

Sex Bias in Drug Development: The Consequences of Excluding Women from Clinical Trials

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Introduction: Historically, women have been underrepresented in clinical trials. This gender gap has led to a male-centric database in drug development, resulting in inadequate treatment outcomes for women. The aim of this study is to highlight the importance of including both sexes equally in medical research.

Methods: A structured literature review was conducted using four peer-reviewed articles selected based on their relevance, recent publication dates, and strong data quality. The studies examined gender bias in clinical trials, adverse drug reactions (ADRs), and differences in pharmacokinetics and pharmacodynamics between sexes.

Results: Women are nearly twice as likely to experience ADRs as men. Key examples include zolpidem, for which the dosage was later halved for women, and cardiovascular drugs that pose a higher risk of torsades de pointes in females. Analysis of the FAERS database showed that 61.9% of drug-related adverse event reports were from female patients, indicating a significant sex-based disparity in drug safety.

Discussion: Biological differences between sexes, such as hormone levels and metabolism, necessitate equal representation in trials. The exclusion of women leads to inaccurate dosing and incomplete understanding of drug effects in female patients. Addressing this gap can improve treatment efficacy and safety for both sexes.

Keywords: Sex bias, clinical trials, adverse drug reactions, pharmacology, gender disparity