Health Research Fundamentals
Dr. Manickam Ponnaiah
ICMR - National Institute of Epidemiology, Chennai
Lecture - 02
Formulating research question, hypothesis and objectives

Hello, welcome to today's session of the Health Research Fundamentals course. In the introductory talk, Dr. Sanjay Mehendale talked about, the scope and focus of health research. He mentioned that the goal of research is to establish facts or principles through careful and systematic investigation in a particular area. Ultimately, the result of such investigation is to improve the health of the population. The first step in such research is formulating research question.

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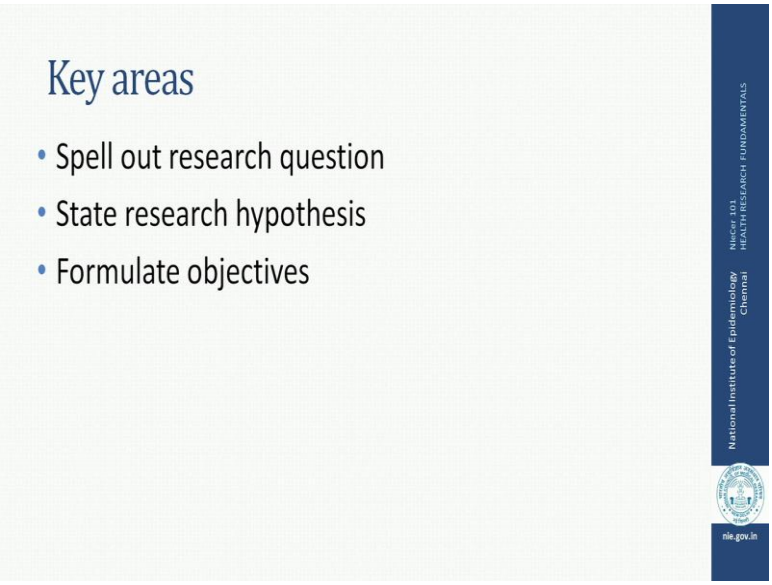

Today, we are going to cover 3 areas - spelling out research question, stating research hypothesis and formulating study objectives.

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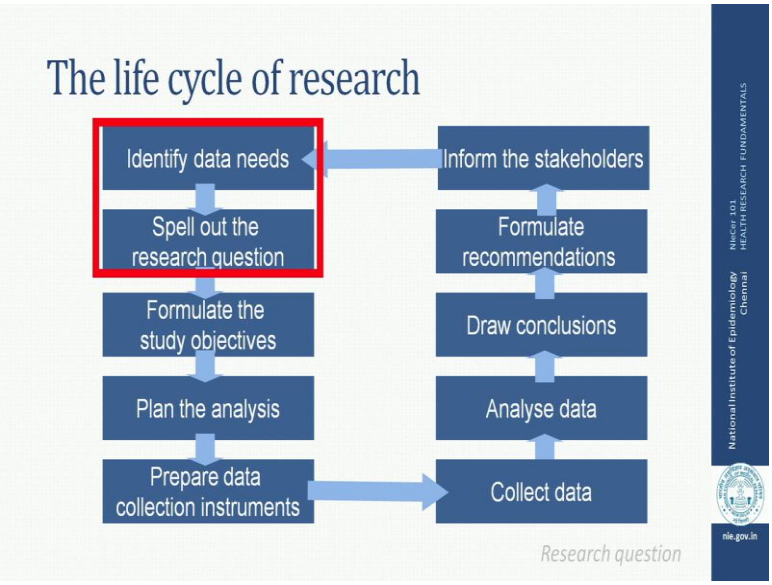

Any research has a life cycle. It begins with an uncertainty or needs in a particular area and that needs is translated into research question. Subsequently as study objectives and a plan of analysis is formulated to guide framing data collection instruments. Using these tools, data is collected and then subsequently is analyzed as per the plan and as per the objectives conclusions are drawn and recommendations are formulated. Ultimately, this particular recommendation is shared with the stakeholders for whom it matters. This process ends with another uncertainty that may begin the cycle once again. Therefore, the first two steps clearly indicate that we need to start with a good research question. Therefore, we are going to see what is research question?

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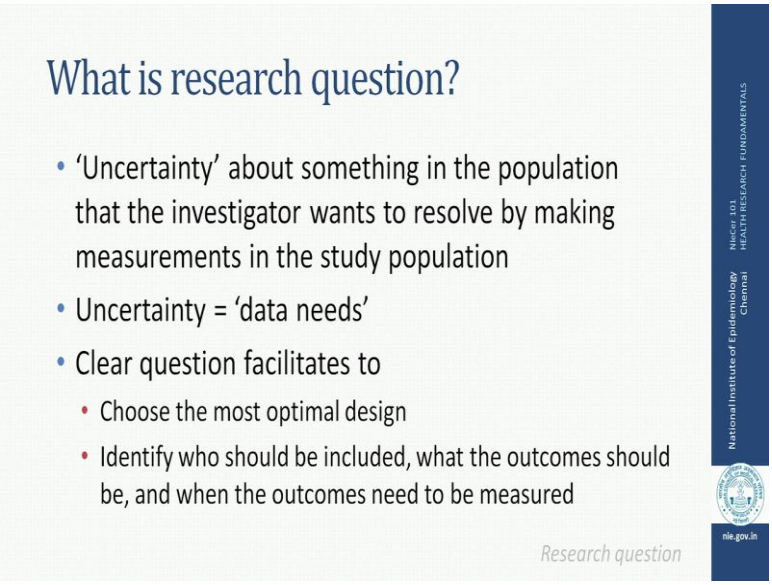

A Research question is an uncertainty about something in the population that the investigator wants to resolve by making measurements in the study population. The uncertainty is referred to as data needs in the life cycle. Therefore, we need a clear question to facilitate choosing an optimal study design and identify whom to be included, what are the outcomes that we need to measure and when these outcomes to be measured.

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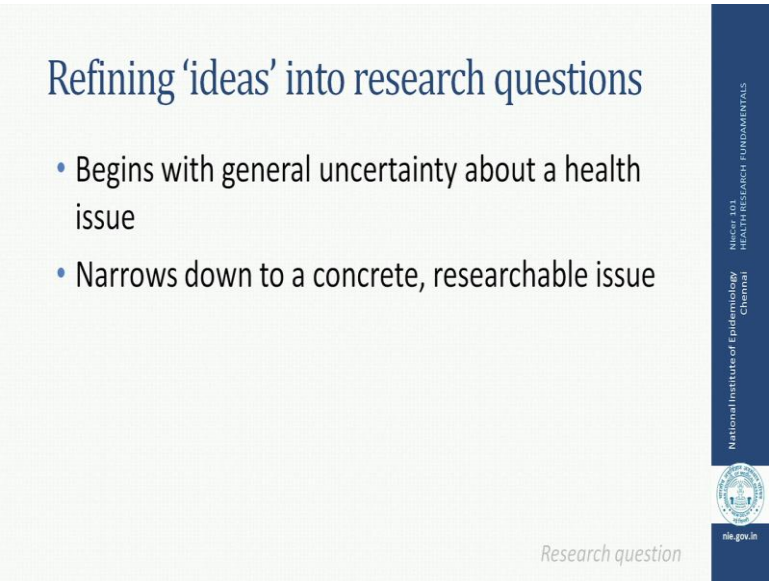

Research question is all about refining your ideas into systematic process of framing a question. It begins with the general uncertainty about a health issue in the context of health research and then it is narrowed down into a concrete researchable issue.

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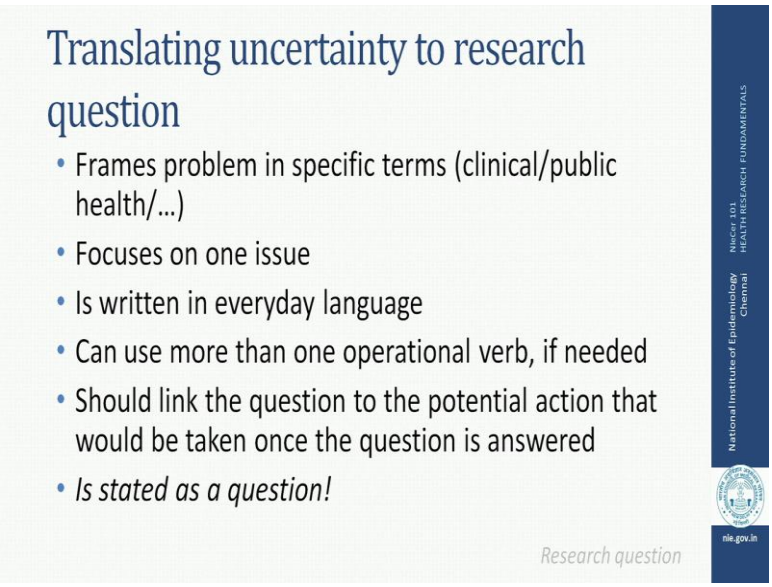

While translating uncertainty to research question, one frames the problem in specific

terms. In health research, it could be in clinical or public health terms. We need to focus on only one issue at a time and it is written in everyday language. So, that everybody understands what the question is. You may choose to use more than one operational work, if needed. It should link the question, if answered what action will be taken and it is stated as a question that is why it is called research question.

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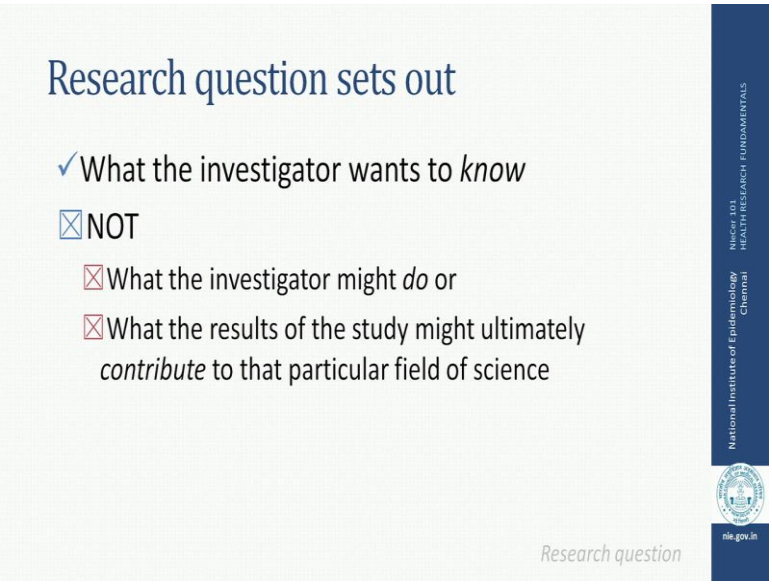

A research question sets out clearly what the investigator wants to know and definitely not what he or she may do or what this results will ultimately contribute to. It does not just include these two aspects; it should spell out what the investigator wants to know.

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There are many sources from which the research questions or ideas can arise from. I am spelling out here four such sources. First is definitely a scholarship in the area of research interest, an up-to-date information from literature will help in generating research questions. The second is being allowed to new ideas and techniques, how does that happen? It can happen through attending research meetings or conferences, where the latest findings are shared and there may be a good discussion in peer group during the conference or meeting. Having a good attitude, skeptical attitude in particular, about the prevailing beliefs and last, but very important, applying new technologies to old issues.

The third aspect could come from careful observation in your clinic or in your basic science work, on your sphere of life. Teachers get enormous opportunities, while they are preparing for teaching and teaching and interacting with students and then finally, tenacity to go to the bottom of the things. Last, but very important, if you have a good guide or a mentor, he can help you in identifying and framing research questions.

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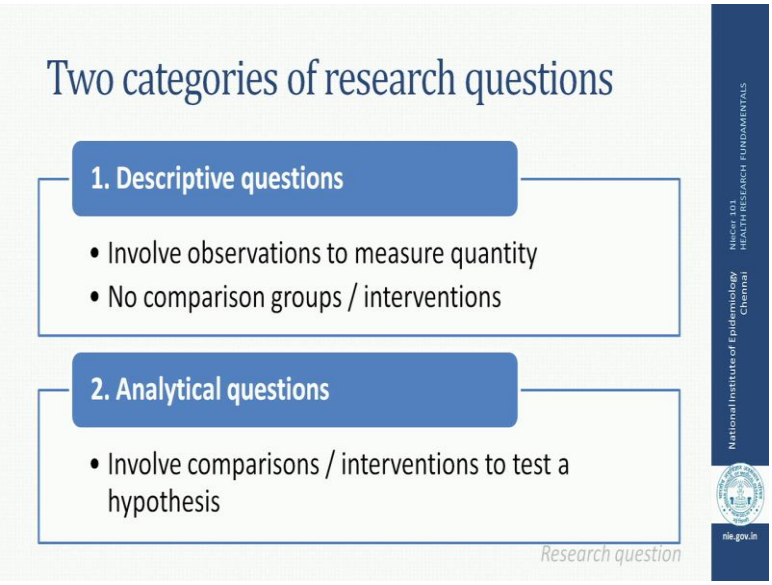

There are two categories of research questions that we need to remember. There are only two categories let me put it that way. One is a descriptive question another is analytical question. So, your research question should fall into in either of these categories. A descriptive question is one which involves observations to measure a quantity. When I say quantity, it could be height, it could be knowledge, it could be to what extent the problem is present in a community, it could be to what extent something is present in a given context. There are no comparison groups, no interventions in a question that is supposed to be called descriptive question.

Whereas analytical question involves comparison groups or it could be involving an intervention or experimental to test a specific hypothesis, so therefore, your research question when you are framing you need to find out, which of these two categories your research question may fall into. This has implications later, while we discuss about the statement of objectives and choosing study designs.

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I am just going to give you some 6 steps as to how one can conceive a research question. One, a review of state-of-art information from the literature, second, you raise a question and the third you decide whether it is worth investigating through a peer review. Forth, by defining a measurable exposures and outcomes and fifth sharpening the initial question based on the above and defining the question by specifying details based on all of the steps that were explained earlier.

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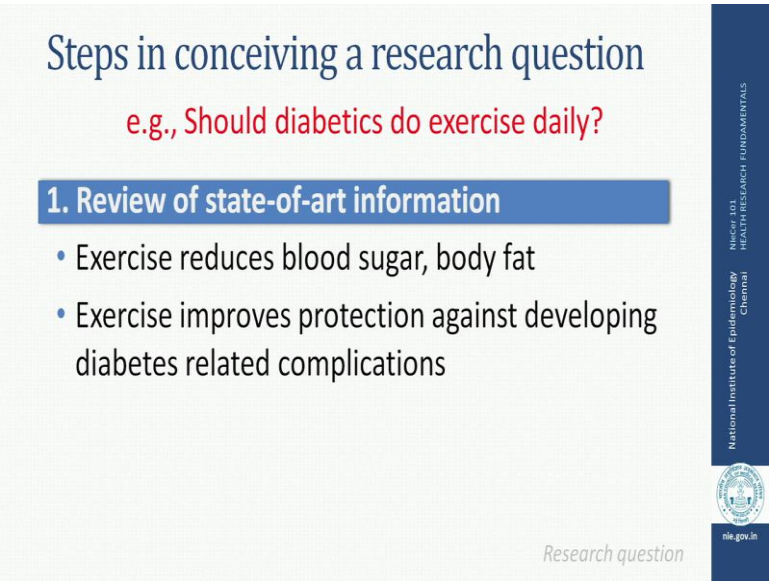

Suppose, let us take an example, should diabetics do exercise daily? That is a very common sensitive question; one reviews a literature as to what is the effect of exercise on human body to begin with. Literature shows exercise reduces blood sugar level and body fat, exercise improves protection against developing complications due to diabetes. So, definitely it is worth investigating.

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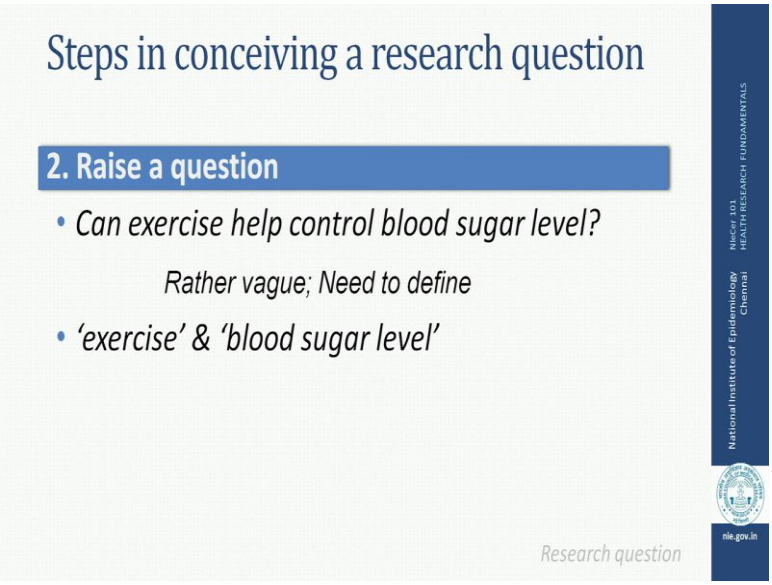

Then, let us raise a question based on our review of literature. Can exercise help control blood sugar level? Sounds better than the earlier question, but definitely this is vague. We need to refine it especially, what do you mean by exercise? What do you mean by blood sugar level?

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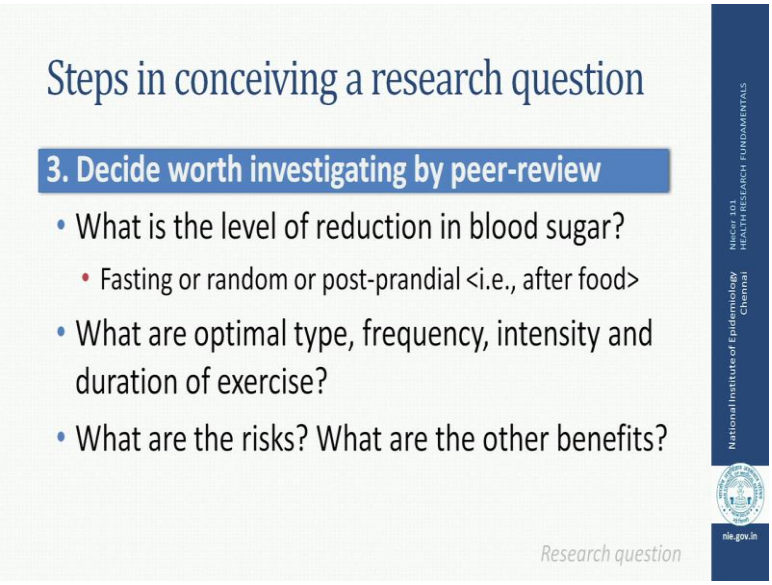

Then we go in to the literature and talk to people, peer group and talk to investigators who was special expertise in this areas, what do you mean by blood sugar? What is the level of reduction? Is it blood sugar level after you don't eat at all or any time during the day, that is called random or after a meal that is called postprandial. So, which type of blood sugar gets reduced? Which of these three types of blood sugar gets reduced? Regarding exercise, a look at the literature suggests more questions, what is optimal type? What is the frequency? What is the intensity? What is the duration of such exercise? And are there any risks for a diabetic to be engaged in exercise? Are there other benefits other than a possible reduction in blood sugar?

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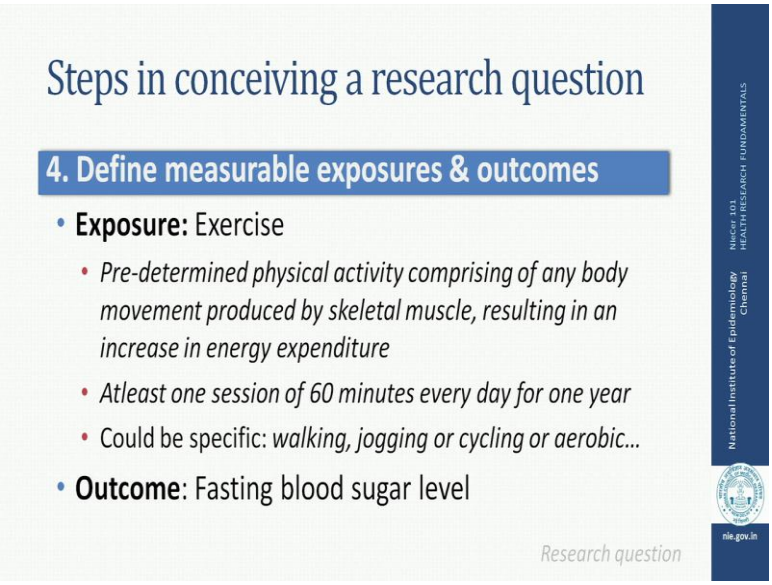

The fourth step is to now, tighten up the framing of exposure and outcome. For example, here exercise could be defined as a predetermined physical activity comprising of a body movement produced by a muscles resulting in increased energy expenditure. At least one session of 60 minutes every day for one year, you can be specific about this exercise or physical activity by specifying whether it is walking, jogging, cycling or aerobic or even dance. Finally, outcome, now we have specified, it is fasting blood sugar level which means after the dinner anybody goes into sleep and the next day morning the stomach is empty after 8 hours. At that time, if you measure blood sugar that is called fasting blood sugar and we are defining that as our outcome.

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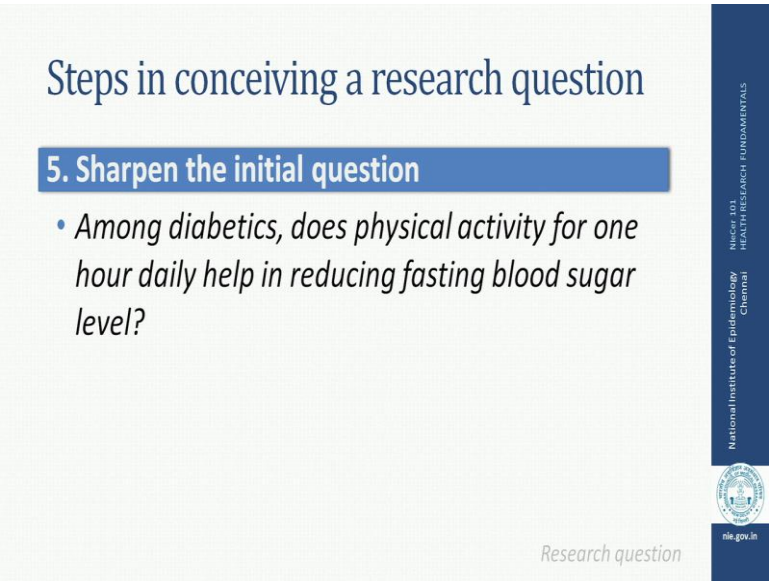

The fifth step therefore, is to sharpen the initial question with these steps in which we have progressed further. Among diabetics, does physical activity for one hour daily help in reducing fasting blood sugar. You can still refine it by specifying further details.

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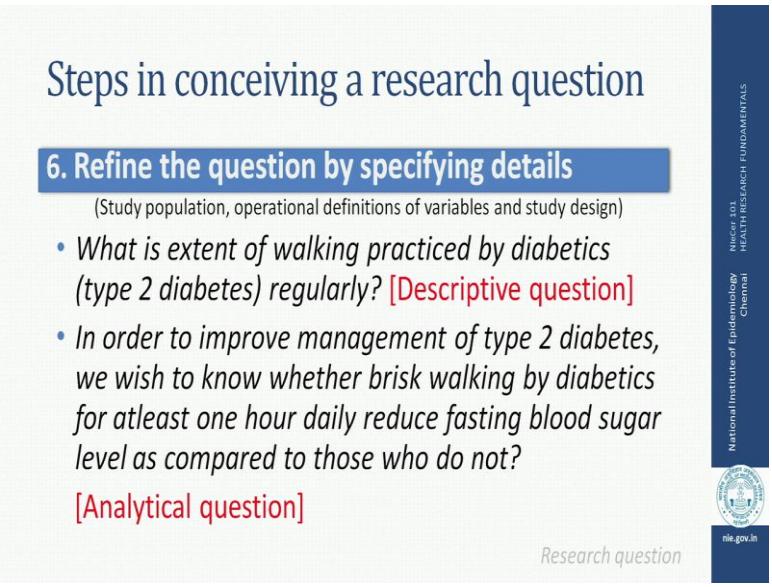

I have just given an example of such specifications in the form of descriptive question as

well as analytical question. When you are specifying the details, you need to specify study population, operational definitions of variables which is exposure and outcome and also if possible study design. An example of descriptive question in the example that we are discussing is that, what is the extent of walking practiced by diabetics that is type 2 diabetes regularly? Or an analytical question could be, in order improve management of type 2 diabetes, we wish to know whether brisk walking by diabetics for at least one hour daily reduce fasting blood sugar as compared to those who do not?

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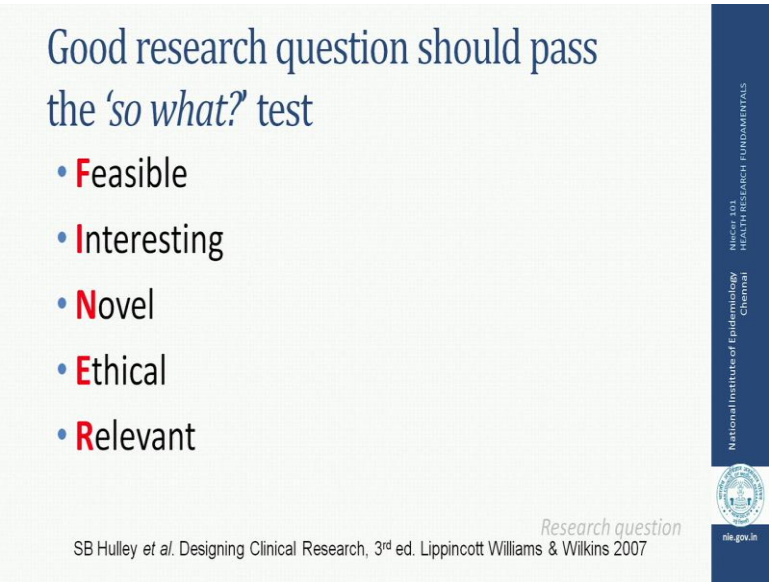

After a framing a good research question, we need to test this question to a test called 'so what?' This test comprises of five elements, it is called FINER as an acronym. Is this research question feasible to answer? Is this interesting to answer? Is it novel? Is it ethical to do studies around this research question? Is it relevant?

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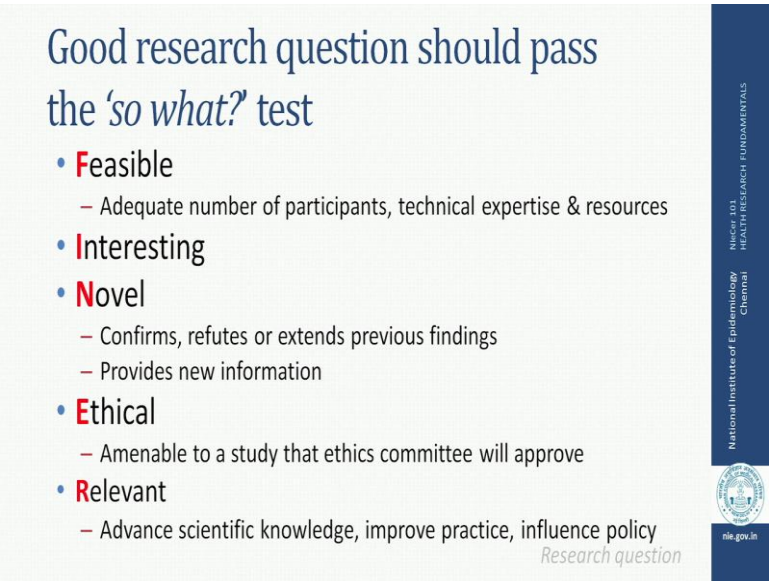

So, basically feasibility means whether we will get adequate number of study participants. Do we have technical expertise to do this study? Do you have resources both material and manpower to do this? Is it interesting? Does it really enthuse people to engage in this particular research? Is it worth doing it? In terms of novelty, does it confirms, refutes or extends the previous findings? Or does it provide new information? That is the question that we are interested in answering and the fourth test is ethical angle. Does this research based on the research question is allowable under the ethical norms? Will an ethics committee pass this research based on the question? Finally, is it relevant in terms of advancing science, advancing practice and also influencing policy?

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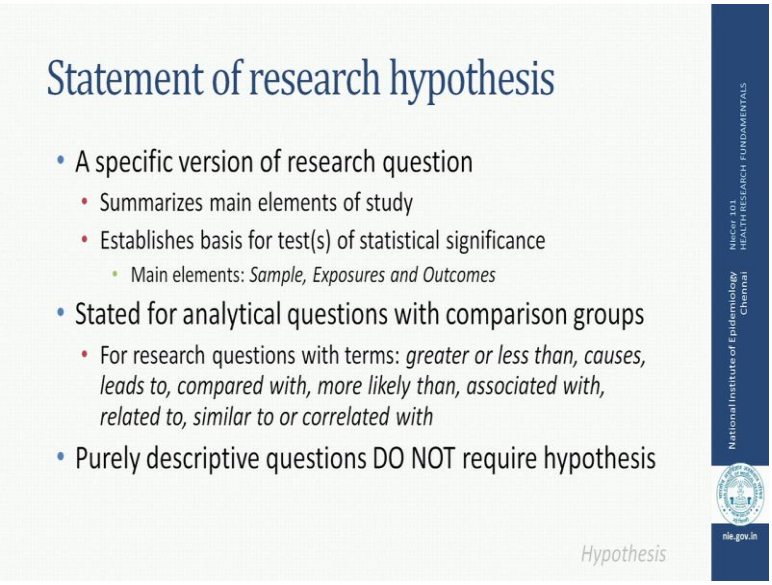

Now, let us look at a hypothesis, what is research hypothesis? It is nothing, but a specific version of the research question that summarizes the main elements of the study that establishes the basis for statistical test of significance. So, it is stated for statistical purposes. The main elements that I mentioned include the sample, the exposures and outcomes. A hypothesis is stated only for analytical questions with comparison groups. Remember, we talked about 2 types of research questions, descriptive questions analytical questions. So, only the second type of research questions involving analytical aspect needs statement of hypothesis.

If you have any doubts about, what is your analytical question? You check in your research questions, if that contains terms such as greater or less than, causes, leads to, compared with, more likely than, associated with, related to, similar to or correlated with. If these terms are contained in your research question, this is an analytical question that needs a statement of hypothesis. Purely descriptive questions do not require a statement of hypothesis.

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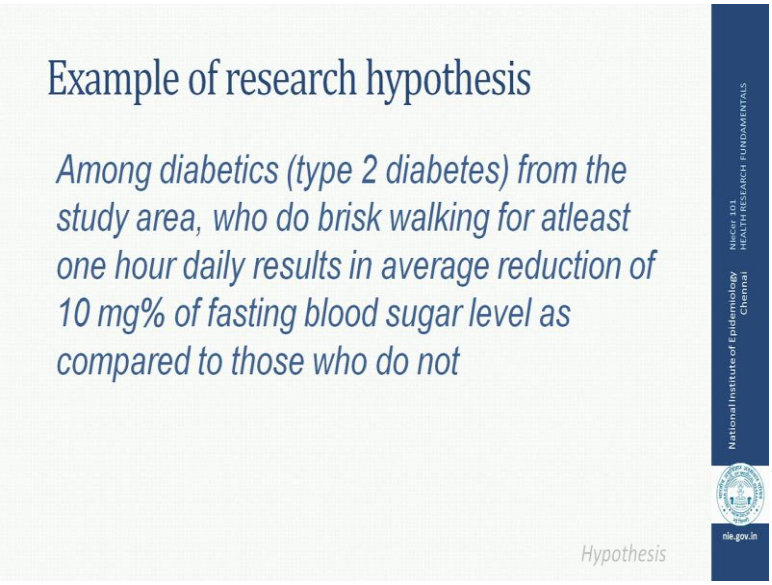

An example of research hypothesis on the basis of example that we are discussing on diabetes and exercise, among diabetics, type 2 diabetes, which means they do not take insulin injection to control the blood sugar level. From an area, who do brisk walking for at least one hour daily results in an average reduction of 10 milligram percentage of fasting blood sugar level as compared to those who do not. This specification of what much level? What study area? What group of study participants helps investigators in tightening the rope in terms of statement of a null hypothesis, statement of alternative hypothesis about which we will see in the sample size section and calculating sample size? So, research hypothesis helps in statement of specifying certain details in the context of statistical test and sample size.

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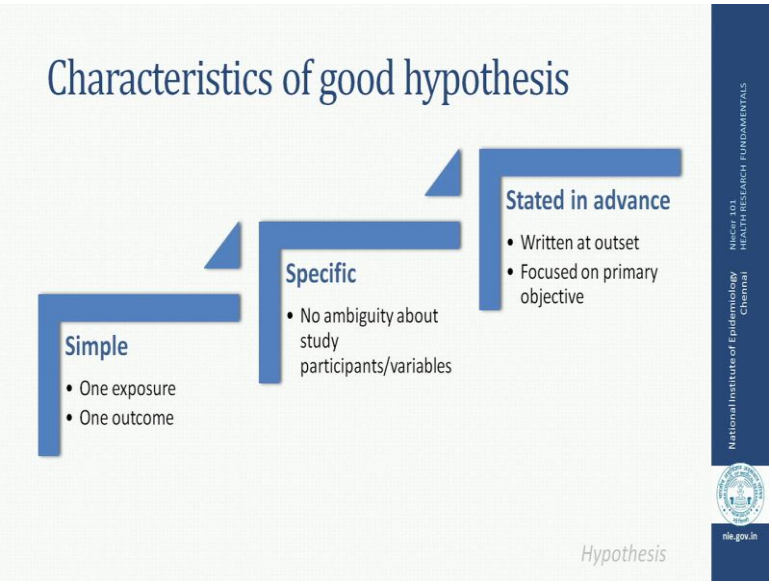

What is a good hypothesis? A good hypothesis should be simple, should be specific and should be stated in advance. What do I mean by simple? It should be one exposure, one outcome. What do I mean by specific? There should be no ambiguity about the study variables or study participants. It should be stated in advance, 'a priori' that is a terminology used. It should be stated in advance, it should not be discovered at a later part of the study and the hypothesis is focused around the primary objective.

Now, let us come back to the life cycle of research. We have now talked about research question and how research question is translated in to research hypothesis for analytical questions. Now, let us see how research question is converted into statement of objectives.

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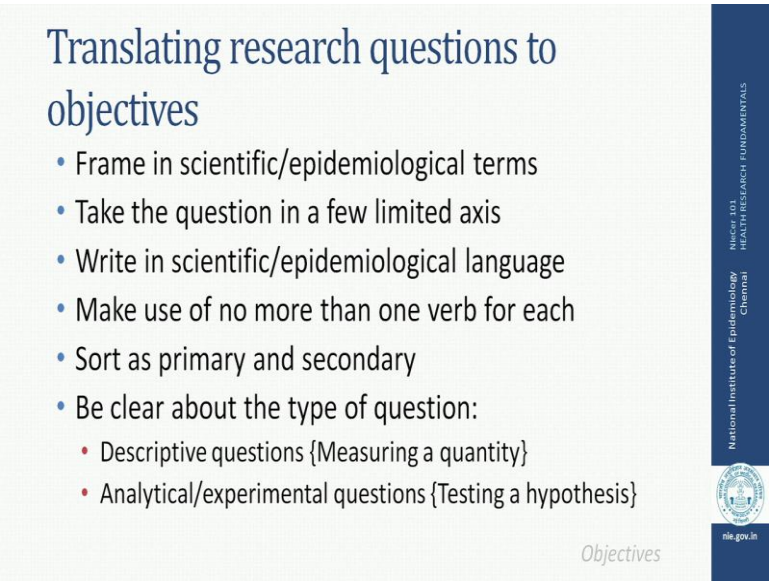

When you translate research question in to objective as compared to research question, a statement of objective is stated in scientific and epidemiological terms. It takes the research question in only few limited axis. It is written in scientific and epidemiological language. It should ideally make use of no more than an operational web for each of those questions. It is ideal to sort them out as a primary objective and secondary objective and the statement of objective should be very clear about what research question it is trying to answer. Is it descriptive question or an analytical or experimental question? So, it should clearly spell out, whether we are answering descriptive or analytical question.

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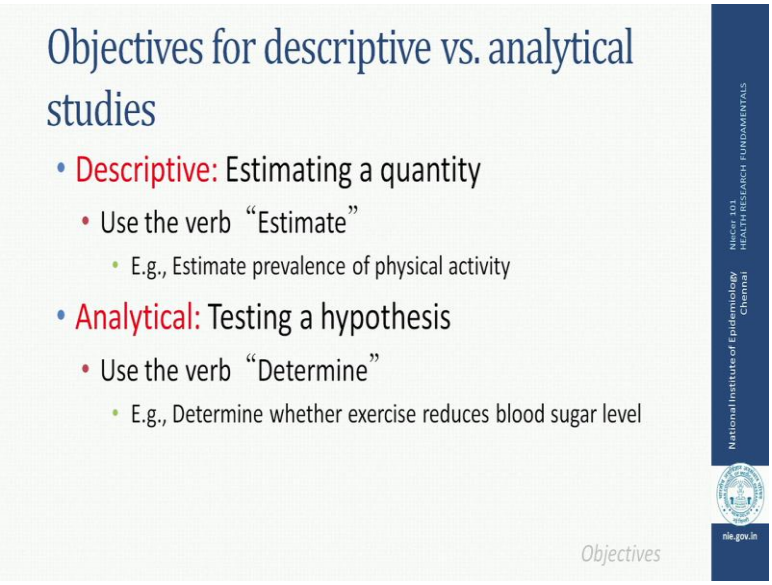

An objective is again based on this understanding; whether it is descriptive analytical is stated as a descriptive objective or analytical objective. We recommend that the statement of objective contains scientific and epidemiological terms. We also recommend that it use uses the terms that denotes the descriptive nature of the study and analytical nature of study. For instance, for a descriptive study in which, we expect that you estimate a quantity by observations, the verb estimate is preferred.

For example, to estimate prevalence of physical activity in diabetics, that is a descriptive objective. For analytical, you use the terms that are more powerful denotes this comparison, connotation. Testing hypothesis has to be denoted in the verb for example, the verb, determine may be preferred for example, in the diabetes and exercise related studies that we are discussing. Determine whether exercise reduces blood sugar level? As you can see, the verb is also equally important and therefore, we do not recommend use of the word study, to study in the statement of objectives at all. To study is a very poor statement of objective.

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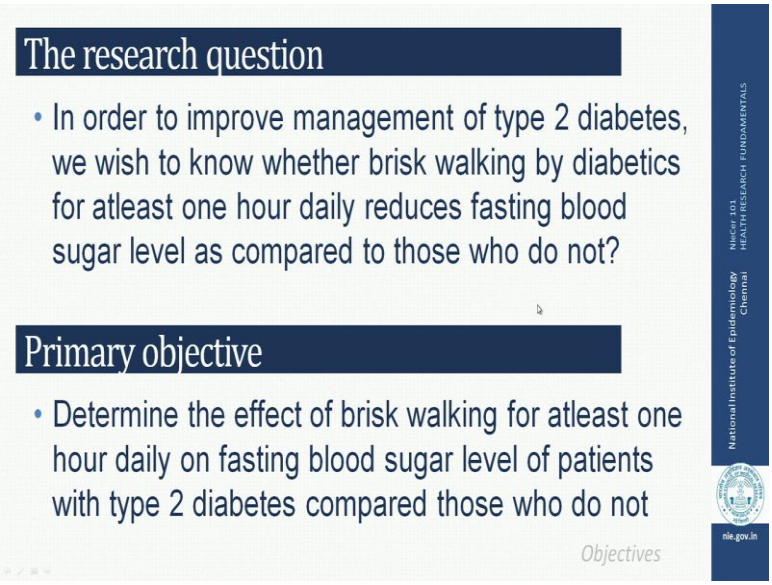

Now, let us go back to our example, the research question that we stated was, in order to improve management of type 2 diabetes, we wish to know whether brisk walking by diabetics for at least one hour daily reduces fasting blood sugar level as compared to those who do not? We can translate this into a primary objective to determine the effect of brisk walking for at least one hour daily on fasting blood sugar level of patients with type 2 diabetes compared to those who do not. So, determine is a very useful word especially when you have an analytical objective.

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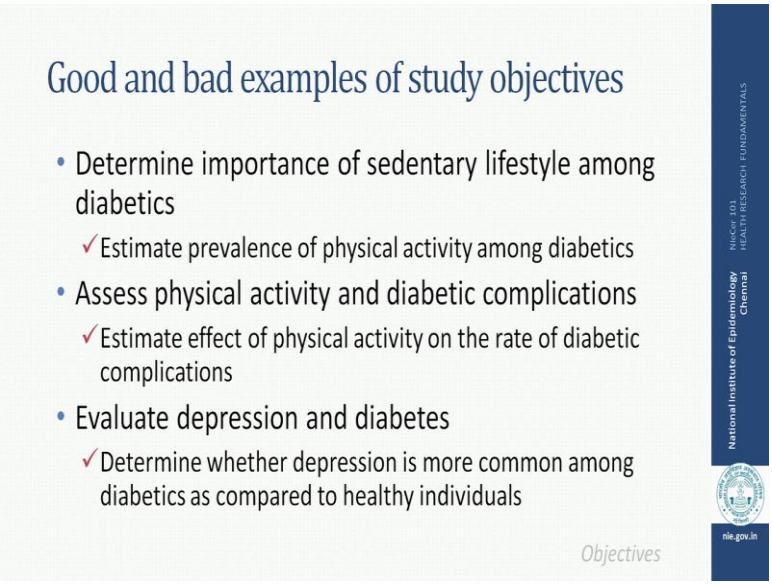

Let me show you some of the good and bad examples of study objectives. Determine importance of sedentary lifestyle among diabetics. The word determine is not particularly suited for this particular statement because it seems to be descriptive studies. Therefore, estimate prevalence of physical activity among diabetics is ideally suited for this statement of objective.

Assess physical activity and diabetic complications. I think they are trying to do again a descriptive study. Therefore, estimating the effect of physical activity on the rate of diabetic complications in a group of diabetes is what they are doing. So, the word estimate is preferable. Evaluate depression and diabetes, it may be preferable since it is analytical study to use a word verb determine than evaluate, but the depression is more common among diabetics as compared to healthy individuals.

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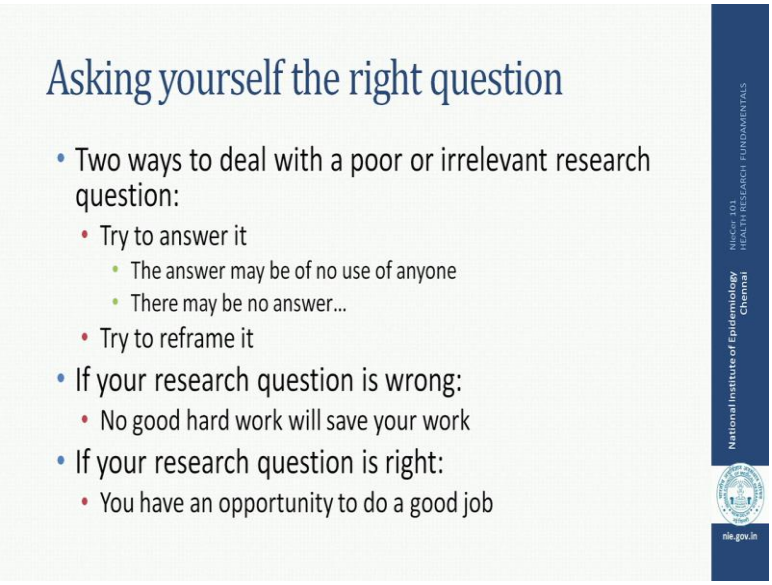

Let me sum up, asking yourself the right question may end up in answering right way. Two ways to deal with a poor or irrelevant research question, first you may answer it, but then the answer may be of no use or there may be no answer. Try to reframe it, if you have a poor question. If your research question is wrong, no good hard work will save your work. If your question is correct you have an opportunity to do a good job, all the best wishes to do a good job.

Thank you.