Basic Epidemiological Study Designs

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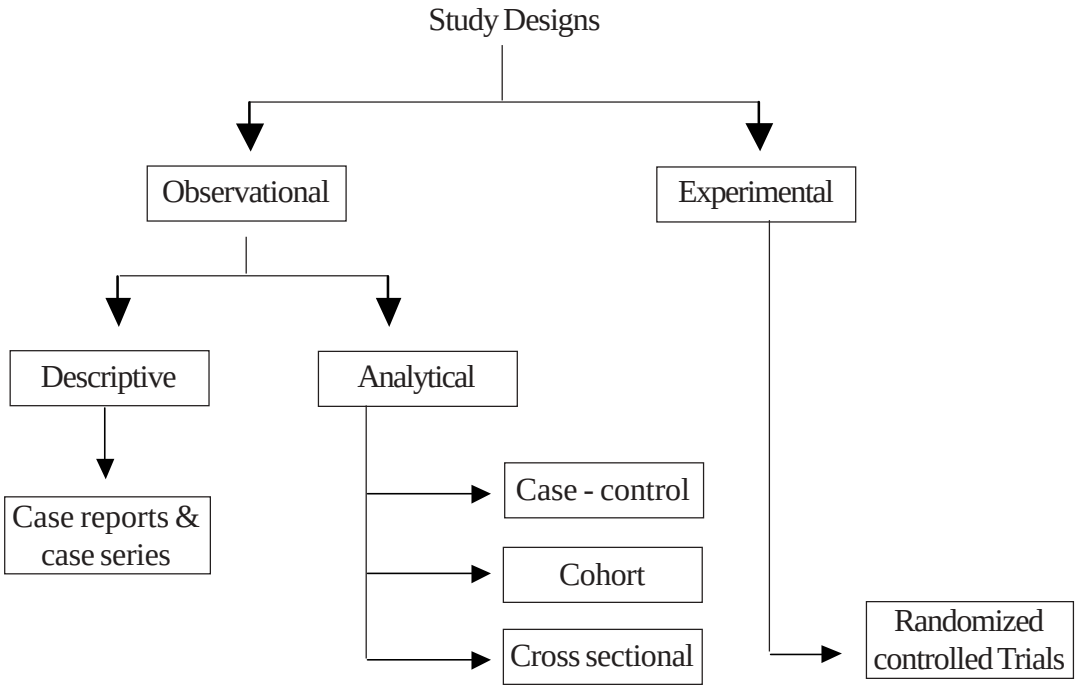
The basis of any research originates when the investigator or experimenter suspects the correlation or causation of some factors of a disease after constant monitoring of morbidity or mortality rates of diseased individuals. The investigator may wish to prove or disapprove his observation. The epidemiological study designs help them to conduct research in a more scientific way. By following such a scientific method one can negate bias and can make the results more applicable and generalisable. Study designs can also be expressed as a 'Plan' for research process.

Every study design has its own way of selecting individuals and conducting studies. Epidemiological studies can broadly be classified as follows.



Cross sectional

As the name indicates, observational studies simply measure or study the nature of diseases and do not involve any intervention or treatment. But experimental studies involve some sort of intervention like medication or surgery and the progression and sensitivity of the disease to the treatment is studied.

There are two types of approaches to the observational studies namely Descriptive and Analytical.

Descriptive study designs tries to observe in detail the distribution of disease in a population by age, gender, race, religion, time, etc., whereas analytical studies focus more on the causes or relation between the cause and effect of diseases. To make it simple, a descriptive study answers to questions like whom, when and where, Case reports and case series:

Case report is a detailed, descriptive study and report of a single patient or case while case series is that of

more than one patient. These types of studies are clinic or lab based and the results cannot be generalised, as patients in such studies are not typical representation of the population. Such studies can be helpful in formulating the hypotheses that will lead to further researches.

Case-control Studies:

Case-control studies are also known as *Retrospective studies*. These types of studies are simple, easy and economic to carry out. A group of individuals (cohort) of particular disease of interest with their corresponding control is chosen. The past history of both cases and controls has to be collected, compared and analyzed. For example, collecting the past history of diabetes for those with Diabetic Retinopathy (Cases) and those without Diabetic Retinopathy (Controls) and comparing the results form a Case-control study. Controls can be drawn from general population or from the cohort who attend the clinic for some other diseases or even from the relatives or attendees of the case. But the mode of selection should be such that the assumption behind the selection of controls is that they should have the same probability of exposure to the risk factor as cases.

This study design is useful in case of rare diseases and also useful in studying multiple possible causes of a single disease. The sample size needed for this study design is also less when compared to cohort designs. The major disadvantage with this design is that the dependence of data is on records and there is a possibility of recall bias in such studies. Selection of appropriate controls is tedious in case of Matched Case-control studies. Also, there is a possibility of recall bias in this type of designs. The Investigator has to go by the assumption that the past history he has obtained is correct even though sometimes it may not.

Cohort Studies:

Cohort studies are sometimes referred to as *Prospective Studies*. A Cohort is a group of persons or patients of same kind or of same illness or disease. Patients with and without exposure of interest are enrolled and are followed up for a certain period and then their results are compared to find whether the particular risk factor is the cause of the effect. For example, smokers (exposure group) and non-smokers (comparison group) are recruited and are followed up for a period of 10 years to find whether smoking can be a cause for cancer.

The main advantage of this design is that one can study multiple possible outcomes from a single exposure. This study enables one to calculate Incidence rates among exposed and comparison groups.

This design is not suitable for rare diseases also most cohort studies are longitudinal and involve much cost, time, labor and the sample size required is also comparatively large.

Cross Sectional studies:

Cross sectional studies are sometimes known as *Prevalence studies*. This design involves the assessment of exposure and outcome of risk factor at the same time. The population is asked for the current status of the disease and the exposure of the present or past risk factors. Cross-sectional studies are easy and also rapid to conduct in population-based surveys but no causal inferences can be made from such studies. In cases of sudden outbreak of diseases, cross sectional studies are of immense use.

Randomized Clinical Trials:

Clinical Trials are known as Planned experiments. In Randomized clinical trials, the investigator assigns the subjects randomly to the treatment or control group and account and compares the results between the two or more groups. Comparisons can be effective only if the treatments are assigned randomly. Randomization avoids interviewer bias. Masking or blocking of treatments plays an important role in RCTs. Masking may be Single masking, double masking and triple masking. In single blind or single masking, the participants or the patients are masked from the treatment or control to prevent the person introducing bias in the study. In double masking, both the participant and the observer are masked from the treatment. In triple masking, the participant, observer and the statistician are blinded from the control and treatment.

Among all, clinical trial is the best method to prove the effect of a treatment in human subjects. Clinical trials should be properly planned and conducted as it involves human subjects. It should have some ethical and logical considerations on human subjects. A study protocol, written informed

consent, randomization of treatment and controls, placebo use in terms of no other alternative best therapy other than the treatment etc., will help one to reduce the bias in the experiments.

References:

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