Health Research Fundamentals
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Lecture - 01
Introduction to health research

Hello, in this online course on Health Research Fundamentals being offered by National Institute of Epidemiology and Indian Council of Medical Research.

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Today, I am going to give you Introduction to Health Research. Primarily, we have to understand that there are many dimensions to health research. Health research is conducted for theoretical purposes and when we have some good evidence created out of that we go for applied research. There are also prevention and therapeutic angles to doing health research as well, in the sense some of the preventive technologies as they emerge, they have to be tested out through research methods as well as newer therapeutic options become available they need to be tested out through research methods.

Essentially, we have many a times heard of and we have seen in the movies the bench best research, where we have seen scientist in white coats working in the laboratories trying to do something with animals like mice and monkeys and so on and so forth, but what they do there has no significance until the findings or the learning's that they have got in that particular research are carried further and they become available to the bed side, that is they are, they can be applied to the human beings either for alleviating

diseases or for preventing diseases. And this is a process which one has to understand and one has to really follow correctly.

Sometimes the research is of exploratory in nature, where in the sense we do not know much about it right in the beginning, but what we try to do is employ various methods and try to figure out if we can get some clues for further research. Sometimes, it can be confirmatory, in the sense some of the clues that have been obtained by people can they be say sort of strengthened or can we get additional information which could be of practical significance? That is called as Confirmatory Research.

There are other terminologies which are also employed; one which has been recently employed in a big way is Implementation Research and Translational Research. Many of the government programs get implemented and what is important to understand at this particular point of time is how these programs are functioning well and it is also therefore important to make mid course corrections, if they are necessary or to decide in which areas you need specific angles of the programs to be strengthened and so on. Transnational research basically talks about the earlier concept of bench to bed site that I talked about. This is a process of development of technologies for human benefit and human welfare.

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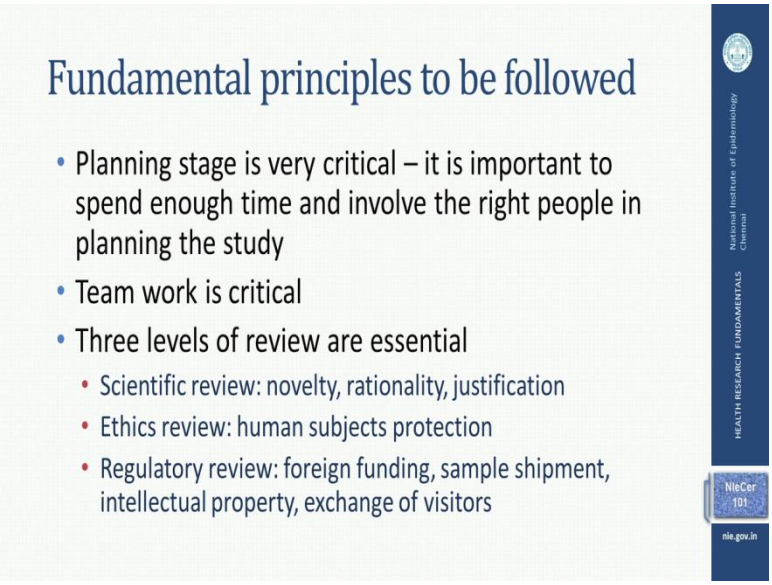

There are some important principles that we have to understand when we conduct health research, but one thing which is really critical is that the planning stage in research is

absolutely critical, why? Because, if we do not spend enough time and if we do not involve the right kind of people in planning the research study, it is very likely that some of the issues that we could have earlier prevented or they get missed which we could have prevented in the real sense. Hence, in my opinion team work is really critical in research, very rarely solo research succeeds. But for any kind of research to happen it has to undergo several layers or levels of reviews.

Scientific reviews are important because they look at, what is the novelty in the concept that is being looked at? Is there rationality behind doing that? And what is the justification for that? And in that particular context the rational for doing that particular study in a specified country is also critically important. Whereas, the ethics review primarily focuses towards finding out, whether the human subjects protection issues have been adequately taken care of or not. What is important is research definitely means development, research definitely means advancements, but it cannot be at the cost of human subjects. People who are participating in the research are described as human subjects or human participants and we should do nothing that can really harm them in the long run or in the short run. So, ethics review ensures that this does not happen.

There are certain ‘in country’ procedures or ‘in country’ reviews called as Regulatory Reviews and they are basically there to decide about, what kind of foreign funding is being received for that particular project? Are there any sample shipments that are going to happen? Because there is a lot of intellectual property also which is attached to this data sharing which happens, we always should be protective of our own intellectual properties and so the regulatory authorities in our country do take care of this and they ensure that our intellectual property is properly protected. Some projects do also involve exchange of visitors and several countries have their own rules and regulations regarding the visitors, who are coming and going. These are mandatory aspects and it is important that the regulatory committees do review that aspect as well.

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One thing I would like to stress, the health research or for that matter any research is a process and it contains multiple components and each and every component in this process is of critical importance. It all starts with collecting data. We have to collect data with a specific purpose and for that data to be of high quality, the data collecting instruments also have to be appropriately designed. If the data quality is good, then we can draw meaningful conclusions based on that and then we can make appropriate decisions.

What is important is once these decisions are made, the policy planners and the program managers of the country , they decide, whether this is the right time to take these particular learning's from research to appropriate actions which can be employed at an individual level or at a mass level. This is what we call as 'Evidence based action'. Primarily, all this is done so that we ensure that there is a reduction in suffering and ultimately improvement in health and well being of the people or the community.

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But when we talk about the kind of information that we collect in research, it can have wide range of breadth and depth as well. There is some information which is required to be collected with respect to the human host for example, and they can be some times healthy, they can be sometimes susceptible to a particular condition or they can be suffering from a particular disease, some of them may have died because of the that particular disease also. We have to figure out, how we can get the required information from these kinds of subjects from these various kinds of host that I just talked about.

The disease cannot occur in an individual unless and until there are many factors which come together and that is why we in the modern times always say that there is a multi factorial origin for occurrence of any particular disease and we all know, the environment which is surrounding us and the society in which we live, plays a very significant role in occurrence of diseases. There could be factors like climatic factors, there could be housing factors, housing related factors, the vectors around us, the animals around us, various socio-cultural practices that we follow, the family structure with which we live, all these factors can affect not only the health of individuals which could be physical or mental as well but they can lead to an occurrence of a disease as well.

In addition to that one more dimension that comes into the picture and which is really important from the context of health is the health care infrastructure. Sometimes, people find it very difficult to access health. The access to health is a critical component because

many of these studies have shown that if people are not able to access health in time, the kind of complications that arise and the death rates that result from that are unusually high in nature. So, there could be multiple angles which are require to be collected, we call all those like study variables. We have to collect correct information on those study variables when we carry out health research.

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Primarily, when we talk about the scope of health research or the objectives of health research they could be many. For example, most of the times when we think of research, we think of something like creating new information but the objective could be creating totally new information but we sometimes also get additional information on something which already exists. Say for example, are more of diphtheria and pertussis cases reported among adults in the recent times? We used to know that these were the diseases of childhood earlier but now, it has been seen that some rare instances the cases in adults are also getting reported, so we need to figure out why this is happening? And where is it happening?

Similarly, in terms of getting new information somebody might want to do research to find out the full genome structure of hepatitis B virus and hepatitis E virus. It could have lot of implications in terms of understanding what kind of pathogenic impact it would have in human beings, also it could have significant decision making with respect to development of vaccine against those viruses.

Another objective that we also can pursue through health research is to verify and confirm available information. Here is where, most of the research that happens in our country is now-a-days happening. For example, are etiologies of pediatric pneumonia, you all know, pneumonia is a very serious disease in childhood particularly in children below 5 years of age. So, are the etiologies different in the developed countries and a resource limited countries like India. If one wants to figure this out, this could fit under this particular objective. Also, have the incidence and complications of diabetes changed with increased consumption of pre-cooked or packaged food. We have seen this to change, the eating habits of people have changed but has it got any relation with the incidence and complications we might want to study through health research.

Many a times health research is also focused on finding out the cause and effect relationship and this could be applied if you think about it in multiple situations. For example, there is a presence of a specific receptor on a type of white blood cells which are called CD4 cells in the human body and they are believed to protect against HIV infection. But whether they project against a particular type of HIV infection, a particular sero-type of HIV infection or they have a generalized effect, this could be evaluated under a cause and effect relationship related research. You must also have heard that in the recent times breast implant operations are undertaken, but do these breast implant operations or do these recipients, are they more likely to develop breast cancers, this is something like a cause and effect relationship, where we can think of breast implant is a cause and breast cancer is a effect.

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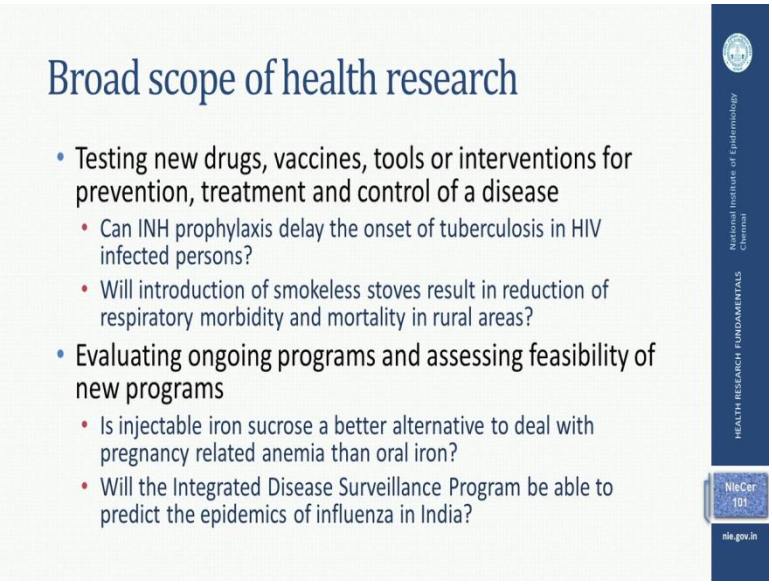

One more important area in health research is that testing of new interventions like say, new drugs, new vaccines new tools or newer prevention treatment technologies, etcetera. For example, it has been said that tuberculosis is one of the most common dreaded complications or diseases to happen in HIV infected individuals and mostly this is the disease which eventually kills them. So, can we introduce INH prophylaxis? INH is a potent drug which is used against tuberculosis, so can it be introduced among HIV infected individuals, so that they can be protected from getting tuberculosis. This is an important intervention which could be tried out and to reduce mortality associated with HIV because of prevention of tuberculosis in them.

Or for example, we are nowadays talking a lot about indoor air pollution, particularly in the rural areas. So, if we decide to introduce smokeless stoves in those areas, would that lead to reduction in mortality and morbidity in the rural areas. This could again be a part of an intervention evaluation. Sometimes, the government has various on going programs, Public Health Programs which are vertical in nature, which are operated by the federal government or the central government in our country. All of you know that the general health services are provided in our country by the state level health services but the national level control programs are operated and funded by the central government.

So, for example, we have seen that there has been large number of women noted with

anemia and this is one reason, why many complications occur in pregnant women. There has been this oral iron supplementation has been the main stay for treatment of this particular condition for many years, but nowadays iron sucrose injectable iron has become avail available and it is believed that it probably can improve or tackle anemia during pregnancy much better then oral iron. So, evaluating that as been given in the program could be an important thing that we can think about under this part of research. Also, the government has introduced a program for several years now called as Integrated Disease Surveillance Project or Integrated Disease Surveillance Programs now. So, can it predict the epidemics of newer and emerging diseases likes H1N1 influenza that has been affecting us recently.

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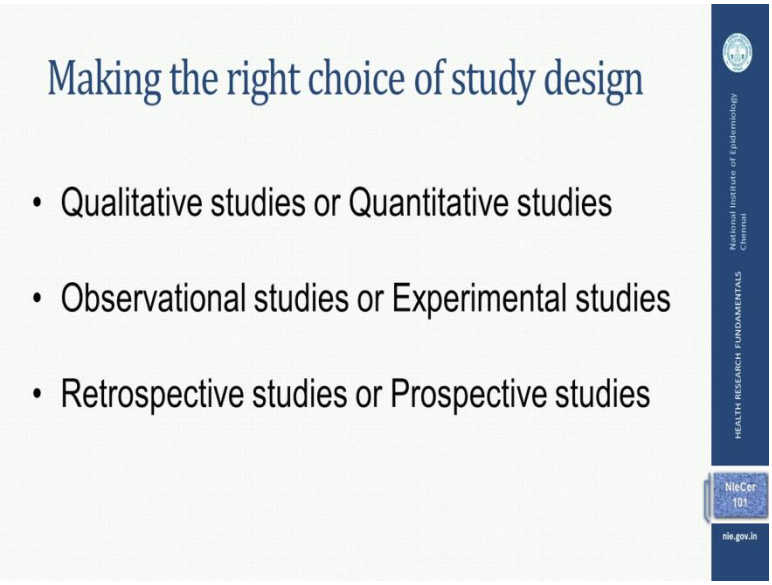

So, these are some important objectives of research that we have to keep in mind but one important thing is, if we want to do sound research, it is really critical that we make the absolutely a right choice about the study design over here because some kind of a miss judgment here can lead to a futile kind of a research or which does not help you to understand it. This can be broadly say described in terms of some enquiries or some kind of health research can be qualitative in nature, which requires person to person interviews or discussion in focus groups or just say free listing or observations and things like that. It mostly is observational in nature and it is open ended and people do probe at times to find out this information. Whereas quantitative studies are mostly based on structured questionnaires, that is where people deal with questionnaires, which are

previously thought of and only the questions with very specified options of answers that can be made available are used or employed in the study.

One more important differentiation that is made is the observational study and experimental studies. In epidemiological terms, observational studies are those wherein the investigators do not change the environment in which the study participants are living and the main thing that distinguishes the experimental studies is, this is where the participants are exposed to some kind of an intervention at the will of the investigators. So, some kind of a change is made and that is how this kind of studies becomes different kinds of studies. They also are described as retrospective studies or prospective studies.

Retrospective studies are classically where the information on the outcome that we are trying to study in a particular health research is already available. But in a prospective study we only start the study with people who are at risk or who are susceptible to a particular disease , also have a comparator arm or control group, comparison group and then follow these two groups to find out how many people in either of these two groups develop a particular disease, which they were free off at the beginning of the study. So outcome happens sometimes in the future and it is called as a Prospective study design.

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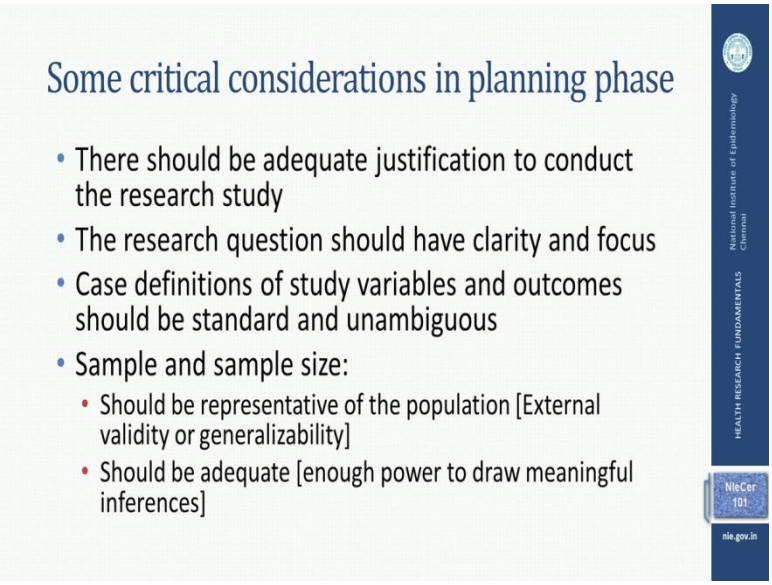

As I mentioned earlier, planning is a very critical stage in research and some important considerations in this particular phase, which have to be kept in mind include, there should be adequate justification for conducting that particular research. Always please

remember research involves investment. Investment in terms of money, investment in terms of manpower and hence, it is absolutely important that there should be adequate rational or justification for conducting any research study. For this to happen, the original research question should have total clarity and focus only then the study becomes a good study.

Another important point to be considered is that, the case definitions used for various study variables and outcomes should be standard and unambiguous. For example, if you are looking at cancer cervix then what we call as carcinoma in-situ and what we call as invasive cancer has to be known to everybody, who is involved in that particular research. For example, if you are collecting information on oral contraceptive pills use, what is considered to be as those women who are using oral contraceptives pills versus those, who are not, should be adequately clarified.

Another critical aspect that has to be kept in mind is the sample and a sample size. It has two dimensions to that, sample has to be qualitatively representative of the population in which the study is being conducted because here this leads to what we call as external validity or generalizability. In simple terms, it means that if we are able to just generalize the findings of our study which are based on a particular sample adequately and comfortably to the whole population from which the sample was drawn then we have served our purpose.

But this also has to be complimented with adequate sample size as well because this is, we should have enough power to draw meaningful inferences and hence sample size should be appropriately decided for any kind of a research study.

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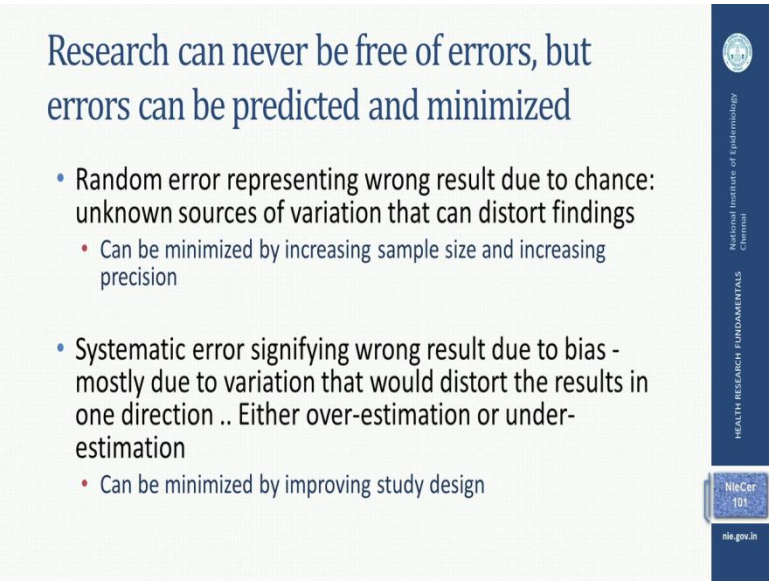

We always have to remember research can never be free from errors, but if we predict them well then they can be minimised through appropriate study design, this is an important aspect. Sometimes errors happen because no two human beings are equal, one person has a different haemoglobin level than the other, one person has a different height and a different weight than the other and hence, we look at many such people together there would be some kind of a variation which would naturally be happening in them and this is what we call as a random error, which anyway is going to be there in any kind of a research study.

How we minimize it is by taking a large sample size. If we take a large sample size this intra individual variation within a particular sample gets minimised to a large extent. But sometimes, there could be another type of error that could occur and the results could be due to a something called as bias. And this is a variation due to some kind of distortion by some kind of a faulty procedure, it might be a measurement error, it is may be due to the kind of way the information is collected, it might be due to the process in which the participants are enrolled in the research study. So, one has to remember this kind of an error can only be minimised by improving the study design and taking care of that very adequately.

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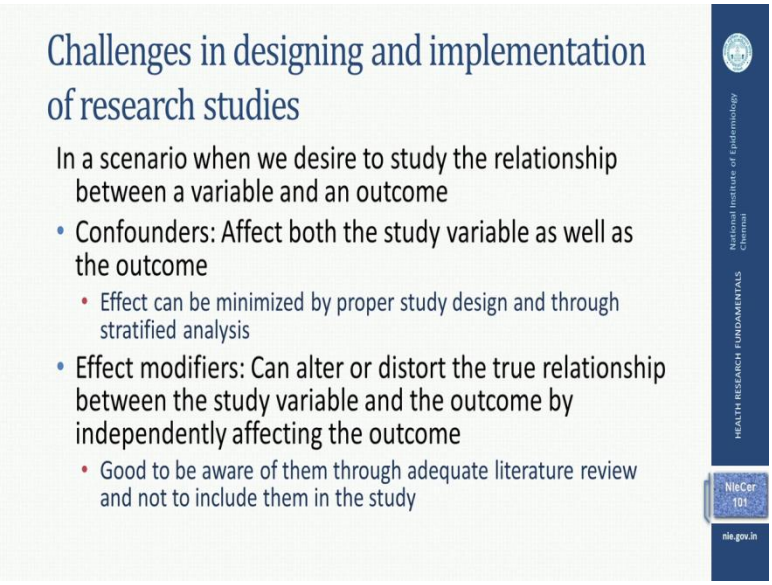

There will always be challenges in designing and implementing any kind of a research study. But the important thing that we have to understand is how we predict those, and one way to tackle this very appropriately is to do a thorough literature research before we do any kind of a study because it gives us an idea about two important say entities which can affect the result, they are called as Confounders and Effect modifiers.

Well, confounders are the entities which affect both the study variable as well as the study outcome and invariably, if you just leave out all those people having this confounding characteristics, it is quite possible that you may land up with a situation where you do not have enough people to do research at all and in this particular scenario therefore, it is important that we understand which are the confounders. Collect the right kind of information on all the confounding factors because statistical analysis can take care of this confounding, which happens in a research setting. Effect modifiers are little difficult to deal with because they can alter or distort the true relationship between the study variable that we are looking at and outcome by independently effecting the outcome itself. So theoretically, it is a good idea to be aware of them and to also understand the kind of effect they are likely to make on the outcome variable, also one strategy that could be tried is to not to include people with effect modifiers in the study.

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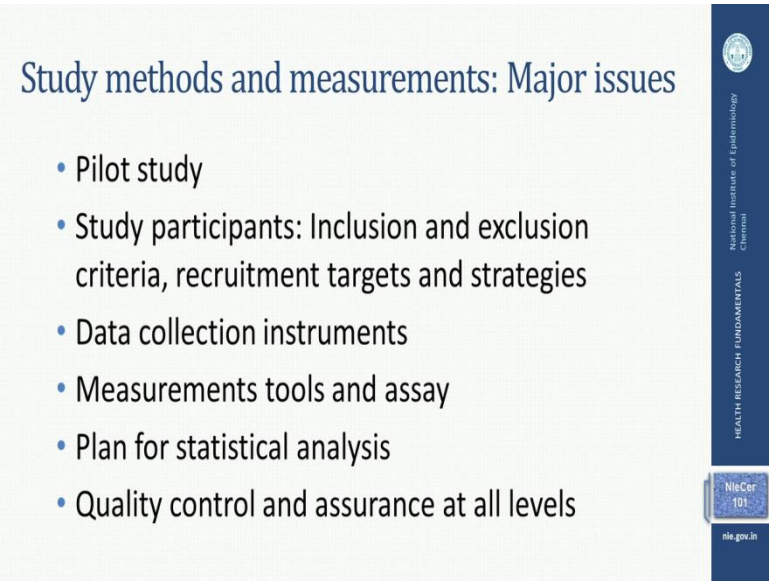

When we do any kind of a study, it can have multiple stages. It might be a good idea to do a pilot study. Pilot study just helps us to carry out all, what we want to do in the study in a say sort a few individuals this kind of becomes a rehearsal. It helps us to understand what kind of difficulties we are likely to face in collecting the information, carrying out certain procedures, doing the interviews, doing the inform consents, peoples understanding about informed consent forms and so on which can be changed.

There have to be certain issues related to study participants that need to be tackled very well, which are the inclusion criteria? And which are the exclusion criteria? One has to be very specific about all of them. Why? Because, if we are very specific about inclusion and exclusion criteria, enrolment of people who are not eligible to participate in the study can be substantially minimized. Also, every research study has to move with very specific research targets and it should follow certain strategies, like in some studies we might want to do the recruitments by going out in the community, whereas in some we might just want to do it based in the healthcare facilities, this decision has to be taken up front. Data collection instruments are really critical because if there are any mistakes the way they have been designed we cannot make any kind of a change at a later stage. So, lot of work has to be done before hand in drawing or in deciding the right kind of data collection tools.

Measurements, here I am referring to all those measurable items which are either using

the laboratory methods or assays. They have to be properly standardized. They should have proper internal and external controls, here positive and negative controls for quality control. This lab also should probably be a part of an external quality assurance program because all this ensures quality control and assurance at all levels. It is also important that the plan for statistical analysis for any kind of a study has to be decided right up front, right in the beginning because that gives you a very clear idea about how we are going to collect this particular information and how the results of this particular study are going to look like eventually.

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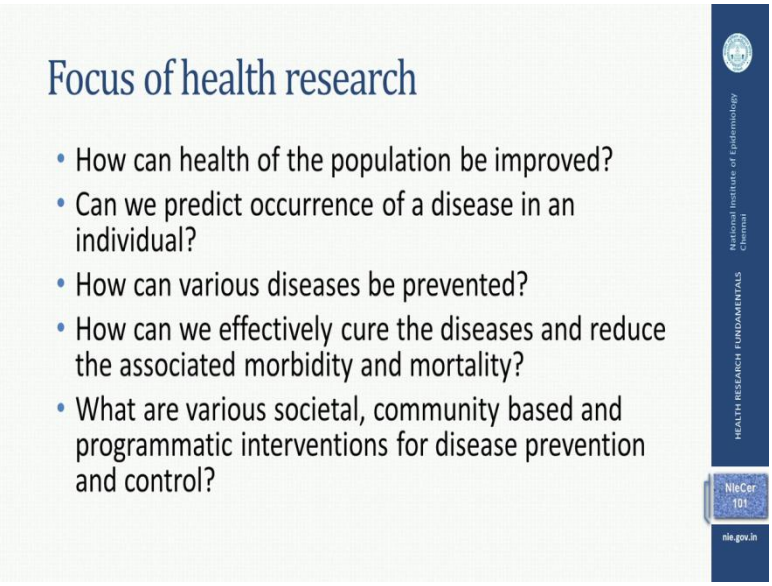

So when we are doing health research, we have to have some kind of an orientation towards either promoting behaviour or promoting health then preventing disease and also preventing mortality and then maybe. So, how can we do that? How can health of the population be improved? This is something like a direction that we have to think about. How can we predict occurrence of a disease in an individual? How can various diseases be prevented? How can we effectively cure the diseases and reduce the cost and also the associated morbidity and mortality? What are the various societal community based and programmatic interventions for disease prevention and control? These are the kinds of directions which health research takes and follows.

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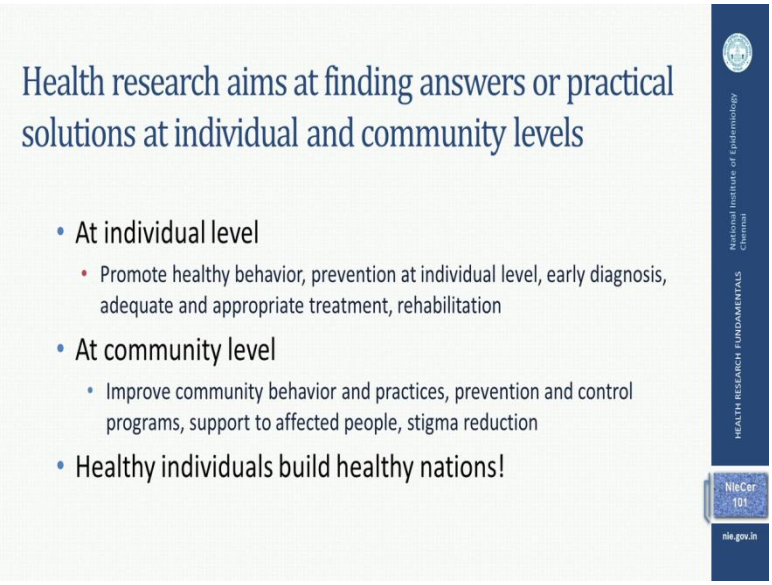

But basically, what we try to do is to find answers or practical solutions at individual and community levels. For example, at community levels we have to see how healthy behaviour can be promoted? What can be the personal prevention achievable at an individual level? How can early diagnosis be achieved at an individual level and adequate and appropriate treatment be instituted? What kind of rehabilitation be done at an individual level? But when we think of the community level we have to think of improving the community behaviour and practices, prevention and control programs as supporting the effected people or stigma reduction. All in all, healthy individuals only can build healthy nations.

Thank you very much.