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# The Clinical Utility of Perinatal Toxicology Testing

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*Improving Care for Opioid-Exposed Newborns (ICON) Annual Statewide Conference  
Perinatal Quality Collaborative Vermont – April 9, 2024*



# Disclosure Statement

I, Davida Schiff, have no relevant financial relationships with the manufacturer(s) of any commercial product(s) and/or provider(s) of commercial services discussed in this CME activity.

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# Learning Objectives

At the conclusion of the presentation, participants should be able to:

1. Explain the differences in approaches to screening and testing for perinatal substance use
2. Understand the unique social and legal consequences of perinatal toxicology testing
3. Review principles of obtaining and documenting consent for toxicology
4. Describe disparities in the use of perinatal toxicology testing at delivery
5. Identify clinical scenarios where neonatal toxicology testing can inform clinical management
6. Advocate for evidence-informed, equity-based toxicology testing guidelines for newborns



# Core Values

Parents who use drugs should be treated with dignity and respect when they seek care for themselves and their children.

Parenting is hard, and non-punitive approaches that allow the parent, infant, dyad, and family to thrive should be promoted.

Child safety is everyone's responsibility



# Case:

27 y/o Black woman, G2P1 → 2, with history of stimulant and opioid use disorder in sustained remission on methadone, but with positive immunoassay toxicology test 6 weeks before delivery for amphetamines, parent does not endorse non-prescribed use at that time. Vaginal delivery at 39 weeks, baby boy w/ APGARS 8/9. Parent was motivated to breastfeed as she heard it can reduce the severity of neonatal opioid withdrawal.

- Hospital policy (2014) was to not support breastfeeding for dyads with third trimester substance use
- Parent breastfed her newborn despite hospital policy
- Child protective services was called, separated mom and baby
- Discharged home in foster care after prolonged treatment course for neonatal opioid withdrawal syndrome



# Many lingering questions from this case...

- What was the evidence informing that breastfeeding guideline?
- How frequently are toxicology test results false positives?
- What is the clinical utility of toxicology testing in the perinatal period?
- Did the parent harm their infant by offering him breastmilk that day?
- Would the same result have happened if this family was not Black?
- How could all of this have been prevented?



# Key Definitions

- **Screening:** use of a validated screening instrument or therapeutic dialogue to elicit information about substance use
  - E.g. NIDA Quick Screen, 4 P's.
- **Toxicology Testing:** collection of urine/serum/meconium to measure capture presence of substances and/or metabolites present at a particular point in time
- **Reporting:** referral to Child Protective Services for concern for child abuse/neglect



# Common Types of Perinatal Toxicology Testing

	Urine	Meconium	Umbilical Cord
Year developed	1971	1989	2006
Collection	Moderate	Moderate	Easy
Typical turn around time	<4hrs	2-5d	1-4d
Window of Detection	Short (3-4d)	Long (14wks gestation)	Intermediate (20wks gestation)
Drug Concentrations	Moderate	High	Low

*(Montgomery, 2006; Ostrea, 1989; Hadland, 2016)*





# Key Points about Toxicology Testing

- Urine toxicology testing measures recent(ish) exposure – cannabis and fentanyl metabolites can linger for weeks
- Most urine tests performed (quick cup, immunoassays) are not definitive and should be sent for confirmatory testing
- Many umbilical cord and meconium testing results do not come back until after the newborn has been discharged

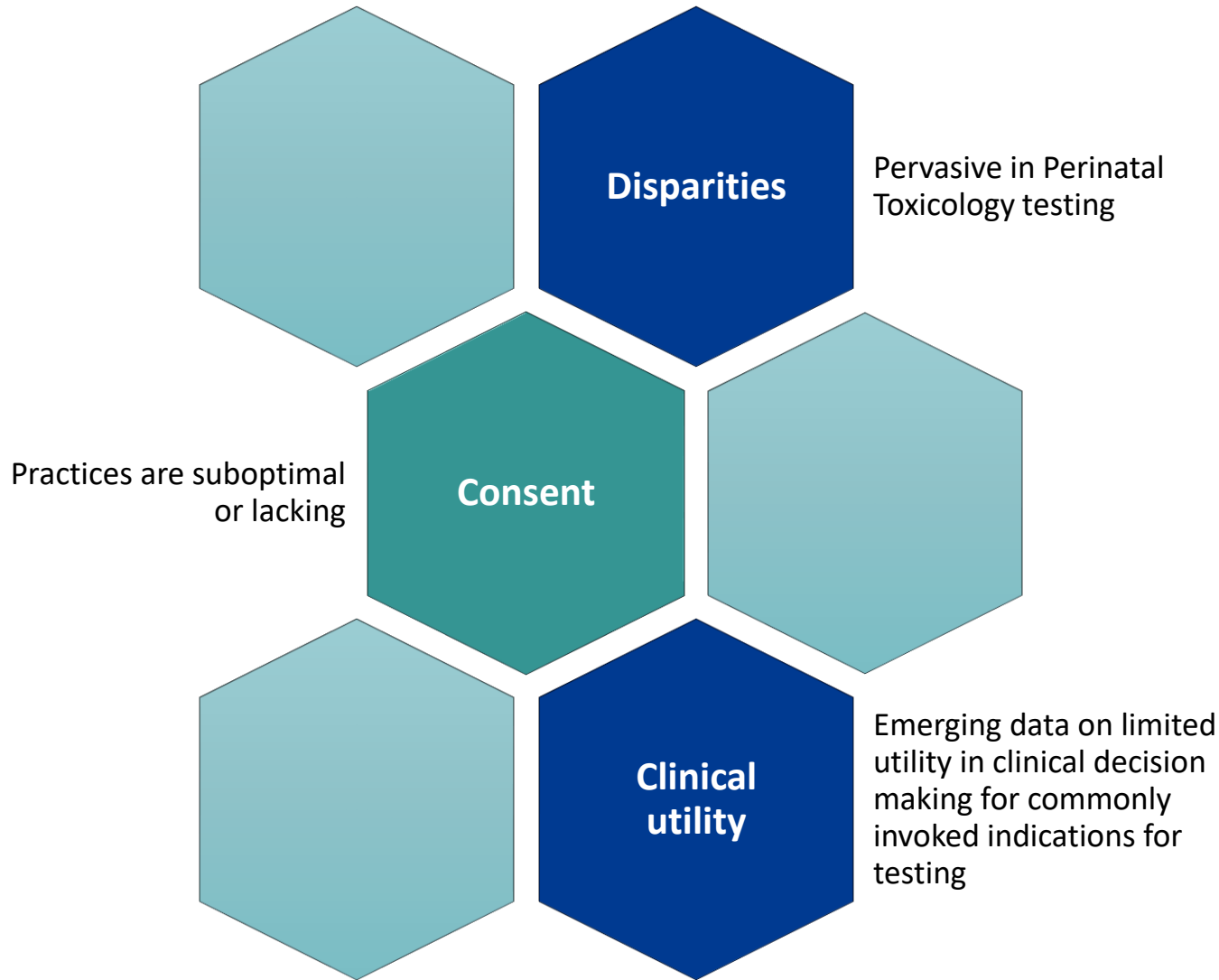


# Key Points about Toxicology Testing

- Urine toxicology testing measures recent(ish) exposure – cannabis and fentanyl metabolites can linger for weeks
- Most urine tests performed (quick cup, immunoassays) are not definitive and should be sent for confirmatory testing
- Many umbilical cord and meconium testing results do not come back until the newborn has been discharged
- Testing does NOT quantify dose, frequency, or duration of exposure, or if a parent has a substance use disorder
- A toxicology test is NOT a parenting test



# Why are many hospital systems and state PQC's re-evaluating perinatal tox testing approaches now?



# Disparities in Perinatal Toxicology Testing

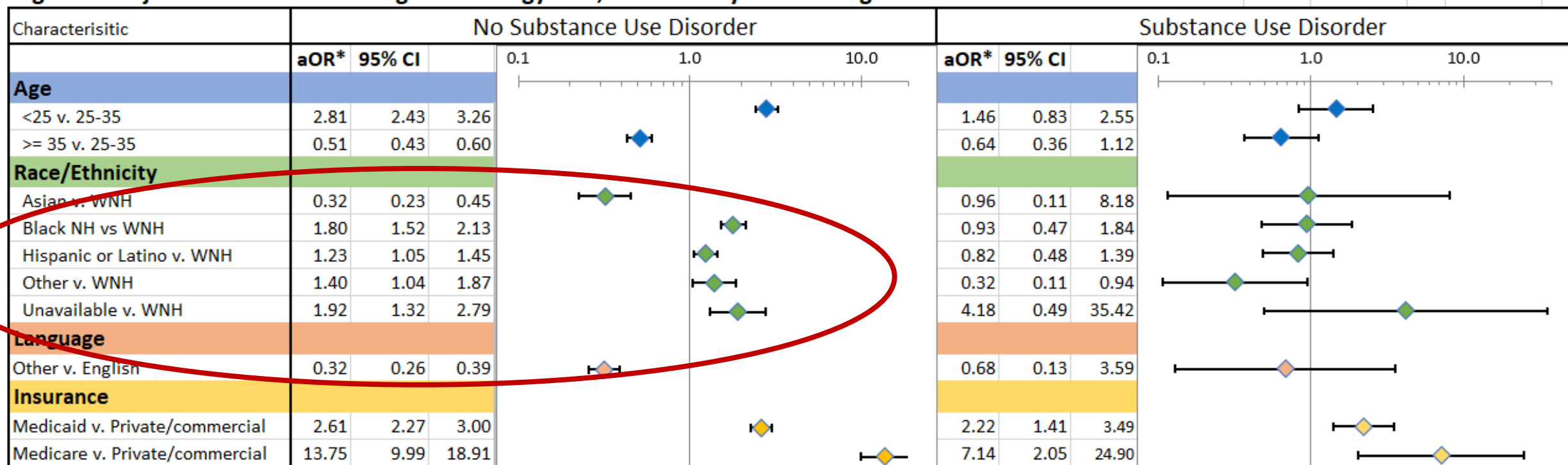


# Toxicology Testing is Inequitably Utilized at Delivery

## Disparities in Maternal-Infant Drug Testing, Social Work Assessment, and Custody at 5 Hospitals

Samuel Cohen, MD; Timothy Nielsen, MPH; Joseph H. Chou, MD, PhD; Bettina Hoepfner, PhD; Kathleen J. Koenigs, MD; Sarah N. Bernstein, MD; Nicole A. Smith, MD, MPH; Nicola Perlman, MD; Leela Sarathy, MD; Timothy Wilens, MD; Mishka Terplan, MD, MPH; Davida M. Schiff, MD, MSc

Figure 1. Adjusted Odds of Receiving a Toxicology Test, Stratified by ICD-10 Diagnosis of Substance Use Disorder



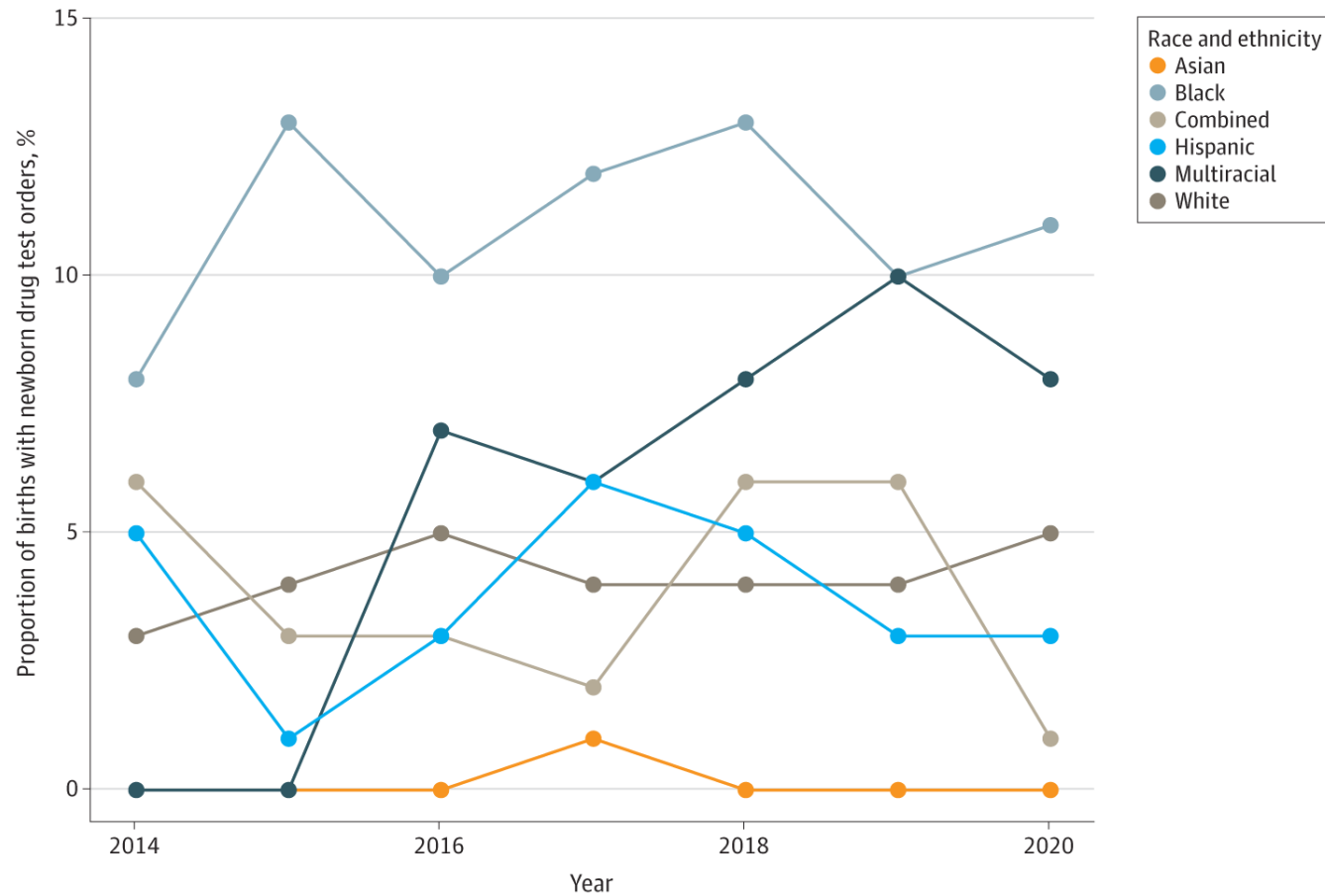
aOR = adjusted Odds Ratio

\*Model adjusted for year, hospital, and all variables listed above



Cohen, 2023

# Newborns born to Black birthing people were more likely to have toxicology testing performed than newborns born to White parents



- In a retrospective cohort study births at an academic center in Michigan from 2014 to 2020, clinicians were more likely to order drug tests for Black newborns (7.3%) compared with White newborns (1.9%) and other racial and ethnic groups

# Disproportionate Toxicology Testing and CPS Reporting Practices in a California NICU

THE JOURNAL OF PEDIATRICS • www.jpeds.com

ORIGINAL  
ARTICLES



## Structural Racism Operationalized via Adverse Social Events in a Single-Center Neonatal Intensive Care Unit

Kayla L. Karvonen, MD<sup>1,2</sup>, Erica Anunwah, MD<sup>1</sup>, Brittany D. Chambers Butcher, PhD, MPH<sup>2,3</sup>, Lydia Kwarteng, BS, MPH<sup>4</sup>, Tameyah Mathis-Perry, BS<sup>5</sup>, Monica R. McLemore, PhD, MPH, RN, FAAN<sup>6</sup>, Sally Oh, BS<sup>4</sup>, Matthew S. Pantell, MD, MS<sup>1,2</sup>, Olga Smith, MS, RN, CCRN<sup>7</sup>, and Elizabeth Rogers, MD<sup>1,2</sup>

Table III. Odds of social adverse events by race and ethnicity<sup>\*,†</sup>

Race and ethnicities <sup>‡</sup>	CPS referral		Infant urine toxicology screen		Any adverse event	
	OR (95% CI)	P value	OR (95% CI)	P value	OR (95% CI)	P value
American Indian and Alaska Native	15.8 (6.9-36.0)	<b>&lt;.001</b>	7.6 (3.4-17.2)	<b>&lt;.001</b>	10.2 (4.7-21.9)	<b>&lt;.001</b>
Asian	0.2 (0.1-0.5)	<b>0.002</b>	0.2 (0.1-0.4)	<b>&lt;.001</b>	0.2 (0.1-0.5)	<b>&lt;.001</b>
Black	3.6 (2.2-6.1)	<b>&lt;.001</b>	2.2 (1.4-3.5)	<b>.001</b>	3.5 (2.4-5.2)	<b>&lt;.001</b>
Latinx	1.3 (0.8-2.0)	.33	0.7 (0.5-1.1)	0.14	0.9 (0.6-1.3)	0.60
Native Hawaiian or Pacific Islander	§	§	1.0 (0.2-4.2)	1.0	1.3 (0.4-4.4)	.66
White	Referent group		Referent group		Referent group	

Bold typeface indicates statistical significance  $P < .05$ .

\*Adjusted for length of stay.

†Outcomes with <50 events were excluded from analysis.

‡“Other” race and ethnicity excluded owing to small sample size.

§Unable to run effect estimate secondary to small sample size.



# Consent for Toxicology Testing





# Guidelines stipulate clinicians should obtain informed consent prior to toxicology testing in pregnancy



ACOG Committee Opinion No. 711, 2017; ASAM, 2017; SAMHSA; Ecker et al. AJOG 2019; Charlestown v. City of Ferguson, 2001



# Maternal Toxicology Consent Poorly Documented at 5 Hospitals in Massachusetts

Original Research

American Journal of Obstetrics & Gynecology  
AJOG MFM

Informed consent is poorly documented when obtaining toxicology testing at delivery in a Massachusetts cohort



Kathleen J. Koenigs, MD; Joseph H. Chou, MD, PhD; Samuel Cohen, MD; Moira Nolan, BA; Gina Liu, MSc; Mishka Terplan, MD, MPH; Brian M. Cummings, MD; Timothy Nielsen, MPH; Nicole A. Smith, MD, MPH; Joseph Distefano, BS; Sarah N. Bernstein, MD; Davida M. Schiff, MD, MSc

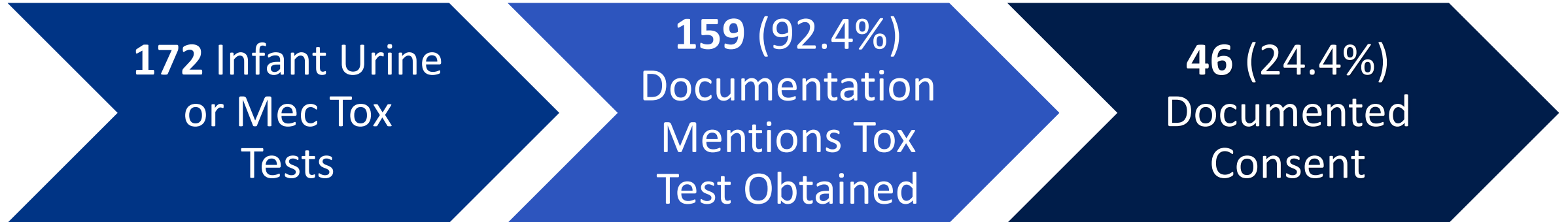


Verbal consent documented  
in ***fewer than 30% of cases***

Koenigs, 2022



# Random Sample of Infant @ MGH with Similarly Low Rates of Documented Consent



*Preliminary MGH QI Data, 2021*



# Components of informed consent



Explicit clarification for the provider and patient about the goal of testing



Discussion of who will have access to the results



Review of ramifications of a positive test



Describe the right for a person to refuse testing, and the limits on refusal (for minors)

Written consent preferred for accountability, as an educational tool, and patient preference



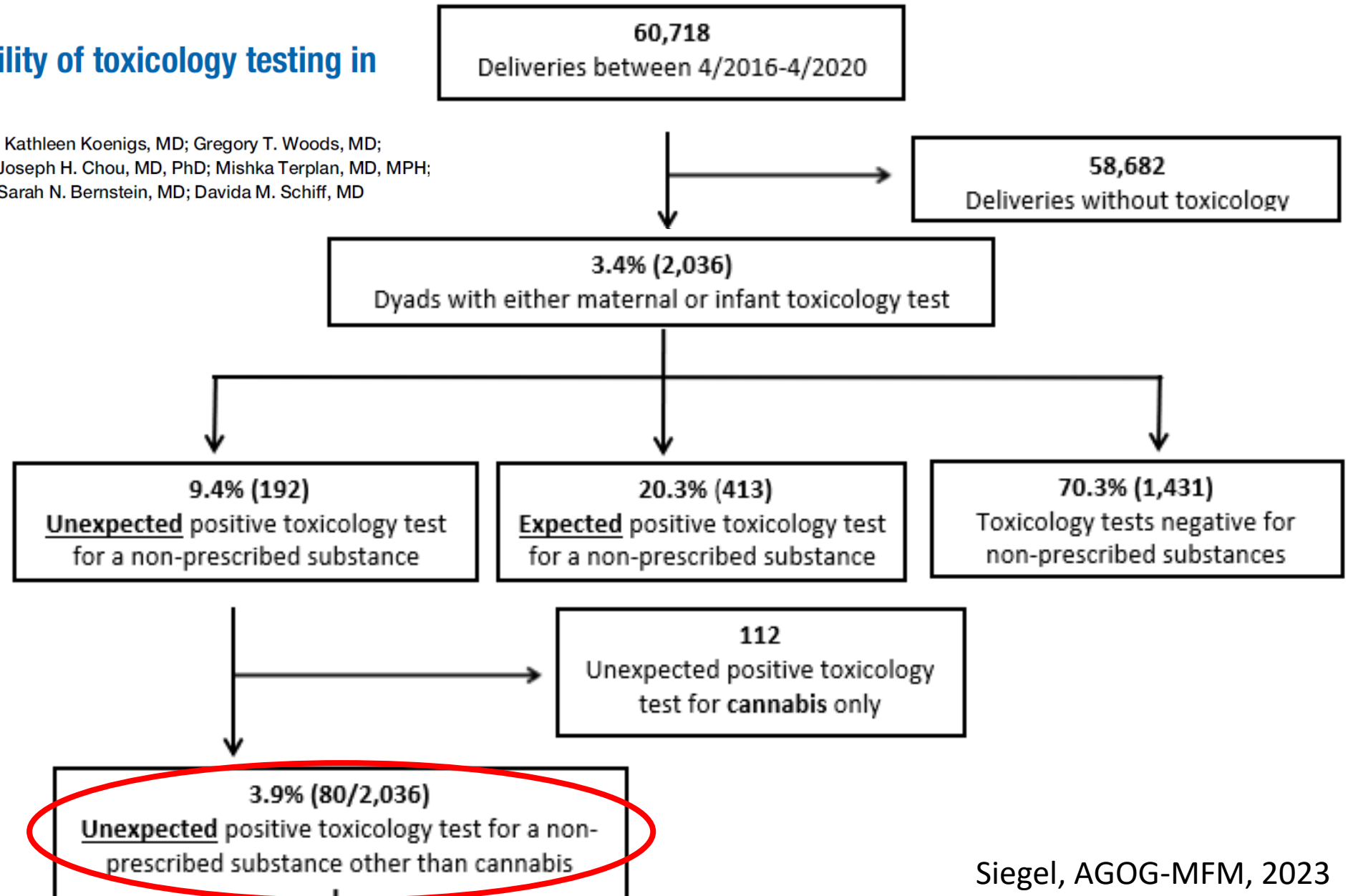
# Utility of Toxicology Testing



# Original Research

## Assessing the clinical utility of toxicology testing in the peripartum period

Molly R. Siegel, MD; Samuel J. Cohen, MD; Kathleen Koenigs, MD; Gregory T. Woods, MD; Leah N. Schwartz, BA; Leela Sarathy, MD; Joseph H. Chou, MD, PhD; Mishka Terplan, MD, MPH; Timothy Wilens, MD; Jeffrey L. Ecker, MD; Sarah N. Bernstein, MD; Davida M. Schiff, MD



# Unexpected Positive Drug Testing by Testing Rationale

Clinical Rationale for Test	Unexpected Positive Results, n (%)
<b>High Yield Indications</b>	
History of Recent SUD (within past 2 yrs) (N=422)	45 (10.7%)
Inadequate Prenatal Care (N=154)	9 (5.8%)
Maternal MOUD w/o active SUD in past 2 yrs (N=159)	6 (3.8%)
<b>Medium Yield Indications</b>	
Maternal Medical Indications (N=351)	8 (2.3%)
History of SUD, in remission >2yrs (N = 159)	1 (1.7%)
Maternal Cannabis Use (N=699)	11 (1.6%)
<b>Low Yield Indications</b>	
Monitoring for Controlled Substance Rx (N=37)	0 (0%)
Infant Clinical Presentation (N=69)	0 (0%)
Other/Unknown (N=83)	0 (0%)
<b>TOTAL (N=2036)</b>	<b>80 (3.9%)</b>

# What are the reasons to perform a newborn toxicology test?

- Will it benefit the patient?
- Will it change disposition/anticipatory guidance?
- [Will it change the need for social work or child protective services (CPS) consultation?]



Slide courtesy of Sarathy and Ostfeld-Johns, 2023



# Meconium and Umbilical Cord Toxicology testing are often opioid negative in clinically diagnosed NOWS

**Table 2**

NAS diagnosis with an opioid positive meconium test result.

					Percent
Meconium		NAS ICD9		Sensitivity	65
		Positive	Negative	Specificity	85
Opioid test result	Positive	65	47	PPV	58
	Negative	35	260	NPV	88

**Table 3**

NAS diagnosis with an opioid positive umbilical cord test result.

					Percent
Umbilical Cord Tissue		NAS ICD10		Sensitivity	79
		Positive	Negative	Specificity	76
Opioid test result	Positive	75	177	PPV	30
	Negative	20	559	NPV	97

Clinical Biochemistry 50 (2017) 1093–1097



Contents lists available at ScienceDirect

Clinical Biochemistry

journal homepage: [www.elsevier.com/locate/clinbiochem](http://www.elsevier.com/locate/clinbiochem)



Method performance and clinical workflow outcomes associated with meconium and umbilical cord toxicology testing

Ruth M. Labardee<sup>a</sup>, Jaime R. Swartzwelder<sup>b</sup>, Karen E. Gebhardt<sup>b</sup>, Justine A. Pardi<sup>b</sup>, Anna C. Dawsey<sup>c</sup>, R. Brent Dixon<sup>d</sup>, Steven W. Cotten<sup>b,\*</sup>



- 35% of all cases of ICD-Dx NOWS were opioid negative in meconium toxicology testing
- 21% of all cases of ICD-Dx NOWS were opioid negative in umbilical cord tissue testing

# Maternal Urine Drug Testing More Beneficial for Predicting Neonatal Outcomes Compared with Umbilical Cord Testing

THE JOURNAL OF MATERNAL-FETAL & NEONATAL MEDICINE  
2023, VOL. 36, NO. 1, 2211706  
<https://doi.org/10.1080/14767058.2023.2211706>



ORIGINAL ARTICLE

OPEN ACCESS

Can umbilical cord testing add to maternal urine drug screen for evaluation of infants at risk of neonatal opioid withdrawal syndrome?

Hannah Gersch<sup>a</sup>, Darshan Shah<sup>a</sup>, Alyson Chroust<sup>b</sup> and Beth Bailey<sup>a,c</sup>

	Dyads with Positive Maternal Urine Tox at Delivery (n=572)	Dyads with Positive Umbilical Cord Testing at Delivery (n=353)	Dyads with Both Positive (n=202)
NOWS Diagnosis	5.62 (3.06-10.33)	2.58 (1.60-4.15)	1.91 (1.03-3.56)

	n	Positive Agreement Between Umbilical Cord and Maternal Urine Drug Testing	Negative Agreement Between Umbilical Cord and Maternal Urine Drug Testing	Mcnemar's Significance, p
All Opioids	202	12.9%	97.1%	<0.001



# How did unexpected toxicology results (n=80) affect decision making at delivery?

(n) % of changes in type of management	Highest Yield Clinical Rationales	Med Yield Clinical Rationales	Total
Maternal Counseling	23 (38.3%)	10 (50.0%)	33 (41.3%)
NOWS Management	12 (20.0%)	6 (30.0%)	18 (22.8%)
Breastfeeding	10 (16.4%)	7 (36.8%)	17 (21.3%)
CPS Reporting	23 (37.7%)	11 (57.9)	34 (42.5%)
Change in Parental Custody at Discharge	16 (26.7%)	2 (10.0%)	18 (22.5%)

**In 18 of 60,712 deliveries, an unexpected toxicology test resulted in a custody change at discharge (0.03%)**



# Infant toxicology testing should be completed when it informs clinical management

- Concerns of chronic opioid exposure in utero AND no screening nor testing of the birthing person available → determine need for appropriate observation period
- Unexpected symptoms manifest which could be consistent with withdrawal and are unresponsive to nonpharmacologic care (ESC) → determine appropriate pharmacologic intervention
- **Meconium testing has limited clinical benefit**
  - In the era of ESC, successful treatment usually does not hinge on rapid identification of specific substance exposure
  - Need for accurate data on substance use during pregnancy as a public health metric is not contingent on clinically performed biochemical testing



*Slide courtesy of Dr. Sharon Ostfeld-Johns*

# Current National Professional Society Guidelines



# Professional Society Recommendations around Perinatal Toxicology testing

## **American College of Obstetrics and Gynecology/Society of Maternal Fetal Medicine (2017, 2019)**

- Universal verbal screening as first-line tool to diagnose substance use disorder in pregnancy
- “Urine drug testing should only be undertaken when it benefits outweigh any harms”
- Consent for urine drug testing
- Explicit criteria for urine drug testing to avoid bias and discrimination

## **American Society of Addiction Medicine (in addition to above) (2023)**

- Right of refusal and refusing a toxicology test should neither be seen as indication of use nor detract from clinical care
- Confirmatory testing should be utilized
- A positive test is not determinative of a SUD
- Parents should be made aware of newborn toxicology testing and whenever possible permission should be obtain
- Infant meconium and umbilical cord testing lack clinical utility and are not recommended



# Professional Society Recommendations around Perinatal Toxicology testing

## American Academy of Pediatrics – NOWS Clinical Report, 2020

“Pediatricians should be aware of and reduce institutional biases in implementing universal toxicology testing for infants, which could result in unequal consequences for mothers and infants on the basis of race, ethnicity, and/or socioeconomic status.”

“Infant toxicology testing should be completed when it will inform clinical management. In some instances, testing of the infant provides no additional clinical information and would not be recommended.”



Addressing commonly  
asked questions when  
considering reducing  
neonatal toxicology  
testing





# What is the value added in obtaining newborn urine toxicology testing in addition to birthing person test at delivery?

- 1573 pregnancies where all birthing person and newborns were testing
- After removing medications dispensed during delivery hospitalization:
  - Positive Predictive Value – 61.3%
  - Negative Predictive Value – 100%

## Original Research

AJOG American Journal of Obstetrics & Gynecology

### Concordance and discordance between maternal and newborn drug test results

Katrina Mark, MD, FACOG; Lauren Pace, MS; Sarah M. Temkin, MD; Sarah Crimmins, MD; Mishka Terplan, MD, MPH



# Epistemic Injustice: Harm from not trusting our patients

## Test or Talk

*Empiric Bias and Epistemic Injustice*



Mishka Terplan, MD, MPH

“When we listen to the drug test and not the patient, we perpetuate a mistaken empiricism—one that **falsely elevates the value of information collected from measurement over the value of information collected from a person.** This is an *epistemic injustice*—a harm done by devaluing a person's credibility and undermining them as a giver of knowledge. The neglect, silence, or erasure of the patient's voice and perspective harms not only them, but it also harms us as physicians—it deflates us in our capacity to know and to heal. To be blunt: **dehumanizing people makes their care environment unsafe,** and to expect people to be forthcoming about sensitive and potentially catastrophic information under such circumstances is irrational.”

*Terplan, Obstetrics and Gynecology, 2022*



# So what do we do if a parent declines testing?

Clinical Decision Making	Birth person/infant	Is there an alternate approach?
Concern for altered mental status	Birth Person	Supportive Management
Will it aid in maternal counselling and referral to SUD treatment?	Birth Person	Verbal Screening
Will it aid in the management of withdrawal symptoms?	Infant	Monitoring infant for clinical s/s
Will it aid in the discussion of breastfeeding recommendations?	Dyad	Universal precautions for breastfeeding recs
Does the result aid in meeting mandated reporting requirements?	Dyad	Assessment of infant safety risks, psychosocial screening



# Is toxicology testing needed to inform anticipatory guidance?

- Safety considerations in the home
- Recommendations for human milk
- Discussions around safe sleep
- Other harm reduction strategies

## Information to know about breastmilk and substance use



Have you thought about breastfeeding or providing your breast milk?  
If you are interested, please talk to your care team.

### **What are the benefits of breastfeeding?**

- Soothing your baby
- May reduce the need for medications for newborn withdrawal
- Decreasing infections in infancy
- Providing nutrition to your baby
- Increasing bonding between you and your baby
- Lowering your risk of postpartum depression and other diseases

### **What are the risks of breastfeeding if I have recently used non- prescribed drugs?**

- You may not be able to safely respond to your baby's cues
- Your breastmilk may contain substances or contaminants from the drug supply that can harm your baby

**Breastfeeding is not recommended if  
you are actively using  
non-prescribed drugs.**

### **What about other conditions or medications?**

- Medications for opioid use disorder (methadone, buprenorphine, Suboxone) are safe with breastfeeding
- It is safe to breastfeed with Hepatitis C, unless you have cracked or bleeding nipples
- You can breastfeed if you smoke cigarettes or vape, but try to minimize how much smoke or vapor your baby is exposed to
- Other conditions? Please talk to your care team

### **What if I plan to stop using non- prescribed drugs?**

- It may take 3-4 days until substances are no longer present in your breastmilk
- If you need to wait to provide breastmilk, you can pump to maintain your supply until it is safe to breastfeed
- Drug testing may be useful to see what level of substance remains in your body
- Your care team can help you create a relapse plan in case you start using substances again



# Breastfeeding is a human right

BREASTFEEDING MEDICINE  
Volume 17, Number 8, 2022  
© Mary Ann Liebert, Inc.  
DOI: 10.1089/bfm.2022.29216.abm

Open camera or QR reader and  
scan code to access this article  
and other resources online.



## Academy of Breastfeeding Medicine Position Statement: Breastfeeding As a Basic Human Right

Lori Feldman-Winter,<sup>1</sup> Trina Van,<sup>2</sup> Daphna Varadi,<sup>2</sup> Amanda C. Adams,<sup>3</sup>  
Bahar Kural,<sup>4</sup> and Elien C.J. Rouw<sup>5</sup>

*Moving towards a culture of shared  
decision making to inform  
breastfeeding decision making*



CocoMilla etsy.com



# AND, we need to carefully track balancing measures

- From 2021-2023 at MGH, there have been no cases of:
  - Readmission for NOWS
  - Readmission for intoxication related to breastmilk exposure
  - Readmissions in 30d for new social concerns or non-accidental trauma/maltreatment evaluation



# Returning to our Case:

27 y/o Black woman, G2P1 → 2, with history of stimulant and opioid use disorder in sustained remission on methadone, but with positive immunoassay toxicology test 6 weeks before delivery for amphetamines, parent does not endorse non-prescribed use at that time. Vaginal delivery at 39 weeks, baby boy w/ APGARS 8/9. Parent was motivated to breastfeed as she heard it can reduce the severity of neonatal opioid withdrawal.

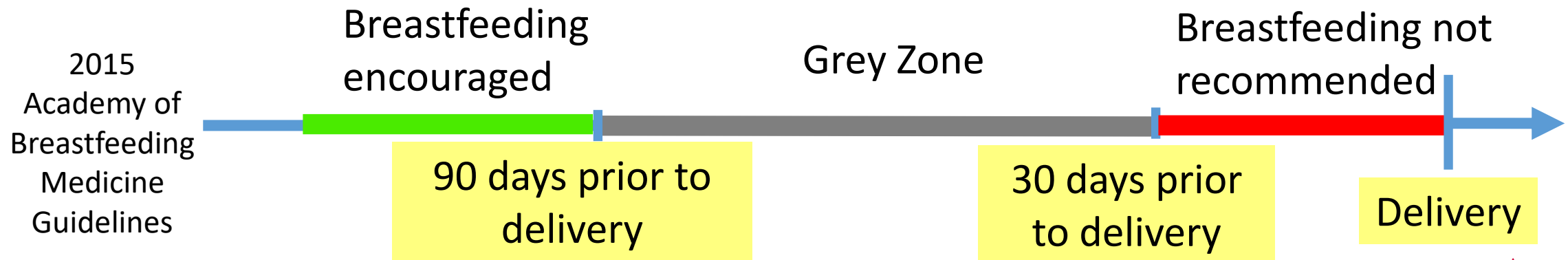
- Hospital policy (2013) was to not support breastfeeding for dyads with third trimester substance use
- Parent breastfed her newborn despite hospital policy
- Child protective services was called, separated mom and baby
- Discharged home in foster care after prolonged treatment course for neonatal opioid withdrawal syndrome





# 2015 ABM Guidelines restricted breastfeeding to pregnant individuals w/o recent substance use

- Support breastfeeding for substance-exposed dyads if the mother is:
  - In a substance use treatment program on opioid agonist therapy
  - Receiving consistent prenatal care
  - No medical contraindications to breastfeeding
  - No non-prescribed drug use for a specified time period prior to delivery:





# Prenatal Toxicology Testing and Breastfeeding Initiation

- A single-site retrospective cohort study of 503 women receiving OUD treatment at Boston Medical Center found that results of urine drug testing at delivery had the strongest association (**aOR 3.72**) with ongoing non-prescribed use postpartum

ORIGINAL RESEARCH

JOURNAL OF  
**Addiction Medicine**  
The Official Journal of the American Society of Addiction Medicine

## A Retrospective Cohort Study Examining the Utility of Perinatal Urine Toxicology Testing to Guide Breastfeeding Initiation

*Miriam Harris, MD, MSc, Kathleen Joseph, MD, Bettina Hoepfner, PhD, MSc, Elisha M. Wachman, MD, Jessica R. Gray, MD, Kelley Saia, MD, Sarah Wakeman, MD, Megan H. Bair-Merritt, MD, MSc, and Davida M. Schiff, MD, MSc*

	90-30d before delivery	Within 30d of delivery	At delivery
Sensitivity	44%	26%	27%
Specificity	74%	79%	93%
Pos Predictive Value	36%	36%	56%
Neg Predictive Value	80%	86%	78%
Chi-Squared Test	P =0.033	P=0.006	P<0.001

Harris et al. JAM. 2020



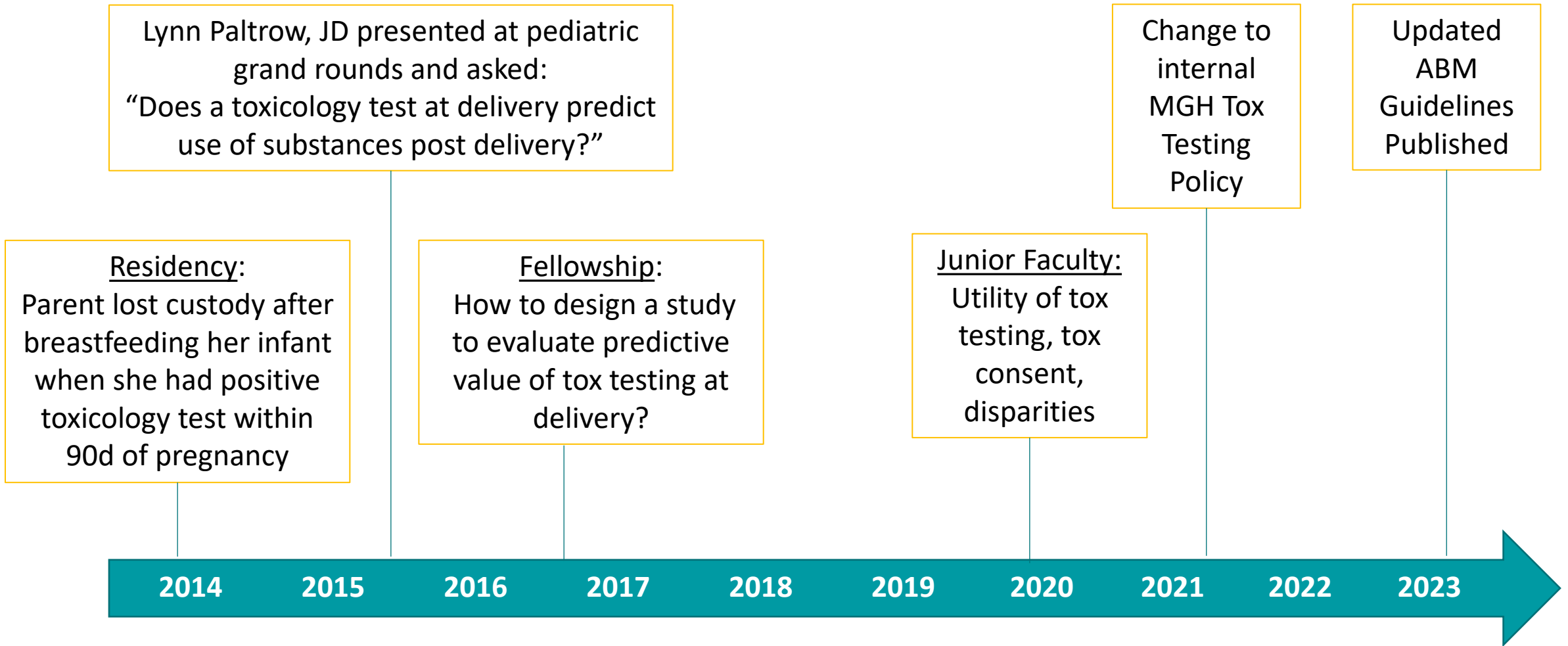
HARVARD  
MEDICAL SCHOOL



MASSACHUSETTS  
GENERAL HOSPITAL



# Anatomy of an idea: the long arc of research



BREASTFEEDING MEDICINE  
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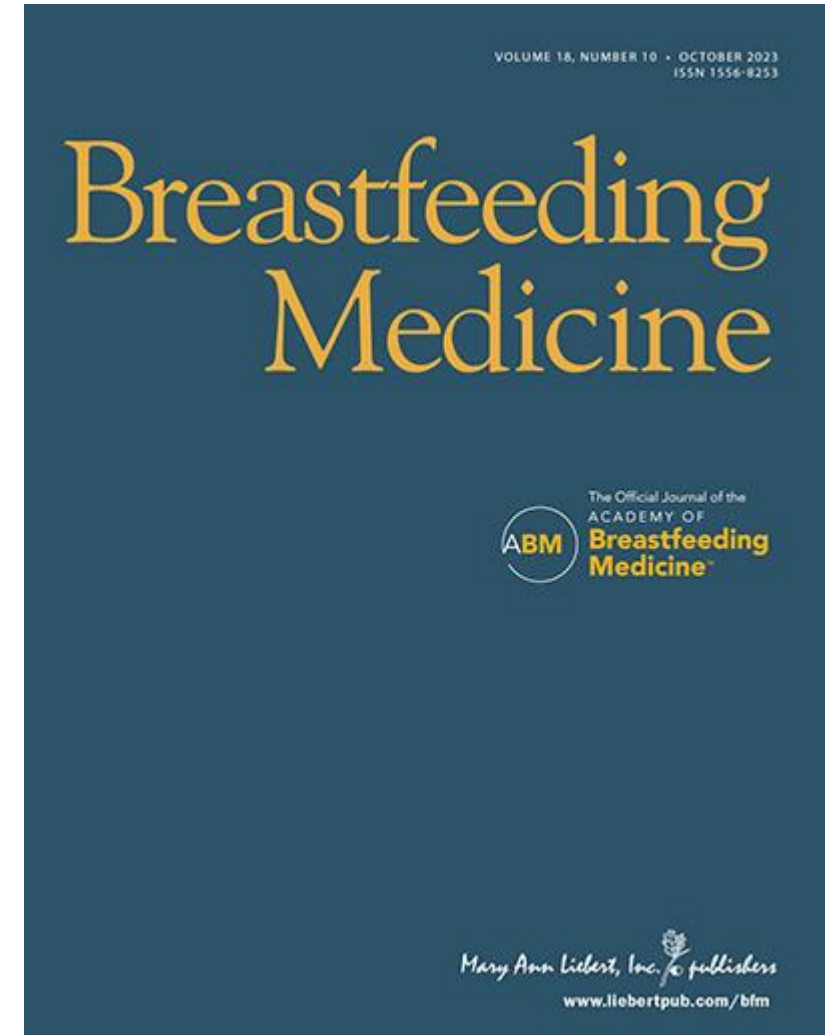
## *ABM Protocol*

Open camera or QR reader and  
scan code to access this article  
and other resources online.



# Academy of Breastfeeding Medicine Clinical Protocol #21: Breastfeeding in the Setting of Substance Use and Substance Use Disorder (Revised 2023)

Miriam Harris,<sup>1,2</sup> Davida M. Schiff,<sup>3,4</sup> Kelley Saia,<sup>2,5</sup> Serra Muftu,<sup>3,4</sup>  
Katherine R. Standish,<sup>6</sup> and Elisha M. Wachman<sup>2,7</sup>



# Changes you may wish to make /are making / have made(!) in practice:

1. Implement written consent as part of drug testing protocols in the perinatal period
2. Review clinical rationales for drug testing, consider removal of low-yield indications
3. Reconsider what information is gained from obtaining a neonatal toxicology test, and how it will help guide clinical management
4. Adopt updated Academy of Breastfeeding Guidelines promoting breastfeeding for parents without substance use at delivery



# THANK YOU!

## Questions?

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<https://www.massgeneral.org/children/research/prism>

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