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# Participation in Perinatal Interventional Research: Which Characteristics Matter?

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## Objectives

Identify characteristics of pregnant women that are associated with the decision to participate in perinatal interventional research.

## Methods

- A retrospective cohort study of two interventional trials conducted on Labor and Delivery
  - **Study 1:** patient-blinded, randomized trial of an adhesion barrier at the time of cesarean delivery
  - **Study 2:** non-blinded, randomized trial of discontinuation of oxytocin during induction of labor once in active labor
- Demographic, medical, and obstetric data were collected from medical records and compared based on participation.
- Stepwise logistic regression was performed to identify independent predictors of study participation controlling for the specific study.

## Results

- 605 subjects screened eligible to participate
  - 363 (60%) agreed to participate
  - 242 (40%) declined participation
  - Participation rates were similar for both studies (~60%)
- Stepwise logistic regression ($R^2$=0.18)
  - Prior obstetrical complications (aOR: 0.6 (95% CI: 0.4, 0.8))
  - History of hypertension (aOR: 3.8 (95% CI: 1.0, 13.4)
  - History of mental health condition (aOR: 1.5 (95% CI: 1.0, 2.3))

***Table 1.*** Demographic characteristics of participants and non-participants for two perinatal interventional trials.

| | Screen Eligible Subjects | | |
|---|---|---|---|
| | Accepted n=361 | Declined n=342 | P |
| Age | 27.8 ± 5.6 | 28.5 ± 6.0 | 0.15 |
| Gravidity | *2 (1-10)* | *2 (1-11)* | *0.04* |
| Parity | *1 (0.6)* | *1 (0.6)* | *0.002* |
| Gestational Age (wks) | 39.2 ± 1.9 | 39.0 ± 1.8 | 0.07 |
| Race | | | 0.21 |
| Caucasian | 71.2% | 65.3% | |
| Hispanic | 19.1% | 19.4% | |
| African American | 4.4% | 6.6% | |
| Other | 5.3% | 8.7% | |
| Married | 55.1% | 63.2% | 0.11 |
| Education ≥ College | 65% | 67.5% | 0.53 |
| Insurance | | | 0.27 |
| Private | 63.5% | 69.8% | |
| Public | 27.6% | 22.3% | |
| None | 8.9% | 7.9% | |
| Private provider | **63.3%** | **73.1%** | **0.01** |
| Employed | 63.3% | 73.1% | 0.01 |
| BMI (kg/m²) | **33.2 ± 7.3** | **32.0 ± 5.8** | **0.03** |
| BMI >30kg/m2 | 67.6% | 63.2% | 0.27 |
| Tobaco Use | 18.8% | 19% | 0.96 |
| Drug use | 2.5% | 2.1% | 0.73 |
| Alcohol Use | 4.4% | 3.3% | 0.48 |

Data presented as mean ± SD or median (range); *n=335

***Table 2.*** Maternal medical co-morbidities, current and previous obstetrical complications based on decision to participate in two perinatal interventional trials.

| | Screen Eligible Subjects | | |
|---|---|---|---|
| | Accepted n=361 | Declined n=342 | P |
| Composite medical conditions | 27.7% | 23.6% | 0.26 |
| cHTN | 3.9% | 1.2% | 0.08 |
| Pregestational DM | 2.5% | 2.1% | 0.73 |
| Other comorbidities | 23.8% | 22.3% | 0.67 |
| Mental health history | 20.8% | 15.7% | 0.12 |
| Composite obstetric conditions | 35.7% | 40.1% | 0.28 |
| Gestational DM | 11.9% | 12.4% | 0.86 |
| Gestational | 13.6% | 12.4% | 0.67 |
| HTN/preeclampsia | | | |
| other | 14.4% | 19.4% | 0.10 |
| Previous obstetrical complications | *16.4%* | *24.9%* | *0.01* |
| Maternal complications | 35.2% | 34.3% | 0.82 |
| Fetal complications | 11.4% | 14.9% | 0.20 |

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## Conclusions

- Small differences exist between pregnant women who agreed and declined to participate in perinatal interventional trials.
- The most important predictors of participation were prior obstetrical complications (less likely to participate) and history of hypertension and mental health condition (more likely to participate).
- These data may help when developing strategies to improve recruitment for clinical research on Labor and Delivery.

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