

How to Formulate a Research Question?

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Abstract: ***Background:** The goal of research is to increase knowledge or to create new knowledge. First step in this process is to frame a research question. The success of any research process relies on how well investigator is able to translate a clinical problem into a research question. All experts recommend formulating a structured research question before commencement of research project. The aim of this study conducted is to examine whether structured research question formulated using the PICOT (previously PICO only) Population, Intervention, Comparison, Outcome, and Time-frame format is associated with better research question or not. **Conclusion:** The PICOT format is a helpful approach for summarizing research questions or helps to develop a specific clinical research question.*

Keywords: Research question, research project, PICO and PICOT

1. Introduction

Research is defined as any systematic activity designed to contribute to generalizable knowledge (expressed as theories, principles, or statements about relationships)¹. Any research project or investigation starts with clinical problem or requirement of patient. Sometimes such problem can be studied through collecting and analyzing data. Interesting problems can be solved enthusiastically. Some problems, although interesting, are not researchable due to their nature. Problems having moral or ethical issues are not researchable. This paper aims to provide a roadmap for proper identification and framing clear research questions.

The goal of research is to increase knowledge or to create new knowledge. First step in this process is to frame a **research question**. This is different from having a research topic in mind. Research topic is a broad concept which is a vague, generalized, not precise, not clearly defined and specific. On the contrary, research question is very systematic, objective and logical. We can formulate a research question from research topic. It is a skill of researcher turn a clinical problem into a research question

Finding the right question increases the likelihood of finding a solution to the problem². It is a formula for successful search for answers³. A clearly defined question can also enhance the clarity of the thought process in developing the protocol, informing the design, and guiding analysis decisions, including ensuring publication⁴.

Importance of topic

Poor quality of reporting of RCTs has been published in leading general medical journals and subspecialty journals^{5, 6, 7, 8, 9}. Such practice can lead to reduction in the confidence of RCT results and discourage their applications in developing clinical practice guidelines and conducting unbiased meta-analyses. To develop science it is mandatory to conduct scientific research and publish it. Consolidated Standards of Reporting Trials (CONSORT) group has been making consistent honest efforts to improve the transparency and quality of RCT reports since 1996.

Characteristics of good research question

Hulley and Cummings have suggested the use of the **FINER**¹⁰ criteria in the development of a good research question. The FINER criteria highlight useful points that may increase the chances of developing a successful research project.

Table 1

Criterion	Strategies for achieving success
Is the research question feasible?	• Do a pilot to assess feasibility.
	• Consider modifying inclusion criteria.
	• Get collaborators, learn the skills, consult other experts.
	• Use less costly designs (e.g., paired designed, cross-over designs).
	• Choose common outcomes.
Is it interesting?	• Use continuous versus binary outcomes.
	Check if it:
	• Interests you as a researcher,
	• Interests your collaborators,
Is it novel?	• Interests the stakeholders.
	• Be familiar with the literature.
	• Get guidance from experienced researchers.
Is it ethical?	• Get a mentor.
	• Be familiar with research ethics guidelines.
	Examples include:
	✓ The Declaration of Helsinki ²⁸
	✓ Tri-council Policy Statement (TCPS) ²⁹
It is relevant—to scientific knowledge, policy, or future directions?	✓ Good Clinical Practice (GCP) ³⁰
	• Get Research Ethics approval prior to conducting research.
	• Be familiar and up-to-date with the literature.
	• Be familiar with policy debates
	• Get guidance from experienced researchers or mentors.
	• Search information about the national and global burden of disease.

See reference 10.

In short a good research question should be appropriate, meaningful, and purposeful¹¹.

Poorly formulated question: A problem

Research question is objective of doing proper study. It is the answer of why does one does the study. Dr. Light, Singer and Wilmette said, well crafted questions guide the

systematic planning of research. Poorly formulated question leads to selection of wrong study design. If research question is not clearly stated, scientists reading the study may fail to understand the objective of the study, and this could negatively impact the likelihood of the study being cited by other researchers. It also discourages further improvement in research process. It becomes very difficult to interpret the results of the study. It also makes difficult to determine whether or not a study fulfills inclusion criteria for systematic review and meta-analysis.^{12,13} It can jeopardize publication efforts¹⁴. Poorly formulated question can make it difficult to interpret the results of the study. It also will not guide studies that examine relationships among the variables. Such question cannot be used to guide both quantitative and qualitative studies. Quantitative studies are often initiated to answer several questions derived from the problem of interest, each focused on a specific variable to be measured in the population.

Ways of generating a research question

So what approach

A strong idea should pass the **SO WHAT** test. Researcher should think about the impact of the research he has proposed. What is the benefit of answering the research question? Who will be helped by this research question? How will it help? So he must be able to make definitive statement about the purpose of research. It should be very narrow not broad. Research question can be generated¹⁵ by following ways.

- 1) Choose a topic that researcher is interested in! The research process is more relevant if one care about topic.
- 2) Reading, interacting with advisor, teacher, colleague, guide during independent study, or working on a research assistantship, some possible projects will emerge.
- 3) Talk about research ideas with a friend. She/he may be able to help focus topic by discussing issues.
- 4) Repeat/validate/verify the work done by other scientists.
- 5) Need of the society or country.
- 6) Keen observation of a prepared mind.
- 7) Serendipity means accidental discovery of any procedure or drug.
- 8) Based on earlier work done by other scientist but a step ahead.
- 9) Persistence on particular problem or consistent efforts.
- 10) Intuition power.

The PICOT approach

The concept of a structured research question was originally described involving four elements called as PICO approach. It was first introduced in 1995¹⁷. PICO format, later expanded to PICOT¹⁸, is now a widely accepted strategy for framing research questions all over the world. This formula is used to form research question in nursing¹⁹, palliative medicine²⁰, transfusion medicine²¹, occupational health²², clinical epidemiology²³, systematic reviews^{24, 25, 26}.

PICOT format¹⁸

Letter	Stands for	Meaning
P	Patient population of interest	What patient population or problem are you trying to address?
I	Intervention or issue of interest	What will you do for the patient or problem?
C	Comparison with another intervention/issue	What are the alternatives to your chosen intervention?
O	Outcome of interest	What will be improved for the patient or problem?
T	Time frame	At what time following the intervention do you decide it is doing more good than harm?

The PICOT method: why and how to use it?

In this formula patient or population of interest, intervention or issue of interest, outcome of interest components must be present but comparison with another intervention/issue and time frame may or may not be present, depending on the question.

Patient population of interest

This describes a group of patients researchers want to involve in study. We can use various factors such as: age group, gender, ethnicity, having a disease or condition to define or describe population. The examples are overweight adult with hypertension, female having age 30 to 39 etc. This population is the target population of the study to which the researchers want to extend their result.

Intervention or issue of interest

This describes the intervention researchers are considering, such as a treatment or diagnostic test or surgical procedure. The intervention is a controlled maneuver or exposure that can be manipulated and is often a new, experimental, or innovative approach. The examples are diet modifications, lifestyle changes, increase or decrease in the dose of particular medicine etc. Stopping the treatment can be also an intervention. Interventions have several potential meanings, depending on the type of the study. It could be the treatment by itself if the comparison (means control) group receives placebo, or it could be the new treatment if the comparison group receives a reference treatment. In etiology and prognosis or prediction studies, the intervention group is the group of patients exposed to the exposure of interest for which the researchers wanted to show that it is a risk factor for the health condition or disease.

Comparison with another intervention/issue

The primary goal of any study is to compare the intervention with an alternative standard (control), placebo (no intervention), or approach. The effect is evaluated by comparing outcomes in the underlying intervention groups at the end of the study. It is not mandatory to allocate the patients into intervention group and control group randomly. But random allocation is generally considered the best approach in generating evidence²⁷. If appropriate, identify the main alternative treatment for comparison.

Outcome of interest

This describes the desired effect or outcome for the patient. The example is *weight* loss and reduction in blood pressure after forty minutes of brisk walking two times in a day. The outcome must be measurable. For example, "feeling better" would not be a measurable outcome as it is subjective criteria. There are some key outcomes²⁸.

A good primary outcome/endpoint should,
• be <i>appropriate</i> (should be fitting for the objectives of the study);
• be <i>objective</i> (i.e., should require less subjective judgment to measure);
• be <i>valid</i> (i.e., should measure that which is intended);
• be <i>reproducible/precise/reliable</i> (i.e., should easily be reproduced in different times/settings);
• be <i>clinically available</i> (i.e., should be available as part of clinical care);
• be <i>easily quantifiable</i> (i.e., should be easily measured);
• be <i>efficient</i> (i.e., should be affordable to measure in terms of time and cost);
• be <i>sensitive</i> (i.e., should correctly specify presence of disease or condition of interest);
• be <i>specific</i> (i.e., should correctly specify absence of disease or condition of interest);
• be <i>responsive</i> (i.e., should be sensitive to changes in treatment). That is, it should:
– rapidly reflect the response to treatment; and
– accurately reflect the response to treatment; and
• be <i>straightforward</i> (i.e., should allow easy interpretation of results).

Time frame

The time frame is the certain length of time required for outcome. It is generally fixed by researchers in cohort studies. But in case-control studies, this information is not accessible.

Example of a sentence built after using the PICOT method

In patients without preoperative anemia undergoing knee replacement surgery (P), does treatment with intravenous iron alone (I1) or intravenous iron with recombinant erythropoietin (I2) compared with placebo (C), administered a day after surgery, increase hemoglobin concentration (O) 7 days after surgery (T)?

PICOT method: A useful tool

- 1) PICOT format is applicable to establish an association between exposure and outcome²⁹.
- 2) Helps to show path to beginners, post graduate students.
- 3) It is a routinely advocated approach in framing research questions in evidence-based medicine³⁰.
- 4) It is associated with improvements in search results for clinical information in PubMed³¹.

2. Conclusion

Person interested in research should consider the use of a literature search and the PICOT format when engaging clinical research. The **PICOT** format is a helpful approach for summarizing research questions or helps to develop a specific clinical research question. The framework of the research question should able to specify the

target population, the intervention, the comparator intervention, and the main outcomes, including the timing of the assessment of outcomes. It should also satisfy the FINER criteria mentioned by (Feasible, Interesting, Novel, Ethical, and Relevant) mentioned by Hulley and Cummings.

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