

# Reluctance to include pregnant women in clinical research: Physiological changes and complexity

Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)

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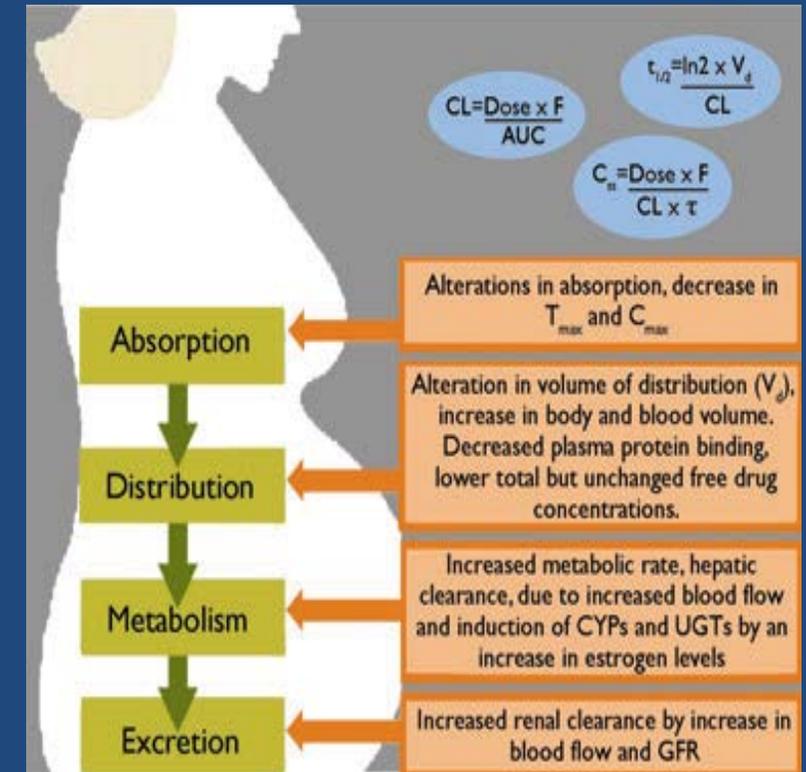
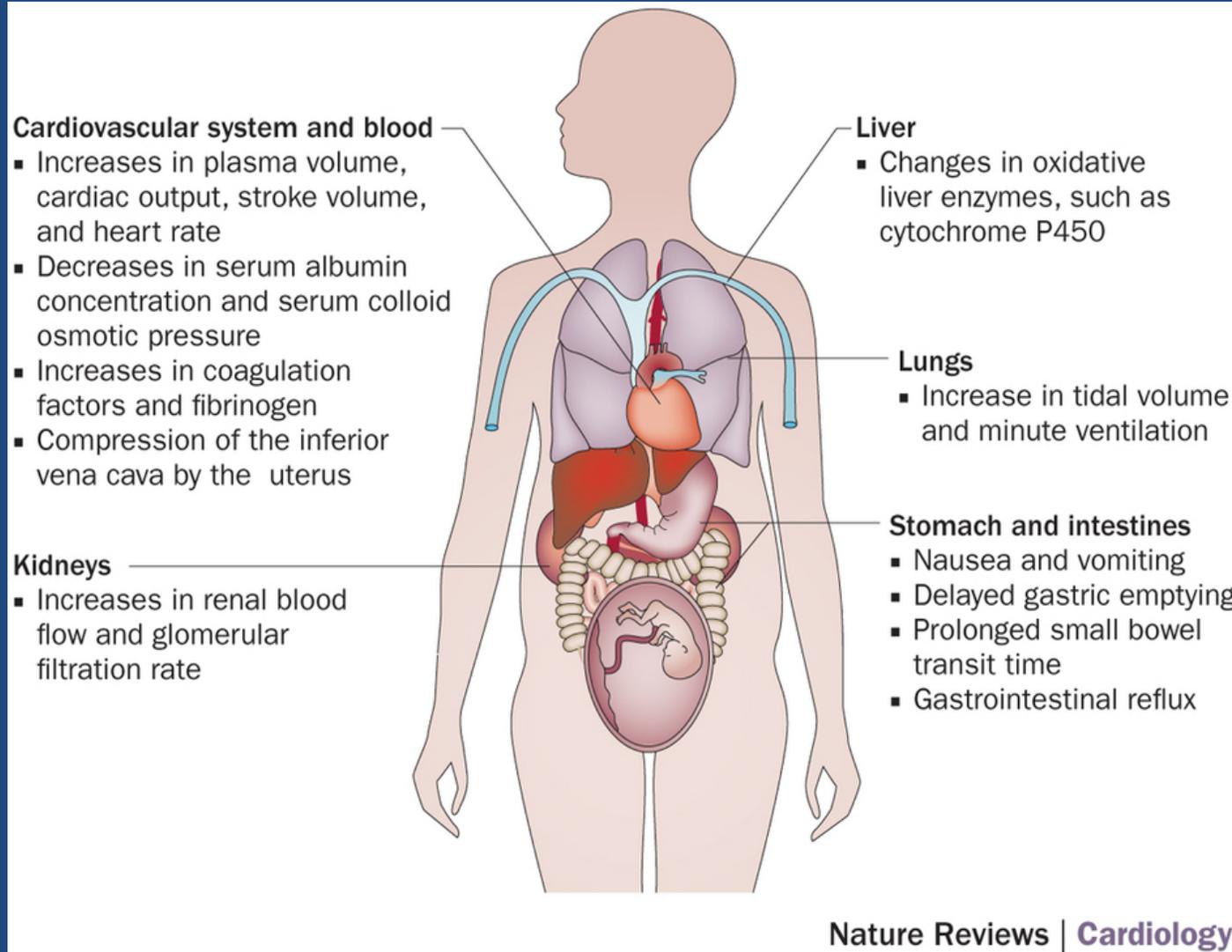
# DISCLOSURE

- No direct financial conflicts of interest
- Research funding related to medication studies in pregnancy from NIH, industry, university, foundation sources

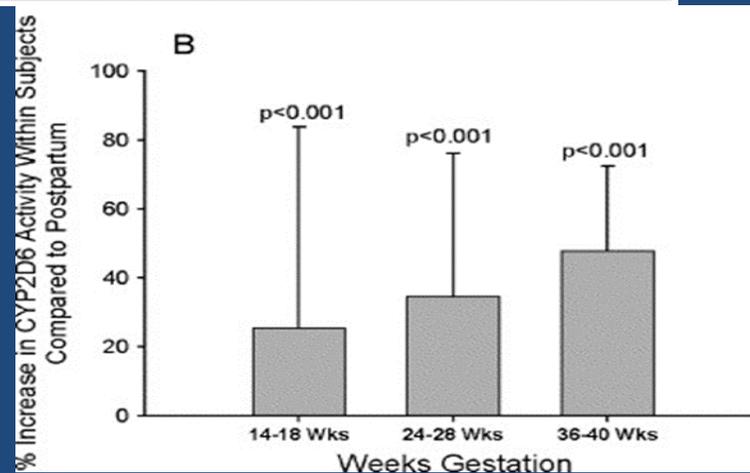
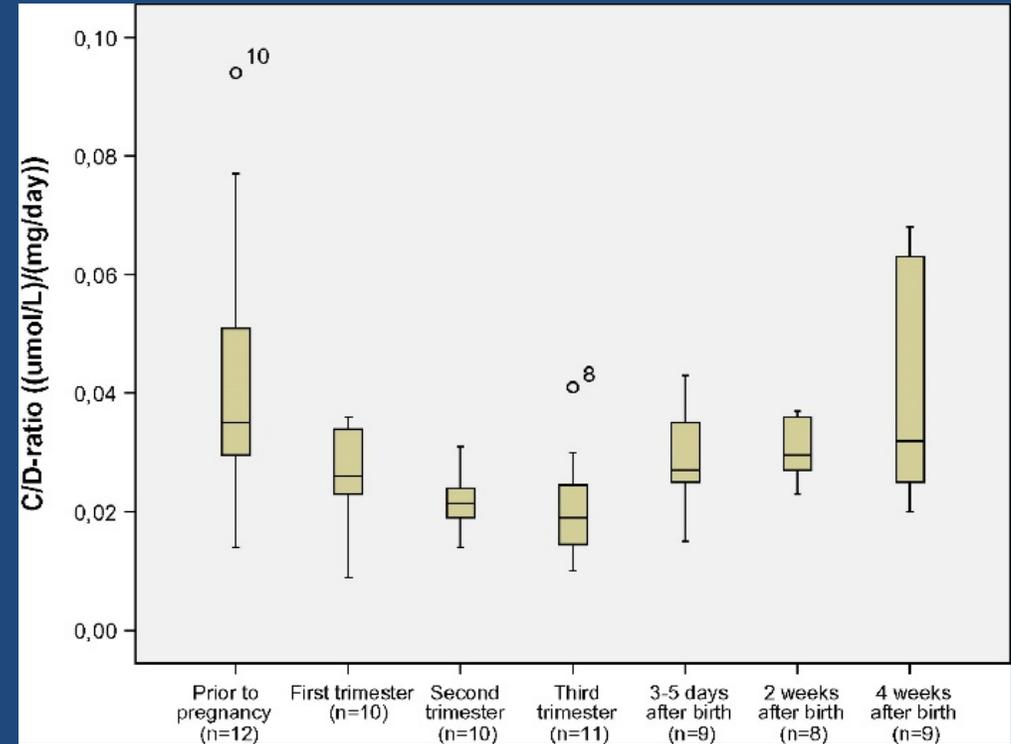
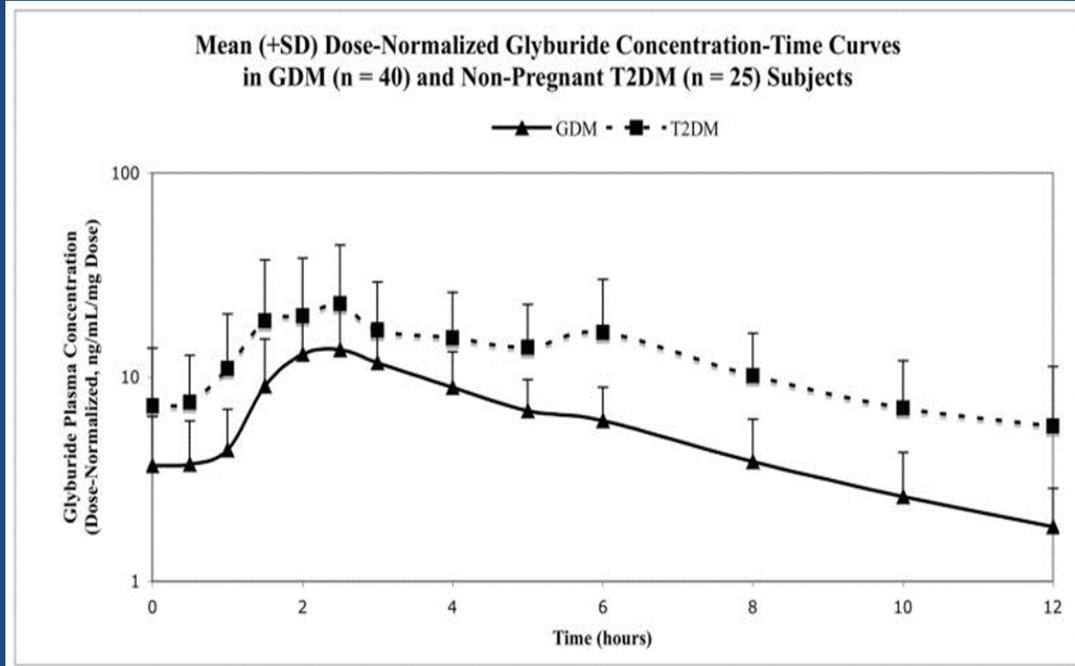
# Reluctance- why?

- History of missteps (next talk)
- Pregnancy-induced differences
- Complexity
  - Regulations and laws
  - Lactation
  - Participant reluctance

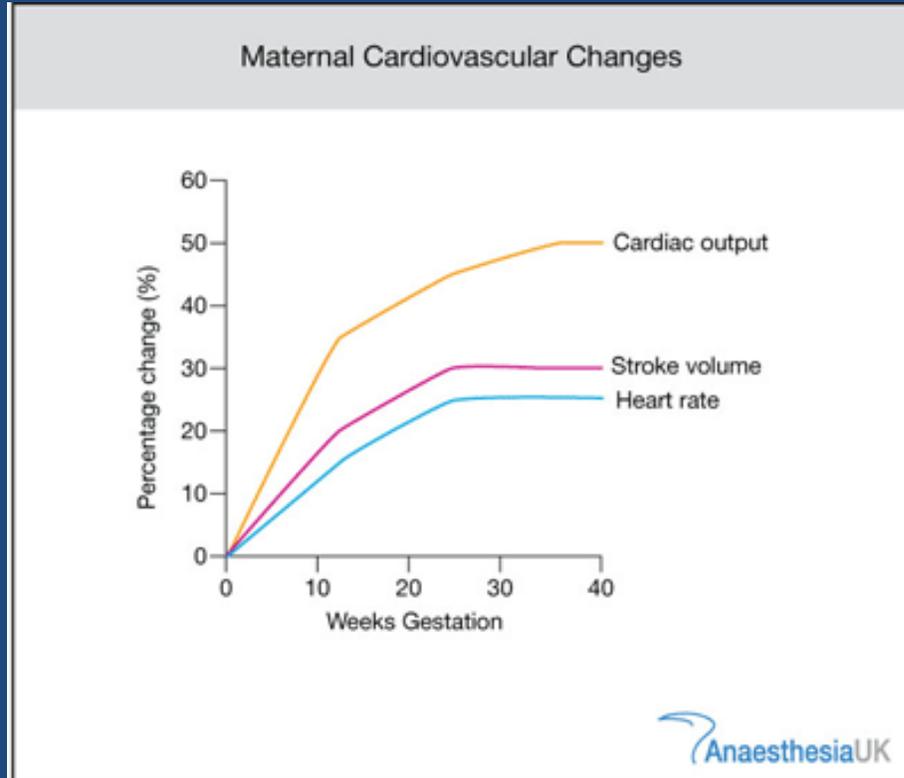
# Women are different when they are pregnant



# Changes throughout pregnancy



# Changes throughout pregnancy



- Labs change
- Physiologic outcomes can be difficult to distinguish from side effects

# Same patient?

- Start with differences and differences can develop as it goes
- Can present analytical challenges



# Complexity

- Regulations
  - 2 participants, increased regulatory requirements
  - Different laws in different states about pregnant minors
  - Protection as vulnerable population
  - INDs needed for medication studies
  - Tight protocols that aren't generalizable

# Lactation

- Attempts to protect babies from any risks
- Women have conditions that need treating
- Navigating balance of need for data and breastfeeding encouragement
- Little data
  - Sampling issues
  - Modeling of effect
  - Short/long-term outcomes

# Participants themselves are complex

- Protective feelings, fear of “research”
- Anxiety with adverse conditions
- Health literacy
- Participant-centered study design
- Protection **through** research, not **from** research