

Book Review: F. Baylis & A. Ballantyne (2016) Clinical Research Involving Pregnant Women

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Résumé de l'article

Les preuves scientifiques à l'appui des soins prénataux sont rares en raison de l'exclusion généralisée des femmes enceintes de la recherche clinique. L'ouvrage de Baylis et Ballantyne, *Clinical Research Involving Pregnant Women*, est un puissant défenseur de la promotion de la recherche clinique avec des femmes enceintes, bien que quelques questions méritent une attention plus soutenue pour faciliter cette recherche.

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COMPTE RENDU / REVIEW

**Book Review: F. Baylis & A. Ballantyne (2016)
*Clinical Research Involving Pregnant Women***Kyoko Wada¹**Résumé**

Les preuves scientifiques à l'appui des soins prénataux sont rares en raison de l'exclusion généralisée des femmes enceintes de la recherche clinique. L'ouvrage de Baylis et Ballantyne, *Clinical Research Involving Pregnant Women*, est un puissant défenseur de la promotion de la recherche clinique avec des femmes enceintes, bien que quelques questions méritent une attention plus soutenue pour faciliter cette recherche.

Mots-clés

recherche clinique, pratique fondée sur des données probantes, fœtus, justice, sélection des patientes, femmes enceintes, soins prénataux

Abstract

There is a paucity of scientific evidence to support prenatal care due to the wide exclusion of pregnant women from clinical research. Baylis and Ballantyne's book, *Clinical Research Involving Pregnant Women*, stands as a powerful advocate for promoting clinical research with pregnant women, although a few issues may deserve further attention to facilitate such research.

Keywords

clinical research, evidence-based practice, fetus, justice, patient selection, pregnant women, prenatal care

Fair participant selection is one of the basic ethical principles for conducting clinical research [1]. Specifically, in terms of women, the Canadian research ethics guideline stipulates that: "Women shall not be inappropriately excluded from research solely on the basis of their reproductive capacity, or because they are pregnant or breastfeeding." [2] Nevertheless, pregnant women have been widely excluded from clinical research across jurisdictions despite their needs for medication and healthcare procedures for both obstetrical and non-obstetrical conditions. Recognizing the underrepresentation of pregnant women in clinical research as a justice issue, in their edited book *Clinical Research Involving Pregnant Women*, Baylis and Ballantyne have compiled the scholarly work of leading authors to argue for a paradigm shift in understanding pregnant women as research participants [3]. Overall, this book stands as a powerful advocate for promoting clinical research with pregnant women, although a few issues may deserve further attention to facilitate such research.

Part I elaborates on clinical problems generated by an almost automatic exclusion of pregnant women from clinical research. The lack of scientific evidence to guide prenatal care seriously compromises both maternal and fetal health. The main argument is clear: Pregnant women should be presumed eligible to participate in clinical research. *Part II* examines reasons behind excluding pregnant women from clinical research, such as fetal safety, liability, and insufficiency of regulatory guidance. An empirical study with pregnant or postpartum women illustrates their attitude of refraining from using medication during pregnancy as well as emotional and physical distress due to the fear of harm when they had to use medication. *Part III* focuses on theoretical issues, specifically, alleged vulnerability of pregnant women and key concepts in study designs. Two chapters concern the inappropriateness of attempting to protect pregnant women by identifying them as a vulnerable population while the other two chapters question critical concepts in study design, namely, the notion of equipoise and randomized controlled trials (RCT). *Part IV* introduces a variety of topics through case studies, starting off with research investigating lifestyle interventions, which is a shift from *Parts I* to *III* where much discussion appears to revolve around medication. Other topics in *Part IV* include cutting edge and/or ethically charged issues, such as maternal gene transfer, research with women seeking abortion, and uterine transplantation.

This book persuasively illustrates current clinical problems and potential paths to enhance clinical research with pregnant women. However, a few critical issues that deserve more discussion include strategies to improve understanding by the general public about clinical research with pregnant women, additional costs for including pregnant women in research, and emerging study designs that could support research with this particular population.

First, a paradigm shift of this contentious issue requires a wide consensus among the general public. In this book, Wild and Biller-Andorno (Chapter 7) have drawn upon their empirical work to illustrate that pregnant women considering participation in research would not accept any fetal risk. In societies where people expect a healthy baby to be born, a persistent desire for fetal safety across cultures is extremely challenging to address. Baylis and MacQuarrie (Chapter 2) rightly emphasize the risk of using drugs off label as part of clinical care – prescribed or over the counter – where monitoring is much less intensive compared with research contexts. Nevertheless, research inherently involves unknowns; and unknown risks in research are worrisome even with a sophisticated monitoring system, given a fetus with a high sensitivity to chemicals or other exposure due to rapid development in-utero. The general public, including pregnant women, may presume that research participation is riskier than receiving clinical care. Ideas are needed to inform the general public about risks, safety, and benefits of clinical research and the importance of research evidence to support maternal and fetal health. Promoting research with pregnant women requires understanding at a societal level to support pregnant women, their partner/family, researchers, and sponsors toward the inclusion of pregnant women in research.

Second, the inclusion of pregnant women in clinical research is costly, even though they constitute a relatively small market. Mandating pregnant animal studies for any product that may be useful for pregnant women, as Ells and Lyster suggest (Chapter 6), may be a way forward. Nonetheless, conducting pregnant animal studies as a prerequisite and a separate analysis for pregnant humans entails additional costs. Will pharmaceutical companies or funding agencies be ready to fund projects for

including pregnant women? In societies where funding can be a major delimiting factor, researchers have been frustrated with resource constraints. Moreover, sponsors as well as researchers may perceive increasing liability concerns for including pregnant women, which might incur further costs. Securing adequate resources is a huge barrier to be addressed in conducting clinical research with pregnant women.

Third, emerging study designs may be a reasonable topic to discuss when seeking optimal approaches to researching pregnant woman. Building pregnancy registries is recommended in two chapters, one from risk perspectives (Ballantyne and Rogers, Chapter 8), and the other from study design perspectives (Healy and Mangin, Chapter 11). Pregnancy registries are indeed useful as they can help accumulate clinical data that informs clinical practice without exposing anyone to additional risks for the sake of research. Healy and Mangin (Chapter 11) argue that a pregnancy registry from “the greatest possible input from the widest range of sources” will be an ideal resource for clinical decision-making. They also lay out reasons against RCTs and the difficulty of employing their recommended approach involving “challenge-dechallenge-rechallenge” tests in drug studies with pregnant women. Nevertheless, the research community has been making advancements in trial design to complement conventional RCTs, the current gold standard. Novel study designs that are in line with precision medicine aim at more tailored approaches in contrast to one-size-fits-all approaches. Also worth considering are adaptive designs where some features are adapted during the course of research based on the data collected earlier in the study. These study designs are all worthy of consideration in the careful crafting of research designs to include pregnant women.

Clinical Research Involving Pregnant Women may interest a wide readership, such as clinicians across specialties who treat pregnant women in their practice, potential investigators of research with pregnant women, basic scientists in reproductive sciences, policy makers, lawyers, and ethicists. Informing the readers, this book sparks further questions and discussions that may keep the ball rolling toward a fair inclusion of pregnant women in clinical research.

Conflicts d'intérêts

Aucun à déclarer

Conflicts of Interest

None to declare

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