



# Formulation of Research Question, Hypothesis and Objectives

CHAPTER

# 2

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“The art and science of asking questions is the source of all knowledge.”  
—Thomas Berger

## Chapter Outline

- ➔ What is a Research Question?
- ➔ An Enlightening Journey from Dilemma to Researchable Query
- ➔ Distinguishing between Descriptive and Analytical Questions
- ➔ What is Hypothesis?
- ➔ Defining Research objectives

## INTRODUCTION

Scientific research is a systematic, objective and self-correcting process of exploration of the natural phenomena.<sup>1</sup> The steps are: (a) to pose a question, (b) to collect data, (c) to analyze data and (d) to answer the question.<sup>2</sup> The beginning of the research process is by posing a research question and all subsequent steps and the study design are influenced by this first step. Even the conclusion drawn is against this research question. It is the foundation on which the research will be conducted and for a good quality research, up to one-third of the time spent in a study may be spent on finding the research question.<sup>3</sup>

## WHAT IS A RESEARCH QUESTION?

A research question is a problem statement or an idea that needs to be systematically studied with careful data collection and analysis for an answer and it needs to be stated in such a way that it can be tested or answered.<sup>4,5</sup>

In biomedical research, the research question addresses a gap in knowledge about a disease or health condition and specifies the population and the variables which will be studied, and suggests the possibility of testability or measurability.<sup>6,7</sup>

## AN ENLIGHTENING JOURNEY FROM UNCERTAINTY AND CLINICAL DILEMMA TO A RESEARCHABLE QUERY

Research question begins as uncertainty or clinical dilemma about a disease or a health condition or its etiology, nature, course, diagnosis or treatment or a possibility that new technology, test, or treatment may improve healthcare.<sup>8,9</sup> The researcher then tries to address this dilemma with his knowledge or knowledge in books and reference materials. This repository of knowledge is called background knowledge, and it pertains to clinical knowledge of general nature or well-established facts.

The researcher may not find the answer in the background knowledge repository and may have to consult the latest journals or scientific proceedings which are said to hold the foreground knowledge or knowledge needed for evidence-based clinical decision making in a specific scenario. This is especially relevant in addressing patient-oriented questions regarding interpretation of therapy or risk-benefit ratio for a particular patient.

But if even after this extensive search, if some or all part of his query remains unanswered then the researcher may conduct the research (Gaps in the literature route).<sup>10</sup>

A researchable question can be a situation where there is scarce evidence in literature to support or refute a hypothesis, diagnostic or treatment strategy. There may be a situation that previous studies are providing conflicting evidence, with some studies supporting a particular hypothesis or management strategy while others are refuting it.<sup>11</sup> There may be another scenario where the application of some modification of diagnostic or treatment protocol or new technology may promise improvement in health care.

Once this knowledge gap has been identified, the researcher needs to fine-tune his query into a researchable question. There should be a focused primary question which the study should aim to answer on completion. Multiple research questions should be avoided as different questions may demand different study designs, population sample, intervention or exposures and one design may be inappropriate for all the questions. Moreover, the study sample required to conduct a study trying to answer multiple questions may make it unwieldy and impractical.

## Paraphrasing a Research Question

### Identification of Focus of Research

Let us take an example of how to frame a research question. A lady dermatologist saw an unexpectedly large number of patients complaining of nocturnal aggravation of pruritus in a week in her outpatient clinic. One-fourth of these patients had scabies, she wondered which all other skin diseases showed nocturnal aggravation of pruritus, and whether the nocturnal aggravation affected the quality of life of these patients.

She knew from background knowledge (textbooks) that a few other inflammatory dermatoses present with itching like superficial cutaneous dermatophytosis (SCD), chronic spontaneous urticaria (CSU), and chronic plaque psoriasis (CPP) but she was not sure of nocturnal aggravation affecting the quality of life.

She again checks the textbooks and reference books but doesn't get the answer. She then checks journal repositories for an answer (foreground knowledge) but the data are scarce and show wide variation in the prevalence of nocturnal aggravation of itch in different inflammatory dermatoses with little information about the quality of life.

This is the decisive point where a gap in current knowledge has been identified. At this point, she decides to do the research herself and paraphrases the query into a problem statement.

## Refining the Query into a Researchable Question

There are two approaches to fine-tune the query into a research question and both should be thought of as complementary tools to formulate the research question. These are known by the acronyms FINER and PICOT.

The FINER acronym stands for Feasible, Interesting, Novel, Ethical, and Relevant adjectives. It encapsulates concepts of a clinically relevant study whose outcome is likely to be of interest to other users in the healthcare system and which is likely to add useful information to existing knowledge and can be conducted ethically with efficient utilization of available resources.<sup>12</sup>

**Feasible:** It refers to whether the study is manageable with available resources. The points to be considered are whether one will get the required number of subjects and controls, whether required laboratory or investigative facilities are available or procurable, whether required technological facilities and expertise are available, whether sufficient trained staff is available, whether the period of study is sufficient and adequate funding is available to manage each of the above requirements. If any of the components of feasible criteria cannot be met, then it may be prudent to modify the research question.

**Interesting:** The second letter of FINER, interesting, suggests that the project should be of interest to the researcher and also to the funding agencies and ultimately to the scientific community. Research is a painstaking systematic and rigorous activity. A researcher should be sufficiently fired up or enthusiastic about his project to take him across the different highs and lows of his endeavor. The ultimate purpose of all researches is to inform all the stakeholders. Interest being a personal preference, it is obviously impossible to perform a study which interests everyone or even the majority of people in an area of science, so this suggested property of a study should basically apply to the person conducting the research, enabling the researcher to keep going when the things get difficult, at times.

**Novel:** New idea and innovations drive modern science including biomedical research, so novelty in research grounded on sound theoretical basis and robust methodology is valued immensely. However, a major amount of the most useful research and answers, may come from the synthesis of preexisting research, in the form of systematic reviews and meta-analyses. Also, reproducibility of results is the cornerstone of science and a lot of research studies are done independently by different research groups to test the results of the original study.

**Ethical:** Ethical principles keep human values of autonomy, beneficence, nonmaleficence, and justice at their core and help in guarding the subject's interests during a research project. Some multinational declarations have now made ethical conduct of research to be the central tenet of clinical and biomedical research. Any deviation from these ethical guidelines is unlikely to be accepted at any of the stages of research, from approval to funding or publication. So adherence to ethical principles right at the beginning while formulating the research question is paramount.

**Relevant:** Clinical or biomedical research should not be an end unto itself. It should serve the society, it should help the scientific community in understanding the disease better or should help the clinicians improve their practice or should result in better policies for health care delivery. In case a definite answer or significant impact on healthcare is not possible with one research project, then at least its aim should be to provide directions for future research.

The other tool which is very helpful in formulating a foreground question is the PICO model. The PICO model lays four essential components in a well-structured research question and often Time (T) is added to make it into a five-component model, making it PICOT. It is more useful for analytical studies.<sup>13, 14</sup>

- P:** Patient or Population of interest. What is the target population, i.e., who will be the subjects of the study? What will be the eligibility criteria? What will be the recruitment strategy?
- I:** Intervention or treatment or the exposure which is being investigated. What type of Intervention is being planned (diagnostic test or treatment procedure)? Is the intervention already standardized? What are the potential adverse effects of the planned intervention? Exposure maybe used to replace I when this model is labeled PECO.
- C:** Comparator or the other group or arm against which the new intervention is to be investigated. It is often the standard of care or a placebo. When using a placebo or a sham procedure ethical concerns need to be meticulously addressed.

**O:** Outcomes being studied. Outcomes are divided into primary and secondary, with primary outcomes being the more important ones. What will be the primary outcomes? Are there other secondary outcomes that will be studied? What type of outcome is expected; *viz* exploratory, explanatory, or confirmatory.

**T:** Time for follow up.

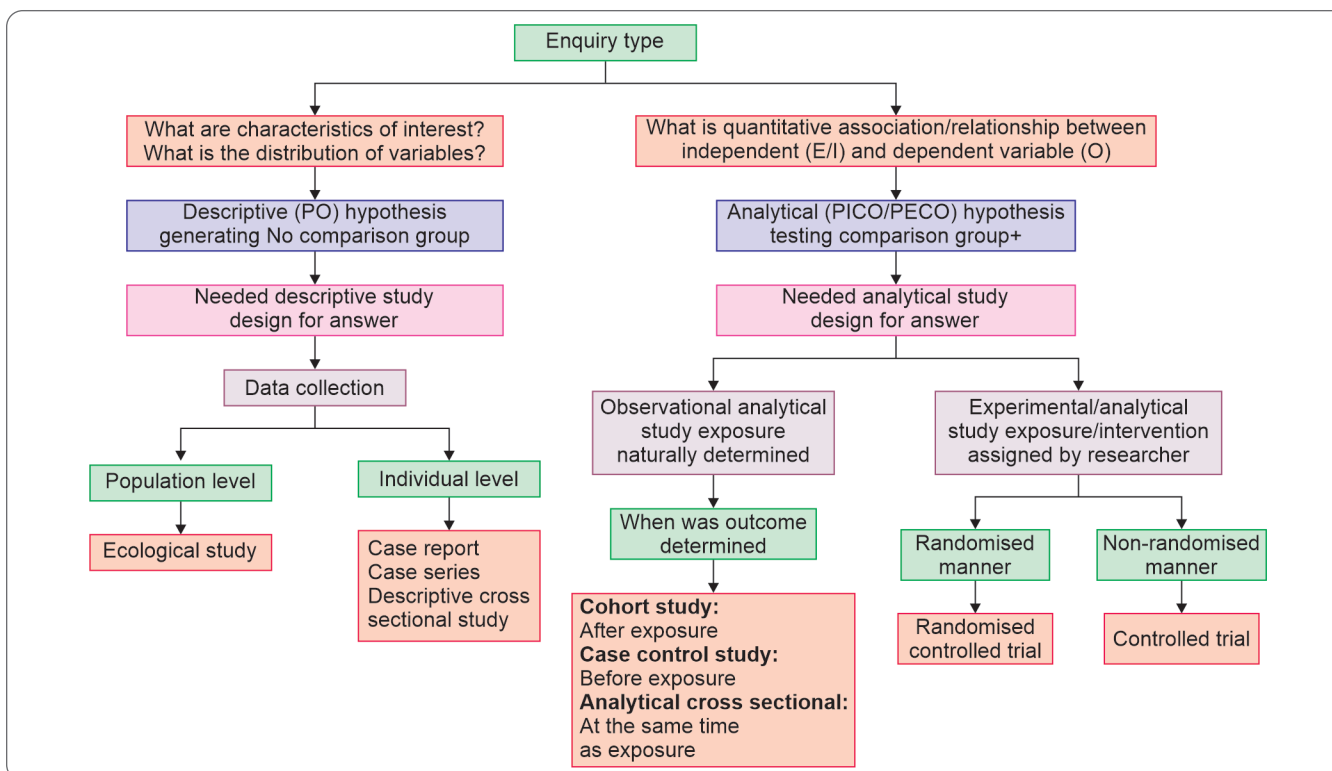
## DISTINGUISHING BETWEEN DESCRIPTIVE AND ANALYTICAL QUESTIONS

Descriptive research questions are asked to know about the pattern of disease occurrence in relation to variables such as time, place, and person without regard to any causal or other hypotheses.<sup>15</sup> Descriptive study designs conducted to answer these questions, describe, measure, or summarize PO statistics (shortened form of PICO where P stands for Population and O stands for Outcome). There is no comparison group here (Fig. 1).

Analytic research questions seek a quantitative relationship between factors and especially in evidence-based medicine, literature follows the PICO (Experimental Analytical study design) or PECO format (Observational Analytical design). There is a comparison group/intervention to test a hypothesis.<sup>16, 17</sup> Let us again take our nocturnal aggravation of pruritus query and analyze it in FINER and PICOT format.

### Analysis in FINER Format

- F:** She decides to limit her study to four inflammatory dermatoses: scabies, SCD, CSU, and CPP. She decides on 80% power of study and 95% significance level and calculates the sample size to meet these requirements. She checks the sample size with past hospital records and after finding that she will be able to recruit the required number of subjects in one year and has all the lab facilities for the study, she goes ahead with her research.
- I:** The query intrigued her and then she discussed it with other colleagues about her research. She got positive feedback and also got to know that if nocturnal aggravation had a high prevalence in other conditions then another study regarding treatment would be warranted to improve quality of life/outcome in inflammatory dermatoses other than scabies and SCD.
- N:** Nocturnal aggravation of pruritus had been scarcely reported in literature other than scabies.



**Fig. 1:** Schematic diagram of research tree based on the research question, the type of study design, the way the exposure was determined, the sequence of collection of data about exposure and outcome and the level of collection of data (individual/population).

- E:** An observational study was planned with no expected adverse outcome. She determines to follow all the ethical guidelines in her study right from inception and research question stage.
- R:** The study is relevant as a finding of high prevalence of nocturnal aggravation in non-scabies inflammatory diseases has the potential of changing the current treatment strategy and improving the health of patients.

### Analysis in PICOT Format

**P:** Patients of Inflammatory Dermatoses (Scabies, SCD, CSU, CPP) with pruritus.

**O:** Nocturnal aggravation of pruritus and quality of life. This will answer the first part of the question “Whether the four inflammatory dermatoses (scabies, SCD, CSU, CPP) all show nocturnal aggravation of pruritus” which basically is a descriptive question to know about the pattern or distribution of nocturnal aggravation of pruritus in different inflammatory dermatoses.

The second part of the question “what was the impact of the nocturnal aggravation on their quality of life?” seeks to compare the quality of life in those with nocturnal aggravation of pruritus versus those without. It is basically

an analytic question that involves a comparison of quality of life in the two groups (with nocturnal aggravation and without the nocturnal aggravation of pruritus) and needs an analytic cross sectional study design. This study should preferably be conducted as a separate study, and not as a part of the first study.

### WHAT IS HYPOTHESIS?

The hypothesis is a tentative statement about the relationship between two or more variables of a research project or study. It is a specific testable prediction about what can be expected at the end of the study.

In biomedical research, the hypothesis specifies the target population, the variables of the study and predicts an outcome or relationship between two variables (exposure and outcome).

It may also be stated in the form of a statistical hypothesis where the tentative prediction may be that no relationship exists between two variables (the null hypothesis, sometimes symbolized as  $H_0$  or  $H_0$ ) or an alternative hypothesis (sometimes mentioned as  $H_1$  or  $H_A$  or  $H_a$ ) which states that a relationship exists between two variables (exposure and outcome).

### Developing Research Hypothesis

The research hypothesis is the operational construct of the research question, shaped by a review of the literature and theoretical framework where a prediction is made about the outcome.<sup>18</sup>

In our example, the hypothesis statement can be written as:

The null hypothesis (H<sub>0</sub>) of the study is that—no statistically significant difference exists between proportions of patients with nocturnal aggravation of pruritus amongst the four inflammatory dermatoses (scabies, SCD, CSP, CPP). It may be noted that this wording is slightly different from the descriptive question, which just sought to know whether all the dermatoses show nocturnal aggravation of pruritus. Here, any difference in proportion is being sought to know and so there is a comparison.

- No statistical difference existed between the quality of life of those with and without nocturnal aggravation.
- Alternative Hypothesis (H<sub>a</sub>): At least one of the inflammatory dermatoses exhibits a statistically significant difference—in the proportion of patients with nocturnal aggravation of pruritus from the rest of the others.
- At least one of the inflammatory dermatoses exhibits a detrimental effect on the quality of life (one-tailed test).

These statements provide an operational framework to test the prediction made either by the null hypothesis or the alternative hypothesis.

### DEFINING RESEARCH OBJECTIVES

Research objectives are the goals or deliverables of the study and are written as statement of purpose. They are stated as verbs (like assess, estimate, evaluate, compare, determine) and state how the research question is being planned to be conducted and the level of evidence that is expected to be obtained through the findings of the study. It helps in identifying the variables which need to be measured or collected. There may be more than one objectives of a research study, in that case it is prudent to identify the different objectives into primary, secondary and sometimes exploratory objectives. These should be stated as numbered or bulleted points and not grouped into one paragraph.

### Primary Objective

It expresses the main goal of the study and is used to decide the statistical planning like sample size calculation, statistical power.

### Secondary Objective

It is used for stating other goals of the study like collecting additional outcome measures. It is not used for statistical planning like sample size calculation. It may involve collection of data about a different set of outcomes or different time period (than specified in primary objective) or a subset of population.

### Exploratory Objective

These objectives are those which may be *less important* part of a particular study but may still be interesting. The word *less important* pertains to the particular study and not mean it being of less value to the research community or society. This maybe because the power of your study may not be sufficient to confidently answer that study or the researcher has some doubt about the feasibility of delivery of result for that objective at the onset or it may be for hypothesis generating purpose and not for hypothesis testing.

In our example, the research objectives may be stated as mentioned here:

**Primary objective for a descriptive study design:** To estimate the proportion of patients having nocturnal aggravation of pruritus in inflammatory dermatoses (scabies, SCD, CSU, CPP).

**Secondary objective for a descriptive study design:** To estimate the proportion of old age patients (age > 60 years) having nocturnal aggravation of pruritus in inflammatory dermatoses (scabies, SCD, CSU, CPP).

**Exploratory objective for a descriptive study design:** To determine the level of inflammatory markers ESR, CRP and IL-6 in patients having nocturnal aggravation of pruritus in inflammatory dermatoses (scabies, SCD, CSU, CPP).

**Primary objective for analytic study design:** To compare the quality of life in patients with nocturnal aggravation and those without the nocturnal aggravation of pruritus in inflammatory dermatoses (scabies, SCD, CSU, CPP).

**Secondary objective for analytic study design:** To compare the proportion of old age patients (age > 60 years) having nocturnal aggravation of pruritus in inflammatory dermatoses (scabies, SCD, CSU, CPP) with age matched patients of depression without inflammatory dermatoses.

## SUMMARY

- A research question begins with an uncertainty or clinical dilemma.
- Then the gap in literature is identified whose resolution will answer the question.
- FINER and PICOT tools help to focus the query.
- A decision is made whether to do exploratory work or to do an analysis of association between exposure and outcome.
- Exploratory work or study of characteristics leads to generation of hypothesis.
- Analytical studies are used to test hypothesis by having a comparison group.
- The research question, hypothesis and objective determine the design of the study, the statistical analysis and the inference which can be drawn from the study.
- Formulation of research question involves a thoughtful step-by-step ascent from a general uncertainty or clinical dilemma to a focused research question written in day-to-day language.
- FINER and PICOT tools help in crystallizing the query into a researchable question.
- Descriptive questions help to explore patterns of occurrence of variables with respect to time, place, and person.
- Analytic questions help to test relationships amongst variables.
- A well-formulated research question is necessary for deciding the research design, statistical tests, the hypothesis, and framing of objectives to answer the query.
- The success of any research project depends upon a good research question.

## EXERCISE

1. **Situation:** A dermatologist is unsure whether a new drug is more effective in erythema nodosum leprosum compared to thalidomide. What is the most appropriate study in this scenario? Frame a research objective for the same.  
**Recommended solution:** The study to answer the question will be a randomized controlled trial (RCT). If several RCTs are available, one should look for systematic review and meta-analysis on the topic.  
**Research objective:** To compare the efficacy and adverse effects of the new drug (apremilast) versus thalidomide in patients with erythema nodosum leprosum.
2. **Situation:** A dermatology resident wants to know if diabetes is more frequent in patients with chronic plaque psoriasis. Which type of study one should look for? How to frame a research question for the same?  
**Recommended solution:** The study to look for will be a cross-sectional study in which the frequency of diabetes is compared between the psoriasis patients and a control group.  
**Research question:** What is the frequency of diabetes in patients with psoriasis versus controls?

## SELF-ASSESSMENT

### Multiple Choice Questions

1. Which is true for PICO model in observational analytical studies?
  - a. Intervention (I) is replaced by exposure (E)
  - b. Recruitment strategy need not be explained
  - c. Intervention given should always be standardized
  - d. Comparator group is always a placebo
2. True about hypothesis in biomedical research is:
  - a. Variables of the study have to be well-defined
  - b. Target population can be nonspecific
  - c. Tentative prediction or statistical hypothesis is not acceptable
  - d. It can be testable or non-testable
3. 'I' in the acronym 'FINER' stands for:
  - a. Intervention
  - b. Investigation
  - c. Impact
  - d. Interesting

**4. Which of the following is not true about descriptive research questions?**

- a. Help to know about the pattern of disease occurrence
- b. There is no comparison group
- c. Show quantitative relationship between variables
- d. Summarize PO statistics rather than PICO

**5. Which of the following statement is not true regarding a good research question?**

- a. A good research question should be in epidemiological terms
- b. A good research question should focus on one issue
- c. A good research question helps us in choosing optimal study design
- d. A good research question should be Feasible, Interesting, Novel, Ethical and Relevant

**Answers Key**

1. a      2. a      3. d      4. c      5. a

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