PhenX Pediatric Development Working Group
Measure Tied to the Opiate Epidemic

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Measure Tied to the Opiate Epidemic

• Definition
  – Testing methods for drugs of abuse

• Concepts
  – Studies involving children include those of pediatric substance use, 2nd hand exposure, and *in utero* exposure
Existing measurement protocols in PhenX Toolkit

• **Measure #1**
  – Lab-based Urine Drug Analysis
    • Detection of cannabis, cocaine, amphetamines, opiates (heroin, codeine, or morphine), methamphetamines, or buprenorphine in urine
    • Enzyme immunoassay targeting the drug or its metabolites
    • Confirmation of a positive screening with gas chromatographic mass spectrometric or liquid chromatographic mass spectrometric analysis targeting the drug or its metabolites
Existing measurement protocols in PhenX Toolkit

• **Measure #2**
  – On-Site Urine Drug Screen
    • Immunochromatographic assay for rapid, qualitative detection of drug combinations and their principal metabolites in urine at specified cut-off concentrations based on the Substance Abuse and Mental Health Services Administration (SAMHSA) drug cut-off concentrations
    • The multidrug cup may be used to test any number of drugs, from a single drug up to 11 different drugs (amphetamine, barbiturates, benzodiazepines, cocaine, marijuana, methadone, methamphetamine, opiates, oxycodone, phencyclidine, and tricyclic antidepressants)
    • Instructions are to collect urine directly into the test cup
Description of measurement protocols in PhenX Toolkit

• Common drugs of abuse included

• Pros/Cons of the measures
  – Pro: Tests for an appropriate array of substances with known withdrawal syndromes following *in utero* exposure
  – Con: Update needed to collection method to include incontinent individuals; i.e., those under 3 years old
  – Con: Not CLIA-certified
Missing elements

- Collection from infants and young children via a urine bag
- Reporting of results as not CLIA-certified – implications for reporting
- Results of testing have varying child protection implications
Filling in the gaps

• Expand Lab-based protocol with update for collecting bagged urine

• Verify minimum volume of urine needed for accurate testing
  – Infants are unlikely to provide the recommended 90mL

• Verify that On-Site protocol can use bagged urine
Recommendations to the WG

• Update/expand existing measures
  – Likely possible for the Lab-based Urine Drug Analysis protocol
  – Need more information to see if bagged urine can be used for the On-Site Urine Drug Screen

• Review implications for child protection involvement