Health Research Fundamentals
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Lecture - 05
Descriptive Study designs

Welcome to this session of Health Research Fundamentals. Today, we will be discussing about Descriptive Study Designs.

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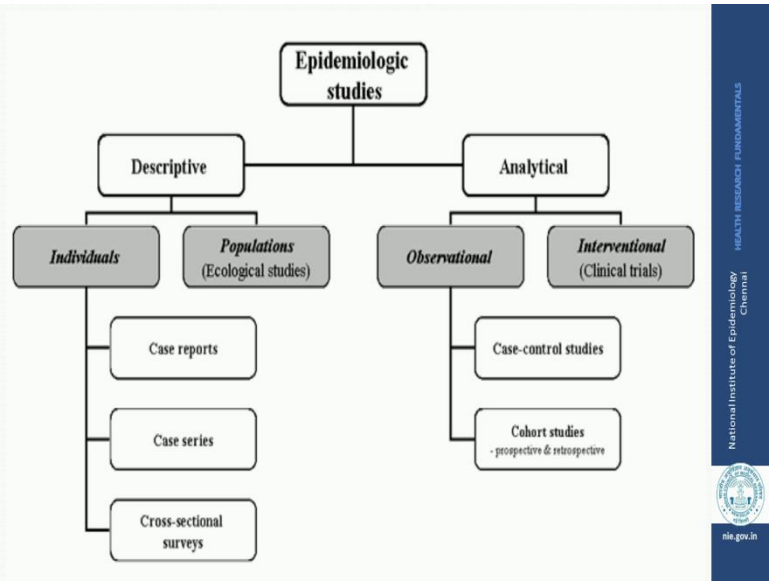

Before we go on to the descriptive study designs, let me walk you through an outline of what are the various designs in the health research. So, as you can see in this slide broadly, the health research studies or the epidemiological studies can be divided into 2 categories; Descriptive studies and Analytical studies. Further, the descriptive studies can be of 2 kinds; one is the studies which are done for individuals and other is the studies which are done for populations. The studies which are done for populations are called Ecological studies and there are various types of studies that can be done at the individual level that include, Case reports, Case series and Cross-sectional surveys.

Now, in this lecture we will not be talking about the analytical study designs which are the other kind of studies, which will be covered in the different lectures. Now, within analytical, the other lectures will walk you through thus observational study designs, such as Case-control studies and Cohort studies.

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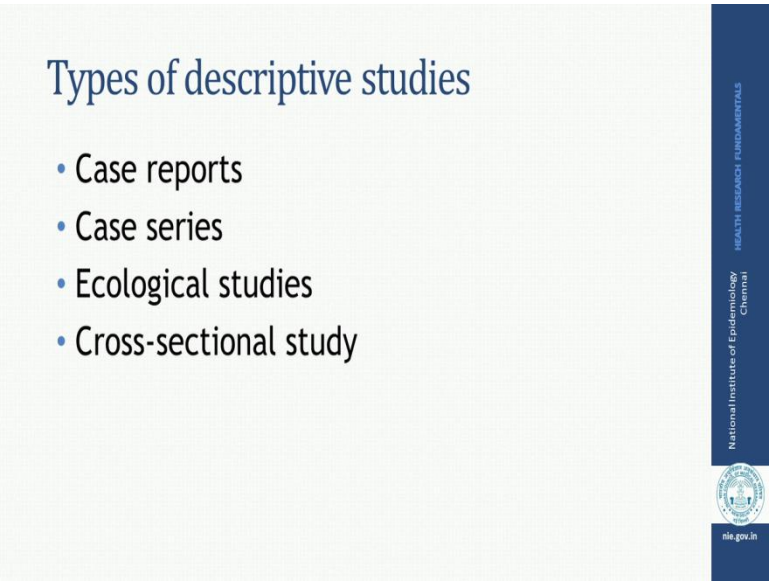

Now, coming to the descriptive studies, in today's lecture, we will be discussing about the 4 main types of descriptive studies that are, Case reports, Case series, Ecological studies and Cross-sectional studies.

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As many of you might be working in the clinical settings or may be clinicians, you might have come across when you read various journals, what is called as Case reports? Some of you may also be presenting the case reports, during your clinical training as well as in various clinical meetings and conferences. So, what is a Case report? Case report is

nothing but a detailed presentation of a single case; what does it mean? It means that, you may find a particular clinical manifestation or you may find some interesting findings in your imaging, interesting findings in your lab or you may find a new kind of manifestation of a disease, which you have never seen before and you may want to document that and share with your peers and this is called a case report.

So, case reports are extremely useful when you want to teach others about or share your experience with others about new diseases, unfamiliar diseases, rare manifestations, though you have seen the disease before, but this particular type of clinical scenario for this disease you have not come across. These kinds of case reports may be extremely useful either to generate a hypothesis about pathophysiological mechanism or just your fellow clinicians to be aware that they may come across this type of clinical manifestation during their clinical practice.

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CASE REPORT

Adenocarcinoma arising from a gastric duplication cyst with invasion to the stomach: a case report with literature review

K Kuraoka, H Nakayama, T Kagawa, T Ichikawa, W Yasui

J Clin Pathol 2004;57:428–431. doi: 10.1136/jcp.2003.013946

This report describes a rare case of adenocarcinoma arising from a gastric duplication cyst, with invasion to the stomach wall, in a 40 year old Japanese man. A cystic lesion was found between the stomach and the spleen. The cyst had a well circumscribed smooth muscle layer, corresponding to the muscularis propria of the stomach and the mucosa of the alimentary tract. A well differentiated adenocarcinoma was found within the duplication cyst, invading its serosa. Well differentiated adenocarcinoma was independently found in the fundus of the stomach; the tumour of the cyst was connected by fibrous tissue. Microscopically, there was neither adenocarcinoma in situ nor precancerous lesions, such as epithelial dysplasia, suggesting that the carcinoma derived from a gastric duplication cyst that invaded the stomach. Duplication cysts should be included in the differential diagnosis of cystic masses of the gastrointestinal tract, and the possibility of malignancy within these cysts should be considered.

fibrofibrinous peritonitis. The cyst was strongly adhered to the stomach and retroperitoneum and did not communicate with the gastric lumen. The patient's postoperative course was uneventful. One month after surgery, a protruding and ulcerative tumour was found at the gastric fundus, where the cyst had adhered, by endoscopic examination. Biopsy specimens from the tumour revealed a typical, well differentiated, tubular adenocarcinoma. A proximal gastrectomy was performed. Seven months after surgery, the patient had multiple liver metastases and received chemotherapy.

METHODS

The surgical specimens from the patient were fixed in 10% buffered formalin and processed for paraffin wax embedding. Multiple sections of different fragments were stained with haematoxylin and eosin. Serial sections were immunostained by the avidin–biotin–peroxidase complex technique with the primary antibodies listed in table 1. Antigen retrieval was carried out using high temperature incubation in citrate buffer (0.01 mol/litre, pH 6.0).

As you can see here, this is an example from a journal how the case reports look like. The case report is usually published in most of the peer reviewed journals, in a separate section, wherein they would mention what the clinical condition is and what the particular case report is covering. In most of the case reports, will also talk about what is the existing evidence or what is a literature about this and whether this type of manifestation has also been observed by other clinicians.

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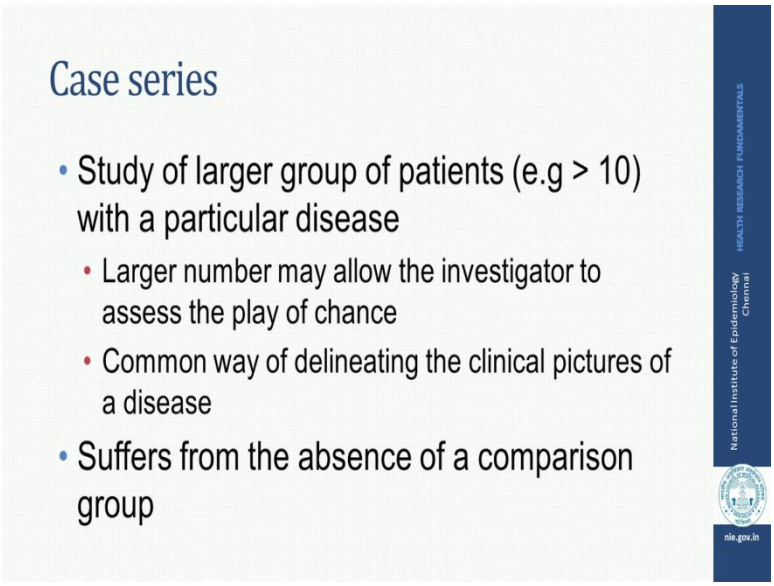

Now as a case reports cover one or two patients, case series is a step ahead of that, wherein you study a relatively larger group of patients who have a particular disease for example, you may study 10 or more patients with some rare type of cancer or with some rare type of tuberculosis or any other disease, how does it help you? It helps you to understand whether these kind of findings that they are observing, are they really due to the disease or is it due to the chance. It may help you understand or develop what would be the clinical picture of patients presenting with a particular type of disease. The only problem with case series is that you don't have a comparison group.

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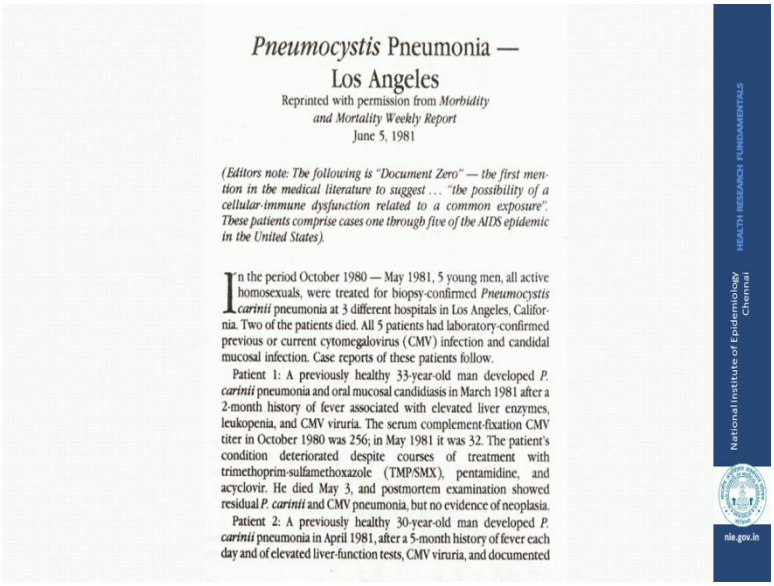
Pneumocystis Pneumonia — Los Angeles

Reprinted with permission from *Morbidity and Mortality Weekly Report*
June 5, 1981

(Editors note: The following is "Document Zero" — the first mention in the medical literature to suggest ... "the possibility of a cellular-immune dysfunction related to a common exposure". These patients comprise cases one through five of the AIDS epidemic in the United States).

In the period October 1980 — May 1981, 5 young men, all active homosexuals, were treated for biopsy-confirmed *Pneumocystis carinii* pneumonia at 3 different hospitals in Los Angeles, California. Two of the patients died. All 5 patients had laboratory-confirmed previous or current cytomegalovirus (CMV) infection and candidal mucosal infection. Case reports of these patients follow.

Patient 1: A previously healthy 33-year-old man developed *P. carinii* pneumonia and oral mucosal candidiasis in March 1981 after a 2-month history of fever associated with elevated liver enzymes, leukopenia, and CMV viruria. The serum complement-fixation CMV titer in October 1980 was 256; in May 1981 it was 32. The patient's condition deteriorated despite courses of treatment with trimethoprim-sulfamethoxazole (TMP/SMX), pentamidine, and acyclovir. He died May 3, and postmortem examination showed residual *P. carinii* and CMV pneumonia, but no evidence of neoplasia.

Patient 2: A previously healthy 30-year-old man developed *P. carinii* pneumonia in April 1981, after a 5-month history of fever each day and of elevated liver-function tests, CMV viruria, and documented

So, just to give you an example. This is a very interesting case series that emerged on pneumocystis pneumonia, which was observed in 5 gay men and this led to an understanding that, how is it that the pneumocystis pneumonia, which is not a very common condition is actually occurring in same kind of individuals, which subsequently led to the discovery of AIDS. Coming to the third type of study design.

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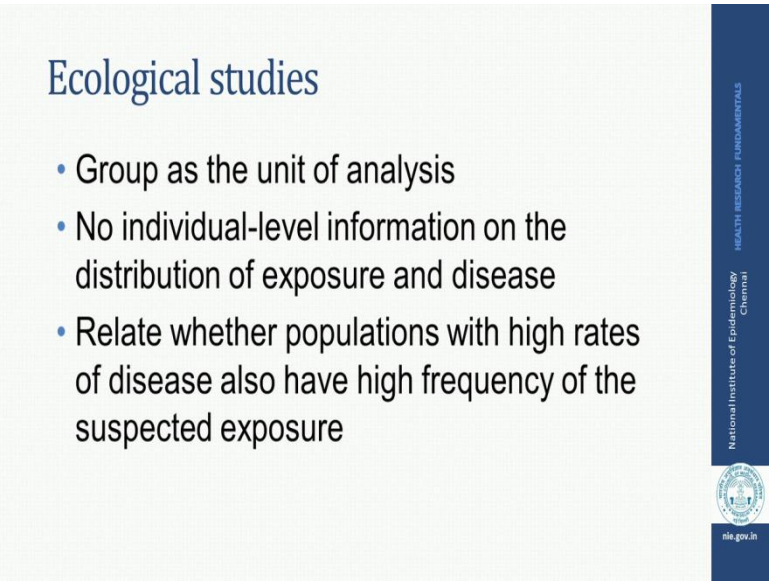

Now, this study design is slightly different. In what way is it different? The difference here is, here individual is not the unit of study or unit of analysis. This is a study that you do for groups, that you can do at a country level, you can do for populations, you can do a particular region of the country and you try to understand a particular problem for a group and you try to relate problem as well as, what could be the possible reason, why that problem is occurring also at the group level. So in this type of study, group is the unit of analysis.

The limitation is that you do not have individual-level data. You really do not know what the individual level exposure is. However, you are able to look at a particular population let us say; we can talk about what is an average intake of fat among people living in a state of Tamilnadu? Or, what is the average intake of carbohydrate among people living in a particular state? And then, you may look at what is the incidence of cardiovascular disease. So, both the measures you only know for the population. But you are not able to have any data at the individual level. How does it help you? It helps you to generate

hypothesis because what you can see here is you can try to co-relate. Let us say, is it so that the states which have high per capita consumption of fat also have higher rates of coronary artery disease or not, if you find that then you could think of doing a further detailed study to actually understand whether there is a correlation between the fat intake and the cardiovascular disease.

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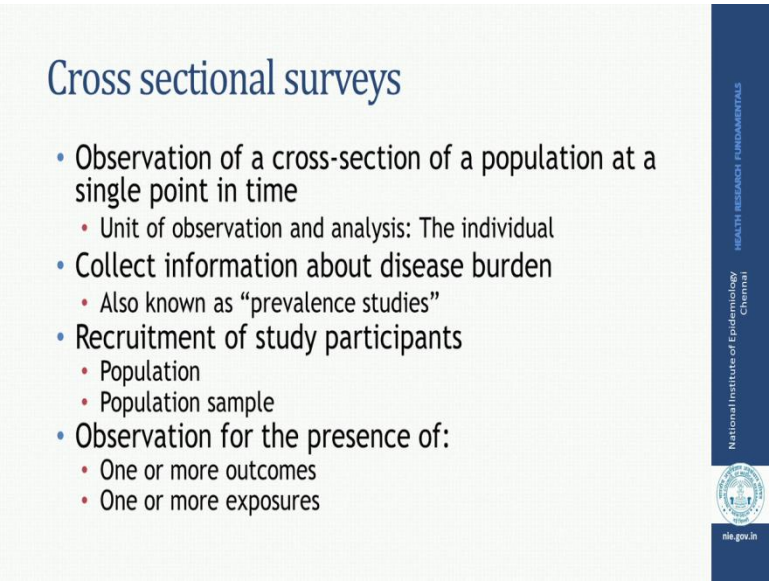

Now, I am going to come to the most important study design and I think this is a study design that many of you might have used in your research studies and obviously, if you are going to be in research, you will end up using this study design for sure. This is the commonest study design and I think you all are aware, you all are aware of census, right? We all have every 10 year census is done for the whole country. Census is nothing but a cross sectional survey, what do you mean by cross sectional survey? It is an observation of cross section of a population at a single point of time.

Now, what happens during census? In the year 2011, somebody would have visited your house they would have come and asked you, how many members are there in your house? How much each person has studied? Where do they go for work? Where do you live? And, this information is for year 2011; however, it may not be the same information in 2012. So, what cross sectional survey captures is, a particular set of information that you want to collect from a population or an individual at a particular point of time.

Now, these kind of studies are extremely useful to know the magnitude, means how big

the problem is, like if suppose if you want to know how many people in the community have high blood pleasure? Or how many people have tuberculosis? Or you may even not about diseases even general information, how many people in this particular area are actually professionals? Any kind of information, any kind of health or non-health information, when it is collected at a particular point of time, it is called cross sectional survey. Now, for a cross sectional survey, you will be learning in other lectures about, what kind of sampling method you can use? How you can select the participants?

But, broadly speaking, census is one example of a survey which covers the entire population; whole country is covered in this kind of survey. However, all surveys are not done like that, most of the surveys they will select a sample. It is not possible to survey one billion people for everything, so you might have come across something called National Family Health Survey, wherein a sample is selected and then the data is collected. Similarly, if you are a clinician, you may want to plan a study in your patients in the clinic. However, it may not be possible for you to include all the patients in your study, and you can think of using a sample. A sample allows you to understand, what is the magnitude of problem in your study population by doing survey at one point of time.

Now, here we can collect data on various type of exposure or outcome, what does it really mean? The exposure here means different types of risk factors for example, you may do a study, wherein you want to know about high blood pressure; high blood pressure could be your outcome, but in addition to that you also want to know whether people are overweight? Whether they are having any behavioral risk factor? Whether they smoke? Whether they drink? So, these are called exposures. So, your survey may include asking questions about their history of blood pressure or doing measurements or asking various questions about what you think are the potential exposures.

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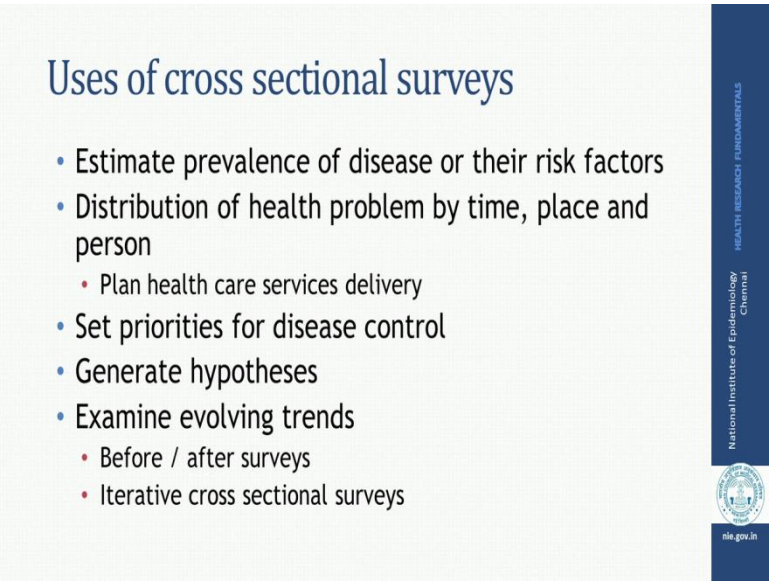

Now, what are the possible uses of cross sectional surveys? First of all, most importantly cross sectional surveys are used to measure burden of disease or prevalence of disease. Let us say, out of 100 people if I am going to survey 100 people, how many actually have high blood pleasure? It can also be used to measure the burden of risk behaviors, you may go and survey 100 men and ask how often do you take alcohol? What is the quantity of alcohol you consume? So, that is a prevalence of a risk factor. It helps you understand distribution of a health problem by time, place, person, what does it mean? It means, when you go and let us take, you take a particular community you went to that area and you did a survey and you ask people, let's say history of diarrhea, and you ask the history of diarrhea in this village as well as in the adjacent village, you ask who gets diarrhea and it allows you to understand how common the diseases in that particular village; are there any particular kind of people who are effected more?

Your study might have included people from all age groups, you may have under 5 children, you may have adolescents, you may have older people and what you can find out from this survey is let us say, of all the people I surveyed I may find the diarrhea is more common in children. So, how it helps the service provider? Cross sectional survey may provide very useful information for planning your health services, at the bigger level. What I mean is at the state level, at the country level or the global level. Cross sectional surveys help us in setting priorities, for disease control.

Now, where should I invest my resources? Which is the most important disease? Should I invest it in a study on hypertension? Should I invest it on a study on depression? To understand that you need to know, what are the big health problems in your country or in your state or whatever be the unit of study? The cross-sectional survey allows you to measure the magnitude of the health problem. Now, cross sectional surveys are not ideal for testing hypothesis, you will be introduced to the analytical study designs, where you can do that; however, they help you generate hypothesis.

You can think of what are the potential risk factors, if you find you did a study and you found that the prevalence of hypertension is very high. Let us say, 40 percent people have hypertension and simultaneously, you might have asked various questions regarding their eating habits, regarding smoking, regarding alcohol use, regarding over weight and you could do a preliminary analysis and understand whether which of these risk factors might be playing an important role. And this part of cross sectional survey is called analytical cross sectional survey.

However, to test your hypothesis you need to use the other study designs. The other use of cross sectional survey is, suppose you want to know after having introduced a particular type of intervention, it could be a clinical intervention for example, you introduced a new drug. A new drug into your regimen of a particular disease for example, for malaria, you are using a particular drug or for TB. You want to know before and after, after introducing your intervention, whether the patient outcomes are better, you can do that using cross sectional surveys. So, this cross sectional survey design is extremely useful design in trying to measure the burden, understand the magnitude, understand the distribution, and sometime even to understand the effectiveness of your interventions.

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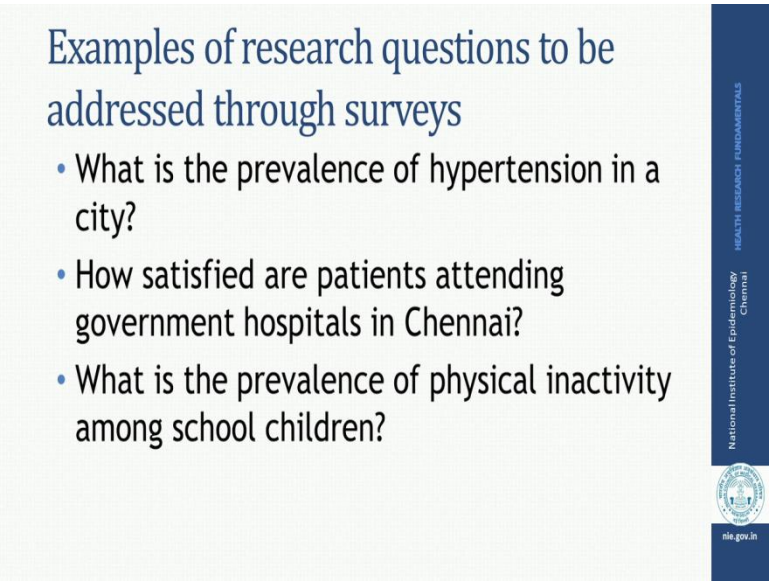

Now, these are the some of the examples of research questions that can be answered through surveys. What is the prevalence of hypertension or prevalence of any disease in an XY city? The other type of study, in many time many of you might be in the health services and you may want to do surveys to understand your patient satisfaction or you may want to even just do a survey to know, what kind of utilization pattern is there of your health facilities? So, you can do cross sectional survey of patients. Many times they are also called exit surveys.

Now, thus cross sectional surveys can be done in any setting. It could be done in schools, it could be done in health facility, it could be done at the community level, it could be done at the clinical level. So, another example would be that you want to know how common is the physical inactivity? As you know, you may be interested in understanding childhood obesity and you may want to know, what is the prevalence of physical inactivity among school children? So, all these kind of questions can be answered using cross sectional survey study design.

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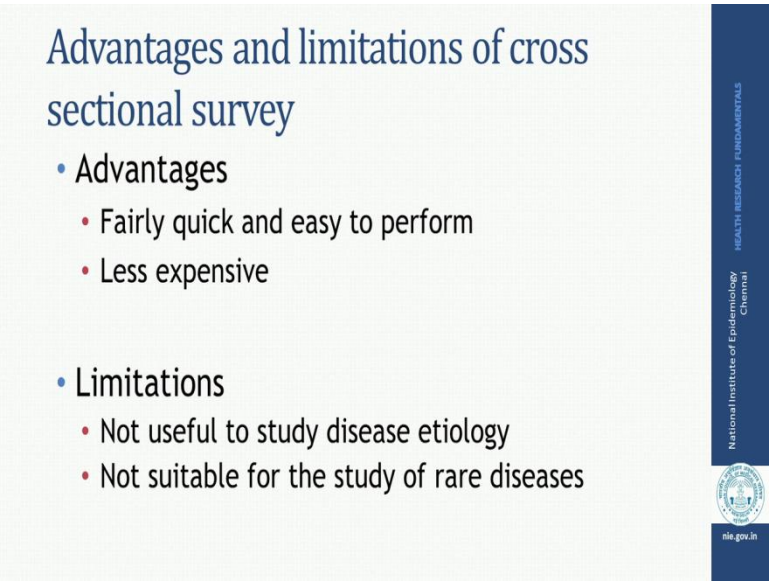

Now, let us come to what are the advantages of this and what are the limitations? Now advantage, I think you all must have realized by now, they are quick you can plan and complete a cross sectional survey in a very short period of time; may be two weeks, one month depending on how big your sample size is. And, as you know I think the biggest cross sectional survey census even that is completed in less than a year where the whole billion population is covered. If you are doing a smaller survey they tend to be less expensive, unlike some other study design where you may have to keep on doing data collection for much longer period of time.

There are few limitations of cross sectional survey that should be kept in mind while designing your study. First of all, they are not useful to study the disease etiology, as I told earlier these are descriptive studies and here you cannot test hypothesis. They are also not suitable in study of rare diseases, let us say if your disease, let us say cancer; now cancer incidences 20 per 100,000 and if you want to measure the burden of cancer, just to get those 20 cases you will have to survey 100,000 people, it is not practical. This kind of situation, it may not be an ideal study design.

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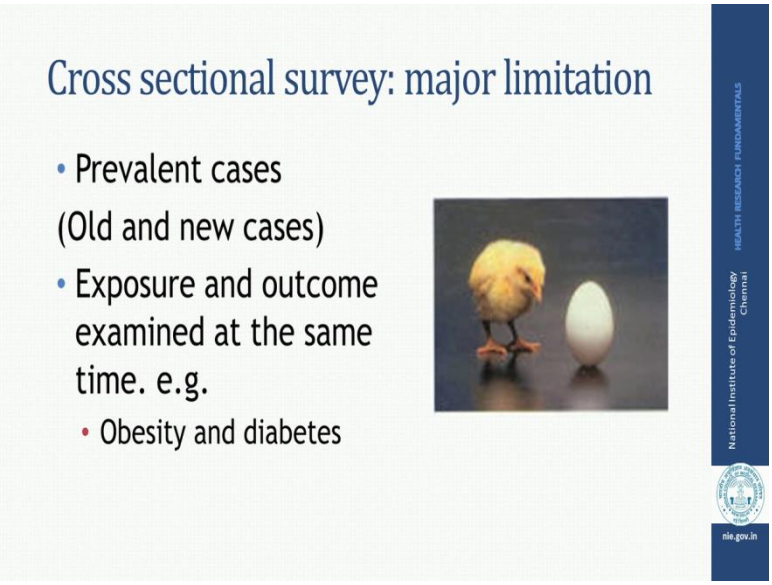

Now, coming to the most important limitations and this you should all be very familiar and keep in mind when you design a cross sectional survey. Now, if you go and collect data on hypertension, there are patients who will tell you that; yes, I have hypertension, I am taking treatment for last one year. Now, you do the blood pressure measurement in addition to these old cases, you are also going to pick up some of the new cases, who were not aware at the time of survey that they have hypertension. In a cross sectional survey, you measure all the prevalent cases, I think in the earlier sessions you might have been introduced to these terms, terms such as prevalence, incidence.

So, cross sectional surveys measure prevalence. Now which is fine, but what is the problem here? Now, if you go and survey an individual and you ask, do you have hypertension? They say, yes and then you ask them, are you a smoker? They say, yes. What it does not tell you? It is the chicken and egg story, you do not know which happened first, whether hypertension happened first or smoking happened first. Similarly, if you take obesity and diabetes, you go in a cross sectional survey you may find people who are diabetic as well as overweight. How do you know which happened first? Whether diabetes happened first or overweight happened first? So, when you do a cross sectional survey, you need to be very cautious in interpreting your results, you need to keep in mind that these exposure and outcome cannot be linked very well in this kind of study design and if you want to do that, you will have to use different kind of study designs that you will be learning in the upcoming lectures.

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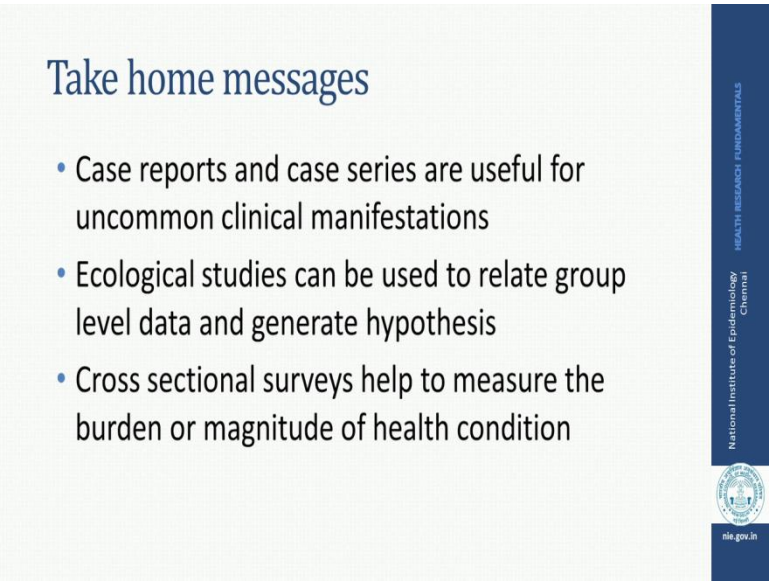

Now, just to summarize, case reports and case series are extremely useful to document uncommon clinical manifestations in a certain set of patients. And, these are extremely useful for the clinicians. Ecological studies are useful when you want to relate a group level data and generate hypothesis. Cross sectional surveys, most common study design and the very useful study design, it is useful to measure burden or magnitude of health conditions.

Thank you very much.