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# Clinical Research Involving Pregnant Women

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BOOK REVIEW

## Clinical Research Involving Pregnant Women by Françoise Baylis and Angela Ballantyne, eds. Switzerland: Springer, 2016.

I shall begin this review with a personal story. My wife was pregnant with our second child. She and I were dedicated to a natural childbirth. She was prescribed iron supplements by her obstetrician, which came in red-colored capsules. My wife was skeptical about the safety of the red dye and asked me to check it out. I contacted the manufacturer of the supplement who then guided me to the capsule maker. I learned that the dye was approved by the Food and Drug Administration (FDA) and that it was derived from coal tar. I could find no articles that discussed the safety of the dye on pregnant women or their fetuses. We took a further step and had a friend undertake an Ames test on the red capsule. The results were negative. I reported that to my wife and explained false negatives in the test. Her final decision was to open the capsule, swallow the iron supplements, and then discard the capsule.

It has been widely reported that pregnant women are largely excluded from clinical trials. And if they are not excluded, then they are hard to recruit. A recent article in *Obstetrics and Gynecology* reported as follows: "Clinical research in the pregnant population allows for delivery of quality, evidence-based care in obstetrics. However, in recent years, the field of obstetrics has faced severe challenges in the recruitment of the pregnant population into clinical trials, a struggle also shared by several other medical disciplines" (Sutton et al., 2017). In large part, the source of this exclusion arose from two pharmaceutical debacles that took place in the 1950s and 1960s. Thalidomide was prescribed for pregnant women to treat "morning sickness." This resulted in severe limb malformation in an estimated 10,000 infants. Diethylstilberstrol (DES) is a synthetic estrogen which was used to treat millions of pregnant women for a variety of conditions, none of which were validated in clinical trials. At the time it was used, the burden to prove that it was safe and effective did not rest with the company that manufactured it, but was left to the FDA.

This volume of scholarly research examines the question of whether pregnant women should be included in clinical drug trials and other experimental interventions and if so under what conditions and for what types of investigations. The book is divided into four parts. Part I provides arguments for why pregnant women should be included in clinical drug trials. Part II discusses the arguments and reasons behind excluding pregnant women from such research, following the ethical boundaries established after thalidomide and DES. Part III develops the moral theory for finding a middle ground that does not preclude women from participating in clinical trials. It also explores the research methods, the protection of pregnant women, and their empowerment to make such decisions. Finally, Part IV looks at some practical cases where clinical trials can advance the health of women and their fetus such as pregnant women with AIDS, uterine transplantation, and the use of interventions such as probiotics in pregnancy.

Notwithstanding the repetitions in a group of independent essays and the poor indexing, the analytical quality and the depth of the contributions make this volume an important addition to the ethical and policy discussions about clinical trials involving pregnant women.

Some examples of what readers will find are as follows. L. Syd M. Johnson in Chapter 9 ("When Hypothetical Vulnerability Becomes Actual") discusses the Common Rule in terms of whether pregnant women are vulnerable populations and if they should be able to make autonomous choices regarding their participation in clinical trials. Chris Kaposy in Chapter 4 ("Presumptive Inclusion and Legitimate Exclusion Criteria") argues that if pregnant women were generally excluded from clinical trials, they will continue to be treated with off-label drugs, where there is no good evidence for safety or efficacy. Indira et al. in Chapter 5 ("Fair Inclusion of Pregnant Women in Clinical Research") reviewed 31 studies that revealed the reasons for excluding pregnant women. Not surprisingly, they found the most frequently cited reason was to protect the fetus. The study reveals a great deal about the rationale behind exclusion. Healy and Mangin in Chapter 11 ("Does My Bias Look Big in This?") takes on the gold standard for any drug evaluation, namely randomized controlled trials (RCT). When it comes to women's health, they prefer comprehensive pregnancy registries based on observational studies over RCTs. It was, after all, a placebo-driven RCT that provided the evidence for prescribing thalidomide to pregnant women. This chapter contributes to the current pushback of RCTs as the sole standard for drug safety and effectiveness.

Like much of the volume, these chapters take a systems approach. Fetal vulnerability can be understood both when the pregnant woman does or does not participate in a clinical trial. Patient autonomy can only be realized when there is full knowledge on which to exercise choice and that knowledge may require pregnant women participating in clinical trials. And lifestyle is the complex system that defies simple answers. Ballantyne et al. in Chapter 12 ("Research into Lifestyle Changes in Pregnancy") explore the role of research in determining lifestyle interventions and behavioral norms for maternal and fetal health.

This volume has much to offer bioethicists, clinical researchers, and health policy specialists as well as those advocates of evidence-based medicine in reproductive care for a more nuanced understanding of pregnant women in research studies.

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