Ethical issues in therapeutic use and research in pregnant and breastfeeding women

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Abstract

Pregnant, or potentially pregnant women have historically been excluded from clinical trials of new medications. However, it is increasingly recognised that it is imperative to generate evidence from the population in whom the drugs are likely to be used in order to inform safe, evidence-based shared clinical decision making. Reluctance by researchers and regulators to perform such studies often relates to concerns about risk, particularly to the fetus. However, this must be offset against the risk of untreated disease or using a drug in pregnancy where safety, efficacy and dosing information are not known. This review summarises the historical perspective, the ethical and legal frameworks which inform the conduct of such research, then highlights examples of innovative practice which have enabled high quality, ethical research to proceed to inform the evidence-based use of medication in pregnancy.

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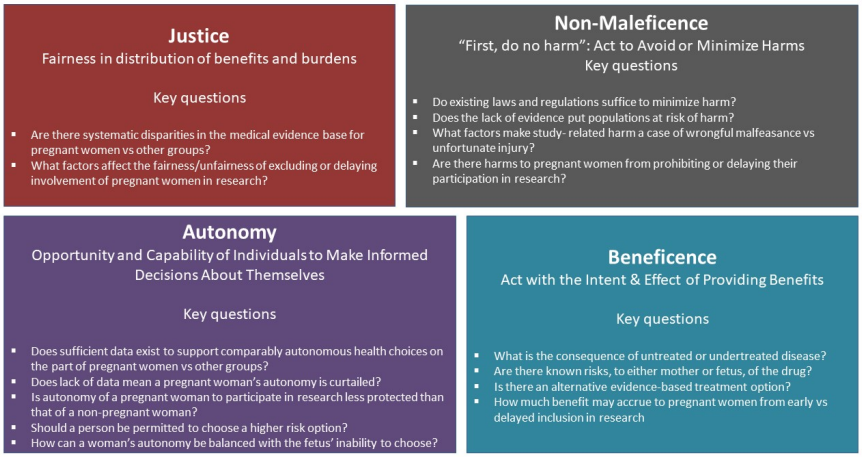
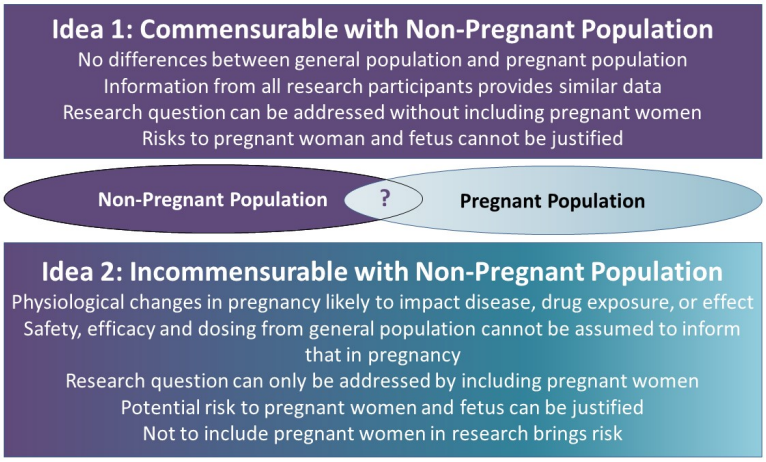
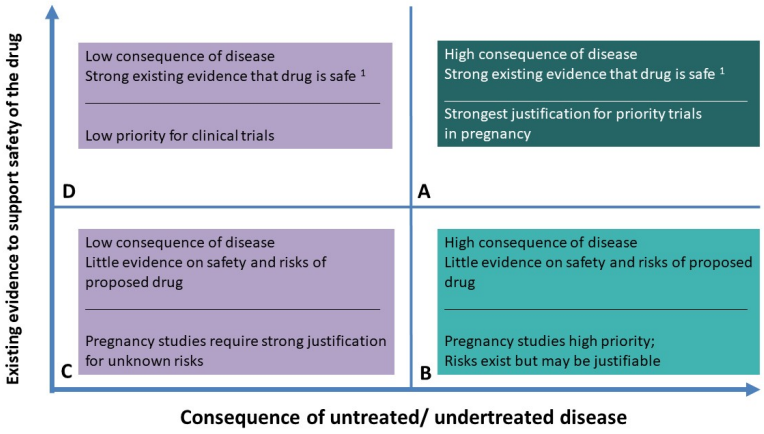
`Ethics in Pregnancy Final Draft.pdf` available at https://authorea.com/users/403986/articles/515306-ethical-issues-in-therapeutic-use-and-research-in-pregnant-and-breastfeeding-women







[1](from trials, pharmacovigilance systems, etc.)