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Randomization, Replication and Local Control in Clinical Trials

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Abstract:

Designing of an experiment means deciding how the observations are taken in a valid, efficient and economical way. Randomization is a process of assigning the treatments in various experimental subjects in a purely chance manner. Replication is a process of of an experiment more than ones or repetition. Treatmentwas repeated to different groups of patients. The process of reducing the experimental error by dividing the relatively heterogeneously subjects in to homogeneous blocks is known as local control. Replication and randomisation leads to validity of the experiment. Replication and local control helps in reducing the error. This paper describes some of the main steps in those performing reviewers of randomized controlled trials.

Introduction:

The Biologist may encounter continuous data that have been collected serially in space or time. Rates of conduction may be measured at successive length along a nurve. A null hypothesis of no difference of conduction rate as on examiner successive portions essentially is stating all the measurements obtained are a random sample from a population of much measurement. Randomization satisfy the assumption required for statistical hypothesis testing. Fixed randomization schemes require consideration of the Allocation ratio, Allocation strata and block size. Here number of patients in each group are decided beforehand and is fixed in priori. Simple randomisation is most elementary form of randomisation. It is usually carried out using a random number table. The advantage of simple randomisation is it is very easy. Thedisadvantage is the possibility of imbalance between groups. Blocked randomisation guarantees that all time randomisation the number of patients in all the groups will be equal. Stratification involves placement of subjects in to different strata. It is done to reduce variation in the outcome measure due to the stratification variables.

Discussion:

ANOVA is the acronym for Analysis of variance. Analysis of variance is a statistical technique specially designed to estimate whether the means of more than two quantitative population are equalie., to make inferences about populations haling the same mean. In unbiased trials if we have more than two treatment groups and blocks we have to make use designing of experiment Techniques. Most trials involving a surgical operation, comparison of various devices applied externally on the body (like acupuncture, physiotherapy or heat or cod application) change in life style like cigarette smoking or learning technique can only be carried out in open form.

Especially relevant for our present topic was Fisher's work on experimental design, a topic he could be said to have invented. This was first presented in Fisher's 1925 book, expanded in a 1926 paper, aimed at agricultural research workers, and developed more fully in his 1935 book *The Design of Experiments.* One of its key features was the technique of random assignment of treatments or varieties to the field plots, and I shall say more about this later. Two points are worth making at this stage. Fisher always thought of design as going hand-in-hand with analysis. A design should maximize efficiency but must also provide a means of valid inference: randomization was an essential condition for the validity of Fisherian analysis. Secondly, note that the experiments considered by Fisher are the somewhat restricted class of controlled comparisons of treatments or varieties on arbitrarily variable experimental plots. The relevance of Fisher's work to medical trials is clear, the 'plots' in this case being the individual patients.

The F-test as it was developed by R.A Fisher in 1920's. The test is conducted in situations where we have three or more to consider at a time an alternative procedure (to t-test) needed for testing the hypothesis that all samples could likely drawn from same population.

Even without systematic error, there will be random error in the responses, and this will lead to random error in the treatment comparisons. Experiments Design to increase precision are precise when this random error in treatment comparisons is small. Precision depends on the size of the random errors in the responses, the number of units used, and the experimental design used. Several chapters of this book deal with designs to improve precision. Experiments must be designed so that we have an estimate of the size of random error. This permits statistical inference: for example, confidence Design to intervals or tests of significance. We cannot do inference without an estimate estimate error of error. Sadly, experiments that cannot estimate error continue to be run.

Treatments are not under the control of the experimenter and its mechanism is usually unknown. Thus observed differences in responses between treatment groups could very well be due to these other hidden mechanisms, rather than the treatments themselves. It is important to say that while experiments have some advantages, observational studies are also useful and can produce important results. For ex- Observational studies are useful too ample, studies of smoking and human health are observational, but the link that they have established is one of the most important public health issues today. list three concepts associated with causation and state that two or three are needed to support a causal relationship: Causal relationships. Consistency, Responsiveness, Mechanism. Consistency means that, all other things being equal, the relationship between two variables is consistent across populations in direction and maybe in amount. Responsiveness means that we can go into a system, change the causal variable, and watch the response variable change accordingly. Mechanism means that we have a step-by-step mechanism leading from cause to effect. In an experiment, we are in control, so we can achieve responsiveness. Experiments can demonstrate consistency and responsiveness.

Summary:

Draw unbiased conclusions and see, if the hypothesis is established in the study trial. Recheck the whole plan and its execution before making logical recommendations regarding the clinical trial. Theory methods such as ANOVA and t-tests are much easier to implement and generalize; furthermore, we get essentially the same inference as the randomization tests, provided we take some care to ensure that the assumptions made by the standard procedures of Testing of Hypothesis.

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