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Importance of Sample Size Calculation in the Original Medical Research Articles from Developing Countries

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Abstract

Sample size calculation is very important for medical research. Because medical data is with uncertainty and most of the studies deals with a small sample and infer about a big population. But most of the researchers from developing countries like Nepal are not aware about this and who aware are not able to use this scientific area. Medical Journals should keep a criterion for publication of manuscripts to the authors that it will not be published, if the sample size calculation is not done. Then only the actual objective of the study will be proved.

Introduction

In Medical research, it is important to determine a sample size sufficient enough to ensure reliable conclusions. If the study is well designed with a desired sample size then the standard error will be less and the power and precision will be good. All statistical procedures become valid in this context. Every researcher must strive for the proper sample size and the protocol should contain its details.

Inferential statistics has two parts: estimation of population parameter and testing of hypothesis. According to the type of medical research, any one of them can be adopted. The estimation method is used in prevalence/descriptive studies and the testing of hypothesis is used for cohort/case control/clinical trials.

Using estimation method, the best estimates for population characteristics such as prevalence, incidence, mean, standard deviation, etc. can be found out.

By testing the hypothesis, correctness of whatever values or any relationship or association between variables derived from estimation can be verified.

These are the two requirements for the analysis of data in medical research. Before the testing of the hypothesis, one must confirm the type of normality of the data so that the type of the test (parametric or non parametric) can be decided. Violation of this rule will result in wrong conclusion. Once the correct test is selected, the next important step is to determine the sample size. If proper attention is not given to the determination of the sample size, a real difference will become statistically insignificant. Thus, the study has to be repeated on a larger sample so that the real difference can be statistically proved. A randomly decided sample will invite non sampling errors in the study. An under sized sample will not give correct information and that will turn into a waste of time and resources. An over sized sample will end up with loss of resources with respect to money, man power and time. As a result, both errors will entail even unethical outcomes.

Therefore, sample size determination is an important issue in medical research but availability of literature in this topic is scanty. On a recent survey a few of them were located[1-24].

Practical Examples

1. Sample size calculation for The Significance of Hepatobiliary Enzymes for Differentiating Liver and Bone Diseases: A Case Control Study from Manipal Teaching Hospital of Pokhara Valley with 95% confidence interval and significance level ? = 5%. We conducted a pilot study of 100 cases each of all the diseases included in this study. In extra hepatic cholestasis, ?= SD of the ALP = 285, allowable error = 35, and required sample size was 255. In Paget's disease, ?= SD of the ALP = 220, allowable error = 25, and required sample size was 298. In Osteomalacia, ?= SD of the ALP = 200, allowable error = 24, and required sample size was 267. ?= SD of the ALP in Osteomalacia cases. In Viral hepatitis, ?=500, allowable error = 57, and required sample size was 296. ?= SD of the ALT in cases of viral hepatitis.

2. Sample size calculation for Depression and its Cure: A Drug Utilization Study from a Tertiary Care Centre of Western Nepal. For 95% confidence interval and, significance level ? = 5%, P = 90%, Q = 10%, allowable error = 11%, required sample size was 35. P = percentage of antidepressants drugs used for the treatment of depression. In the pilot study done prior to the original study with 10 patients were admitted in the

psychiatry ward with depression.

3. Sample size calculation for Attitude of Basic Science Medical Students towards Post Graduation in Medicine and Surgery: A Questionnaire based Cross-sectional Study from Western Region of Nepal. For 99% confidence interval and, significance level ? = 1%, P = 70%, Q = 30%, allowable error = 10%, required sample size was 218. P = percentage of students selected their PG as Medicine and surgery.

4. Sample size calculation for Suicidal ideation among students of a medical college in Western Nepal: A cross-sectional study. Minimum sample size calculated was 185, after considering the findings from the pilot study which showed that 10% had recent suicidal ideation and keeping the confidence level at 95% and fixing the allowable error at 10%.

5. Sample size calculation for Estimation and Comparison of Serum Levels of Sodium, Potassium, Calcium and Phosphorus in Different Stages of Chronic Kidney Disease. In a pilot study of 9 patients with stage I CKD, we found Mean potassium was 4 and ? = 0.1 = standard deviation. For, 95% confidence interval, Z = 1.96, 5% significance level, E = 0.04 = Allowable error. Therefore required sample size with n = $\{Z^2 * ?^2\}/E^2$ was 24.

There are several other good studies which will be helpful for the researchers to understand the methodology of sample size calculation in Medical research[25-36].

Suggestions

1. If the effect of a clinical treatment is not marked when compared to a placebo, or power of the study is low, or a lower significance level (lower ‘p’ value) is expected, the sample size should be increased.
2. If the measurements are highly varying, use the average of repeated measurements.
3. Determine the scientifically acceptable power and level of significance.
4. Estimate the event rate form similar population.
5. In research protocols, statistically determined sample size, power of the study, significance level, event rate, duration of the study, and compliance should be mentioned.
6. The sample size should be increased to adequate level for each sub-group when dealing with multiple sub-groups in a population.
7. Always aim for a cost effective sample size.
8. In small negative trials, meta analysis can be tried.
9. When a study requires very large sample size net working with other researchers engaged in similar projects and Multi-centre trials will be beneficial.
10. A study which needs a large sample size to prove any significant difference in two treatments must ensure the required sample size. Otherwise such studies may not provide much information by any method and are better terminated so that the money and time are at least saved.

Conclusion

Carefully and well planned Medical research will result in relevant and socially useful results. Planning has several parts, such as well defined relevant research hypothesis, objectives, subjects must be selected from appropriate population, and instruments should be reliable, carefully undergone through best possible procedures and other guidelines. Sample size determination is very important and always difficult process to handle. It requires the collaboration of a specialist who has a good scientific knowledge in the art and practice of medical statistics.

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