

**Improving Outcomes and Mortality from Fentanyl
– MOUD split dose, Toxicology, Breastfeeding:
Toxicology Testing during Pregnancy and in
Newborns**

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Disclosure Information

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- ◆ No conflicts of interest to disclose



Learning Objectives

1. Discuss the clinical utility and complexity of maternal toxicology testing, including the complexity of toxicology testing in the setting of fentanyl
2. Discuss the clinical utility and complexity of newborn toxicology testing and review the impact of putting an objective clinically-focused guideline in place with respect to testing and health equity
3. Discuss implications of screening and toxicology testing strategies in clinical practice

Screening recommendations

- ◆ “The official position of the American Society of Addiction Medicine (ASAM) and the American College of Obstetricians and Gynecologists is that all women should be screened using a validated screening test, and not biochemical measures.”

Screening Pregnant Women and Their Neonates for Illicit Drug Use: Consideration of the Integrated Technical, Medical, Ethical, Legal, and Social Issues. [Hayley R. Price](#), [Abby C. Collier](#), and [Tricia E. Wright](#): [Front Pharmacol](#). 2018; 9: 961.



Example of validated screener:

TAPS: Tobacco, Alcohol, Prescription medication, and other Substance use Tool

- ◆ In the past 12 months, how often have you used tobacco or any other nicotine delivery product (i.e., e-cigarette, vaping or chewing tobacco)?
 - ◆ Daily or almost daily, weekly, monthly, less than monthly, never
- ◆ Repeats with alcohol, prescription medications (“just for the feeling, more than prescribed or that were not prescribed to you”), or other drugs (“any drugs including marijuana, cocaine or crack, heroin, methamphetamine (crystal meth), hallucinogens, ecstasy/MDMA”)
- ◆ If any positive response, ask “In the past 3 months have you used _____?”
- ◆ If yes, ask “In the past 3 months have you had a strong desire or urge to use _____ at least once a week or more often?” and “In the past 3 months, has anyone expressed concern about your use of _____?”

- ◆ “self-reports of substance use are most likely to be valid when participants believe that they will not suffer negative consequences.”

Hilario et al. Denial of urinalysis-confirmed opioid use in prescription opioid dependence. *J Subst Abuse Treat* 2015 48:85-90.

- ◆ Correlation 96-98% of self-reported cigarette smoking with biochemical detection

Baheiraeia et al. Association of self-reported passive smoking in pregnant women with cotinine level of maternal urine and umbilical cord blood at delivery. *Paediatric and Perinatal Epidemiology*. (2011) 26, 7076.

Editorial

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*

In diagnosis and management of SU/SUD, what is the role of toxicology testing?

- ◆ “While it can be a powerful tool, a drug test is designed to answer a rather narrow question: is substance X detected in sample Y?”
- ◆ “Drug testing provides another source of information to complement self-report, collateral report, and provider assessment. Having an additional alternative means of assessing a patient’s recent substance use is important to treatment planning and ongoing treatment adjustment.”
- ◆ “...drug testing has the potential to improve patient outcomes if used correctly and consistently to monitor and adjust treatment plans.”



Legal considerations when obtaining toxicology testing on pregnant patients

- ◆ “Biomedical surveillance should be conducted only for clinical purposes having to do with ensuring access to and delivering quality health care.”

AMA Journal of Ethics. When Should Screening and Surveillance Be Used during Pregnancy? Nancy D. Campbell, PhD, March 2018.

- ◆ “The U.S. Supreme Court has ruled that it is unconstitutional to use the results of drug testing obtained in the guise of medical care for law enforcement purposes without informed specific consent to a search for evidence of a crime.”

Ferguson v. City of Charleston, 532 U.S. 67 (2001); Id. on remand, 308 F.3d 380 (4th Cir. 2002)

Cited in National Advocates for Pregnant Women policy statement: Clinical Drug Testing of Pregnant Women and Newborns March 2019

ACOG Committee Opinion No. 711, 2017; ASAM, 2017; SAMHSA; Ecker et al. AJOG 2019
Koenigs et al. Informed consent is poorly documented when obtaining toxicology testing at delivery in a Massachusetts cohort. *AJOG MFM*. 2022



What is the purpose of drug testing in pregnant patients?

- ◆ Results of tests do not provide information about parenting
 - ◆ “Routine urine drug testing...does not provide valid or reliable information about harm or risk of harm to children.”

ACOG Toolkit for State Legislature Pregnant Women & Prescription Drug Abuse, Dependence & Addiction

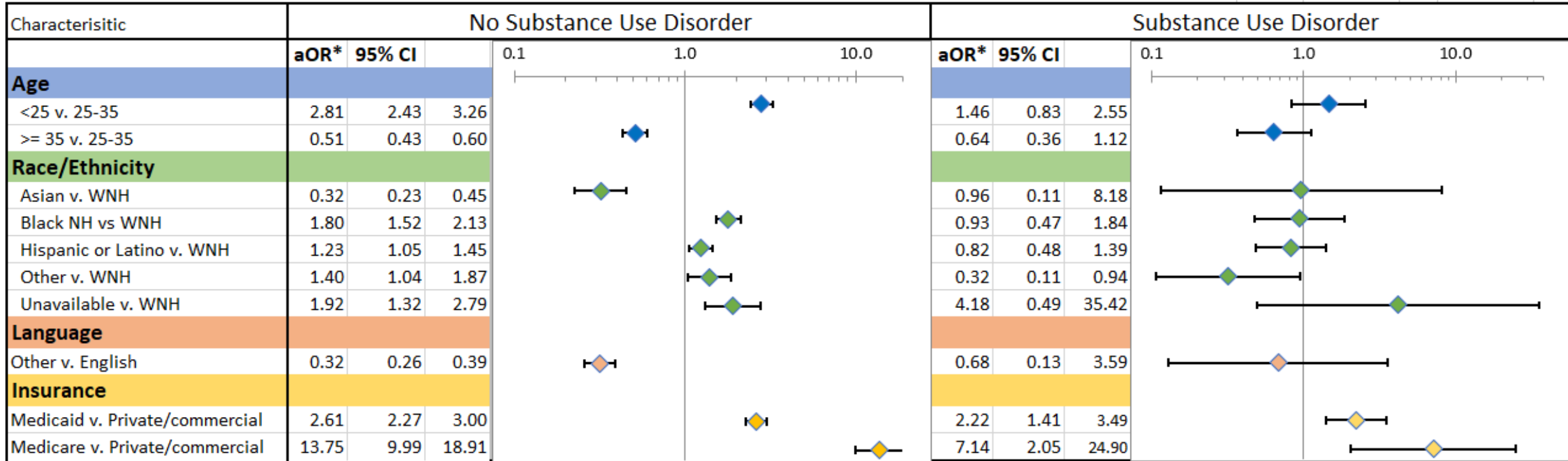


DISPARITIES

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

GAPS ARE NARROWED WHEN SUBSTANCE USE DISORDER IS PRESENT

Adapted from Dr. Davida Schiff



Newborn toxicology tests...

- ◆ ...are often redundant to known information
- ◆ ...rarely alter medical care
- ◆ ...rarely alter consultation or disposition
- ◆ ...should be ordered only for medical reasons, unless specific informed consent for obtaining for legal purposes is obtained
- ◆ ...rarely are required by law
- ◆ ...may be interpreted by the legal system incorrectly
- ◆ ...reinforce stigma against people who use substances
- ◆ ...may be used in ways that differentially harm patients of color and families parenting in poverty



AAP Technical Report 2013 Prenatal Substance Abuse: Short- and Long-Term Effects on the Exposed Fetus

NYU Review of Law & Social Change 2019 The Harm of Child Removal Shanta Trivedi Mical Raz, Alan Dettlaff, Frank Edwards; The Perils of Child "Protection" for Children of Color: Lessons From History. *Pediatrics* July 2021; 148 (1).

Mark et al. Maternal and infant cannabis testing and associated birth outcomes. *Arch Gynecol Obstet.* 2023
Mark et al. Concordance and discordance between maternal and newborn drug test results. *Am J Obstet Gynecol MFM.*

Ferguson v. City of Charleston, 532 U.S. 67 (2001); Id. on remand, 308 F.3d 380 (4th Cir. 2002)

Cited in National Advocates for Pregnant Women policy statement: Clinical Drug Testing of Pregnant Women and Newborns March 2019

ACOG Toolkit for State Legislature Pregnant Women & Prescription Drug Abuse, Dependence & Addiction

Terplan, M. Test or talk: Empiric bias and epistemic injustice. *Obstetrics & Gynecology.* Volume 140; No. 2, Aug 2022.

AMA Journal of Ethics. When Should Screening and Surveillance Be Used during Pregnancy? Nancy D. Campbell, PhD, March 2018.



Newborn toxicology testing

- ◆ The point is this isn't relevant in the vast majority of cases including:
 - ◆ Optimal clinical care for newborns with prenatal substance exposure
 - ◆ Breastfeeding recommendations for newborns with prenatal substance exposure
 - ◆ Legal mandates related to promoting treatment for prenatal substance exposure and maintaining family togetherness

Conversations began...

- ◆ Ideas percolating within Pediatric Hospital Medicine Section
- ◆ Support from Section Chief
- ◆ Support from head of Child Abuse Section
- ◆ Support from medical director of Newborn Nursery
- ◆ Conversations with OB team
- ◆ Support from SW leadership
- ◆ Trainee involvement
- ◆ Support from Addiction Medicine colleagues

New connections

- ◆ Connections made with workers and researchers at DCF to generate data about CAPTA referrals
- ◆ Use of tests as substantiation of claim of harm
 - ◆ Mutual deference
 - ◆ Usually ordered when requested by SW or DCF (or expectation of this)
 - ◆ Per discussions with DCF, they thought they were ordered for medical purposes
- ◆ Now: working on future projects and research, involved in state level policy groups

What kind of test?

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

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

Review of all umbilical cord tests sent at L&M in the last 3 years

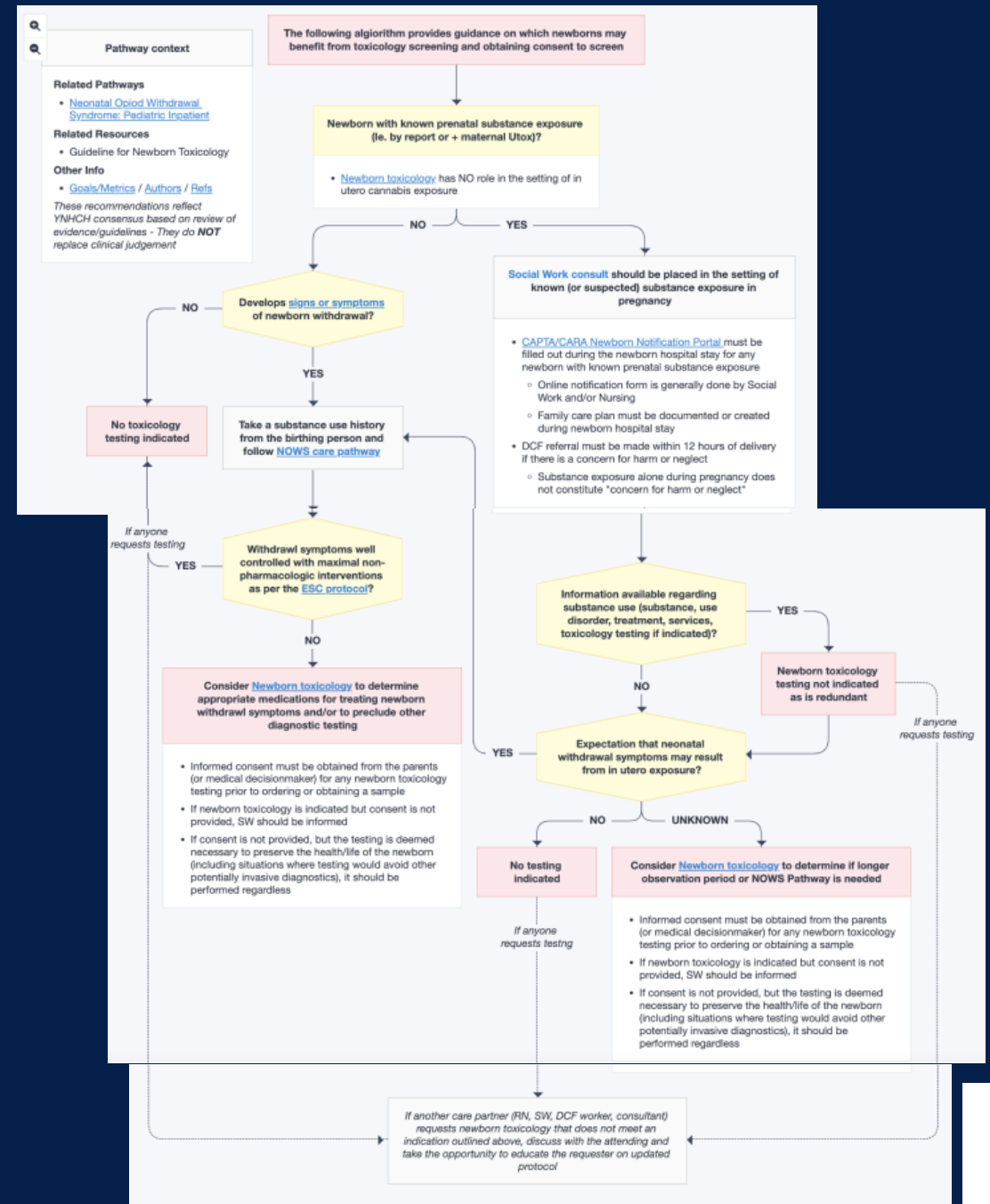
- ◆ Unexpected positive results (ie there was no known substance use but a clinical concern arose and a test resulted positive)
 - ◆ 0%
- ◆ Test results changed clinical care or treatment plan
 - ◆ 0%
- ◆ Test results changed Family Care Plan or disposition plan (ie home with family)
 - ◆ 0%

If toxicology testing is deemed relevant to the clinical care of the newborn

- ◆ Urine toxicology testing is standard of care for withdrawal in adult population and is deemed appropriate for detection of substance resulting in withdrawal
- ◆ Urine toxicology is the only kind of testing that provides actionable information

UpToDate: Opioid withdrawal in adults: Clinical manifestations, course, assessment, and diagnosis

The newborn toxicology pathway





Pathway context

Related Pathways

- [Neonatal Opioid Withdrawal Syndrome: Pediatric Inpatient](#)

Related Resources

- [Guideline for Newborn Toxicology](#)

Other Info

- [Goals/Metrics](#) / [Authors](#) / [Refs](#)

*These recommendations reflect YNHCH consensus based on review of evidence/guidelines - They do **NOT** replace clinical judgement*

The following algorithm provides guidance on which newborns may benefit from toxicology screening and obtaining consent to screen

Newborn with known prenatal substance exposure (ie. by report or + maternal Utox)?

- [Newborn toxicology](#) has NO role in the setting of in utero cannabis exposure

NO YES

Social Work consult should be placed in the setting of known (or suspected) substance exposure in pregnancy

- [CAPTA/CARA Newborn Notification Portal](#) must be filled out during the newborn hospital stay for any newborn with known prenatal substance exposure
 - Online notification form is generally done by Social Work and/or Nursing
 - Family care plan must be documented or created during newborn hospital stay
- DCF referral must be made within 12 hours of delivery if there is a concern for harm or neglect
 - Substance exposure alone during pregnancy does not constitute "concern for harm or neglect"

Develops **signs or symptoms** of newborn withdrawal?

NO

YES

No toxicology testing indicated

Take a substance use history from the birthing person and follow [NOWS care pathway](#)



If anyone requests testing

YES

Withdrawal symptoms well controlled with maximal non-pharmacologic interventions as per the [ESC protocol](#)?

NO

Consider [Newborn toxicology](#) to determine appropriate medications for treating newborn withdrawal symptoms and/or to preclude other diagnostic testing

- Informed consent must be obtained from the parents (or medical decisionmaker) for any newborn toxicology testing prior to ordering or obtaining a sample
- If newborn toxicology is indicated but consent is not provided, SW should be informed
- If consent is not provided, but the testing is deemed necessary to preserve the health/life of the newborn (including situations where testing would avoid other potentially invasive diagnostics), it should be performed regardless

Information available regarding substance use (substance, use disorder, treatment, services, toxicology testing if indicated)?

YES

Newborn toxicology testing not indicated as is redundant

NO

Expectation that neonatal withdrawal symptoms may result from in utero exposure?

YES

NO

UNKNOWN

No testing indicated

If anyone requests testing

Consider [Newborn toxicology](#) to determine if longer observation period or NOWS Pathway is needed

- Informed consent must be obtained from the parents (or medical decisionmaker) for any newborn toxicology testing prior to ordering or obtaining a sample
- If newborn toxicology is indicated but consent is not provided, SW should be informed
- If consent is not provided, but the testing is deemed necessary to preserve the health/life of the newborn (including situations where testing would avoid other potentially invasive diagnostics), it should be performed regardless

If anyone requests testing

Research questions

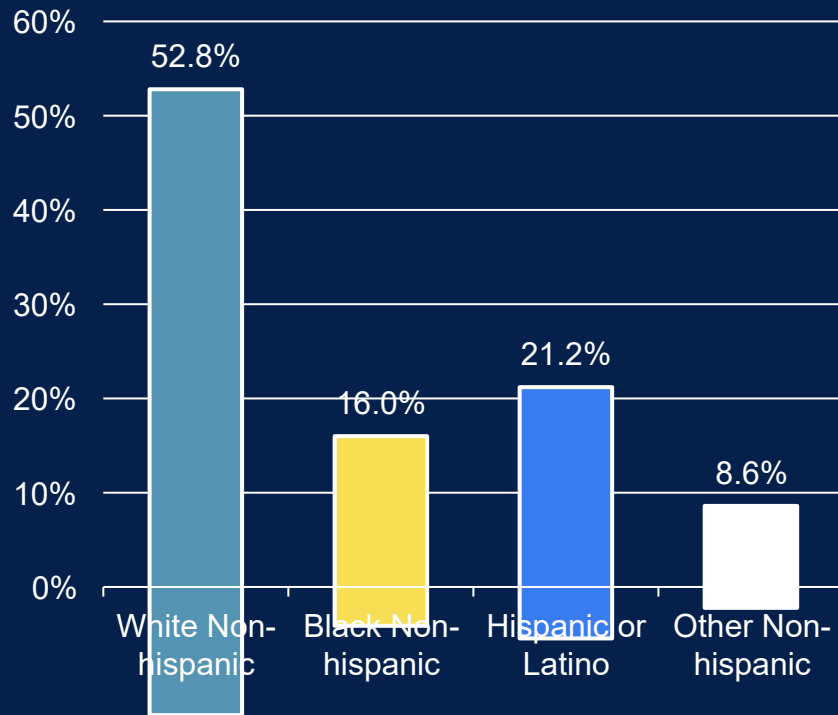
- ◆ Within our health system, prior to an objective protocol, what were the rates of toxicology testing in newborns, and were there differences in the rate of testing in different groups?
 - ◆ Race (NHB, NHW, HL, Other)
 - ◆ Insurance (Medicaid, private insurance)
 - ◆ Income
- ◆ What were the differences in the rates of positivity of testing?
- ◆ What were the differences in what the tests were positive for (e.g. cannabis only, MOUD medications only, etc)?

Research questions

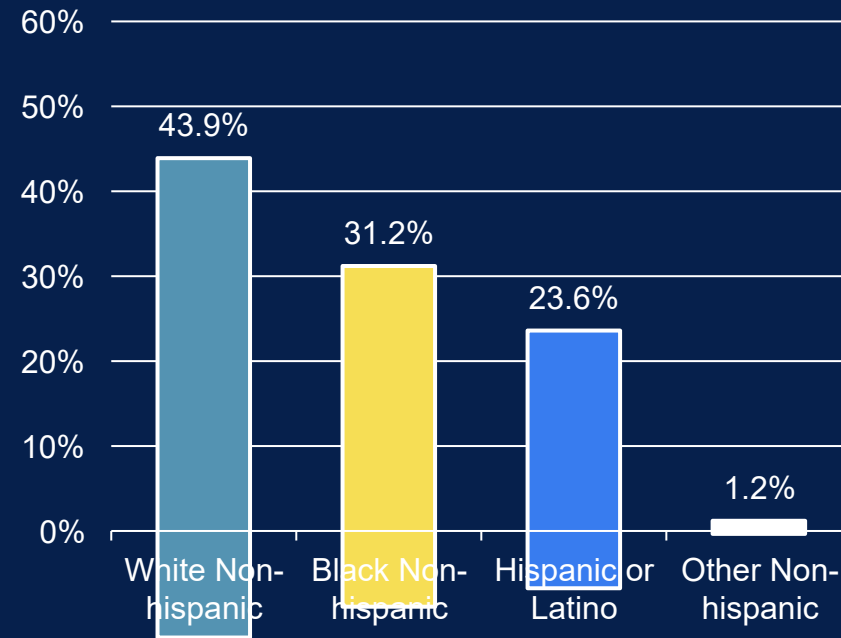
- ◆ Were we making unnecessary/low yield DCF referrals?
- ◆ When we put in place an objective clinically-directed testing protocol, did we change testing patterns, disparities, and downstream outcomes?

Differences in test collection by race

Newborns by Race

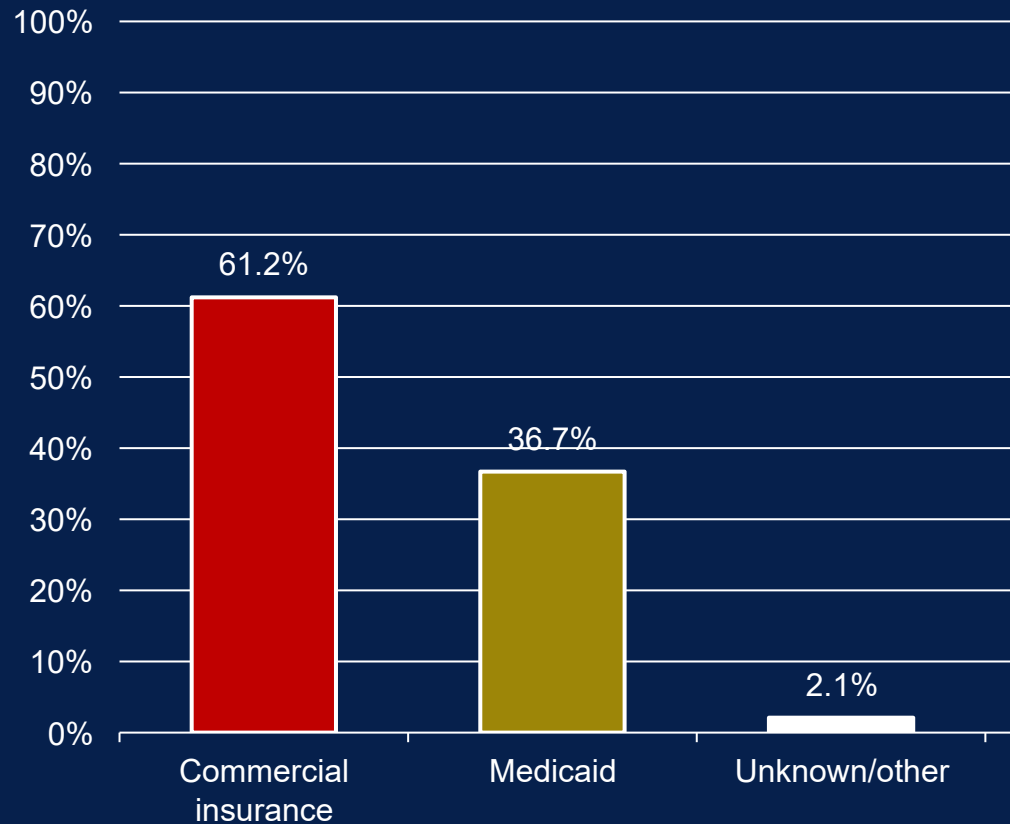


Toxicology Tests Collected by Race

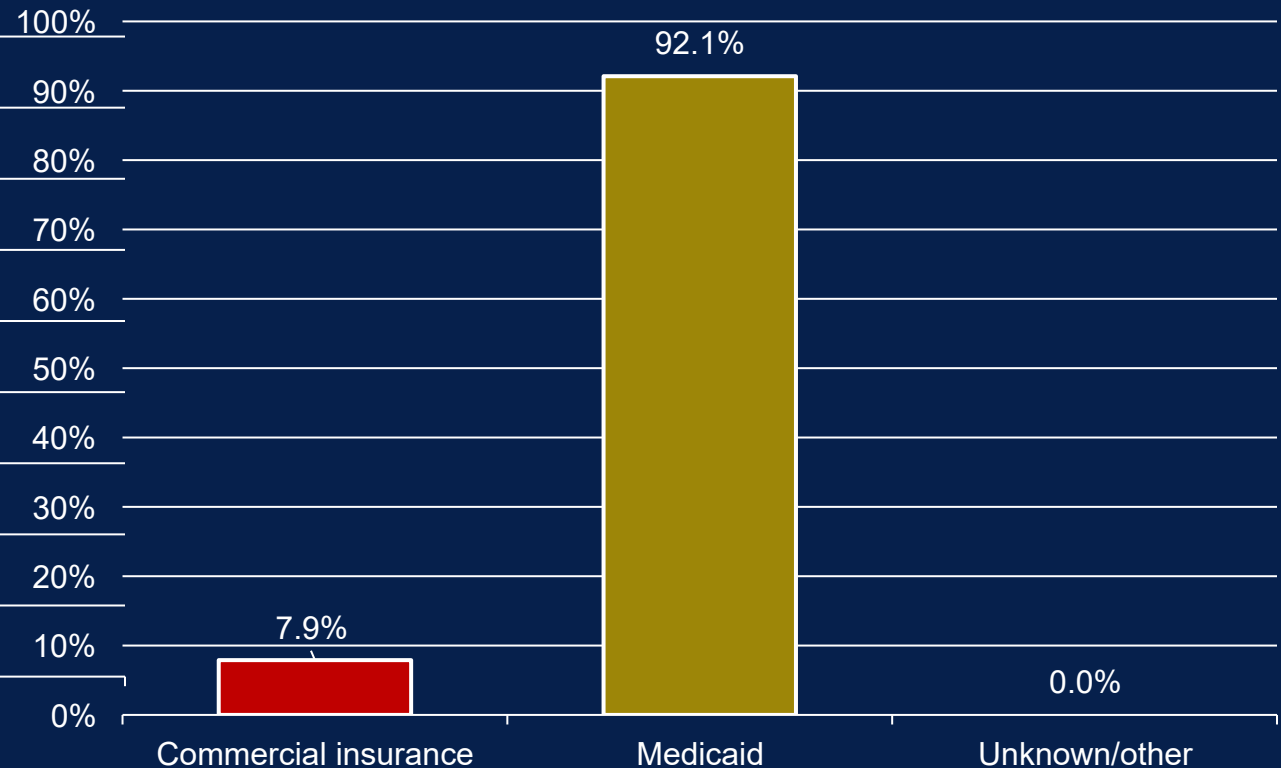


Differences in test collection by insurance

Newborns by insurance provider

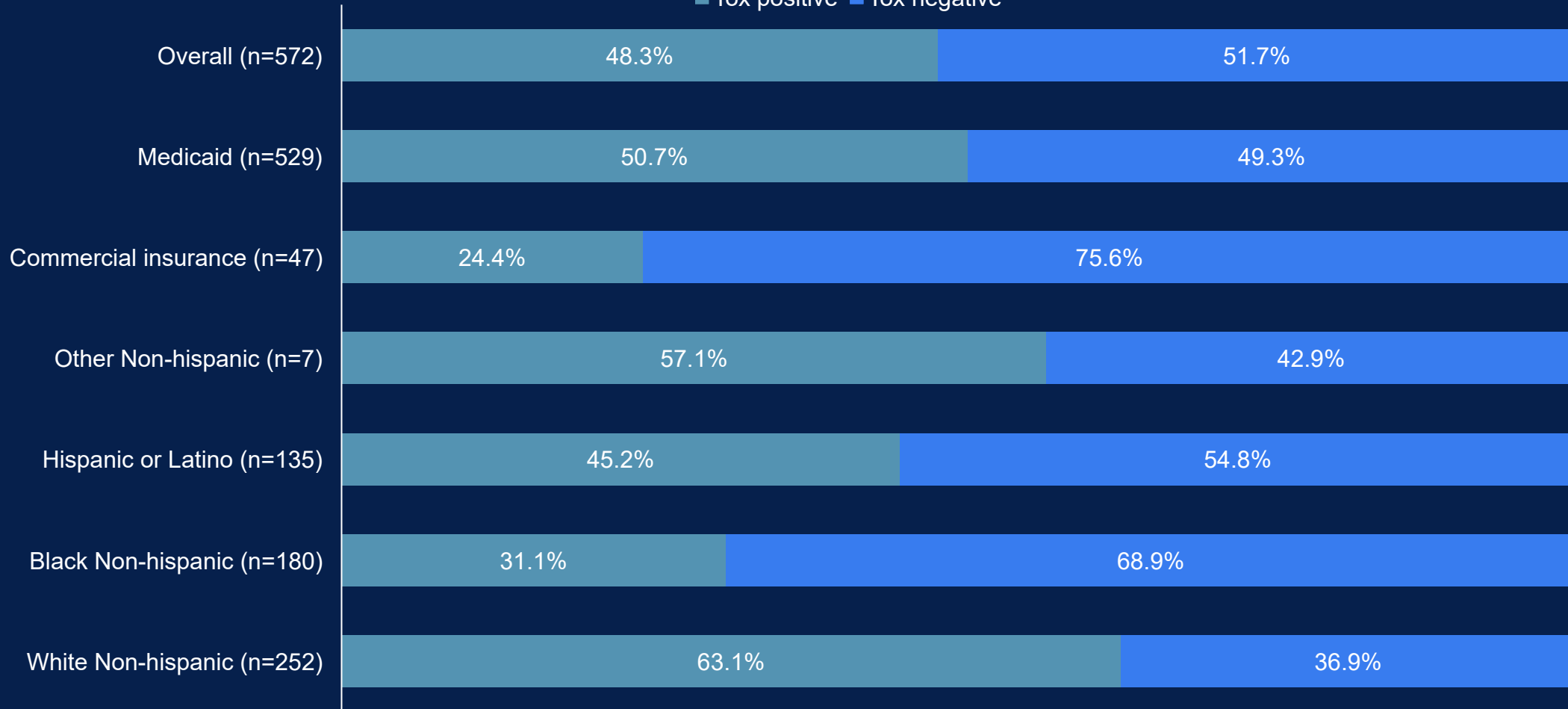


Toxicology tests obtained by insurance provider

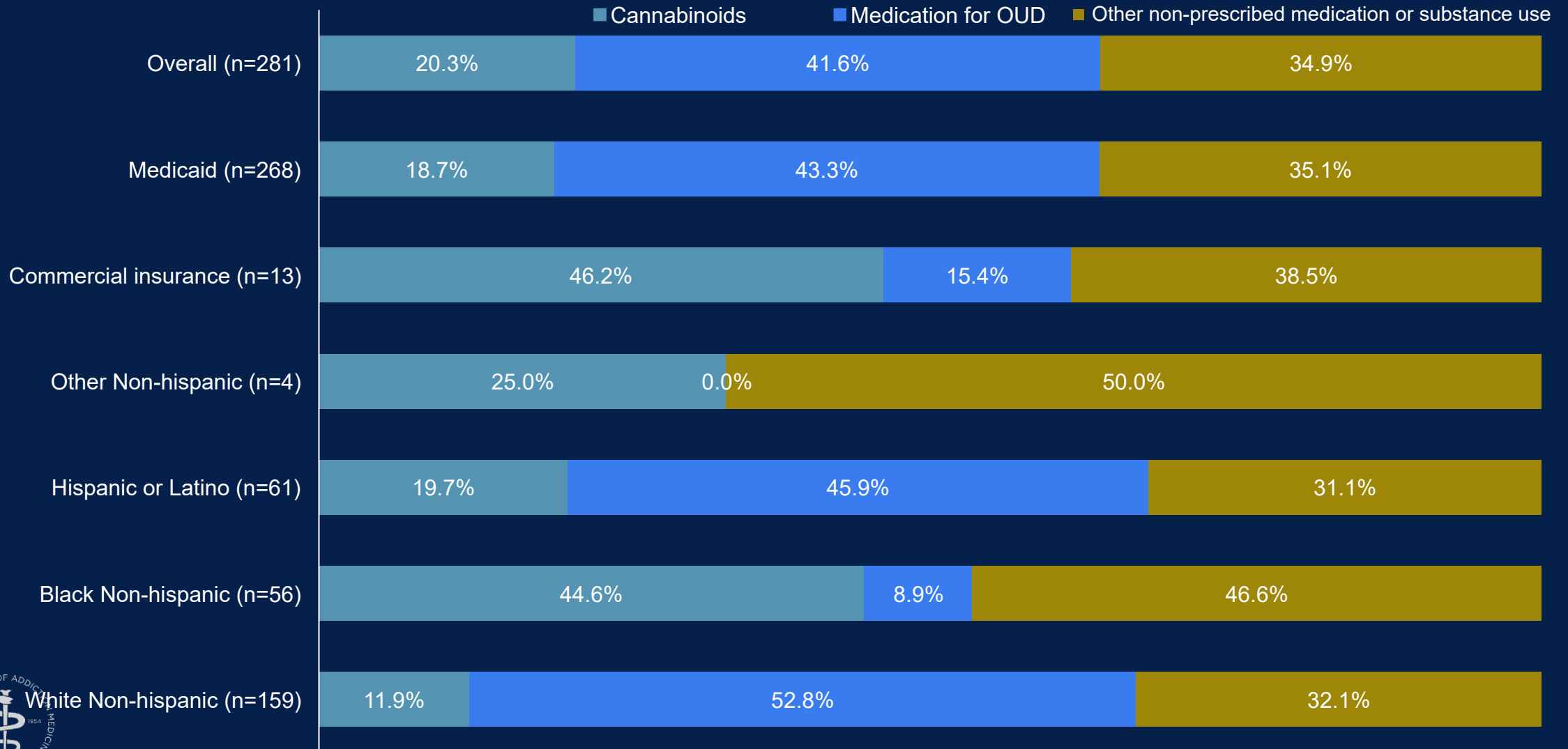


Rates of test positivity

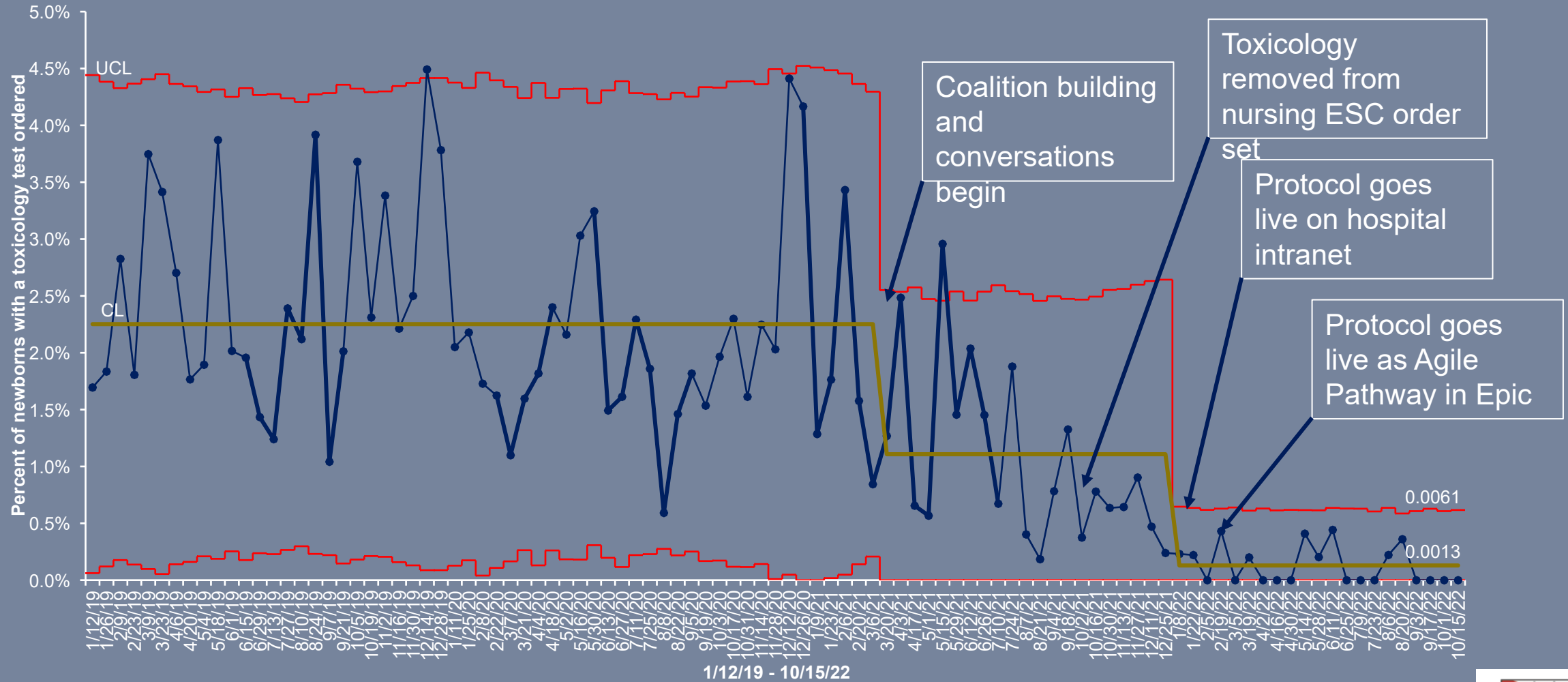
■ Tox positive ■ Tox negative



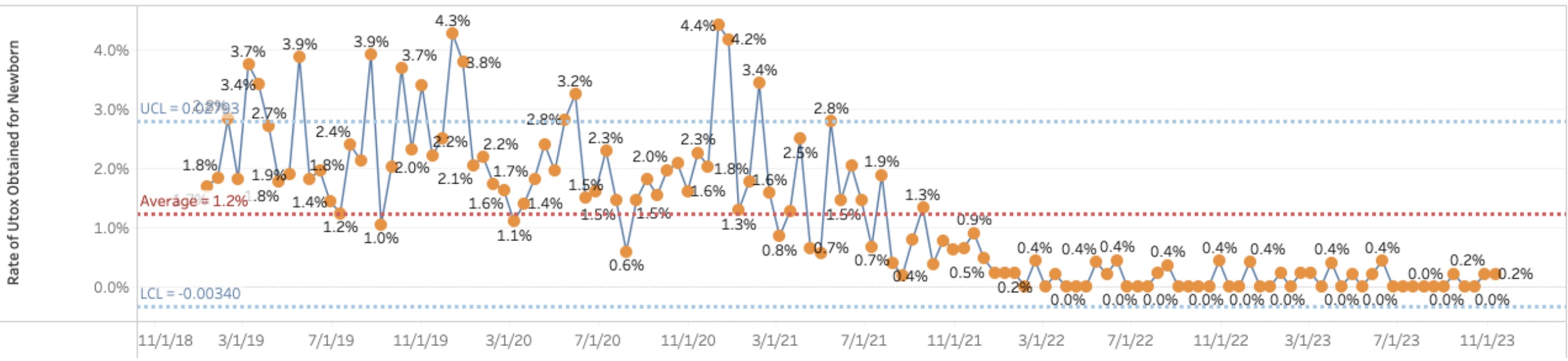
Rates of test positivity



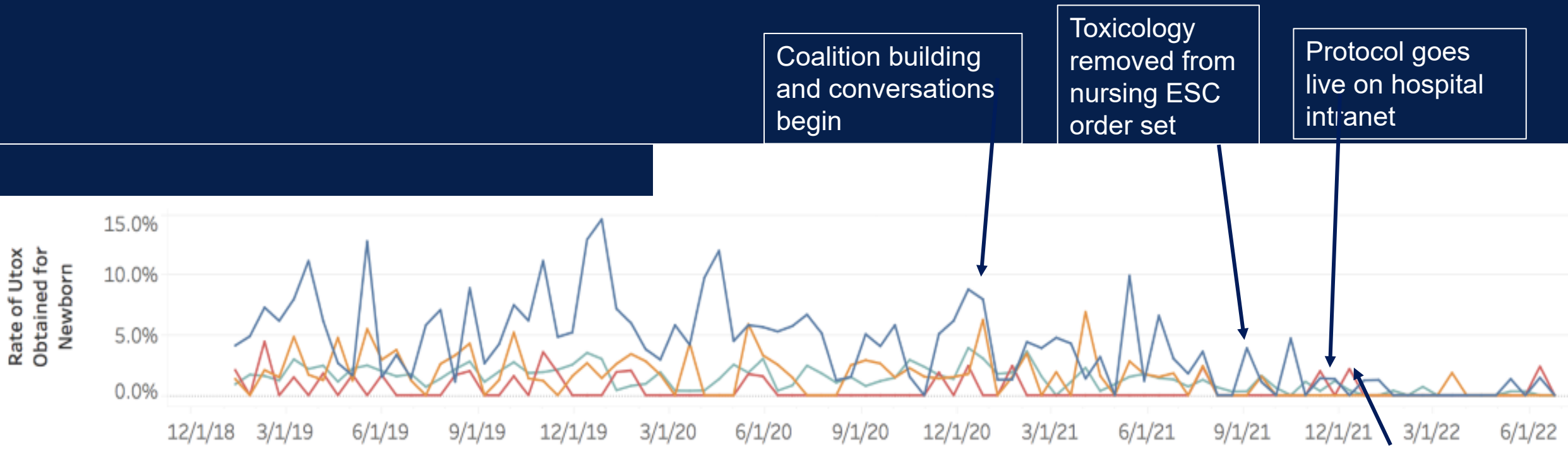
Control chart



Rate of Utox Obtained for Newborns



Control chart by race

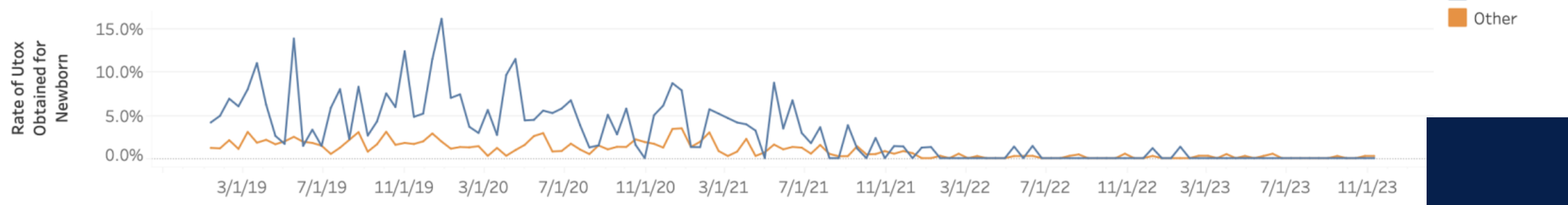


- Race/Ethnicity
- Black
 - Hispanic or Latino
 - Other
 - White

Protocol goes live as Agile Pathway in Epic



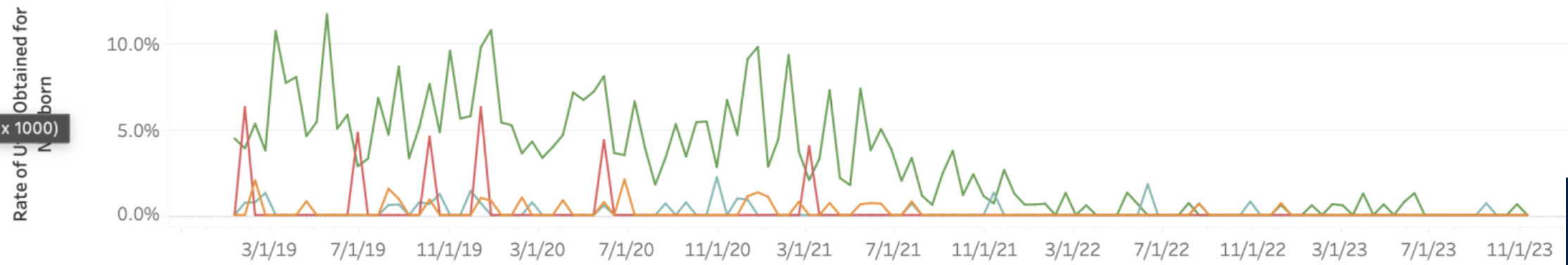
Rate of Utox Obtained for Newborns By Race



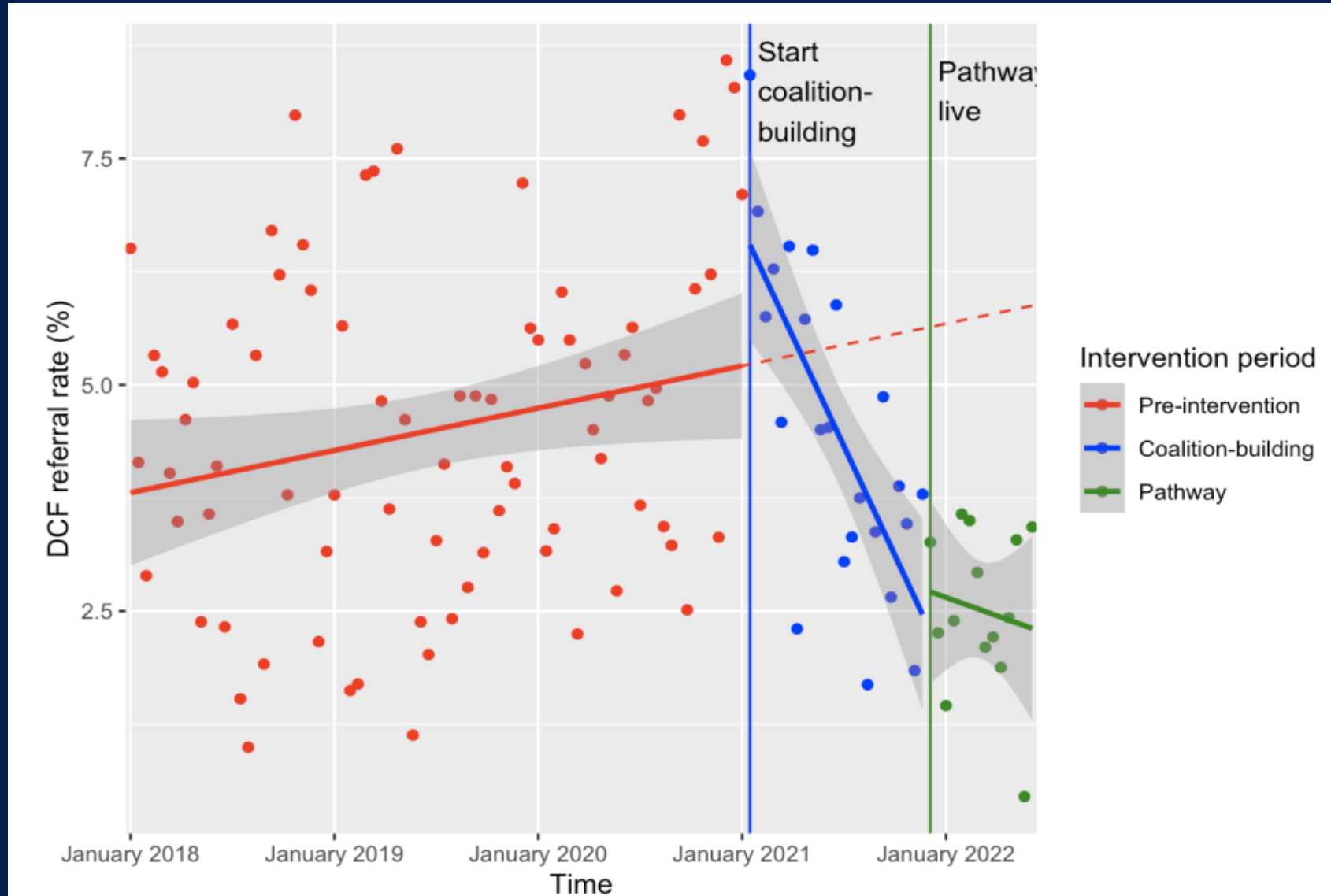
Insurance

- BCBS
- Commercial
- Managed Care
- Medicaid

Rate of Utox Obtained for Newborns By Insurance



DCF referrals (in all newborns)



Balancing measures

- Will newborns return to the hospital with untreated/uncontrolled withdrawal symptoms?
 - None before (collection of data established during Eat, Sleep, Console QI project)
 - None after
- Will children present with neglect in the setting of ongoing parental substance use?
 - No cases identified via Child Abuse ongoing data collection or High Risk Newborn Working Group
- The underlying aspect of these questions is: “in situations where the newborn toxicology test would have been the only piece of information that led to a suspicion for and subsequent evaluation of prenatal substance use”
 - Rare
 - A failure of multiple systems that we are concurrently working to strengthen

Key takeaways for newborn tox testing

- Newborn toxicology testing in the setting of prenatal substance exposure is usually not necessary to provide optimal clinical care
- When it is clinically indicated, urine toxicology testing provides actionable clinical information
- Informed consent should be obtained before ordering newborn toxicology testing in the vast majority of circumstances
- Implementing an objective protocol for toxicology test ordering resulted in significantly decreased rates of testing across all groups and differences between groups became minimal
- In enacting a practice guideline with these key messages, we did not see safety events occur as a result