Perceptions of Pregnant Women with Low Educational Attainment about Informed Consent after Registering into Randomized Controlled Trial in India: A Qualitative Study
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Problem/ Issue Statement: A number of studies on informed consent indicate that improving consent forms and the overall consent process can lead to better patient comprehension and recall. But, a major challenge posed was to assure subject’s perception about the informed consent basic components, particularly among those with low educational attainment. Little has been done to determine either what patients want to know or what they think about informed consent after enrolling into the trial. Our aim was to assess the perceptions of pregnant women with low educational attainment about informed consent after registering into randomized controlled trial.

Research method: A cross sectional study was carried out among 120 pregnant women age 18 or above, participating in ongoing randomized controlled trial was surveyed. The purpose of the study was explained and the individual interview was carried out using interview schedule. All items regarded basic components of the informed consent such as: study objectives, potential benefits and risks, and participants’ rights and obligations were included. The interview started with brief introductory session. The questionnaires were filled in right after they had agreed to participate and signed the consent. Descriptive statistics were provided to measure subjects understanding of the informed consent.

Results: Out of 120 enrolled, 78% had high-school education or less, and only 2% had attended college. Mean age of the participants were 24±3.5 years. All individuals were participating in a randomized controlled trial for the first time. About 81% of subjects were satisfied with the information given. About 80% of the volunteers were able to identify correctly study objectives and potential benefits. Only one third acknowledged that there could be no benefit from enrolling in the trials. About 30 % of the participants did not follow the meaning of trial. The vast majority understood the right to withdrawal from the study without prejudice (83%), but a lower percentage (16%) did not understand the term research purpose. All subjects reported being comfortable about giving consent, and none felt pressured by any site personnel to enroll in the trials.

Conclusions: In general, the understanding about basic components of the informed consent in this population of low educational attainment was good, particularly, in regard to study objectives and participants rights. However, knowledge about potential study risks and the term like trial was poor. These items should be the focus of strategies to improve subjects understanding of the informed consent.