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Inherent variability among measures of fertility of rats and its implications in the design of mating trials

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Mating trials are used extensively to assess the effects of experimental treatments on the fertility of male or female subjects. Such trials are often insensitive because many measures of fertility are associated with large inherent variability, which makes it difficult to confirm, by statistical significance, that observed differences among treatment means are actually due to treatment rather

than due to chance. Unfortunately, and despite this insensitivity, most researchers choose replication arbitrarily on the basis of cost, convenience, or conventional practice and interpret results without assessing the actual power and sensitivity of their experiments. This study was undertaken to characterize the relationship between the number of rats used in fertility trials and experimental power and sensitivity. The variables examined included pregnancy rates, numbers of fetuses per mated or per pregnant female, numbers of fetuses per corpus luteum, and numbers of fetal resorptions. The relationship between replication and experimental power and sensitivity was estimated via statistical approaches utilizing data from Sprague-Dawley rats used in a mating trial at 105-109 days of age. Tabular data are presented showing the numbers of rats needed per treatment group as a function of the minimal treatment differences to be detected and type II error probability selected. The application of these data in the planning of future studies and in interpreting their outcome is discussed.

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