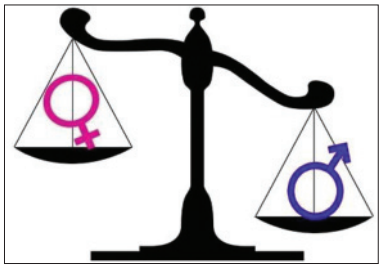
Trial Women: Empower Women

It is an established fact that, the two genders are different biologically, and likewise manifestations and progress of diseases differ accordingly. Taking this into account, both genders must be included in medical research to enable results to be assessed more specifically. Women in most of the studies have been discriminated with regard to their involvement in research. Women who are biologically capable of becoming pregnant have been customarily excluded from formal research procedures. Consequently, little is known about the safety and efficacy of most drugs, vaccines or devices for such women and this lack of knowledge can be dangerous. A general policy of excluding from such clinical trials women biologically capable of becoming pregnant is unjust in that it deprives women as a class of persons of the benefits of the new knowledge.

Nevertheless, although women of child-bearing age should be given the opportunity to participate in research, they should be helped to understand that the research could include risks to the fetus if they become pregnant during the research. When women in such situations are potential subjects in research, researchers need to exercise special care in the informed consent process. In the research involving women only the informed consent of the woman herself is required. In no case should the permission of a spouse or partner replace the requirement of individual informed consent. For women who are not pregnant at the outset of the study but who might become pregnant while they are still subjects, the consent discussion should include information about the alternative of voluntarily withdrawing from the study and, where legally permissible, terminating the pregnancy. Also, if the pregnancy is not terminated, they should be guaranteed a medical follow-up. In such cases underlined language of informed consent must be solicited.

"If you are a woman who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to potentially dangerous agent with unknown risk. If you are pregnant or currently breast feeding, you may not participate in this drug study. You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unknown risk [or state specific risk. To confirm to the extent medically possible that you are not pregnant, you agree [to have a pregnancy test done before beginning this research study] [to begin the study after the onset of your next menstrual period] (choose one). You must agree to avoid sexual intercourse or use birth control method judged to be effective by the investigator, and that will not interfere with the proposed investigation. You must accept the risk that the pregnancy could still result despite the responsible use of a reliable method of birth control. You agree to notify the investigator as soon as possible of any failure of proper use of your birth control method, or if you become pregnant, either of which may result in your being withdrawn from the study. "

Researchers, conducting biomedical research, should not be afraid of involving women of reproductive age. There shall be no reason to exclude them from the study due to the fact of becoming pregnant during the study. However, Investigators, & ethical review committees should have a thorough discussion of risks to the pregnant woman and to her fetus. In this discussion, if participation in the research might be hazardous to a fetus or a woman if she becomes pregnant, the investigators should guarantee the prospective subject a pregnancy test and access to effective contraceptive methods before the research commences. According to National Institutes of Health (NIH) the research ethics committees are responsible for keeping abreast



of developments in respect of the inclusion of both genders in medical research and for revising these guidelines as required. The evidence basis of medicine may be fundamentally flawed because there is an ongoing failure of research tools to include sex differences in study design and analysis. The reporting bias which this methodology maintains creates a situation where guidelines based on the study of one sex may be generalized and applied to both. Although significant social progress has been made since then, the application of the principles behind the legislation to women's health and gender-based research have not been so positive. Minimizing gender bias in health systems requires systematic approaches to building awareness and transforming values among investigators, steps to improve access to health services and developing mechanisms for accountability. Moreover, mechanisms and policies need to be developed to ensure that gender imbalances in both the content and processes of medical research are avoided and corrected.

Prof. S. K.Jain
Editor-in-Chief

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