

Status Report: Research Needs *Using Buprenorphine to Treat Opioid Dependence During Pregnancy*

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Presentation Goals

- Present state of the knowledge
- Questions for future research

What Is Our Current State of Knowledge Around:

- Medications during pregnancy
- Neonatal abstinence
 - Possibly largest issue around agonist treatment of pregnant opioid-dependent women
- Prenatal exposure (open-label)
- How to best impact clinical practice
 - RCT
 - ❖ Funding
 - ❖ Consortium
- Needs for future research

Medications During Pregnancy

- No medications approved for treatment of pregnant opioid dependent women
- Methadone is only medication recommended
- Methadone and buprenorphine in FDA pregnancy category C

Neonatal Abstinence Syndrome (NAS)

- Neurologic excitability
(hyperactivity, irritability, sleep disturbance)
- Gastrointestinal dysfunction
(uncoordinated sucking/swallowing, vomiting)
- Autonomic Signs
(fever, sweating, nasal stuffiness)

Literature Summary of Prenatal Buprenorphine Exposure

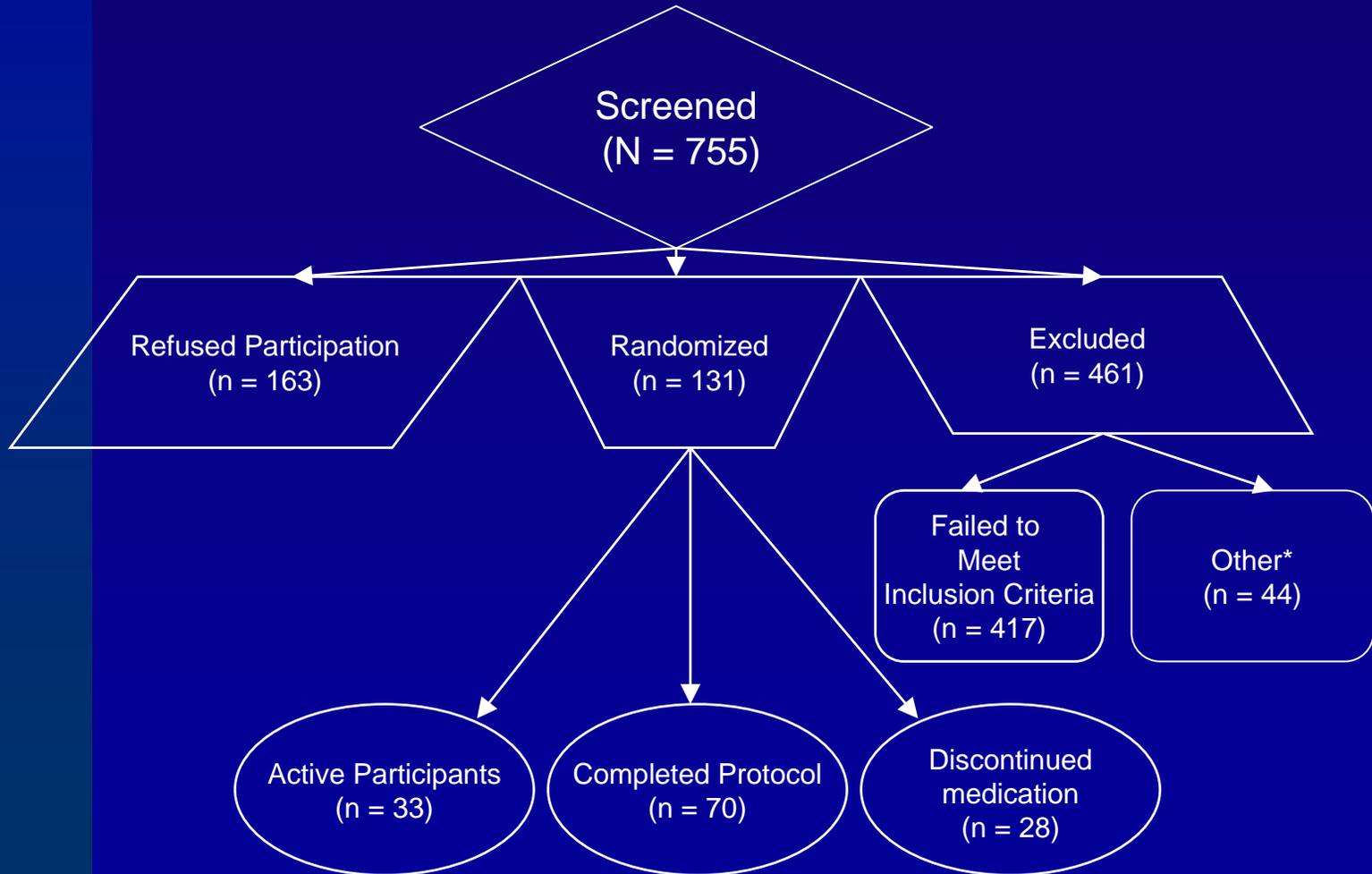
- Since 1995, over 32 published reports of prenatal exposure to buprenorphine maintenance
- Approximately 546 babies prenatally exposed to buprenorphine (number of cases per report ranged from 1 to 159; median=14)
- 61% babies with NAS signs/symptoms; 51% requiring treatment

NIDA funded multi-center trial

- MOTHER study (Maternal Opioid Treatment: Human Experimental Research)
 - International eight-site study
- 2 group, randomized, double-blind, double-dummy design
- Goal is N = 300 deliveries

Modified CONSORT

1/08



Questions for Future Study *Child*

■ NAS

- Tools to measure NAS
- Medications to treat NAS
- Role of concomitant drug exposure in NAS expression

■ Short and long term outcome

- Growth, learning, development, behavior

Questions for Future Study *Mother*

- Buprenorphine pharmacokinetics and pharmacodynamics during pregnancy and post-partum
- Methods for smooth transition from long-acting opioids onto buprenorphine
- Pain management during labor, delivery and post-partum
- Medication exposure during breast feeding

Questions for Future Study

Other issues

- Outcomes of buprenorphine exposures outside of RCTs
- Safety of buprenorphine exposure from conception (Open-label, Case Reports, AE's)
- Safety and efficacy of Suboxone (Case Reports, AE's)
- Patient/medication matching

Summary

- Having more medications to treat opioid dependent pregnant women will optimize care
- To date, mono buprenorphine (Subutex) appears as safe and effective as methadone in pregnant women
- Many questions for future research regarding buprenorphine exposure in the perinatal period remain

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