Unit 4: Applied Epidemiology and Public Health in One Health Research

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Module - 9
Lecture - 16
Basics of Epidemiological Studies

Namashkar and welcome to today's session on Basics of Epidemiological Studies.

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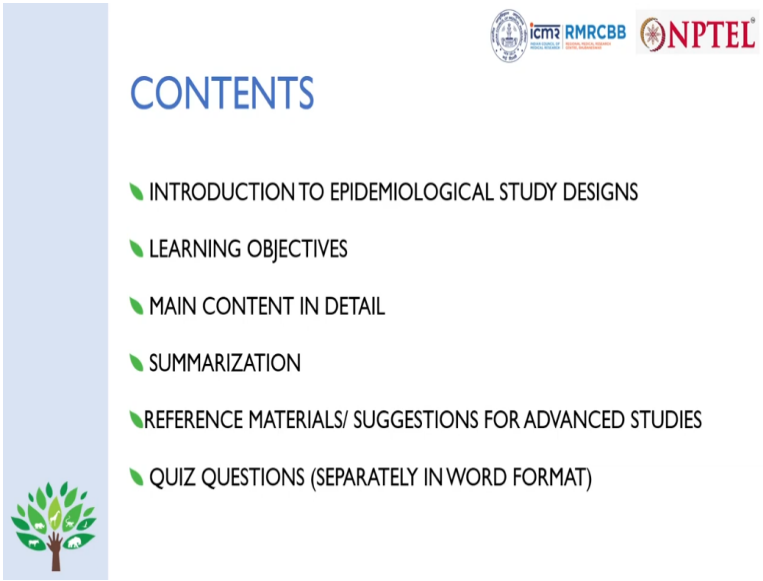

While epidemiological studies do not form the core module of this training on One Health, it is however an important concept that all aspiring public health specialists need to know. It forms the crux of any research activity that will be carried out on One Health or any other topic for that matter. So, we will briefly go through the epidemiological study designs. We will not be going into details of the study designs because that in itself will be a very long topic and there are better resources and avenues to learn those things.

So, we will first go through the basics of epidemiological studies. We will then learn how to identify the right study design for your research and then we will briefly go through the few commonly used epidemiological studies in One Health research specifically, but these can be applied for any type of health research that you may wish to carry out.

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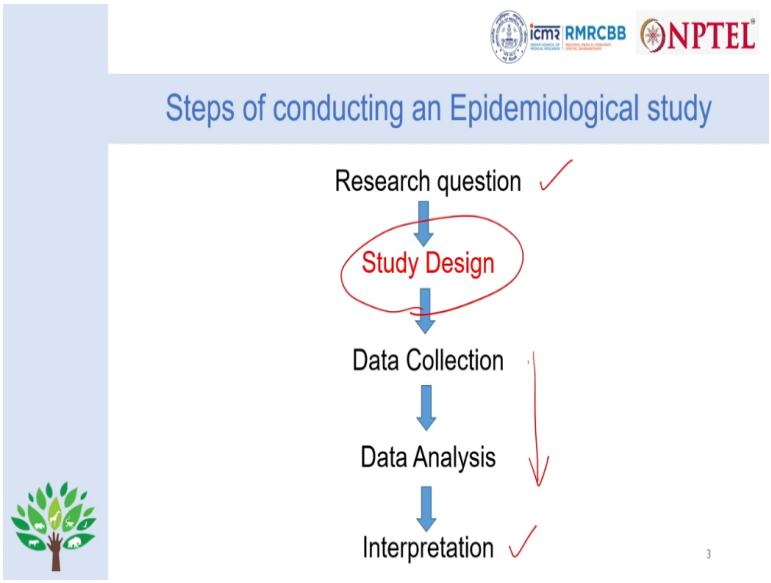

Now, the role of study design is very crucial in the research pipeline. Any research begins with the conception of a research question. Following that, the next step is choosing the right study design and that is what we will be discussing today. After you choose the study design, you carry out your research, you collect data, you analyse the data and then you interpret the data which comes later on.

So, as you can see in this research pathway, a very important step is study design. How do you choose the right study design and what are the types of study designs that you must be aware of.

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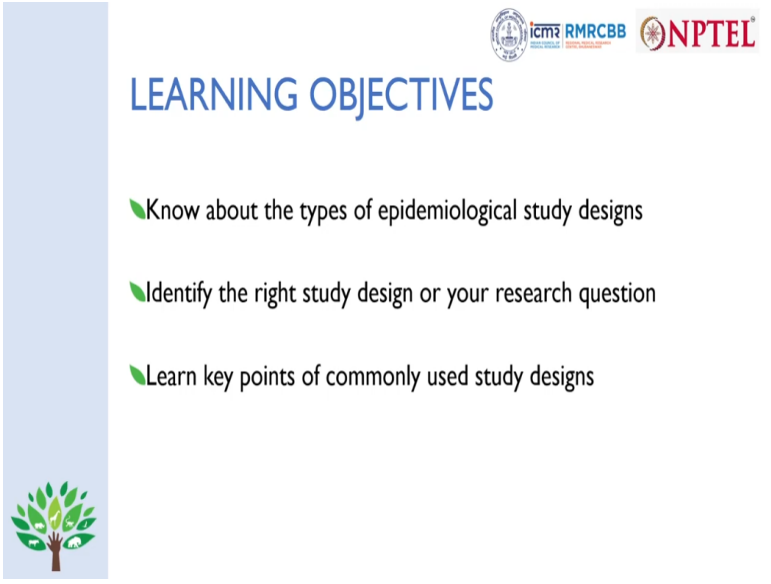

So, in today's module, we will know about the types of epidemiological study designs available, we will learn how to identify the right study design for your specific research question and we will also learn some key points of few commonly used study designs. Let me reiterate again; we will not be going into details of these individual study designs because that will be very time consuming.

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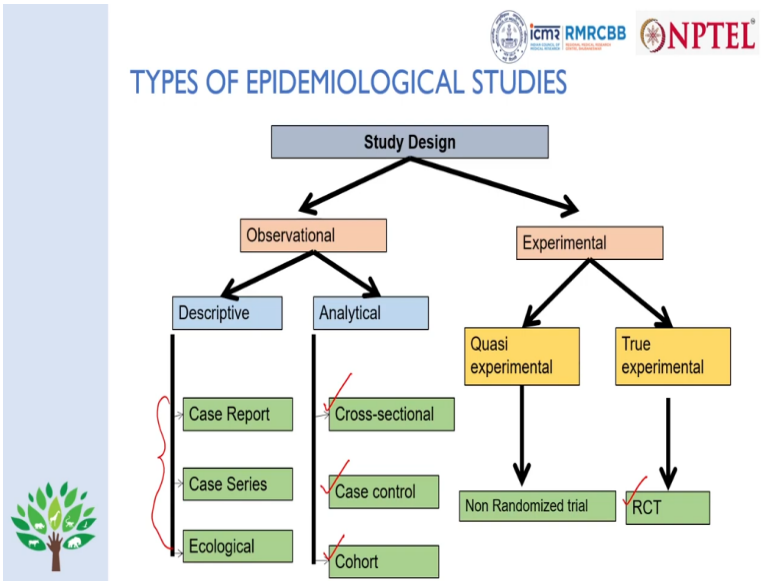

Now, this table shows the basic types of study designs. Broadly, study designs can be classified into 2 groups. They can either be experimental or they can be observational. Under observational studies, we have descriptive studies and we have analytical studies. Descriptive studies include designs such as case reports, case series and ecological studies. The purpose of descriptive studies are, to describe a particular condition of interest in the time, place, person and other attributes.

If you wish to carry out some detailed analysis of the collected data, you want to reach at some interpretations, you want to test some hypothesis, then you have to choose analytical study designs. Broadly, analytical study designs are classified into 3 types. They can either be cross-sectional or case control or cohort. The second type of study designs are experimental study designs. These again can be either quasi experimental or true experimental.

True experimental study designs are also commonly known as randomised control trial. However, there are other names for those, such as clustered randomised trials and community trials. Quasi experimental essentially means that they are not randomised trials. In this module, we will be covering some basics about cross-sectional study design, case control design, cohort studies and RCTs as these are the most commonly used study designs in One Health related research activities.

The remaining study designs, I request the viewers to kindly look into the resources that I will be providing at the end. Case reports are for rare conditions that clinicians usually use to document their clinical practice and experience. These are usually single individuals that are included and these do not intend to be generalised to other populations. If a number of case reports are aggregated and documented, that forms a case series.

If the unit of data collection or the unit of participation is a geographical entity, be it a district or a population entity which can be either a village or a community, then that type of study design is called ecological study designs. Now, all these 3 study designs are in descriptive study designs; and in the classic pyramid of evidence hierarchy, these form the lowest level of evidence.

However, it may be noted that these are also very crucial as they form the foundation from where hypotheses are generated, which can be tested in analytical study designs. Like I mentioned earlier, the next important step after you know the types of study design is to choose the right study design.

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This is an important step and this depends on the objectives of your study, most importantly, what is your research question, what is it that you want to answer. That determines the choice of your study design. It also depends on the characteristics of the exposure and the disease that you are willing to study and also the current state of knowledge. If there is no basic information about a particular condition, you cannot jump directly to a track, you have to carry out basic research first; the foundation has to be built first before you build the house.

So, the current state of knowledge and the relationship between the variables of interest in your study also determines the choice of your study design. The research setting and the resources available are crucial because not all research questions will get funding. You will not necessarily have the resources for something like a trial which is very resource intensive or a cohort which includes a large time period.

So, these are the criteria that you may need to choose the right study design; but provided these criteria are met, let me present you with an algorithm that will help you technically choose the right study design.

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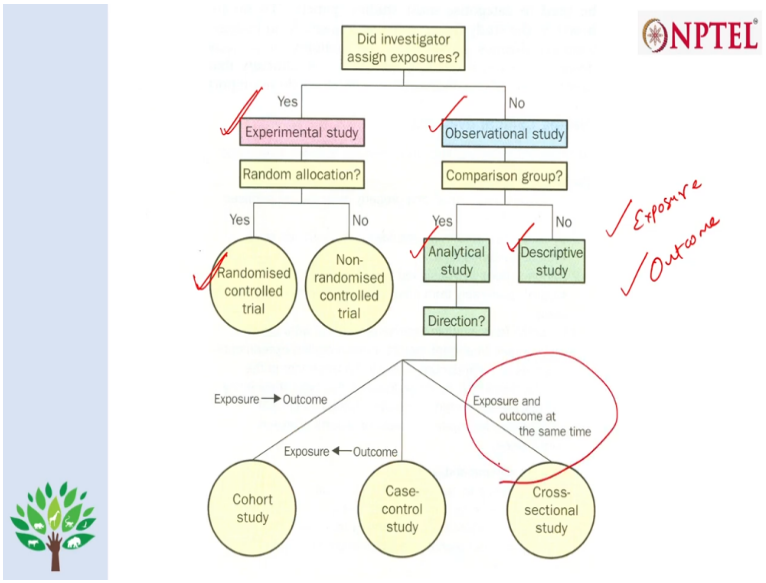

Now, the first thing you need to ask yourself is, did the investigator assign exposure? I am assuming the viewers are aware of these two criteria, exposure and outcome. Any disease that we will be discussing will have to be classified. The variables that data will be collected will have to classify as either exposure variables or outcome variables. Exposure is generally spoken in terms of the risk factors and outcome is the disease of interest or any outcome of interest.

The first thing you need to know, did the investigator assign the exposure? If that is so, if someone has intervened and assigned the exposure, this exposure can be a drug, can be a new program, it can be stopping of a drug, it can be any unnatural thing that in the normal disease course will not happen. If that is done by the investigator, then that type of study design is experimental study design.

If there is no exposure from the investigator and the investigator only intends to observe and document the existing risk factors or exposures and the relationship with the outcomes, then that type of study design is observational study design. This is the first step in deciding whether your research question needs experimental study or an observational study. Now coming to experimental studies first, if we intend to do a random allocation of participants of our study, we randomly divide the participants into 2 groups.

In one group, we will give the exposure of interest and in other group, we will not give the exposure, and then we will measure the outcome of interest. In that case, the study design is called randomised controlled trial. There are 2 groups in this. One is called the experimental group and the other is called the control group, and this study design is called RCT or randomised control trial.

If we are not doing random allocations or random allocation is not possible, then the study design is called non-randomised control trial or as previously discussed, quasi experimental study designs. In the observational study, if there are no comparison groups, that becomes purely a descriptive study and the types of descriptive studies, we have already discussed. If there are some comparison groups, if we want to derive some interpretations and comparisons to be made, then that study is analytical study.

It is crucial next to determine the direction of our study. Like I said, there are 2 key things to note, exposure and outcome. If our study follows the population from exposure till their outcome, that type of study design is called cohort study. If it is the reverse and we intend to follow back in time and assess the outcome as well as the exposure, that type of study design is called case control study. Lastly, if both are assessed at the same point of time, that type of study is called cross-sectional study.

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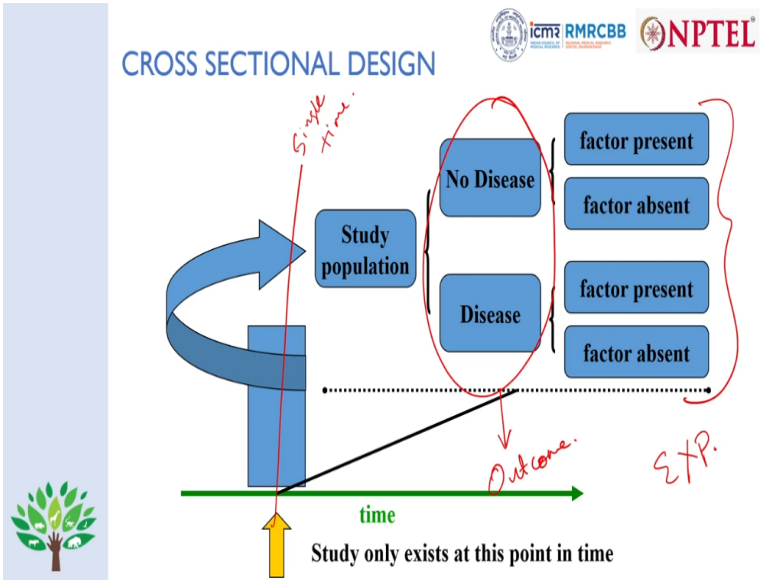

Next we will briefly cover the important types and commonly used types of study designs. The first one is cross-sectional study design. It is by far the most commonly used study designs in epidemiological research, mostly because it is easier to do and it is essential first step for further study designs to be contemplated. Cross-sectional study design implies that data is being collected from the participants at a single point of time.

So, any data that is being collected is at a single point of time. We are measuring both the exposure and the outcome at this point of time. These are the risk factors that we are assessing which can also be called as exposures and this is the outcome which in this case may be a disease of interest and that is also being assessed at the same point of time. It may not be so that the same point of time is 1 day but even if it is 1 year or 2 years of data collection, we are visiting and collecting data from the participants at a single point of time and we are not following them up for any duration.

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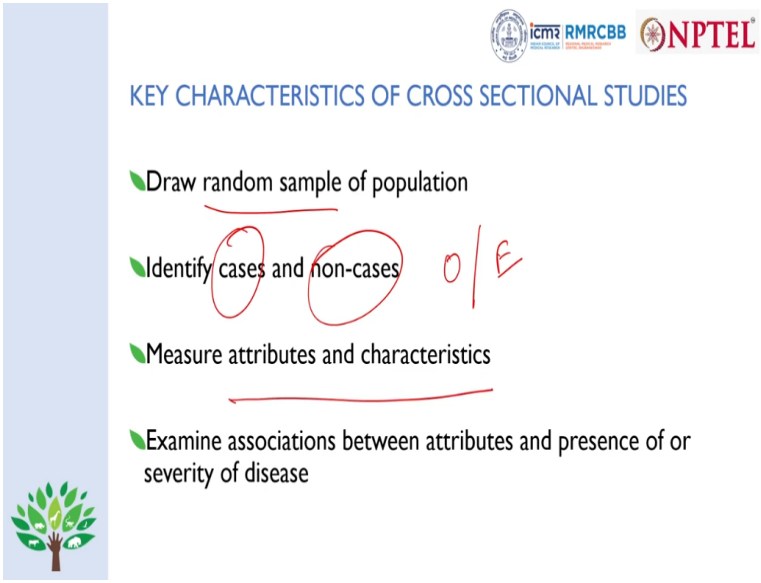

Let me spend some more time on cross-sectional studies as these are, like I said, most common study designs. The key characteristics of cross-sectional studies include random sampling. By random sampling I mean the random selection of participants in your study is essential for generalisation of your findings towards the target population and that is why random sampling is important step in cross-sectional study designs.

However, it may not always be possible and there are other designs that take care of that; but random sampling as far as possible is an essential step in cross-sectional study designs. The second important step is your tools and your protocols to measure both cases and non-cases that means the outcome as well as exposure. Both the outcomes and exposure need to be measured in a standardised way; that means the same way in all the participants.

Attributes and characteristics mean the variables that you are collecting data on. These need to be standardised and collected in the same way in all the participants. You can examine the associations between these type of exposures and outcomes during analysis of the data.

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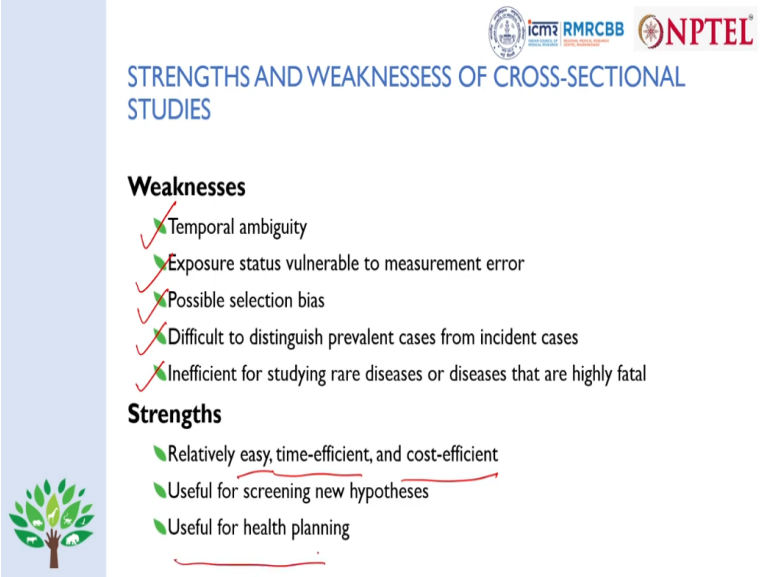

However, it is important to note that cross-sectional study designs have some inherent weaknesses. The most important one is called temporal ambiguity which essentially means that we have no way of knowing which happened first, the exposure or the outcome. We have data on both which has been collected at a single point of time but we have no way of knowing whether exposure preceded the outcome or not.

This is a major limitation of cross-sectional study which will be answered by cohort studies which we will see later on. The second weakness or limitation of cross-sectional studies is bias. Bias is something that creeps in systematically into your study due to some errors on your part. There is a bias on called selection bias. If our selection of participants is not random in nature,

implying that some participants had a higher chance of getting selected in our study, that leads to selection bias.

If our measurement methods are prone to some error, if our tools that we are using to capture information are prone to some error, that leads to measurement bias. We may sometimes be unable to differentiate between newly occurring cases and cases that have been there since some considerable amount of time; that is the limitation of cross-sectional studies. And obviously, if we intend to capture some rare outcomes, rare diseases, then the samples as required are too high for cross-sectional studies, and this is also a limitation of such type of study designs; but there is a reason why this is a commonly used study designs.

These are easy, these are efficient in terms of time and cost and these are useful for screening new hypothesis. Actually, these are essential first step for screening of the hypothesis and these are very useful in planning health programs.

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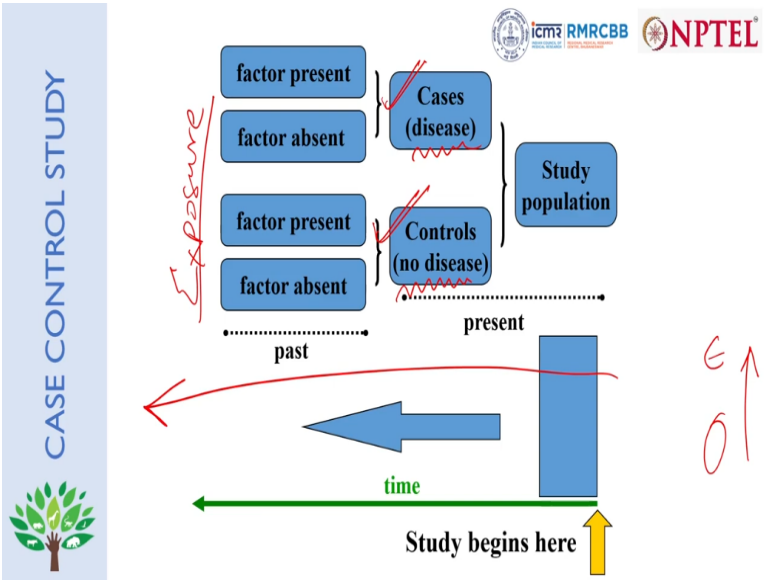

The second type of study design that we will discuss today is called case control study. Like I discussed previously, case control study follows individuals from their outcome to exposure, which essentially means that when we begin our study, we classify participants into cases which is individuals who have the disease and controls, meaning individuals who do not have the disease.

In the next step, we assess their exposure or risk factor. This is done in both cases and control. That means that we are following the participants back in time and trying to assess their risk factors for outcomes that have already been occurred. There are some key steps in case control studies such as matching. The way we select cases and controls are important. Cases and control need to be very similar in their nature, in their characteristics other than the risk factors that we are trying to assess.

So, this is a commonly used study design for rare exposures and this is also a cost efficient study design; and in most clinical settings, this is a preferred study design over cross-sectional studies.

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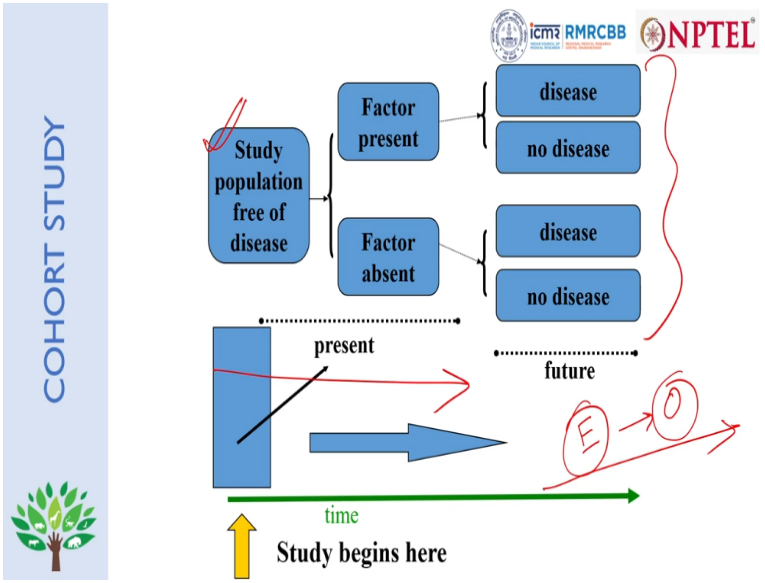

The next study design that we will discuss is cohort study. This is also called longitudinal studies. In this case, we follow participants from their exposure to their outcome; sometimes, even before exposure, we enrol the participants and then see if exposures are there and then we follow up till outcomes. Firstly, we recruit a study population. This is called a cohort. A cohort is a group of participants with similar characteristics.

Then we follow them up in time and then we collect data from them at multiple points of time and then we see whether the risk factors are present, exposure has developed or not and follow them up till the disease has occurred or not occurred. So, this is a very costly study design. It

requires, sometimes for public health problems, it requires very huge sample sizes. It is very time intensive. The longest running cohort run into decades themselves.

So, usually, this type of study design is used for multiple exposures and outcomes because we invest a lot of resources into such study designs. One point to note here is that cohort studies or longitudinal studies gave us a parameter called incidence. Incidence is something which is related to new cases. Incidence of a particular disease means the number of new cases that occur of that disease in a particular time period.

As opposed to this, cross-sectional studies give us something called prevalence. Prevalence is something which includes both the new as well as the old cases. So, prevalence is estimated in cross-sectional studies, that means prevalence is estimated by data collected at a single point of time, whereas incidence needs longitudinal cohort studies with multiple data collection points for it to be estimated.

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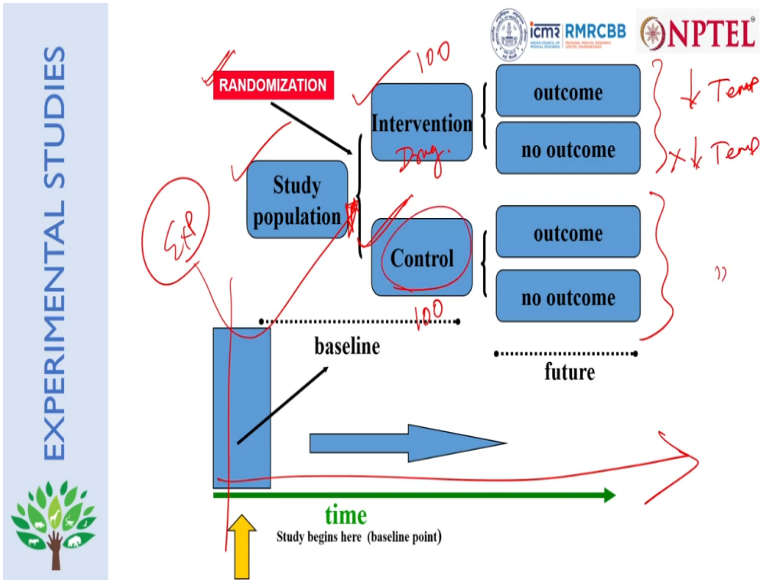

The last study design that we will discuss today is experimental study designs, particularly, randomised controlled trial. Like previously discussed, the key point here is that exposure in this case is man-given or man-made. We classify participants ourselves into 2 groups, intervention or experimental group and control group.

Apart from this, most of this is similar to, as you may note, a cohort study which means we begin the study, we recruit the participants and then we follow them up in time and collect information from them, the key difference being that the division of participants into intervention and control group is by the investigators; exposure is assigned by the investigators but this division if done in a random way which is termed as randomisation, that is the key characteristic of a randomised control trial.

And then, outcome of interest, it can be one, it can be many. Usually, there is one primary outcome of interest that is assessed in the future. So, if this intervention let us say is a drug, I classify my study population into 100 people who will receive the drug and 100 people who will not receive the drug and I will see the efficacy of that drug in time and see how many of this drug, if it is for fever reduction, how many of my participants in the intervention group had reduced fever and how many had no reduced fever.

Similarly, we will assess the same for the control group. This is the flow of an experimental study design. Now, these are the commonly used study designs.

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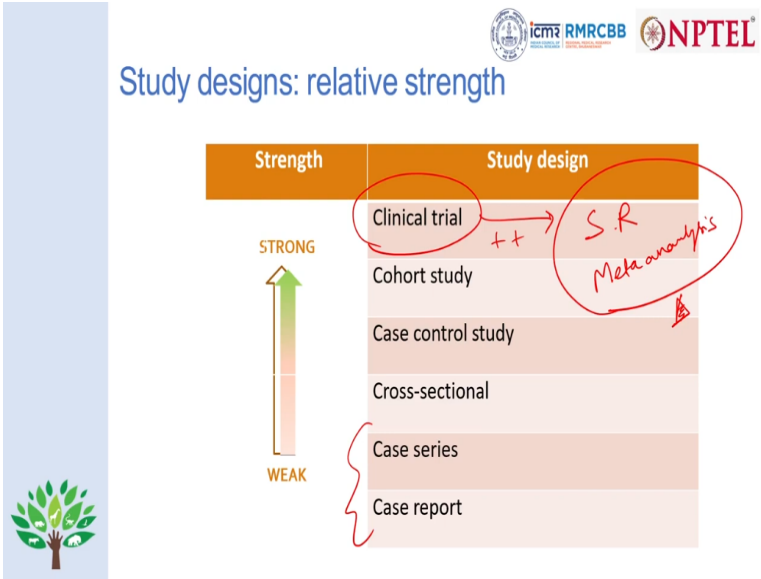

Not all study designs are of equal strength of evidence. The weakest strength of evidence is given by case series and case reports and ecological studies which means descriptive studies, and the highest evidence is provided by clinical trials, randomised controlled trials. There is another

level of evidence here. If you combine the results of multiple clinical trials, that process is called systematic review.

Statistical combination method is called meta-analysis. And generally, this is considered to be the apex of evidence tree. This is the best quality of evidence on any particular topic that you may seek. So, this was basic information on study designs used in epidemiological research.

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As we saw, there are multiple epidemiological study designs that we can choose from and that depends most importantly on your research question but also on other aspects such as the resources available and your budget. No study design is flawless; every design has its advantages and disadvantages. It is important to understand the strengths and limitation of each of these study designs before you choose the appropriate one to answer your research question.

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Here are some additional learning resources that you may seek into if you want to know the details of these individual study designs which were beyond the scope of this presentation. Thank you for your attention; thank you.