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Formulating research questions for evidence-based studies

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ABSTRACT

Formulating a research question is a crucial step in directing any scientific study. The classical evidence-based approach to formulating a question uses the PICO framework, consisting of population, intervention, comparison, and outcome. However, the PICO framework is not suitable for formulating research questions in some types of evidence and studies. This paper reviews and summarizes different frameworks introduced for formulating research questions over time. For this purpose, we explore the complete application of the PICO framework, clarifying its flexibility and subtleties for various research designs. Also, this review navigates the complexities of creating research questions, clarifying the minor variations needed within the PICO framework for various study designs through a thorough analysis and synthesis of the existing literature. Clarifying these customized strategies is intended to assist researchers, physicians, and scholars in appropriately formulating questions, improving the strength and relevance of research findings throughout the scientific investigation spectrum.

Introduction

In a world where knowledge is growing expeditiously, accessing the necessary evidence from this volume of information in a reasonable time is a serious challenge. In the meantime, the contradictions in the new findings make decision-making in various fields of medical sciences more difficult. These factors led to the emergence of a new set of principles called evidence-based medicine (EBM), further progressing to evidence-based practice (EBP) and evidence-based research (EBR), in order to include using the most up-to-date guidelines, research, and

Abbreviations: CoCoPop, Condition, Context, Population; COVID-19, Coronavirus disease 2019; EBM, Evidence-based medicine; EBP, Evidence-based practice; EBR, Evidence-based research; F/TDF, Emtricitabine–tenofovir disoproxil fumarate; FINER, Feasible, Interesting, Novel, Ethical, Relevant; HIV, Human immunodeficiency virus; MRI, Magnetic resonance imaging; PEO, Population, Exposure, Outcome; PFO, Population, prognostic Factor, Outcome; PICO, Population, Intervention, Control, Outcome; PICo, Population, phenomena of Interest, Context; PICOC, Population, Intervention, Comparator, Outcomes, Context; PICOS, Population, Intervention, Control, Outcome, Study type; PICOT, Population, Intervention, Control, Outcome, Time; PIRD, Population, Index test, Reference test, Diagnosis of interest; PPhTS, Participants, central Phenomenon, Time, and Space; SR, Systematic review.

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practices to inform clinical decision-making [1,2].

As one of the three pillars of EBM and EBP, the production and implementation of the best available evidence both require sufficient proficiency in finding and evaluating the available evidence [3]. A primary step in this regard is to search for resources by formulating an appropriate question. At this point, PICO, which stands for Patient/-Population, Intervention, Comparator/Control, and Outcome(s), was created to facilitate structured questions.

The PICO approach is helpful in the rapid synthesis of clinical questions, mainly the therapeutic, diagnostic, prognostic, and etiologic evidence; however, it is incapable of supporting some types of evidence and studies [4–6]. This paper aims to review and summarize different frameworks introduced for formulating research questions through time.

The value of a good question in research and practice

Formulating a perfect research question is an act of art. As a pillar of critical thinking and problem-based approach to science, a good research question helps catalyze inquiry and exploration, directing the course of investigation while stimulating a deeper understanding of the subject matter [7]. It encourages the identification of factors, approaches, and possible results, which, in turn, result in acquiring new knowledge or refining existing theories. Furthermore, a well-structured research question stimulates an analytical mindset in researchers, encouraging them to assess the available evidence, take into account competing viewpoints and perspectives, and draw well-reasoned conclusions [8]. This helps to advance the field and address relevant issues within it.

The importance of formulating a sound and proper research question is summarized in three main motives:

1. Conducting an evidence-based study: Evidence-based studies, particularly, the systematic reviews in this case, rely on a research question developed to specifically address the problem with all required details
2. Designing search strategy: Formulating a strategy for searching the electronic databases based on a well-defined research question is the fundamental step for every specific attempt to access the evidence for educational, clinical, and research purposes.
3. Highlighting the literature gaps: Apart from the study design, a formulated research question is a necessary part of the literature review in order to find and specify the knowledge gaps.

Systematic reviews (SRs) are at the pinnacle of the evidence pyramid – also known as the hierarchy/levels of the scientific evidence. SRs are capable of addressing any type of question [9]. Formulating a suitable question considering the type of evidence to review helps the researchers obtain the appropriate literary sources and correctly include, exclude, and interpret the data. SRs can be used in various contexts, including uncovering evidence, validating current methods, identifying areas for future research, investigating controversial results, and making statements to guide decision-making [10].

Respecting information overload, the scientific community has come across sources with weak or insufficient supporting evidence, resulting in deceptive, misleading, or conflicting information [11,12]. An unorganized question is highly prone to collection of useless information and waste of time and effort, or uncertain data and development of low-quality or false evidence.

How to formulate a research question

Several key elements typically characterize a good research question:

- Clarity and specificity: The research question should be precise, focused, and clear, exactly outlining what it aims to investigate.
- Relevance: The question should address a significant issue within the context and scope of the field or subject.
- Feasibility: The question should be researchable within the constraints of time, resources, and available data or methods.
- Originality: While it is not required to be entirely unique, a good research question should address an aspect that has not been extensively studied, or offer a novel perspective on an existing topic.
- Measurability: The question should be answerable, allowing for measurable outcomes or data that can be analyzed and interpreted.
- Significance: Answering the question should contribute valuable insights to the field.
- Interest: A good research question should pique the curiosity and interest of the intended audience or the scientific community.
- Ethical considerations: The research question should comply with the ethical considerations and guidelines.

Previous studies have suggested the research questions to be feasible, interesting, novel, ethical, and relevant (FINER) [13–15]. Formulating a good research question often involves repetitions and several refining to meet these criteria.

Common frameworks for formulating research questions

Although PICO is accepted among scholars as a universal approach for formulating a research question or planning a search strategy, it does not apply to most types of evidence. Hence, researchers and experts in the fields have introduced approaches and frameworks for certain types of evidence/studies, most clinically used of which are explained below along with examples from famous previous studies. [14,16–24]. A complete list of research question formulating frameworks has also been

Table 1
Common approaches in formulating research questions, according to the type of study.

Type of study	Question framework	Components of the model
Interventional/ Effectiveness	PICO(T/S)	Patient/Population, Intervention, Comparator, Outcome, (Time/Study design)
Etiologic/Risk/Cause	PEO	Population, Exposure/Environment, Outcome
Incidence/Prevalence	CoCoPop	Condition, Context, Population
Diagnostic test accuracy	PIRD	Population, Index Test, Reference Test, Diagnosis of Interest
Prognostic	PFO	Population, Prognostic Factor (or model of interest), Outcome
Economic/Cost-effectiveness	PICOC	Population, Intervention, Comparator, Outcomes, Context
Methodologic	SDMO	Study type, Data type, Method type, Outcome
Theory/Model	BeHEMoTh	Behavior of interest, Health context, Exclusions, Models or Theories
Psychometric	CPTM	Construct of interest (measurement instrument), Population, Type of measurement instrument, Measurement properties
Qualitative	PICo	Population, Phenomena of Interest, Context
Qualitative	PPhTS	Participants, Central Phenomenon, Time, and Space
Qualitative: Public health	SPICE	Setting, Perspective, Intervention, Comparison, Evaluation
Qualitative/Mixed-Method: Experience and views	SPIDER	Sample, Phenomenon of Interest, Design, Evaluation, Research type
Qualitative: Organizational and policy evaluation	CIMO	Context, Intervention, Mechanism, Outcome
Qualitative: Health policy and management	ECLIPSe	Expectation, Client group, Location, Impact, Professionals, Service
Scoping	PCC	Population, Concept, Context

presented in Table 1.

Interventional studies

PICO, first introduced by Richardson et al. in 1995, is used to evaluate the effectiveness of an intervention [25]. PICO, also reported as PICOT and PICOS on different occasions, stands for:

- P – Patient, population, or problem: Who is defined as a patient? What is the common problem, and what are the characteristics related to the population?
- I – Intervention: What is the main intervention?
- C – Comparison or control: What is the major intervention of comparison or alternative intervention (if present)?
- O – Outcome(s): What outcomes are anticipated to be achieved, assessed, measured, or improved?
- S – Study type (if applicable): What types of studies or interventions are considered?
- T – Time (if applicable): What timeframe or duration is considered for the measurement/study? What is the required time to achieve the result of the intervention?

Examples [26,27]: What is the effectiveness of Remdesivir for treating severe COVID-19 in adults, compared with no/placebo treatment? What is the effectiveness of low-dose aspirin in preterm delivery prevention in nulliparous women compared with placebo treatment?

Etiologic and risk studies

Systematic analyses of cause and risk are used to determine the relationship between exposure and health outcomes, helping the decision-makers decide on health policies and prevent adverse health outcomes. PEO is the framework used for these studies, consisting of the following components:

– P – Population or patient: What groups of population/patients with common characteristics are targeted?
– E – Exposure/Environment: What is the primary exposure? What environment or environmental factors are the interests of the study?
– O – Outcome: What outcomes are anticipated to be achieved, assessed, measured, or improved?

Examples [28,29]: How does exposure to air pollution affect dementia in older adults? How are the cognitive and motor functions of children affected by prenatal opioid exposure?

Qualitative studies

In qualitative studies, PICo, which stands for Population, Phenomena of Interest, and Context, is used. These studies focus on the participant's relationship with the intervention and their experience, leading to a better understanding of the patients.

– P – Population: What groups of participants are study interest?
– I – Phenomena of Interest: Which experiences or events are primarily concerned?
– Co – Context: What are the primary conditions and background circumstances?

Examples [30,31]: What are the psychological experiences during hospitalization in adult COVID-19 patients? What is the experience of primary care physicians about using telemedicine during the pandemic?

Incidence/Prevalence studies

In prevalence or incidence surveys, the burden of an event is measured and allows policymakers and health professionals to assess changes over time and inform the extent of health service development. The model used in these studies is CoCoPop, which includes Condition, Context, and Population.

– Co – Condition: What condition/disease is the interest of the study?
– Co – Context: In what background settings should the condition be studied?
– Pop – Population: What groups of participants/patients are followed or studied?

Examples [32,33]: What is the prevalence of motor problems in children with autism spectrum disease? What is the prevalence/incidence of cancer in patients with psoriasis and psoriatic arthritis?

Diagnostic test accuracy studies

Diagnostic tests are used to check the presence or absence of a disease. In diagnostic test accuracy reviews, the accuracy of these tests is measured and generally compared with the gold standard in this field. The model used in these studies is PIRD, which stands for Population, Index Test, Reference Test, and Diagnosis of Interest.

– P – Population: What group of patients will undergo the diagnostic measures?
– I – Index Test: What diagnostic test/tool/measure is proposed for assessment?
– R – Reference Test: Which diagnostic test/tool/measure is currently used (gold standard), or is compared to the proposed tool?
– D – Diagnosis of Interest: What condition should the test diagnose with acceptable sensitivity and specificity?

Examples [34,35]: What is the diagnostic accuracy of non-invasive tests for diagnosing advanced fibrosis in non-alcoholic fatty liver patients? What is the diagnostic accuracy of serum/sputum/tissue biomarkers in early non-small cell lung cancer detection?

Prognostic studies

Prognostic research provides information about the course of the disease, determining the general prognostic overview of the condition and disease, the possibility of clinical outcomes, and the relationship between specific prognostic factors. In these studies, the PFO template is used, which includes Population, Prognostic Factor (or model of interest), and Outcome.

– P – Population: What group of participants will be followed or studied?
– F – Prognostic Factor: What prognostic factor will be evaluated?
– O – Outcome: Which is the outcome/disease/condition of interest?

Examples [36,37]: What is the prognostic value of patient-reported outcomes for mortality in patients with cancer? What is the clinical prognosis of asymptomatic intracranial stenosis in patients with transient ischemic attack?

Economic and cost-effectiveness studies

In economics reviews, the costs of an intervention (typically a population-based intervention) are evaluated and usually reported in terms of cost-effectiveness. The importance of these reviews is in decision-making in the health system, to allocate the resources most efficiently and achieve the best use of available resources. PICOC, which stands for Population, Intervention, Comparator, Outcomes, and Context, is used in these studies.

- P – Population: What population or subgroup of the population is under the influence of the intervention?
- I – Intervention: What intervention is studied on the population?
- C – Comparator: What is the primary comparison intervention (if present)?
- O – Outcomes: Which outcomes are assessed? On what scale is the effectiveness evaluated?
- C – Context: In what background settings is the intervention studied?

Examples [38,39]: Among the United States population, what is the cost-effectiveness of the long-acting HIV prophylaxis compared to F/TDF? In women with over 20% of familial risk for breast cancer, how cost-effective is MRI screening?

Conclusion

Although PICO is accepted as a universal approach to formulating the research question or planning a search strategy, it might be incapable of supporting some study types. Hence, researchers and experts in evidence-based practice have introduced other approaches for specific types of studies.

In brief, PICO is one of the most famous and efficient ways of composing a research question. However, some study designs might need an alternative model due to differences in details and design. Nevertheless, all these models are based on the classic PICO, and various models are introduced just for convenience.

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Declaration of Competing Interest

The authors declare no competing interests.

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