

Welcome!

Neonatal Abstinence Syndrome Project Level I Webinar

Legalities and Practicalities

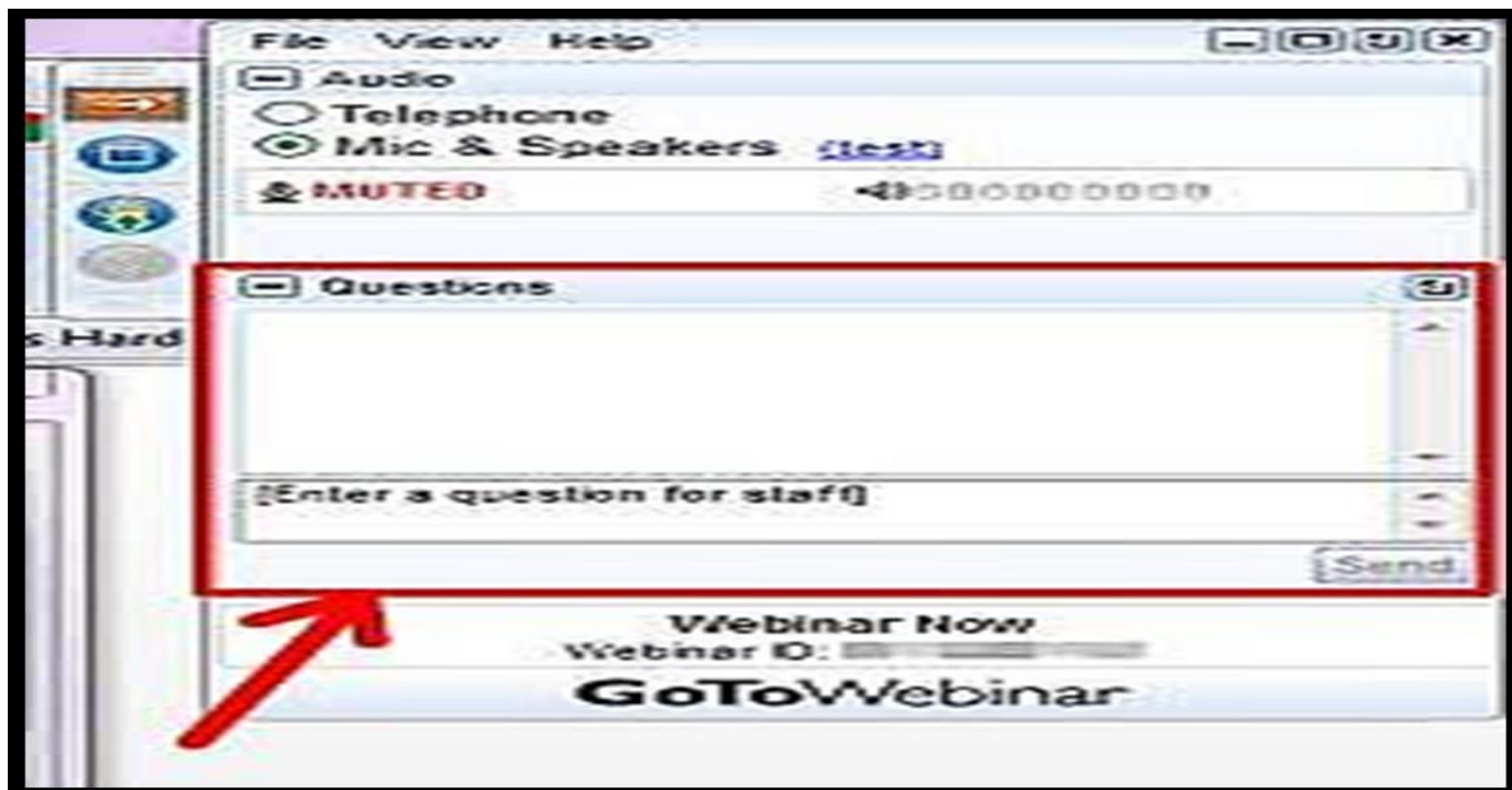
Ohio Perinatal Quality Collaborative

September 19, 2014

September 26, 2014



Please sign in with the names & organization of everyone on the call in the question box



CME Requirements for Internet-based Activities

Policy on Privacy and Confidentiality: I understand and agree that I will maintain the confidentiality of all information that is made available as a result of my attendance to this webinar. This means that I may not provide or otherwise share any of this information with any individual or entity other than my staff or the OPQC and then only in a meeting setting and as permitted by the OPQC standards or applicable state or federal law. If I am unsure as to whether certain information may or should be disclosed, I will contact a representative of the OPQC prior to making any disclosure.

All materials used in the presentation are owned and copyrighted by OPQC.

**OPQC Continuing Education Program for Level 1 Hospitals in Ohio.
Webinar #2: Neonatal Abstinence Syndrome (NAS): Identification
of substance abuse in Pregnancy: Legalities and Practicalities**

Presenters:

Moira Crowley, MD

**Co-Director, Neonatal ECMO Program, UH Rainbow Babies and Children's
Hospital**

Assistant Professor, Pediatrics, CWRU School of Medicine

Scott Wexelblatt, MD

**Assistant Professor at Cincinnati Children's Hospital Medical Center, Perinatal
Institute; University of Cincinnati College of Medicine Department of
Pediatrics. He is also the Medical Director of Regional Newborn Services.**



Michele Walsh, MD, MSE
Division Chief, Neonatology, UH Case Medical Center
Division Chief, Neonatology, UH Rainbow Babies and Children's Hospital
William and Lois Briggs Chair in Neonatology, UH Rainbow Babies and Children's Hospital
Professor, Pediatrics, CWRU School of Medicine

Beth White, MSN, CNS
BEACON Quality Improvement Coordinator

Disclosure: Financial disclosure information (planning committee and presenters):
Planning committee members/faculty were determined to have no conflicts of interest
pertaining to this activity.

Commercial Support:

Commercial support received: None

If at any time during this activity you feel that there has been commercial or promotional
bias, please indicate on the online evaluation.

CME:

Cincinnati Children's Hospital Medical Center is accredited by the Accreditation Council for
Continuing Medical Education to provide continuing medical education for physicians.

The Cincinnati Children's designates this live activity for a maximum of *1.0 AMA PRA
Category 1 Credit(s)*[™]. Physicians should claim only the credit commensurate with the
extent of their participation in the activity.



Objectives:

- Describe diagnostic tests that are used prenatally and postnatally to identify NAS
- Discuss practice based implications of legalities in drug screening and testing for prenatal drug exposure

Hardware/Software Requirements:

Compatible with Mac and Window users and common web browsers. High-speed access recommended though not required (responsiveness may be noticeably slower using dial-up connection). Adobe Flash Player 9.x is required and Speakers/headphones required to listen to audio

Provider Contact Information:

If you should have any questions about the content of the meeting, please contact Dr. Moira Crowley or Dr. Wexelblatt .

If you should have any questions regarding CME credit, please contact the CME office at cme@cchmc.org.



Screening and Testing Considerations

Scott Wexelblatt, MD

Cincinnati Children's Hospital

Regional Newborn Services

Screening versus Testing

- ACOG recommends that every woman is screened at beginning of prenatal care with a questionnaire.
- Testing is performed in a subset who screen positive for at risk status, or for a limited set of behaviors- no pnc, appears intoxicated.

Screening For Drugs of Abuse

- **Best practice:**

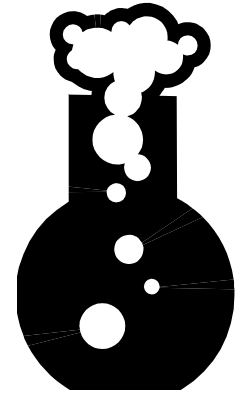
- ACOG: Screen everyone with a short questionnaire asked at first prenatal visit and on admission to L&D.
- Hospital has standard policy applied to **ALL** admissions that specifies triggers for sending a maternal urine drug test.
- Specifies historical triggers (no prenatal care, prior positive tox screen) and/or observed behaviors that will lead to a screen.
- Some advocate universal screening to prevent biased assessments
- Person should be informed that it is being sent.

Maternal Toxicology Test Options

- Urine: most rapid screens are done on urine using immunoassays.
- Advantage:
 - Fast and relatively inexpensive screen.
- Disadvantage:
 - Detects only exposures in the prior 24-48 hrs.
 - All positives require confirmation with GC/MS
 - False positives and false negatives.

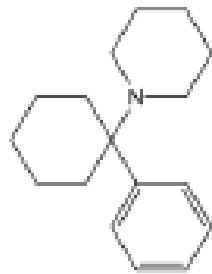


False Negatives and False Positives

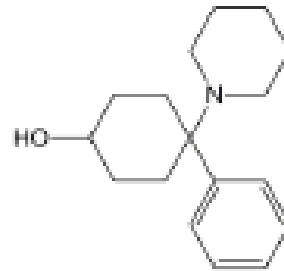


- **False Negatives:**
 - If urine is too dilute
 - Deliberate attempts to adulterate tests: added nitrites, or Visine, or using “clean” urine, water
- **False Positives:**
 - Immunoassays cross react with similar molecules
 - Infant urines higher false positives (esp THC) than adults
 - Amphetamines highest false-positive rates- 4%
 - PCP – 1.5% false positive
 - Opiates- cross react with Levofloxin

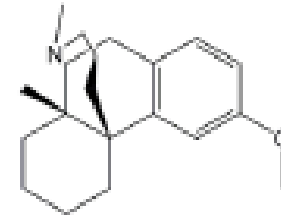
Structural Similarities



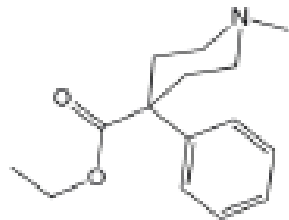
Phencyclidine
(target compound)



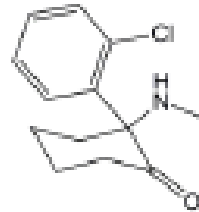
4-Phenyl-4-piperidino-cyclohexanol
MDL similarity = 0.784



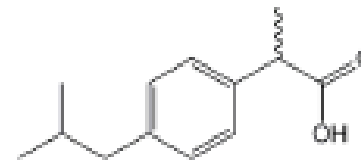
Dextromethorphan
MDL similarity = 0.565



Meperidine
MDL similarity = 0.538



Ketamine
MDL similarity = 0.333



Ibuprofen
MDL similarity = 0.100

Figure 1
Illustration of structural similarity. Using phencyclidine

From: Krasowski MD, BMC Emergency Medicine 2009: 9: 5.

Newborn Test Options

- Urine
- Meconium
- Umbilical Cord Sample
 - Hair
 - Nails
 - Vernix

Newborn Test Options

- Urine: may be difficult to collect
 - Relatively short window on exposure (days)
- Meconium:
 - may be delayed passage especially in preterm infants
 - Reflects months of inutero exposure
 - High false positive rates
 - Opiates: only 59% Positives confirmed by GC/MS

Screening and Testing for Drug Use

Moira Crowley, MD

Universal Screening Approach

- ACOG and AAP recommend against universal toxicology testing
- Screening essential part of complete obstetric care
 - Preconception and early in pregnancy
 - Every woman

- Ask to ALL patients
 - Disclose that everyone is asked
 - Non-judgmental
 - Confidential
 - Adequate care for mother and fetus
 - Illicit and prescribed substances

Tools

- 5Ps¹
 - parents, peers, partner, past, pre-pregnancy
- CRAFFT²
 - 16-26 yo
 - 6 items measuring use of substances/concerns
- SURP-P³ (Substance Use Risk Profile-Pregnancy Scale)
 - 3 questions

Our Approach

- All women screened early and when arrive to L&D
 - General admission consent includes consent for testing
 - Must disclose to woman that test is being sent → she can refuse
 - Situations where testing is indicated
 - + screen
 - + toxicology screen in the past 2 years
 - Referral from outside social services or social work
 - Clinical indications

When Testing Is Indicated...

- Document indication and disclose to mother
 - If she declines → document and discuss with pediatric team
- Test infant
 - Mother declines testing and there is concern
 - Mother has a positive toxicology screen
 - Exhibits signs/symptoms of withdrawal

Do We Miss Babies?

- No readmissions for NAS in past 6 months

Methods of Screening

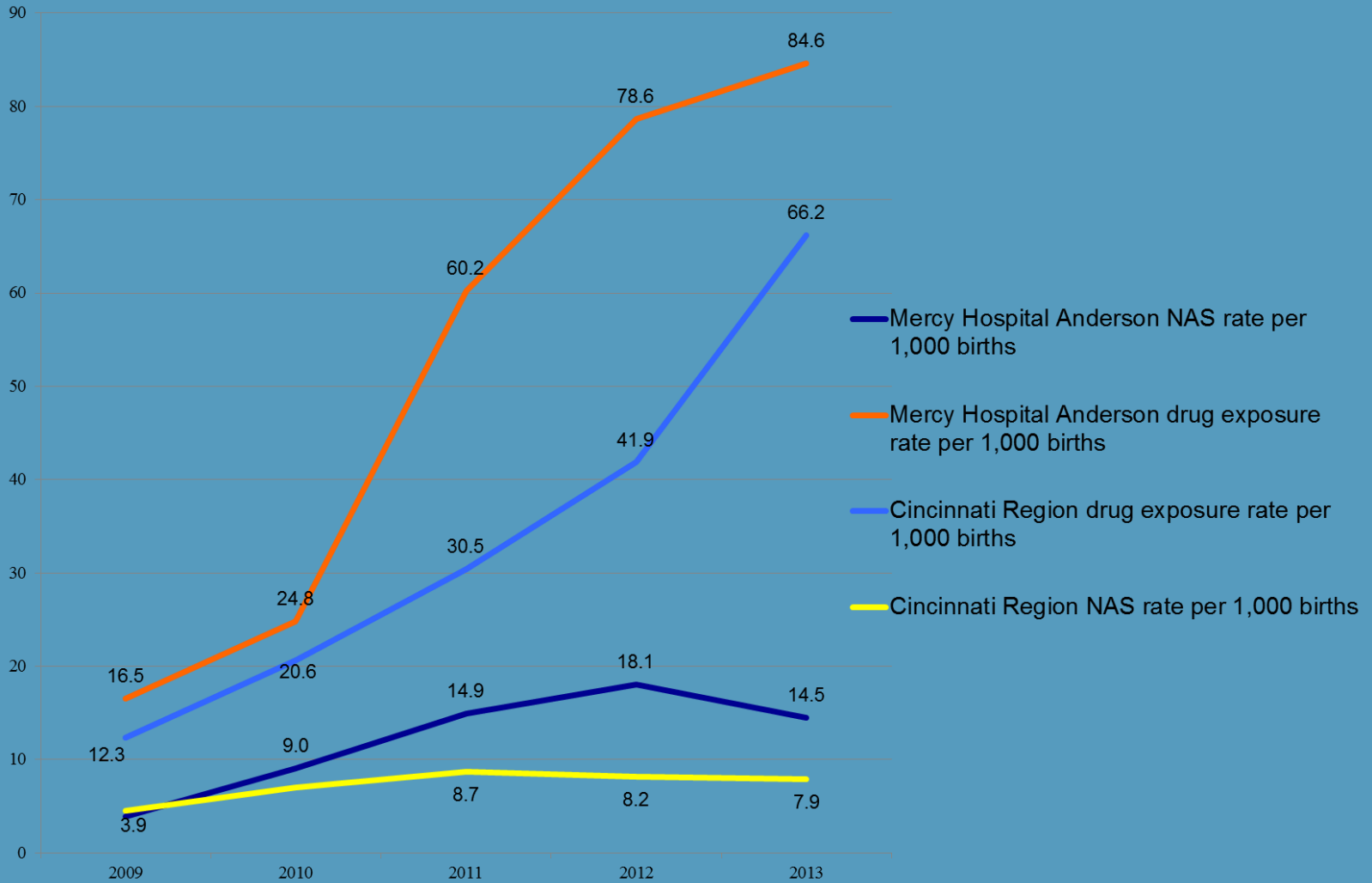


Scott Wexelblatt, MD
Medical Director, Regional Newborn
Services Cincinnati Children's Hospital

METHODS OF SCREENING/TESTING

- Maternal Interview Screen
- Maternal Urine Drug Test
- Infant Urine Drug Test
- Meconium Toxicology Test
- Umbilical Cord Toxicology Test

Mercy Anderson Rates per 1000 births



Maternal Risk Based Screen

ACOG Committee Opinion 524, May 2012.

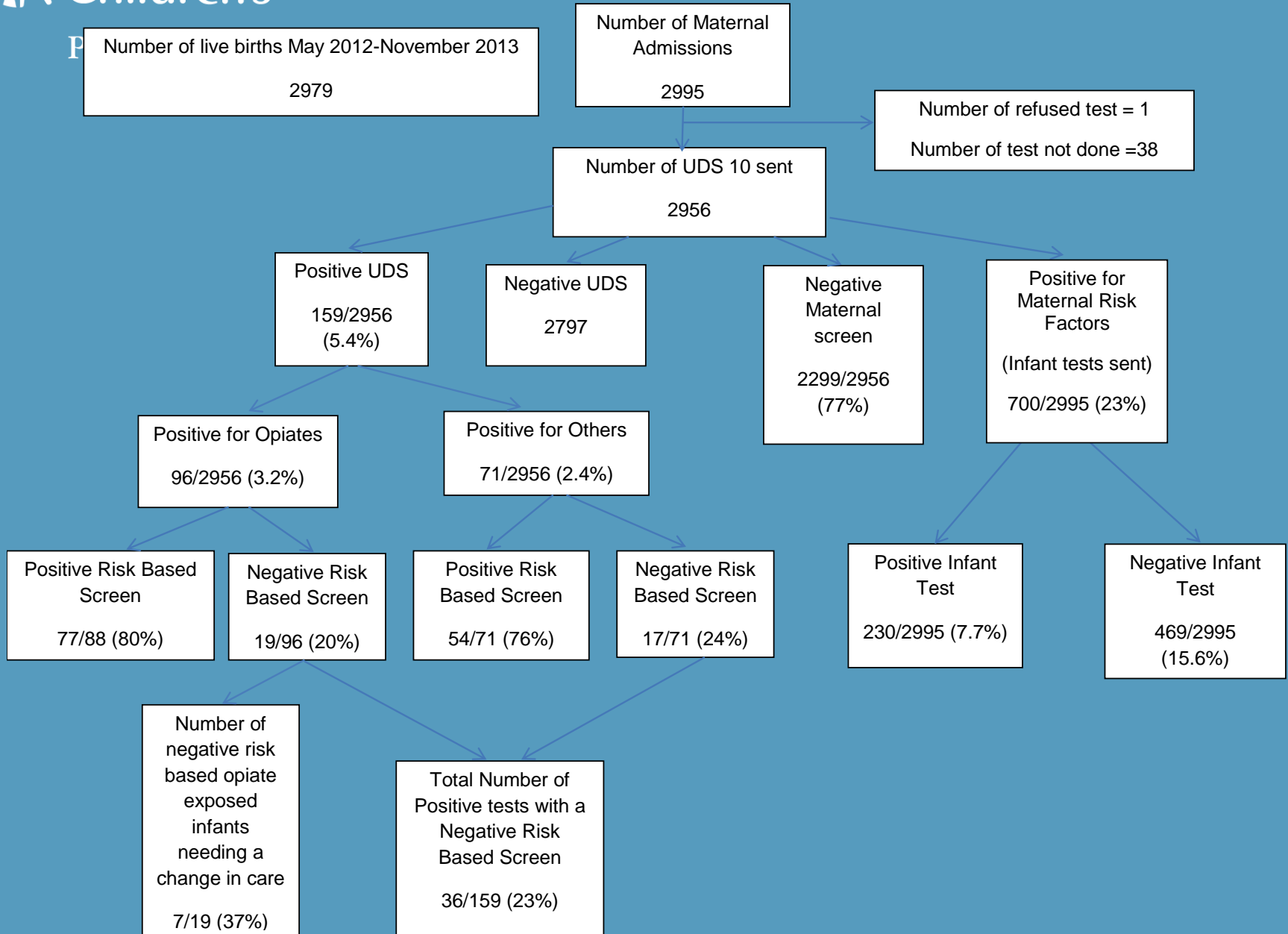
Recommends universal *screening*.

Recommends obtaining consent prior to testing.

Maternal Risk Based Screen

- Documented, suspected, or acknowledged maternal history of drug use
- Insufficient prenatal care, defined as starting care after 12 weeks of gestation
- Placental abruption
- Admission from a justice center.
- Positive for Human immunodeficiency virus
- Positive for Hepatitis B Surface Antigen
- Positive for Hepatitis C virus
- Maternal history of Gonorrhea or Syphilis

Universal Testing



Universal Testing



Started Universal Testing on Sept 1st.

Encourage consent

Recommend DAU 13 for mother and infant

Universal Testing



**GREATER
CINCINNATI
HEALTH
COUNCIL**

Creating connections. Improving care.

Delivery Service Hospitals

Atrium Medical Center

The Christ Hospital

Dearborn County Hospital

Fort Hamilton Hospital

Highland District Hospital

Margaret Mary Hospital

Cullough-Hyde Memorial Hospital

Mercy Health Partners

St Elizabeth Hospital

TriHealth

UC Health

Poll #1– Screening of Mothers

Do you have a policy for screening pregnant women for drugs at your hospital?

- Yes, we screen ALL pregnant women for drug use
- Yes, we screen, but only with a hx of drug use
- No, we do not screen pregnant women for drug use
- N/A; we do not provide care to pregnant women

Poll #2 – Testing of Babies

Do you have a policy for testing babies at your hospital?



- Yes, we test all babies for drugs
- Yes, we test only babies with a maternal history of drug use
- No, we do not routinely test our babies for drugs

Poll #3 – Testing of Babies

Do you have a policy for testing mothers at your hospital?



- Yes, we test all pregnant women for drugs
- Yes, we test only pregnant women who have a history of drug use
- No, we do not routinely test pregnant women for drugs
- N/A. We do not provide care for pregnant women

Legal Implications of Testing in Ohio

- Moira Crowley, MD
 - Rainbow Babies and Children Hospital, Neonatology Services, Cleveland, Ohio



Legal Implications for Testing in Ohio

OPQC Webinar
September 2014

With Thanks To:

Jonathan Fanaroff, MD, JD

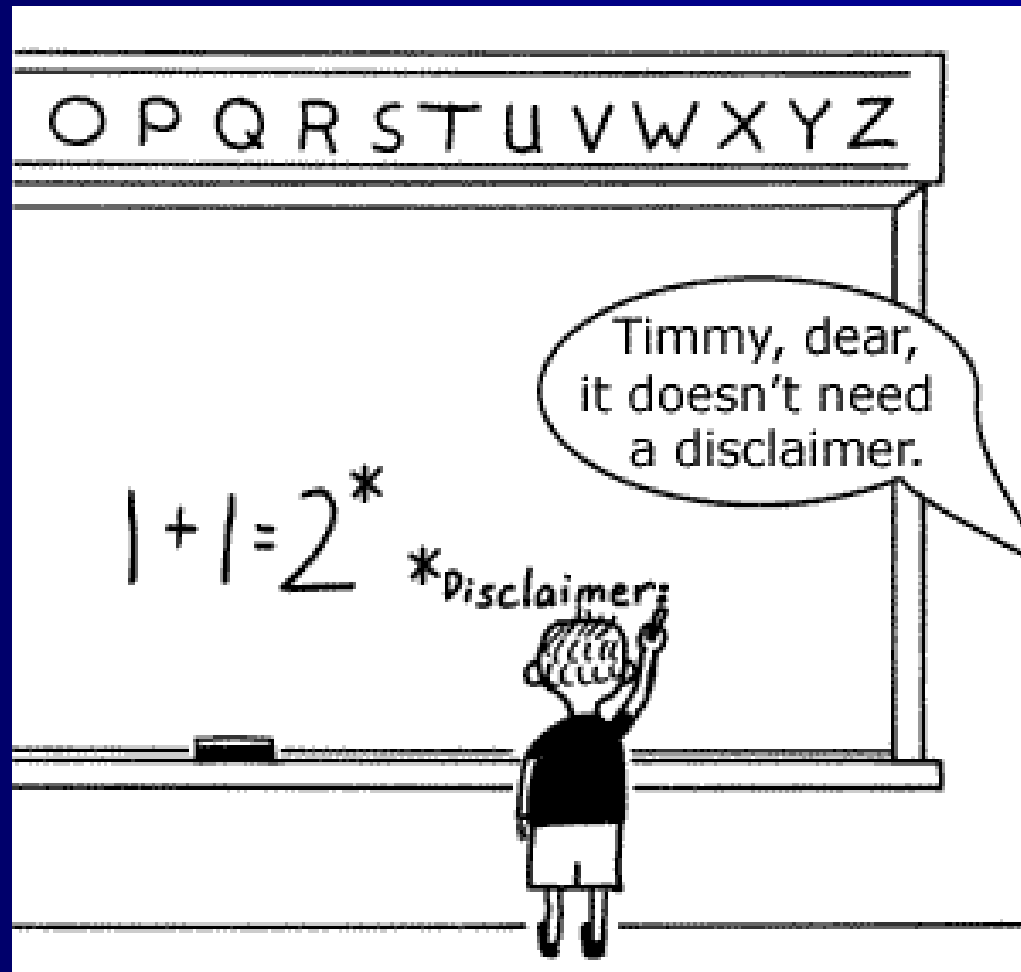
Rainbow Babies & Children's Hospital

Case Western Reserve University

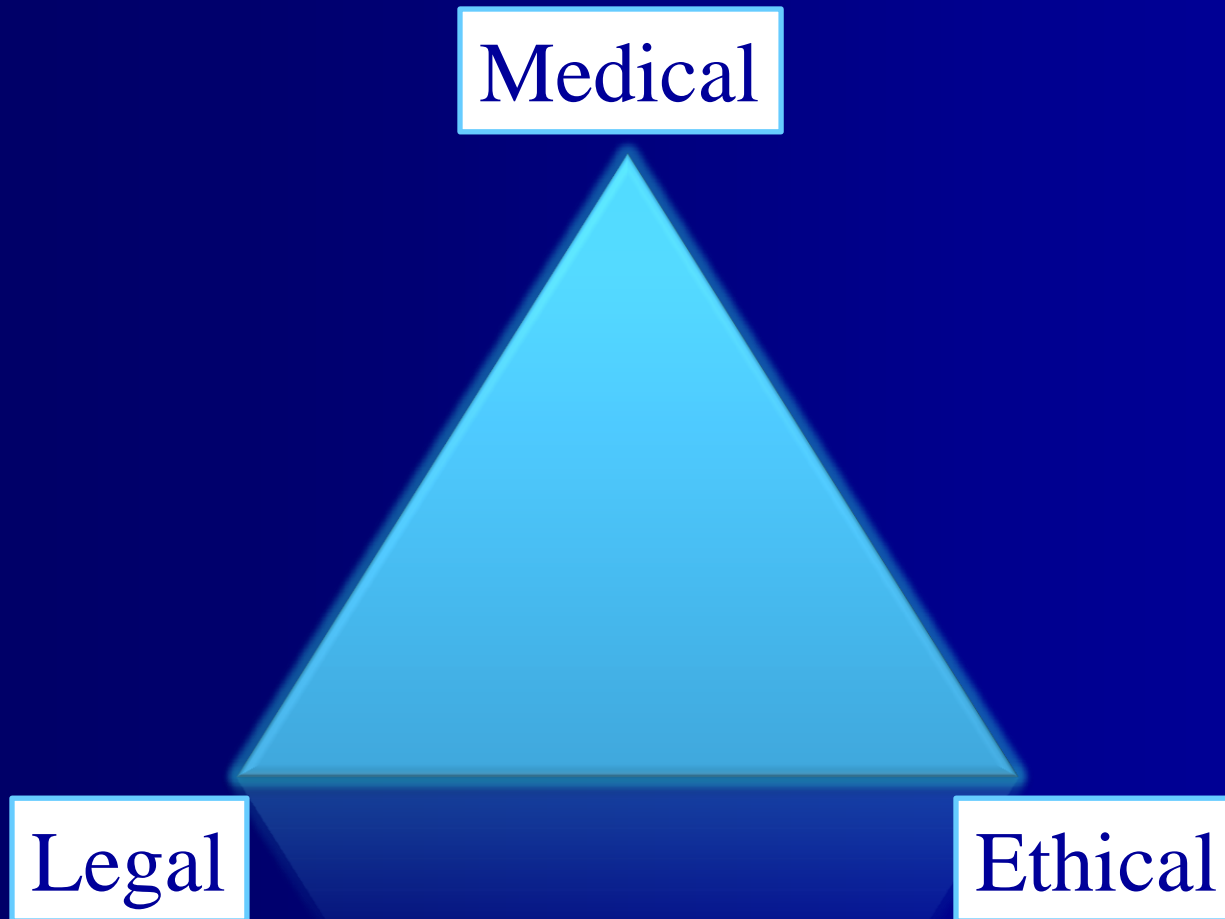
Cleveland, Ohio



Disclaimer



Balancing Considerations



WE THE PEOPLE of the
insure domestic Tranquility, provide for the common defence,
and our Posterity, do ordain and establish this Constitution

Article I.
Section 1. All legislative Powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and House of Representatives.
Section 2. The House of Representatives shall be composed of Members chosen every second Year by the People of the several States, and in each State shall have the Qualifications requisite for Electors of the most numerous Branch of the State Legislature.
No Person shall be a Representative who shall not have attained to the Age of twenty five Years, and seven Years a Citizen of the United States, and who shall not, when elected, be an Inhabitant of that State in which he shall be chosen.
Representatives and direct Taxes shall be apportioned among the several States which may be included within this Union, according to the Number of Representatives which shall be made within three Years after the first Meeting of the Congress, and thereafter every third Year, by adding to the whole Number of free Persons, including those bound to Service for a Term of Years, and Indians not taxed, three fifths of all other Persons. The actual Enumeration shall be made within three Years after the first Meeting of the Congress, and in each subsequent Term of Years, in such Manner as they shall by Law direct. The Number of Representatives shall not exceed one for every thirty thousand Persons; but each State shall have at least one Representative, and until such Enumeration, the States of New Hampshire, Massachusetts, Connecticut, Rhode Island, New York, New Jersey, Pennsylvania, Delaware and Maryland, shall be entitled to three Representatives each, Virginia to five, and North Carolina to three. The Electors in each State shall have the Qualification requisite for Electors of the most numerous Branch of the State Legislature.

Scene at the Signing of the Constitution – Howard Chandler Christy



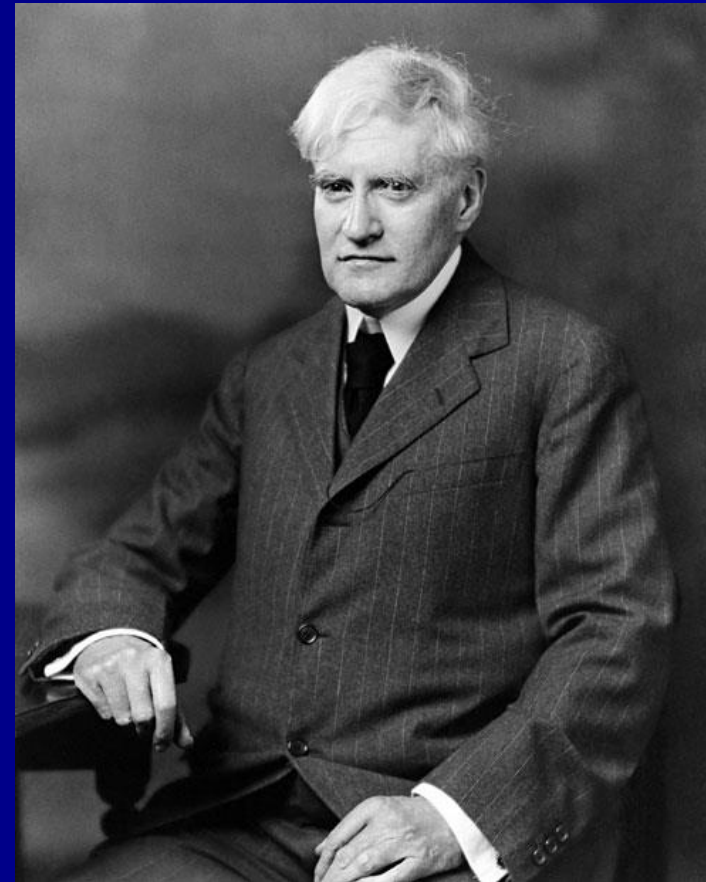
Bill of Rights

- ① Religion, Speech, Press, Assembly
- ② Bear arms
- ④ No unreasonable searches and seizures
- ⑤ Right to due process of law
- ⑥ No Cruel and Unusual Punishment
- ⑨ Other rights of the people
- ⑩ Powers reserved to the states

Schloendorff v. Society of NY Hospital

“Every human being of adult years and sound mind has a right to determine what shall be done with his own body.”

Justice Cardozo





4th Amendment



“The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.”

Ferguson v. City of Charleston

532 U.S. 67 (2001)

- Staff at MUSC concerned about increase in “crack babies”
- Began testing → refer for counseling
- No change in incidence
- Began to work with law enforcement
- New program implemented



Gordon Wiltsie / National Geographic Image Collection

Criminal charges

- Felony child endangerment
- Corruption of a minor
- Chemical endangerment
- Assault with a deadly weapon



Parens Patriae

- Children are not property
- Government has the power and duty to protect the safety and well-being of children

Child Abuse Prevention and Treatment Act (CAPTA)

- The current incarnation of the Baby Doe regulations
- Provides federal funding to the states
- Defines “child abuse and neglect” as, “at a minimum, any recent act or failure to act on the part of a parent or caretaker which results in death, serious physical or emotional harm, sexual abuse or exploitation, or an act or failure to act which presents an imminent risk of serious harm.”

Child Abuse Prevention and Treatment Act (CAPTA)

- Healthcare providers must have policies and procedures in place to notify Child Protective Services of *all* infants born and identified as affected by illegal substance abuse, withdrawal symptoms resulting from prenatal drug exposure, or a Fetal Alcohol Spectrum Disorder and to establish a plan of safe care for these newborns
- Reports of prenatal substance exposure shall not be construed to be child abuse or neglect and shall not require maternal prosecution

Medical Practice is mainly regulated by the State



Ohio Department of Health Approach

- Substance abuse during pregnancy is not automatically considered
 - Criminal act
 - Child abuse
 - Grounds for civil commitment
- A \$4.2 million, three year targeted drug treatment program for pregnant women supported by the Ohio Department of Health is promising

Drug Testing Mothers and Newborns

1. Obstetricians, Pediatricians, and Administration should develop policies to be followed consistently.
2. Hospital counsel should ensure compliance with state and federal laws

Drug Testing Mothers and Newborns

3. Maternal and infant drug testing should be based on specific evidence-based criteria and medical indicators to avoid discriminatory testing. Open-ended criteria such as “clinical suspicion” are inadequate.

Drug Testing Mothers and Newborns

4. All mothers should be informed about proposed drug testing prospectively and the rationale for testing should be documented in the medical record. The discussion should include the nature and purpose of the test and how testing will guide care.
5. If a woman refuses testing, document the refusal and do not test over her objection.

Drug Testing Mothers and Newborns

6. When medically necessary for the proper and safe care of the infant, testing may be done without specific informed consent of the mother. This includes
 - Newborns who exhibit signs and symptoms of drug exposure
 - Newborns whose mothers have been identified as probable substance users
 - Newborns whose mothers have signs and symptoms of drug use

Drug Testing Mothers and Newborns

7. Remember that under Ohio law all healthcare providers are mandated reporters of child abuse/neglect are required to report when there is reasonable cause to suspect that a child “has suffered or faces a threat of suffering any physical or mental wound, injury, disability, or condition of a nature that reasonable indicates abuse or neglect of the child”



Discussion and Questions

- What method do you use at your hospital? Why was this method chosen?
- What challenges have you had regarding maternal screening or testing? How did you overcome them?

References:

- Gray T., Huestis M. Bioanalytical procedures for monitoring in utero drug exposures. *Anal Bioanal Chem.* 2007; 388: 1455-1465.
- Krasowski MD, et al. Using molecular similarity to highlight the challenges of routine immunoassay-based drug of abuse screening in the ER. *BMC Emer Med* 2009; 9:5
- Brahm NC, et al. Commonly prescribed medications and potential false-positive urine drug screens. *Am J Health Syst Pharm* 2010; 67: 1344-50.
- Huestis M, Choo RE. Drug abuse's smallest victims: in utero drug exposure. *Forensic Science Intl.*

