



Gideon Koren MD  
Motherisk and Ivey Chair  
U of Toronto and UWO



# DRUG RESEARCH IN PREGNANCY; ETHICAL AND SAFETY CHALLENGES

# Motherisk Program

- Est. 1985
- Counsels up to 200 women and their health professionals daily
- Followup of pregnancy outcome
- 30%- drugs in breastmilk
- Long term neurodevelopmental outcome
- Special lines: Drugs-Alcohol; Morning Sickness
- 900 peer review papers , 15 books
- Training physicians from over 40 countries

# Safety Concerns

- During embryogenesis- drugs may arrest fetal development, causing morphological and/or neurodevelopmental harm
- Thalidomide
- Isotretinoin
- Valproic acid
- Cytotoxic drugs

## Safety in Pregnancy (2)

- Physicians practice as if every drug is a new thalidomide
- In reality- very few drugs cause fetal damage
- Industry does not wish to touch pregnant women
- How can we then advance therapeutic options for pregnant women?

# Optimal Safety Studies in Pregnancy

- With half of all pregnancies unplanned- tens of thousands of babies are exposed in utero to medicinal drugs
- Cohort studies, capturing these events, follow up and comparison to comparison groups= can yield initial estimates of risk/safety
- Later case control studies, database linkage studies and meta analyses can refine these estimates

# Ethical Challenges(1)

- “Due to the ethical dilemma of exposing the fetus- our company cannot study effectiveness in pregnancy in a controlled intervention studies”
- “ Older drugs with better safety profiles should have priority over new drugs”condition
- “The risk benefit balance must include the risk of the untreated maternal condition(e.g. montelukast)

# Ethical Challenges (2)

- “Maternal- fetal conflict”
- Research on fetus/fetal tissues during elective abortion
- Communication of Safety-Risk balance when there is no RCTs

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