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Determination of the Size of a Trial, Using Lindley's Method

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Extended Abstract. When a new treatment is being considered, trials are carried out to estimate the increase in performance which is likely to result if the new treatment were to replace the treatment in current use. Many authors have looked at this problem and many procedures have been introduced to solve it. An important feature of the analysis in this work is that account is taken of the fact that only if it turns out that the new treatment, in a statistical sense, is clearly better than the previous treatment will the number of subsequent users of the new treatment be high.

Traditional classical methods of selecting sample sizes are based on the required size, and the required power of the test for a specified treatment effect. The most frequently used sample size formulae arises from the relationship between the standard error of the estimator of the parameter of interest and the sample size.

Since the formulae can be highly sensitive to the choice of inputs, careful selection of the parameter estimates and target criteria are essential steps in determining the sample size. Classical or frequentist methods are unable to take into account uncertainty in point specifications. Bayesian methods are ideally suited for design since they provide a tool for specifying uncertainty, and how it changes in response to further information.

In this work we figure out the optimal size of randomised trial for which the utility function is assumed to be a function of the ratio of the posterior variance.

A Bayesian approach which was introduced by Raiffa and Schlaifer (1961) and developed by Lindley (1997) and O'Hagan and Stevens (2001) is applied. Our assumptions are somehow oversimplified and it might differ from what happens in reality. The aim is to show that the problem in a certain case has an explict solution and it could be extended to more complicated cases.

We assume that the data have come from a normal distribution for which its variance is supposed to be known. The objective function which is the

expected benefit from the resulting change in the number of subsequent users of the treatment minus the cost of the trial is maximized. We also assume that the cost of a trial is a known function of its size and the benefit per user of the treatment is a known constant. An explicit expression is obtained for the expected net benefit of the trial, and for the maximizing sample size. It is shown that the optimal sample size depends on parameters, C, T, and D. These parameters have the following interpretations:

C is a cost/benefit ratio,

T is a measure of our prior ignorance of parameter of interest,

D is a measure of our prior expectation of superiority of the new treatment.

If the benefit of using the new treatment is written from the standpoint of a company selling the new treatment, it may be appropriate to assume that the total benefit would be equal to the number of users times a fixed constant b per each user. For this case we have shown that the optimal sample size n^* is

$$n^* = \left[\left(\frac{D}{2C} \right)^2 - T^{-2} \right] + 1,$$

in which $[x]$ is the greatest integer less than or equal to x.

Our calculations show that n^* is a decreasing function of C and an increasing function of both T and D.

The limitations of the model, such as the problem caused by assuming an unbounded linear increasing function representing the number of subsequent users of the treatment, are also discussed.

Keywords. sample size; Bayesian approach; cost; net benefit; maximization of expected utility (MEU).

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