Health Research Fundamentals
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Lecture - 14
Study plan and project management

Hello. In our course of Health Research Fundamentals, today we are going to discuss Study plan and project management. It is really critical that lot of energy and time is spent by all who are involved in the project or in the research study plan development in planning it really well.

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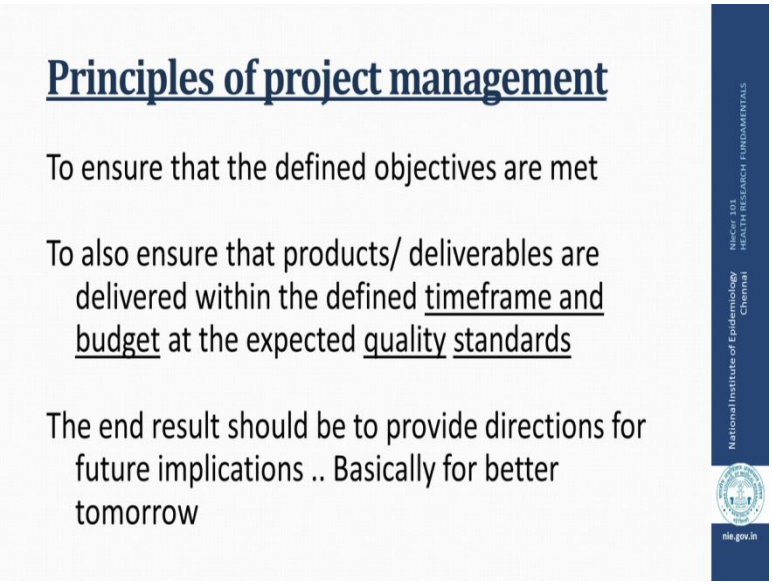

Because, only a well planned study succeeds. Most of the times if we have not thought of all the eventualities, will land up in certain situations where there are difficulties which are faced while implementing the study and also while interpreting the study. And today, what we are trying to discuss is what kind of systematic process or approach can be taken to ensure that the project is implemented appropriately or the study is implemented appropriately.

What is important in project management is to ensure that the defined objectives are adequately met and there are certain deliverables, which are defined right at the beginning of the study that this is what we want to achieve, which is our definition of objectives, and so they should be reached within the defined time frame and with the

available budget not compromising the quality at all. So, all this is achieved through effective project management. Primarily, because what we do is the project if it ends successfully the result should be able to provide direction for future implications, basically what it means is whatever research we do it should help us to do something better tomorrow.

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It is important that we understand that any kind of implementation process involves some kind of underlying principle, with a primary objective of achieving a specific goal. Let me take an example of the process of resource allocation and resource management. Well, the principle here is appropriate time management. The resources have to be allocated in a timely manner, if it is going to be a long term study it will be on multiple occasions that the resources will have to be mobilized. So, that timing really becomes very critical because only then we are able to achieve the goal of efficient, we can progress efficiently towards achievement of our goals.

Another critical aspect in the process is planning and scheduling the activities. This is the important principle which undergoes behind that and to ensure that, this happens is the monitoring and supervision. Every single detail has to be planned out appropriately so that when we reach the goal, we reach it with the best possible quality standard and hence it is important to keep this whole process in mind and the principles in mind.

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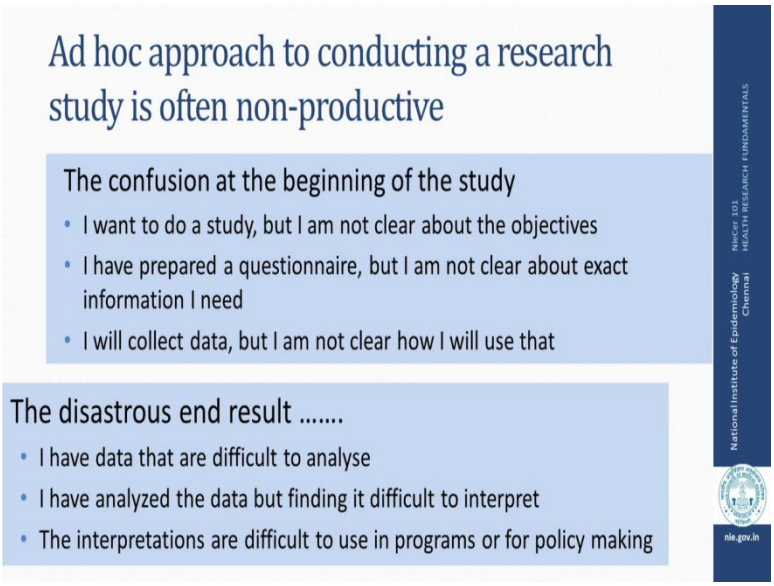

Ad hoc decisions which are taken or ad hoc approach which is taken while conducting research study often becomes non-productive. So, there can be lot of confusion at the beginning of the study in the minds of people. So, like I want do a study, but I am not clear about what the objectives are. I have prepared a questionnaire, but I am not clear about exactly what information I need. I also feel that I will be able to collect the data, but I am not clear how will I use it. All these kinds of confusions arise because the investigator himself has not understood what the research is all about.

What is going to happen as a result of this? This is going to result in a disaster, because this will be a situation which will lead to production of data or compilation of data which is difficult to analyze or then the analyzed data becomes difficult to interpret and even if the interpretations are made probably they are of no use to the program or also in the policy making. So, eventually what it means is any kind of an ad hoc approach, ad hoc approach which is taken without proper thought being given to that is not likely to succeed.

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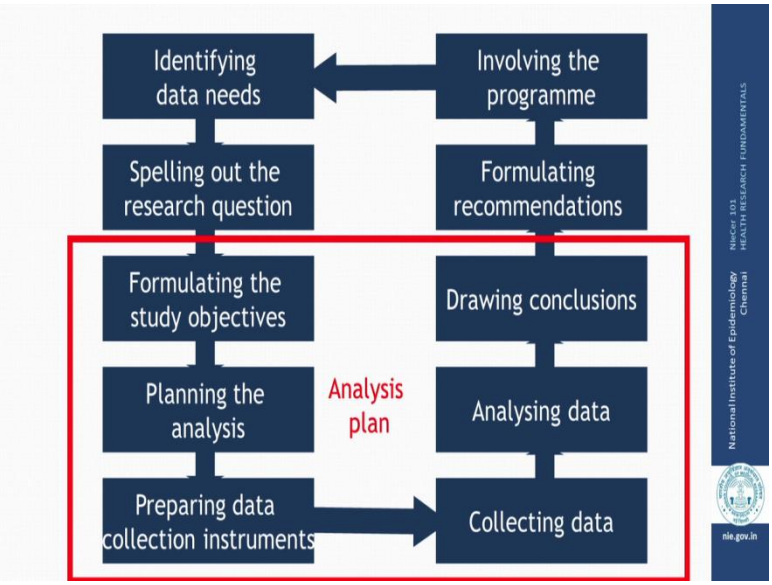

Any research process typically starts with identifying the need for that particular research, then correctly verbalizing the research question or spelling out the research question, formulating the study objectives, planning the analysis, then preparing data collection instruments, then collecting data, analyzing data, drawing appropriate conclusions, making the specific recommendations to the concerned people and eventually again accessing, whether our needs that we had initially identified have been fulfilled or not or whether there is any need to do anything else.

If we look at this whole process, in terms of identifying data needs and spelling out the question this all is the planning stage or the initial stage even while the study is being conceptualized. This is a pre-planning phase. The steps of formulating the objectives and the analysis plan and deciding about the study instrument methodology, where the way in which data will be analyzed and then the way it will be interpreted, this all is a part of analysis plan. And, what we do after that is the dissemination of these findings to the concerned stake holders so that they can use it for appropriate programmatic absorption or policy making.

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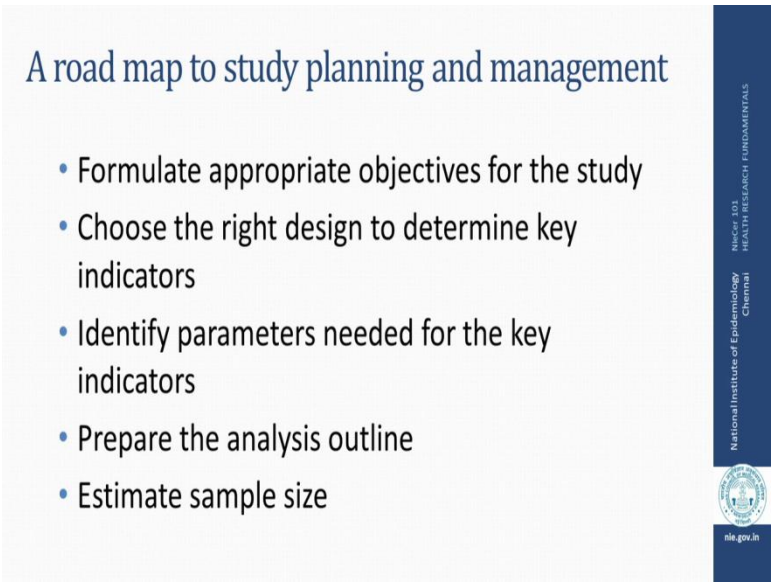

So, basically the road map to study planning and management involves multiple steps. It all starts with formulating appropriate objective for the study, then choosing the right design to determine the key indicators. Please understand, I am going to walk you through this particular thing but proper decision about what kind of study is required to answer the objectives that we have framed is very critical and important one.

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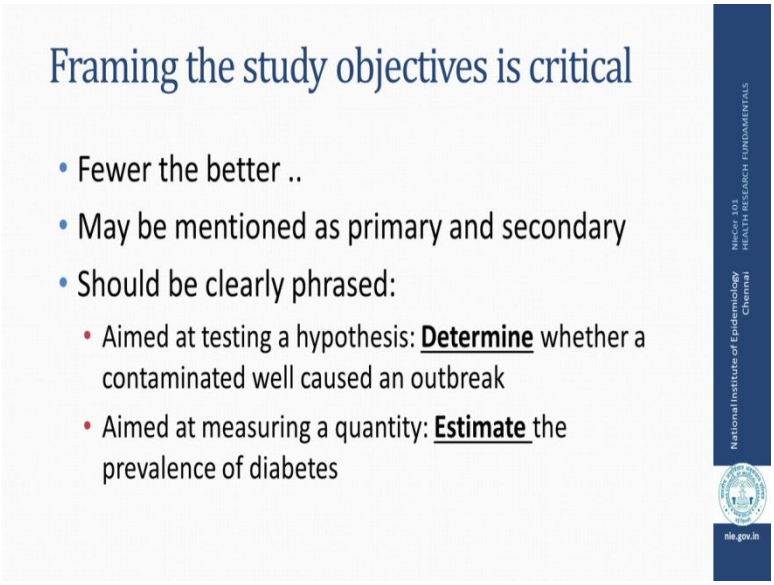

We have to also identify the parameters that are needed to estimate the indicators that we find, that we have decided, that are important for this particular study and then prepare

the analysis out line. Also, important to estimate the sample size before the study is initiated, because the study conducted on a small sample also will be not generalizable. When we talk about the study objectives, the basic principle is fewer the better. Most of the studies with a long list of objectives often become very confused studies because many of these objectives remain unfulfilled, because they become complex, the data collection tools increase, there are lots of variations that come in while collecting the data and in general there is a chaos. So, fewer the better is the principle.

They can be described. Objectives can be described as primary objectives and secondary objectives. It is important, the primary objective is important because that generally decides the sample size for that particular study. Often in any study, sample size is calculated based on the presumption that we should be able to achieve the primary end point at least. Secondary end points are the analyzable issues, which are the additional information, pieces of information that we obtain in any research study. But it is important that the objectives are clearly phrased.

Normally, they could be of 2 types, they could be more of a exploratory type or what we call it as aimed at testing a hypothesis and here is, where we use the word determine. So, determine whether a contaminated well caused an outbreak that is an example. Or they could be say sort of confirmatory in nature or estimating in nature, say to actually decide the prevalence of a particular condition, for example, diabetes in a population. So, we have to keep in mind and use the appropriate verbs while defining the objectives.

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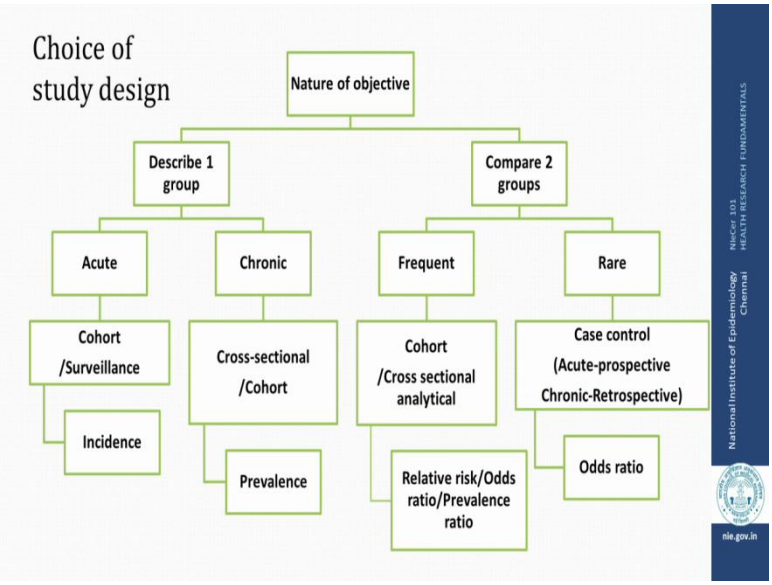

There are different types of study designs, which are adopted to answer various research questions. Whenever we talk about or whenever we think about descriptive objectives, whenever we are exploring the acute conditions like for example, pneumonia case is occurring in children, the right kind of designs or diarrheas occurring in children and etiology.

The right kind of designs would be to do cohort studies or surveillance studies which are may be hospital based surveillance or community based surveillance. And normally, the major that you derive out of it is, incidence; this is true in case of acute conditions. But when we talk about chronic conditions, once that conditions occurs it persist for a long time either on treatment or not on treatment. So, the major that we normally get out of such kinds of studies is prevalence. And here, the right kind of designs to be used are either the cross-sectional studies or the cohort studies.

Well, many of the epidemiological studies deal with comparing 2 groups say for example, people who are exposed to a particular condition not exposed to a particular condition, people suffering from a particular disease not suffering from a particular disease, and so whenever we are moving from the variable or the exposure to the outcome, we call it as cohort study. As we know it is a prospective assessment and whenever we try to look at the exposure after the outcome has already developed it is called as a retrospective approach and often the commonest study design which is

employed is a case control study here.

But, what is important to understand and remember here is a cohort study can be undertaken only when the outcome is more likely to occur frequently, because if it is going to take a long time to happen then probably the study will be of enormously long period and the adequate number of outcomes may not be achieved. So, for a frequently occurring outcome which, wherein from exposure to the outcome the length is likely to be minimal, cohort study is a good approach to take or alternatively a cross sectional analytical study can be under taken; but in case of rare exposures and where the duration between the exposure and the outcome is likely to be very long, then it is better to go for a case control approach and in these situations the relative risk and odds ratio. In case of cohort studies, it is the relative risk which we obtain which is a more definitive say indicator of relationship and odds ratio is also is a strong indicator of association.

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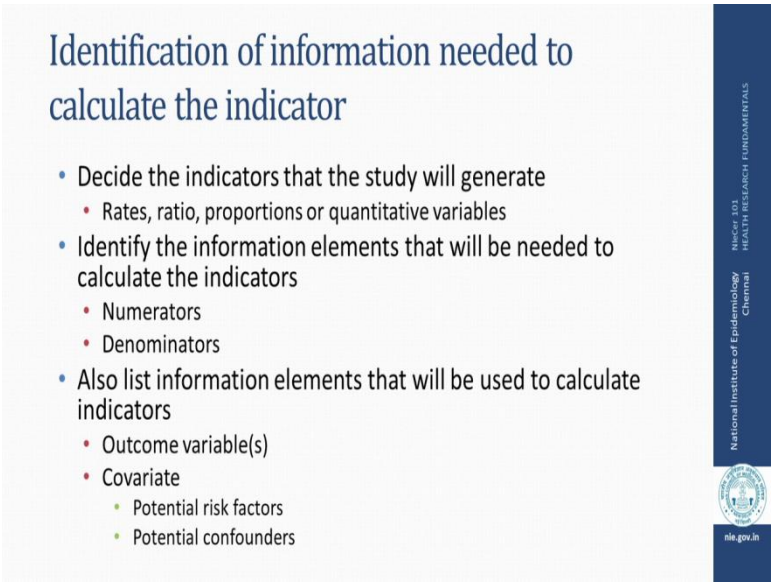

It is important that the discussion in the planning stage focuses a lot on the information needs that with respect to the indicators. There are rates that we calculate, sometimes we calculate ratios or proportions etcetera, but for all of these indicators we do need a numerator and we do need a denominator. We have to understand exactly how we are going to collect the information that is going to be required to determine the numerator also the denominator. But sometimes, this relationship between the exposure and the outcome also is affected by lot of other co-variates, they are called as risk factors or con-

founders and I will discuss some of them.

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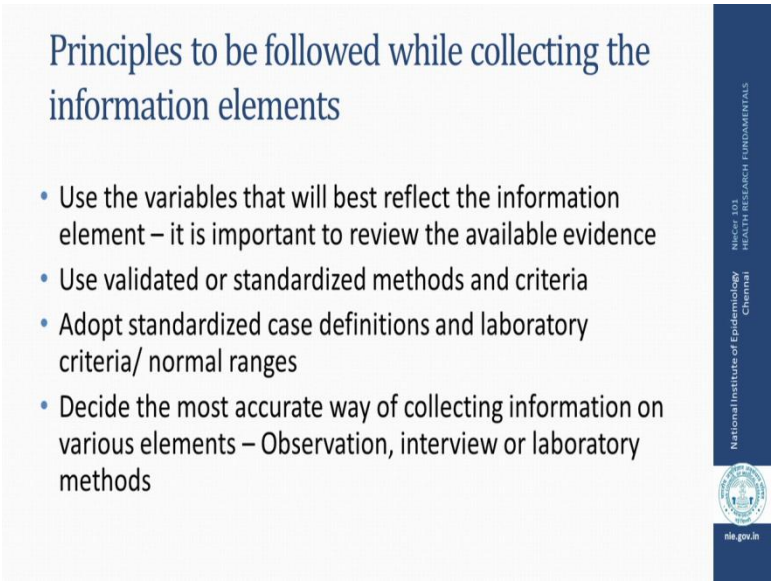

But the basic principles that we have to follow while we collect the information elements is that, we must use the variables which will be actually analyzable, this information we can obtain by reviewing the literature fairly scrupulously because it provides us a lot of evidence of which variables co-variates are important. It is important to also use validated or standardized methods because then the chances that this particular study will be accepted globally are maximum. We must adopt standardized case definition, for example, when we are going to talk about pneumonia; what is pneumonia? We should define it properly.

If we are going to talk about smoking, this as an exposure variable, what is that we are going to consider as smoking? Is it the frequency of smoking? Is it, yes or no? Or the number of cigarettes smoked per day? We have to have clarity on these matters. Sometimes, we also use laboratory criteria and so we have to have also well defined definitions there, for example, if you have to define anemia; how do we define anemia here? Does it depend on age? Does it depend on gender? All these have to be specified right in the beginning; we have to then decide which is the most reliable and accurate way of collecting that information. Sometime it could be just the observation or it is a questionnaire through which we collect this information or it could be actually laboratory assay through which we get this information.

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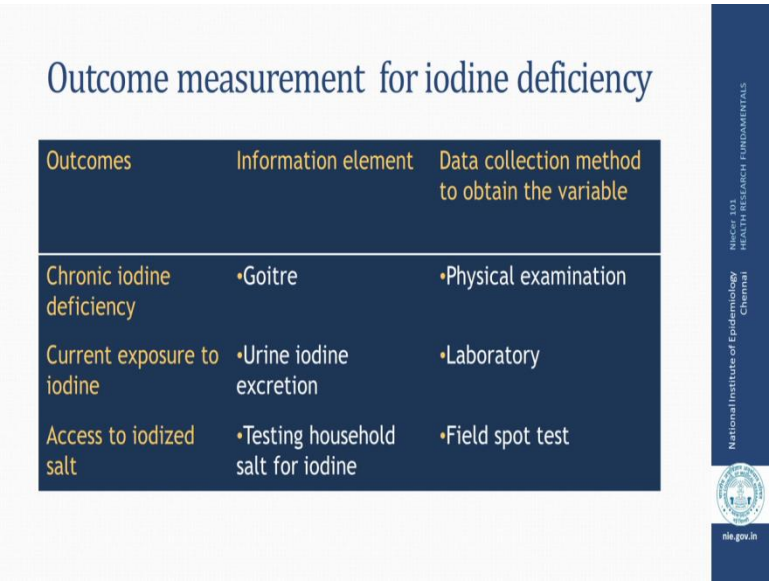

For example, if we are going to talk about as an outcome, whether there is an evidence of chronic iodine deficiency. The way to look at it is, we would look at what is the say prevalence of goitre in a specified community, and how we will do it is by actually doing physical examination. But if our objective is to find out what is the current exposure to the iodine here? What we would try to do is, at an individual level try to estimate the urine iodine excretion and for this we would require some laboratory methods to actually estimate this.

But sometimes, it also becomes important to go one step behind and find out what are the dietary patterns? Is there an adequate iodine being provided through the diet? And so, what one would want to do is to test the household salt for iodine and this would involve some kind of field level spot test which are done to figure out, whether the salt which is consumed in the various households actually has enough iodine in them.

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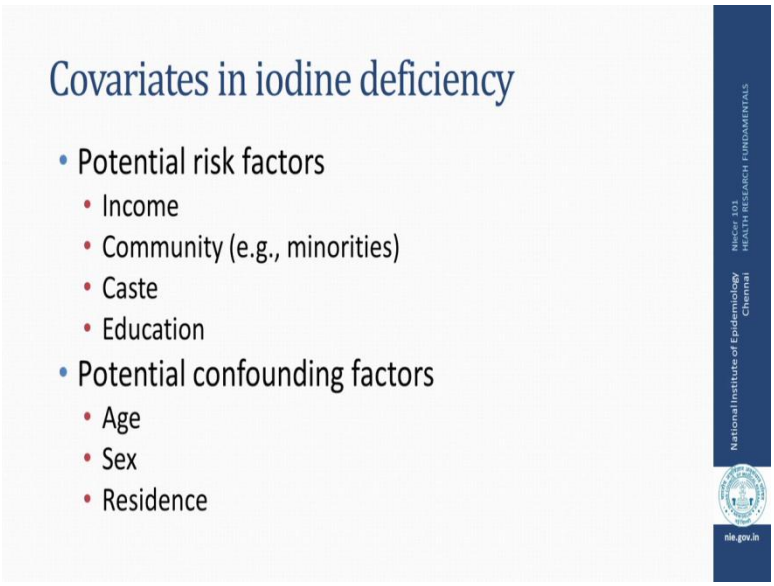

I did mention about the risk factors, about the confounding factors. There are certain risk factors like income and the community which are related to access for example, or the level of literacy, the practices, cultural and social which are observed by the community, the dietary patterns all these also influence the outcome. Then they also have to be appropriately analyzed when we do the interpretation of our results. Similarly, with age the risks sometimes vary with gender, the risks vary the residence, they also vary. They are considered as confounding factors, if they affect both the exposure as well as the outcome variable. There is no harm, even if the confounders are there, provided we have collected information on all of the confounders as a part of our study and in the questionnaire. We can always analyze the effect of the confounders.

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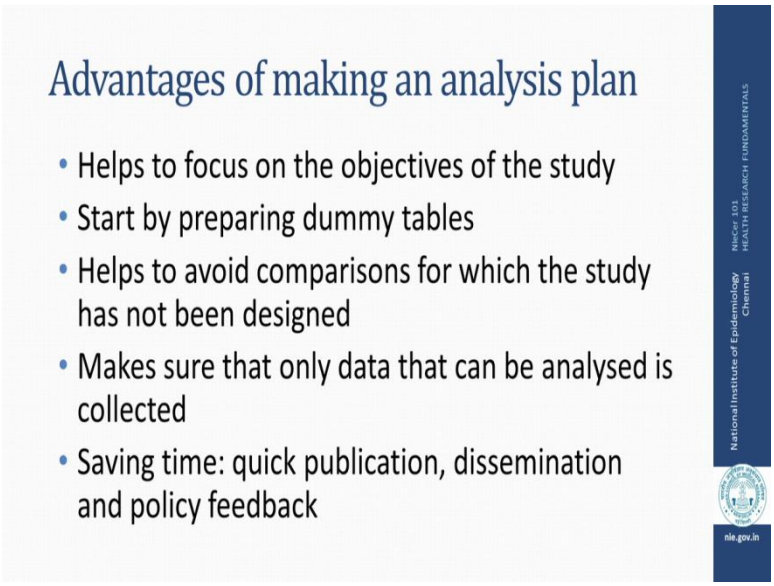

It is important to make the analysis plan because it helps to focus on the objectives of the study. This all thing can start by once, if you have clarity in our mind, what study we are doing. We can also prepare dummy tables right in the beginning of the study because then we know what we must do and what we must not do. We also know what data we should collect and what data we no need to collect because it saves time. It can result in to quick publication and quick dissemination of findings and early policy feedback. So, this is important to make a good analytical plan.

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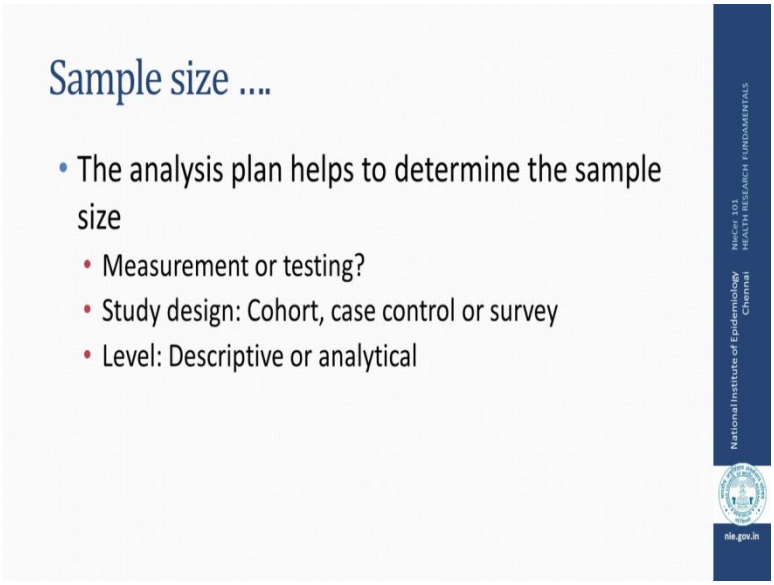

Sample size is really critical because it is decided by what exactly is the type of outcome assessment that we are doing; whether it is by measurement or by testing. What kind of study design we are doing? Whether it is a cohort study, case control study or a survey and whether it is a descriptive study or an analytical study. This is in itself is a sort of a big lecture point and so what is important to understand is when a study is being planned, it is important to involve a statistician, who would help you to analyze, help you to determine the sample size for the study.

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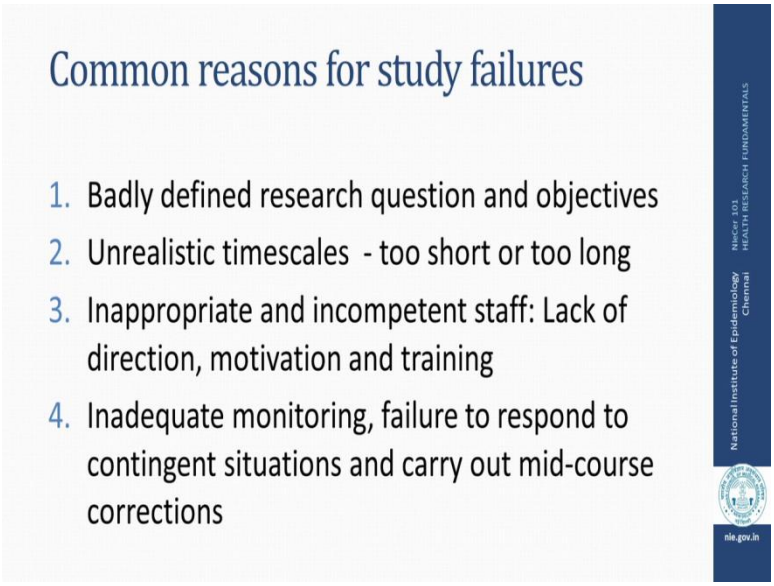

Often it happens that the studies fail, why do the studies fail? It is because, either they are badly defined research questions or objectives are not correctly defined. The time skills that have been decided either are too short or too long. Sometimes, the staff is inappropriate, incompetent. This might be because of lack of correct direction, lack of motivation or lack of training. So, all these have to be taken care of. Or sometimes, it can also result from everything else is right, but there is no adequate monitoring and there is a failure to respond to contingency situations and carry out mid-course corrections that is where monitoring and supervision becomes important.

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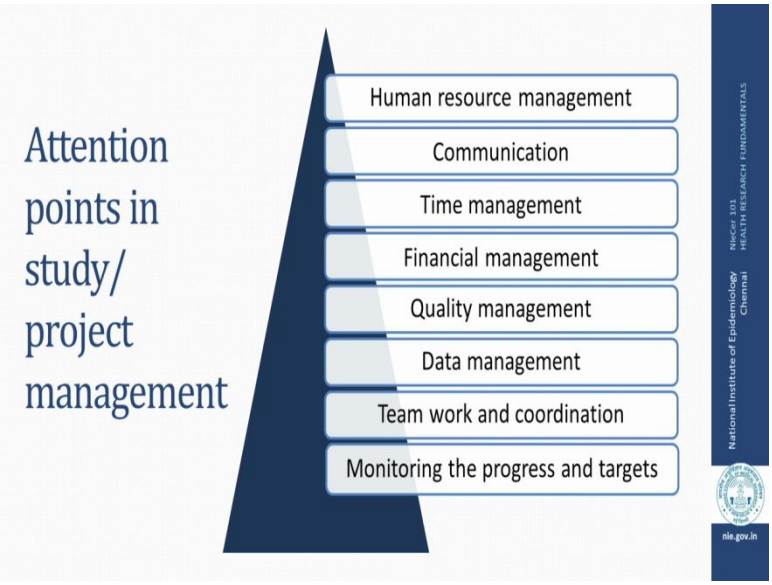

So, for success of any kind of a study there are certain attention points one has to look at. And they start with human resource management, a very critical aspect. The study staff has to be carefully chosen, appropriately trained and with appropriate communication there should be a good dialogue. Only, generally the observation is a team succeeds, but the individuals fail. And so, between the various members of the team, there should be good bonding, extremely good communication and the leader has to ensure that this often team meetings take place and this rapport between individuals builds strongly.

Time management essentially is the responsibility of the leader, and one has to ensure that this is taken due care of. Time management in terms of appropriately scheduling various activities ensuring that they are done in time, this is really important. Financial management is also critical. Sometimes it so happens that the study starts well with the funding being given, but suddenly some kind of glitch develops by which the finances are not being granted or given in a continuous manner, suddenly the activities of the project stop. And hence, this also is an important part of the planning. This has to be planned well in advance at what stage what kind of money will be released and it must be ensured by the researchers that targets which are defined well in advance are appropriately met. So, the financier does not find it difficult to release the money what is earlier decided on.

Quality management at all levels is critical. Quality management in data collection,

various clinical procedures, data management, various laboratory procedures, in supervisory visits, every single aspect of a study that we can think of quality is really critical and if that is maintained then often the studies are very successful.

Data management is important. Often the studies that take care of data management in a timely manner, where concurrent data management is planned they are able to give away the results in a timely manner. If the researchers have not planned it well and then they decide to do the data management at the end of this study, often it is disaster because if there are some issues that are happening in the way the data is being collected, if the data is being managed in a timely manner, somebody is looking at it, finding the faults in it, there is a possibility to make a change, do necessary corrections this opportunity gets lost if we are handling this whole issue at the end. I did talk about team work and coordination, which is really critical and important.

And monitoring the progress and target, here it is to be decided depending on the budget whether it is an internal mechanism that is set up for the supervision and monitoring of the study or an external monitor is brought in to take care of what is happening in this particular study. But, this is again a very important step. Whether it is a research project or it is any other project, there are various aspects that we have to think about; it is a teamwork, it is about communication, it is about human resource management, it is about time management, all these factors are important and we succeed as a team.

Thank you for your attention.