Regulation of Research with Pregnant Women in Latin America

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Regional regulatory landscape

- From nothing to too much (at least for clinical trials)
  - Regional taste for legal / regulatory "density"
- "Restrictive": Allow only subset of what is ethical based on international guidelines
  - Tendency (at least initially): Forbid in all cases what is unethical in some cases

    Are we throwing the baby out with the bathwater?
  - Ethics confused with compliance: No need for ethics analysis

Lack of trust as background

- Negative perception of research
- Lack of trust of key players: ERCs, researchers
  - Regulations (i.e. categorical prohibitions) meant to address it: No room for ERCs to make decisions based on analysis of cases
    - ERCs often support this view: Lack of training, out of comfort zone
    - Strong hand of the law, ethics is “soft”
- Lack of trust –also of pregnant women as a research subject?
  - Others have to step in: consent of partner / father

Research with pregnant women

- Protection interpreted as requiring categorical exclusion due to vulnerability
- Mostly: Inclusion only for pregnancy studies, if minimal risk to fetus, with extra provisions (consent by others, no extra vulnerability)
  - Extreme case: in no circumstances
- Required active measures to prevent pregnancy during clinical trials
  - E.g. two simultaneous contraception strategies for inclusion of women of reproductive age

Zika Ethics Consultation:
Ethics Guidance on Key Issues Raised by the Outbreak

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Is it ethical to do research with pregnant women?

- Yes, and morally important
  - Critical to providing pregnant women with safe and effective medical treatment: Imperative for their own health and the health of their offspring
  - Urgently needed due to changes in pregnancy.
- Zika: different studies with pregnant women are needed and should be promoted