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Letter to the Editor

Applying sex as a biological variable in research and clinical care: a need for uniform policy

Sir,

Sex as a biological variable (SABV) has to be recognized in both preclinical (basic) and clinical research, as a major contributor to disease risk, phenomenology, natural history, treatment and adverse effects, and disease severity.[1]

To consider sex as a biological variable in research, it is necessary to appreciate the following: to define and distinguish sex from gender: "sex" originates from sex chromosome complement and is involved in all aspects of physiological functioning, the term "gender" refers to the human male and female traits in the context of social, cultural and psychological factors; there are differences between the sexes at the cellular, molecular and genetic levels; without applying SABV in research there will be gaps in our knowledge of how similarly or differently the sexes function or respond to treatment; and research findings in men cannot necessarily be applied to women, and vice-versa.

For many decades, in preclinical neuroscience research, male rodents had been the default model organism, which most likely contributed to higher rates of adverse effects of drug treatment in women. Studies have shown male rodents only were used in 80% or more animal studies in the fields of neuroscience, pharmacology, endocrinology, immunology, and physiology.[2]

Several drugs would have been recalled because of severe adverse effects in women, as the clinical trials were carried out often without sufficient population of women.[3]

To deliver gender appropriate medical care for both women and men, and to fill in the gaps of our knowledge of male and female biology, studying both sexes in clinical and preclinical research is necessary.

The medical research bodies should therefore formulate research policies, that ensures the inclusion of SABV into research designs, analysis, and reporting in both animal and human studies.

This will help the entire medical scientific community to produce a more representative, equitable, reproducible, and therefore translational body of knowledge.

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