

## Study Design Workshop

Robert L. Reid, M.D.

Queen's University



Copyright 30/09/05 by Robert L. Reid

## Retrospective Study

### Design

- To study factors associated with development of congenital heart disease (CHD) in fetuses
- 200 women with first trimester spont AB in which CHD is identified on pathology
- Control group: induced 1st trimester AB with no CHD
- 100 Variables assessed by interview in 120/200 with CHD and 80 / 200 Controls

## Findings

- CHD fetuses 3x more anti-nauseant exposure ( $P < 0.05$ )
- No difference in tranquilizer exposure
- CHD maternal age 23 vs. Control 18 yrs
- CHD coffee 3.7 cups/day vs Control 3.5 ( $P < 0.05$ )
- Of remaining 96 variables blonde hair and height  $> 5'6''$  significantly associated with CHD

## Conclusions

- Anti-nauseant drugs cause CHD
- Tranquillizers are safe
- Women should be encouraged to have children before age 20
- Coffee drinking should be avoided in pregnancy
- Unsuspected risk factors of height and hair colour were established

Dogs Aren't Often Allowed in Elevators

### Design

Assignment

Outcome

Analysis

Interpretation


Extrapolation

## Design

What Design?

- Was a Specific hypothesis stated
- Were study groups properly selected

## Design

- Case / Control
- Fishing Expedition
- Design
  - 1) Assumes common etiology, CHD Septal Defects / Outflow Anomalies
  - 2) Only detects CHD severe enough to  
     SpAB

## Assignment

- Were Controls similar to Cases?
- What possible differences?

## Assignment

### Differences:

- Age
- Attitudes to pregnancy
- Drug /Alcohol exposure

## Outcome

- How determined?
- Follow up rates satisfactory?
- Biases?

## Outcome

- High “Lost to follow up”
  - Weakens conclusions
  - Fewer controls – supports different attributes
- Recall bias
  - SpAB highly emotional

## Analysis

- Relationship CHD and anti-nauseants?
- Safety of Tranquillizers?
- Significance of height and hair colour?

## Analysis

- Lack of cause – effect relationship
  - Cause precedes effect
  - Change Cause changes Effects
  - Dose / Response
  - Biological plausibility
- Tranquillizers used by a small “n”
  - Sample size
- Height / Hair colour
  - 100 Variables, Bonferonni Correction

## Interpretation / Extrapolation

- Are tranquilizers safe?
- Should teen pregnancy be encouraged?
- Should coffee be avoided?

## Interpretation / Extrapolation

- No proof of tranquillizer safety
- Teen pregnancy  $\Rightarrow$  benefits vs. risks
  - Common sense
- Coffee - Statistical vs. Clinical significance