / No	
CONSOLING	
Takes > 10 min to console (*or* **cannot stay consoled for** ***at least*** **10 min) due to NOWS/NAS?** Yes / No	
Consoling Support Needed **1:** Able to console on own **2:** Able to console within (and stay consoled for) 10 min with caregiver support **3:** Takes > 10 min to console (*or* cannot stay consoled for *at least* 10 min) despite caregiver's best efforts	
CARE PLAN	
Formal Parent/Caregiver Huddle Performed to formally review NPIs to be increased further? Yes / No	
Full Care Team Huddle Performed to formally consider all possible etiologies for symptoms, re-assess if NPIs are maximized to fullest extent possible, and determine if NOWS/NAS medication treatment is needed? Yes / No	
Management Decision **a: Continue/Optimize NPIs** **b: Initiate NOWS/NAS Medication Treatment** (e.g., if baby's symptoms & timing of symptoms are consistent with mother's particular opioid *and* NPIs are maximized to fullest extent possible in infant's clinical setting, *OR* other significant NOWS/NAS concerns are present (e.g., seizures, apnea) – please list medication(s) initiated **c: Continue NOWS/NAS Medication Treatment** **d: Other** (please describe – e.g., Start 2nd Pharmacologic Agent (indicate name); Wean or Discontinue Medication Treatment)	
PARENT/CAREGIVER PRESENCE SINCE LAST ASSESSMENT	
> 3 hours (includes if parent/caregiver present entire time), **2-3 hours, 1-2 hours, < 1 hour, 0 hours** (no parent/caregiver present)	
NON-PHARM CARE INTERVENTIONS (I = Increase Now, **R** = Reinforce, **E** = Educate for Future, **NA** = Not Applicable/Available)	
Rooming-in (i.e., caring for infant in their own room with earlier caregiver response to infant stress or hunger cues)	
Parent/caregiver presence to help calm and care for infant	
Skin-to-skin contact when caregiver fully awake/alert to help organize infant feeding behaviors, calming & sleep	
Holding by parent/caregiver/cuddler to help calm infant & aid in sleep (with caregiver fully awake/alert)	
Safe & effective swaddling (e.g., extremities swaddled in flexed position, blanket snug, no extra blanket around baby's face)	
Optimal feeding (e.g., baby offered feedings when showing hunger cues & fed till content)	
Non-nutritive sucking with infant's hand, pacifier, adult caregiver's washed or gloved finger	
Quiet, low light environment to help limit overstimulation of infant (e.g., tv volume down, quiet "white noise" machine or phone app)	
Rhythmic movement provided by parent/caregiver or infant calming device (e.g., "jiggling" or infant swing in presence of alert adult)	
Additional help/support in room (e.g., other parent, family member, friend, cuddler, staff member, recovery coach, DCYF worker)	
Limiting # of visitors & duration of visit(s) to minimize disruptions in infant's care environment & sleep	
Clustering care & assessments with infant's awake times (e.g., RN & infant provider perform assessment together after infant feedings)	
Safe sleep/fall prevention (e.g., infant sleeps on back, safely swaddled, in own sleep space)	
Parent/caregiver self-care & rest (e.g., identifying another adult to care for infant so parent can rest or take a walk/break)	
Optional Comments: (e.g., staff caring for/consoling baby as parents not available or able to safely care for baby)	

****Special note:*** *Numbers above are* ***not*** *intended as a "score" but instead may indicate/identify a need for increased intervention.*

Standardized training and implementation across two perinatal collaboratives

1. Formal symptom prioritization
   - Focus on function based assessments of eating, sleeping, and consoling
2. Parental involvement and communication
3. Non-pharmacologic care
   - Clear communication about interventions
   - Emphasizes importance of parents as treatment

Enhancing Non-Pharmacologic Care

- Cuddler program expanded from the NICU to the Mother Baby Unit
- Exploring collaboration with Doula Program to provide off-hours on-call cuddler support
- Exploring options to maintain rooming in during pharmacologic treatment (minimize unnecessary separation / NICU stays)
- NICU trialing weighted sleep sack (while infants are on cardiopulmonary monitors)

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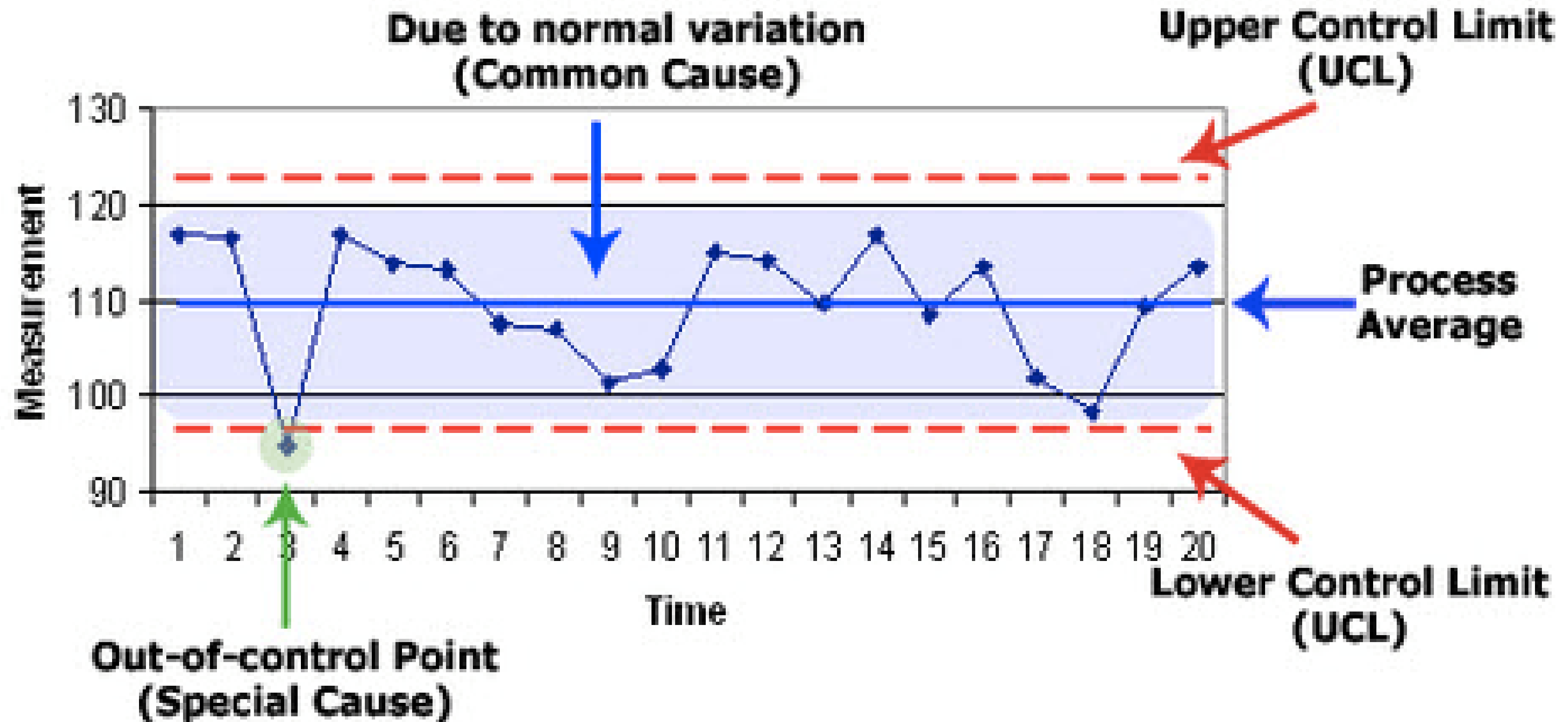
Process Control Chart



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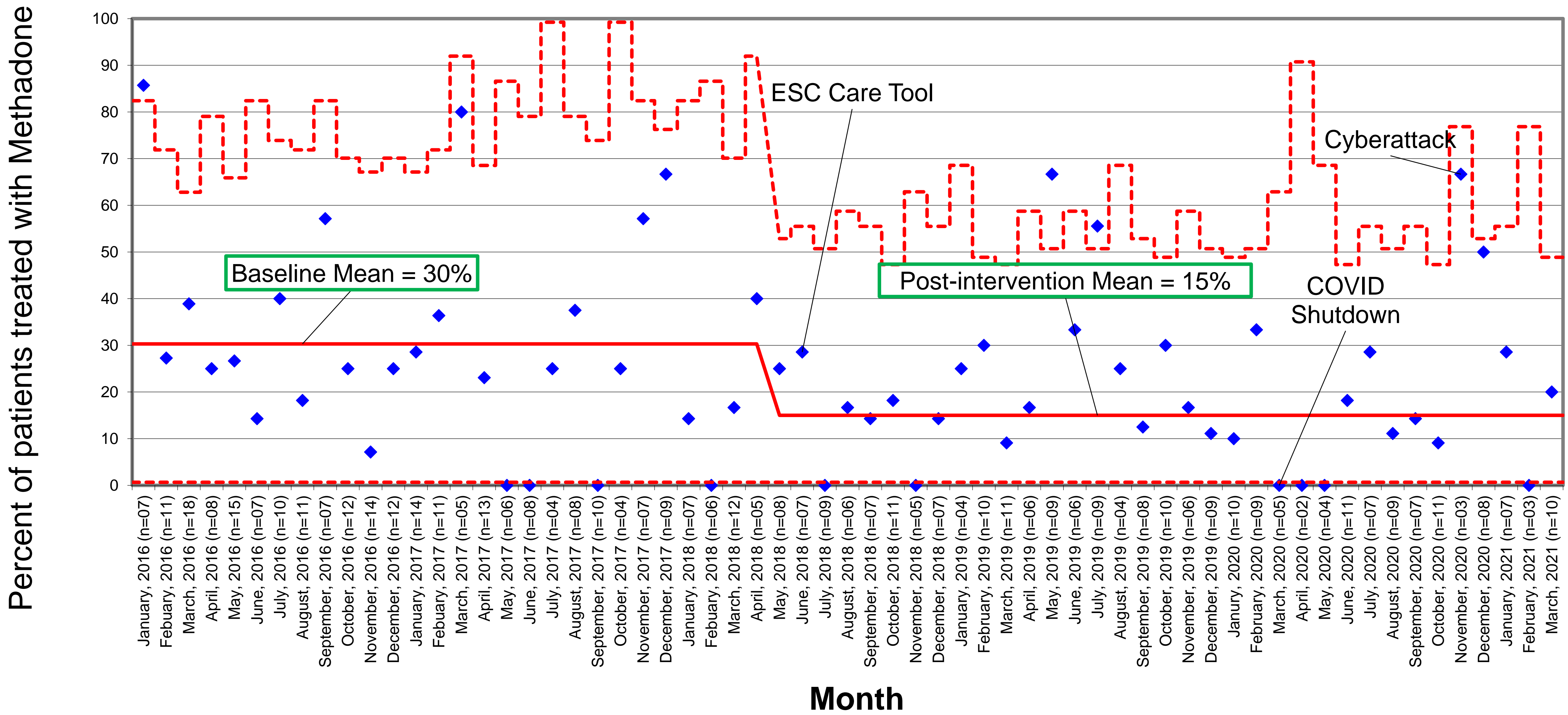
Percent of Opioid Exposed Newborns Treated with Any Methadone



◆ Monthly percent of patients treated with Methadone — Mean - - - Control Limits

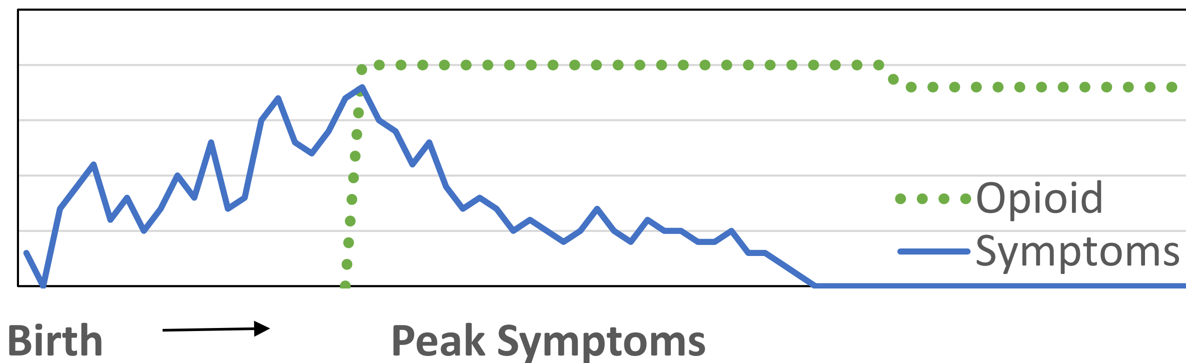
Changes to the Model of Care – 2019 - 2020

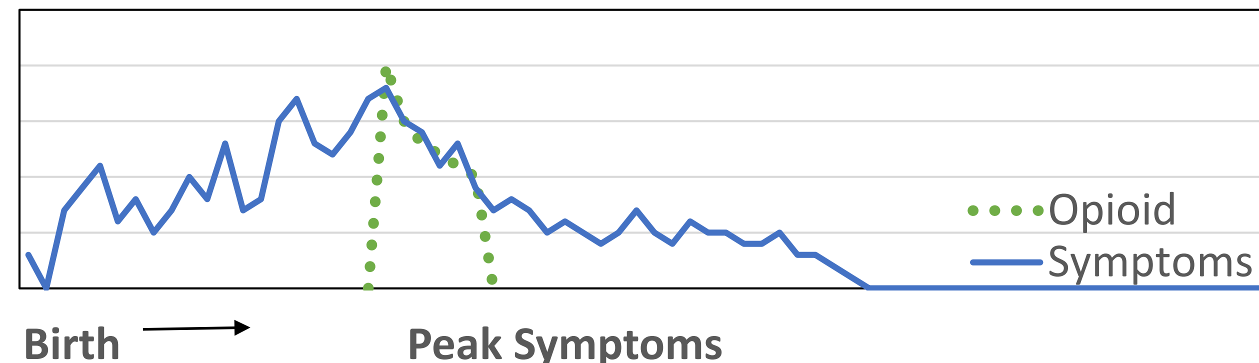
Scheduled Taper

- Scheduled medication that is weaned slowly
- Continued dosing based on hospital protocol
- Prolonged opioid treatment

Just-in-Time Dosing

- As needed medication based on symptoms with continuous reassessment
- Often effective in 1-2 doses
- Reduces iatrogenic withdrawal





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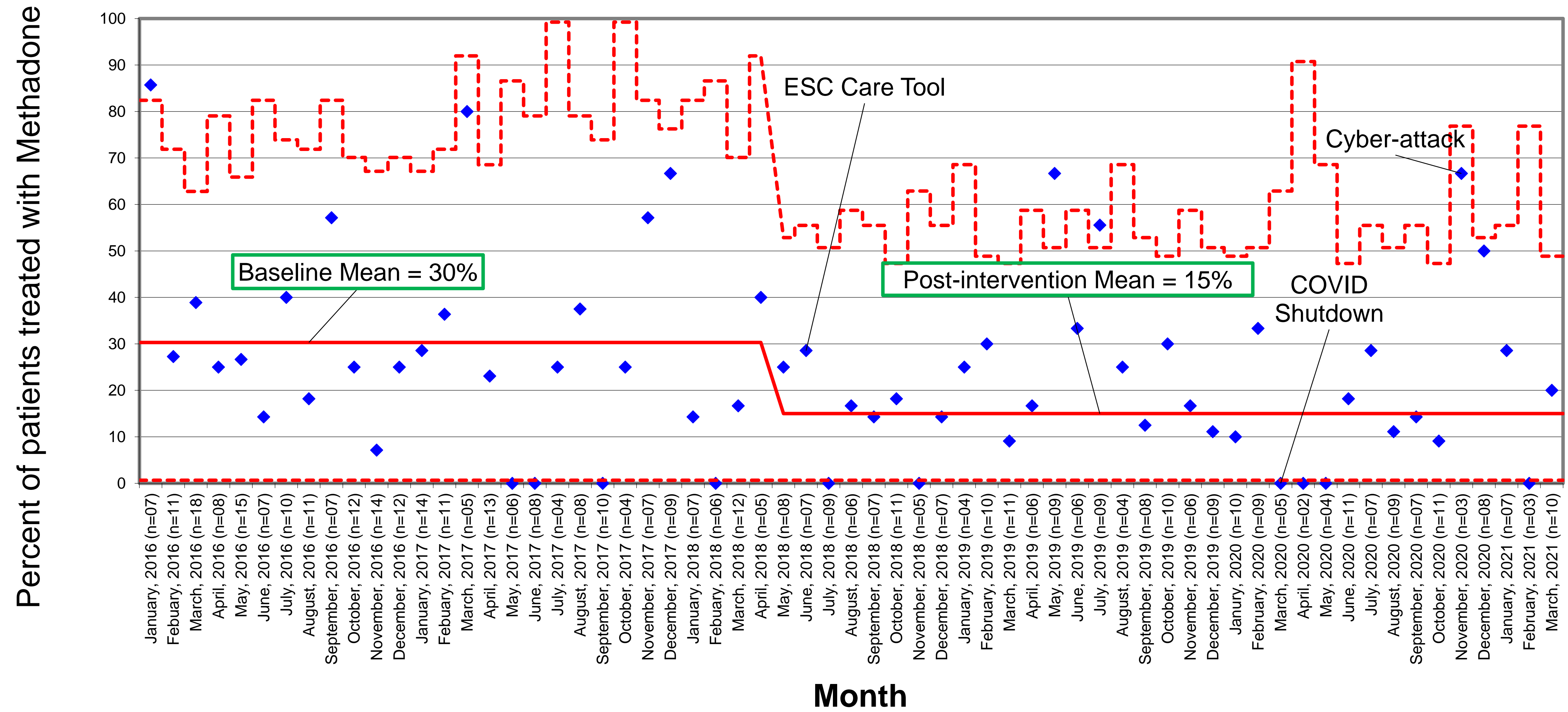

◆ Monthly percent of patients treated with Methadone — Mean - - - Control Limits

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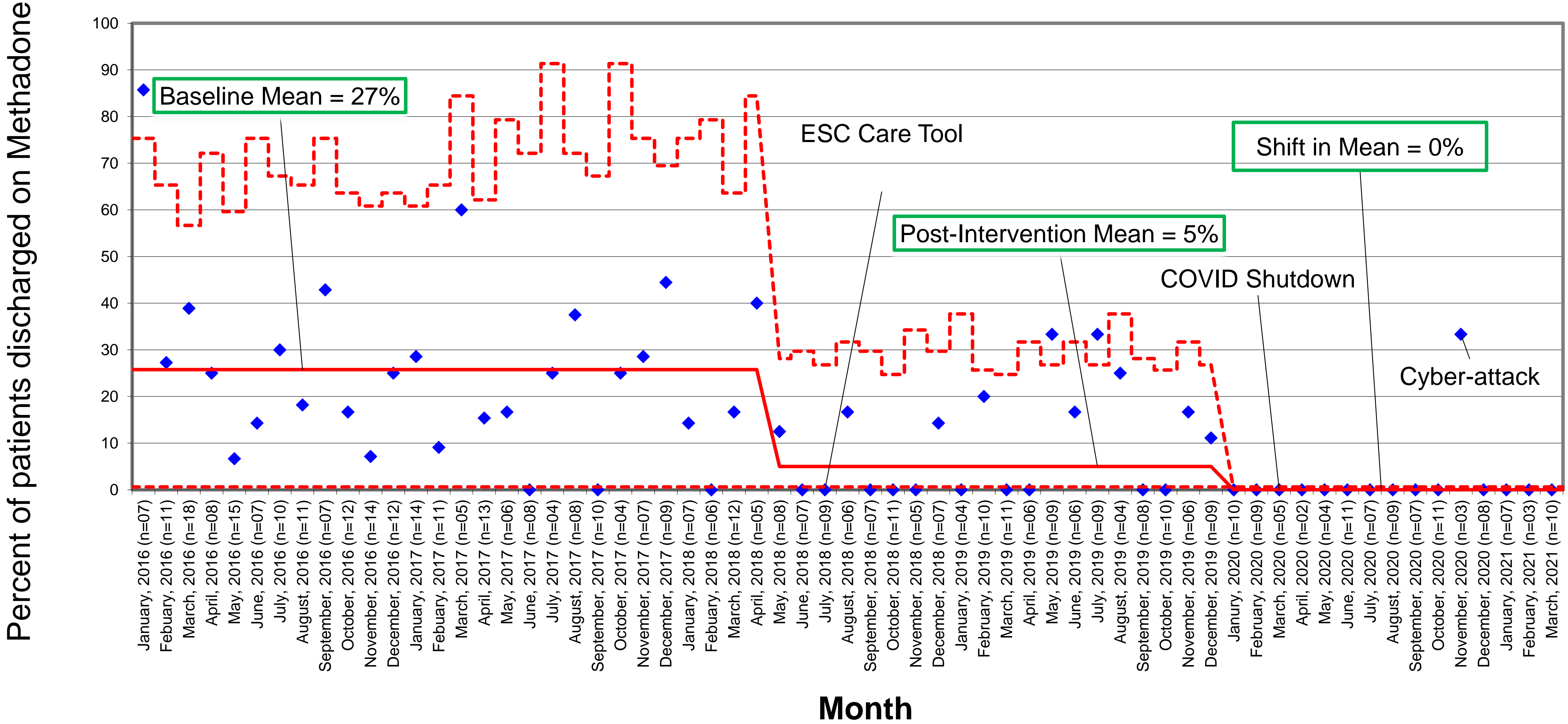
Percent of Opioid Exposed Newborns Discharged on Methadone



◆ Monthly percent of patients discharged on Methadone — Mean - - - Control Limits

Changes to the Model of Care – 2020

Pre-COVID

- Enhanced outpatient support with frequent touchpoints
- In person NeoMed visits every 2 weeks if discharged on Methadone
- Safety monitored through dose checking
- Outpatient support network available if safety concerns arise or patient did not come to appt

Post-COVID

- Touchpoints reduced or eliminated for social distancing
- NeoMed visit options reduced by at least 50% (telemedicine, exposure/quarantine)
- Unable to dose check by telemedicine
- Outpatient in person support network limited

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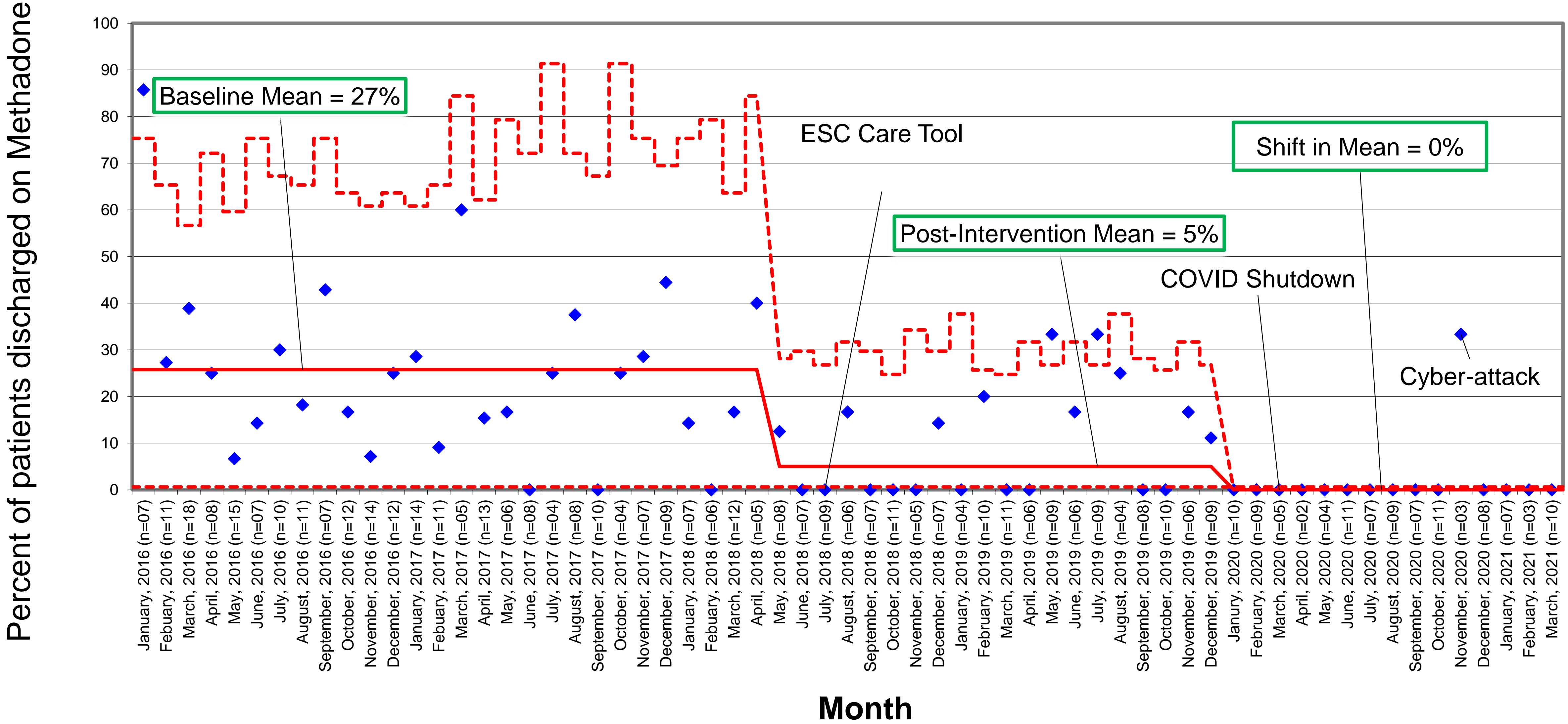
Percent of Opioid Exposed Newborns Discharged on Methadone



◆ Monthly percent of patients discharged on Methadone — Mean - - - Control Limits

Inpatient Wean

Key Driver: Changes to system related to COVID

Outpatient wean could be considered on a case by case basis

- Methadone vs Morphine
- Just-in-time dosing
- Pharmacokinetic model

JAMA Pediatrics | Original Investigation

Comparison of Safety and Efficacy of Methadone vs Morphine for Treatment of Neonatal Abstinence Syndrome
A Randomized Clinical Trial

Jonathan M. Davis, MD; Jeffrey Shenberger, MD; Norma Terrin, PhD; Janis L. Breeze, MPH; Mark Hudak, MD; Elisha M. Wachman, MD; Peter Marro, MD; Erica L. Oliveira, BA; Karen Harvey-Wilkes, MD; Adam Czynski, DO; Barbara Engelhardt, MD; Karen D'Apolito, PhD; Debra Bogen, MD; Barry Lester, PhD

ORIGINAL ARTICLE

Methadone versus morphine for treatment of neonatal abstinence syndrome: A prospective randomized clinical trial

MS Brown[1], MJ Hayes[2] and LM Thornton[3]

RESEARCH ARTICLE

Standard Fixed-Schedule Methadone Taper Versus Symptom-Triggered Methadone Approach for Treatment of Neonatal Opioid Withdrawal Syndrome

Elisha M. Wachman, MD,[a] Susan Minear, MD,[a] Meshelle Hirashima,[b] Aaron Hansbury, MPH,[c] Elizabeth Hutton, MD,[a,d] Hira Shrestha, MA,[a] Ginny Combs, RN,[a] Karan Barry, RN,[a] Cheryl Slater, RN,[a] Donna Stickney, RN,[a] Alexander Y. Walley, MD, MSc[e]

Pharmacokinetics of Oral Methadone in the Treatment of Neonatal Abstinence Syndrome: A Pilot Study

Jason R. Wiles, MD[1], Barbara Isemann, RPh[2], Tomoyuki Mizuno, PhD[3], Meredith E. Tabangin, MPH[4], Laura P. Ward, MD[1,5], Henry Akinbi, MD[1,5], and Alexander A. Vinks, PharmD, PhD[3,5]

Changes to the Model of Care – 2021

Outpatient Wean

- Stabilized on Methadone and discharged home (~10 hospital days)
- Methadone weaned twice weekly over 2-3 months (up to 100 days)
- Enhanced outpatient support
- Contract for dose check at in person NeoMed visits every 2 weeks
- Safety monitored through outpatient support network

Inpatient Wean

- Methadone weaned in the hospital (17-56 hospital days)
- Methadone weaned based on symptom assessment over weeks
- Enhanced inpatient support
- Developmental follow up in NeoMed, no contract
- Safety monitored by hospital personnel

Next focus?

CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care

Neonatal Opioid Withdrawal Syndrome

Stephen W. Patrick, MD, MPH, MS, FAAP,[a] Wanda D. Barfield, MD, MPH, FAAP,[b] Brenda B. Poindexter, MD, MS, FAAP,[c] COMMITTEE ON FETUS AND NEWBORN, COMMITTEE ON SUBSTANCE USE AND PREVENTION

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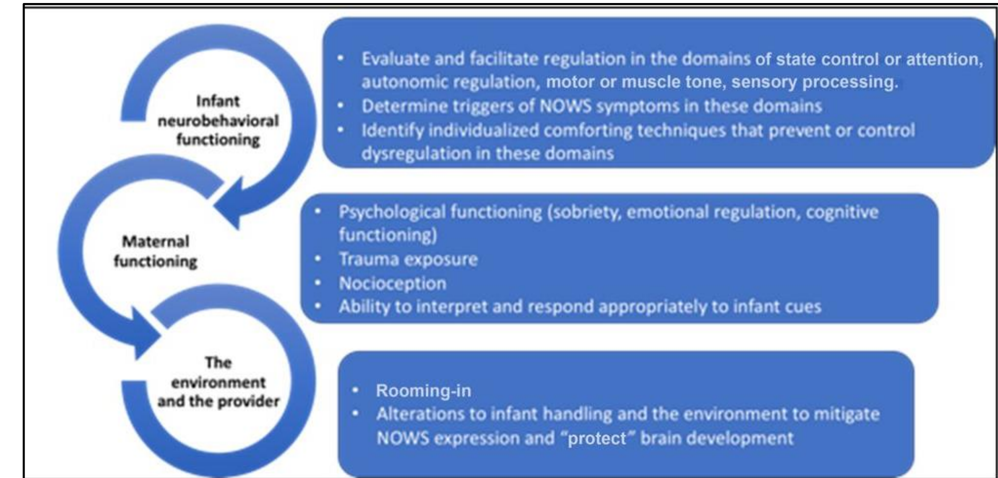
- Enhance family support in the hospital
- Encourage rooming in and breastfeeding when safe
- Connect families to resources
  - Social determinants of health
  - Maternal depression
  - Safe sleep
  - Tobacco cessation



Healthy moms = Healthy babies

Next focus?

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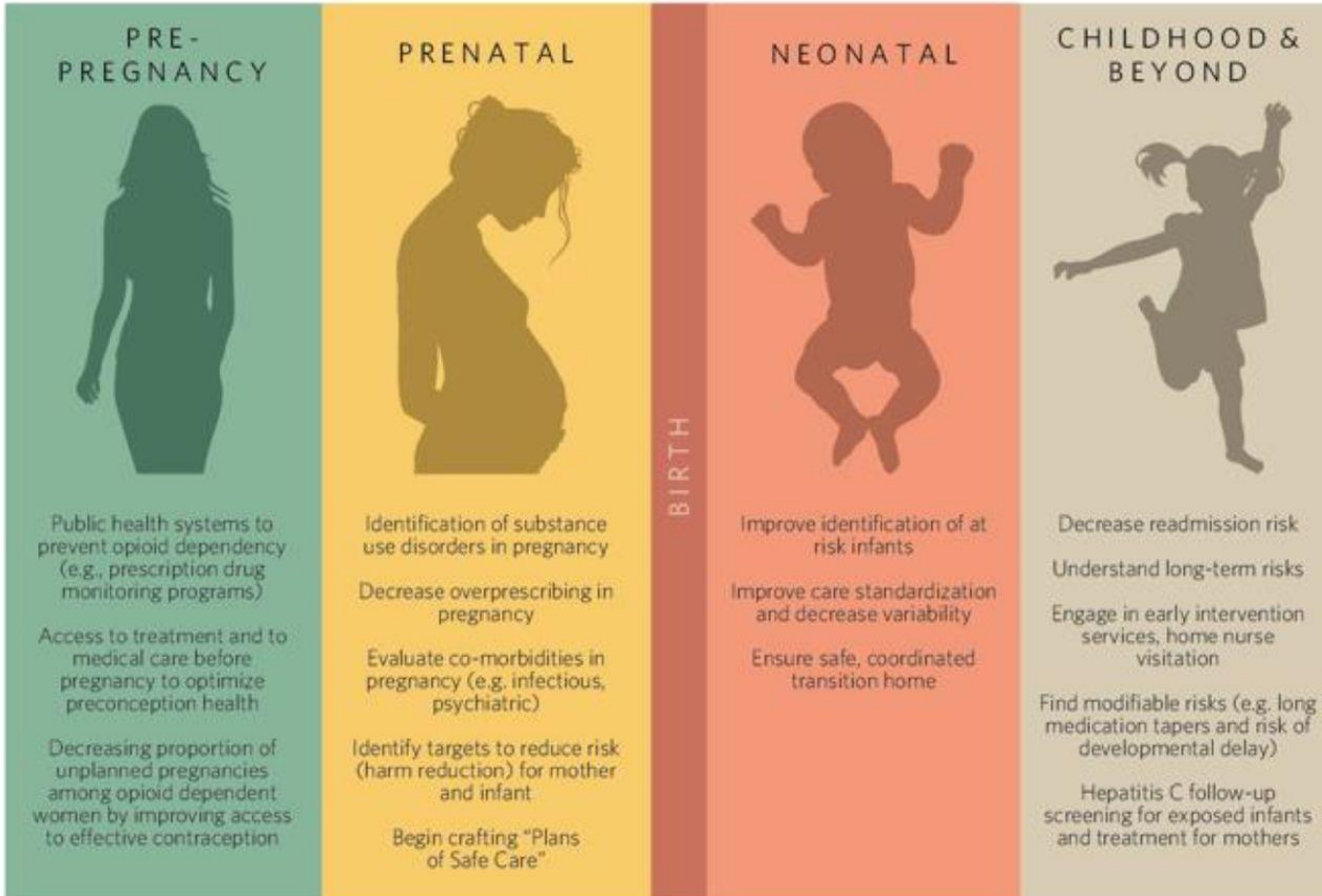

- Provide anticipatory guidance through antenatal counseling
- Provide a warm handoff to outpatient providers
- Optimize communication using the Plan of Safe Care

Healthy moms = Healthy babies