Formulating the Research Question and Framing the Hypothesis

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An understanding of the research process is an essential skill for designing a study and developing the research protocol. Poor study design can lead to fatal flaws in research methodology, ultimately resulting in rejection for publication or limiting the reliability of the results. Following the steps of the research process and devising the research question and hypothesis prior to study initiation can avoid common problems encountered with research questions and study design. Formulating the research question is the first step in the research process and provides the foundation for framing the hypothesis. Research questions should be feasible, interesting, novel, ethical, and relevant (FINER). Application of the FINER criteria can assist with ensuring the question is valid and will generate new knowledge that has clinical impact. Utilization of the population, intervention, comparison, and outcome (PICO) format helps to structure the question as well as refine and narrow the focus from a broad topic. The hypothesis is derived from the research question and is used to determine the experiments or interventions that will answer the question. This aim of this paper is to provide guidance for developing research questions and forming a testable hypothesis through application of the FINER criteria and the PICO process. *Key words: research; study design; scientific method; research question; hypothesis; FINER criteria; PICO.* [Respir Care 2023;68(8):1180–1185. © 2023 Daedalus Enterprises]

Introduction

Clinicians starting a research project for the first time often find it challenging with uncertainty of how or where to begin. An understanding of the research process is an essential skill for designing a study and developing the research protocol. Poor study design will lead to fatal flaws in research methodology and ultimately result in rejection for publication or limit the reliability of the results.[1] Fortunately, this can be avoided with adequate planning prior to study commencement.[2] Novice researchers are encouraged to seek out resources, including guidance from an experienced research mentor to prevent problems with study design, interpretation of results, and other related issues.[3-5]

The steps of the research process have been described using varying models with different number of stages.[6] However, the basic tenants remain the same and align with the steps of the scientific method. Developing the research question is considered one of the most important components for conducting a study.[6-8] Identification of the research question is the first step in the research process and provides the foundation for framing the hypothesis. Formulating the question usually starts with a broad topic and is refined following a literature search to establish what is known about the topic.

The research question and hypothesis are separate but related entities. The hypothesis is derived from the research question and is used to determine the experiments

or interventions to answer the research question. Lack of a hypothesis has been identified as one of the most common issues in poorly designed studies.[1] The aim of this paper is to provide guidance for developing research questions and forming testable hypotheses. Criteria for establishing a valid research question and the framework for formatting questions are discussed.

Research Question

Research questions originate from many different sources including clinical observations, a questioning attitude, or gaps in the literature.[9,10] Questions may arise from an identified problem or observation in clinical practice. This can generate questions about how or why certain practices are done, what is the evidence to support various procedures, or if there is a better or more efficient way to achieve the desired outcome. When searching the literature for answers, the available information on the topic may be lacking, indicating a knowledge gap, which may stimulate additional questions.

Research questions often begin with a broad topic that is narrowed and refined by performing a literature search to determine what is already known on the subject of interest. Questions that are too broad can be difficult or impossible to answer. For example, the clinician may be interested in best practices for ventilator management. It would need to be clarified if this were invasive or noninvasive ventilation, acute management in the hospital or long-term management in the home setting, and if it applies to a specific condition or certain patient population. Narrowing the topic will make the question clear, concise, and focused so that it can be developed into a testable hypothesis.

There are distinct differences between the research question and the hypothesis. The question is used to guide the literature search and establish the study design or what will be done to test the hypothesis. The research question should be hypothesis driven rather than data driven.[8] This means the approach to answer the question is directed by the hypothesis, or the anticipated result or outcome, and is developed prior to the start of the study. Questions that can be answered with a simple yes or no are generally not researchable questions.[11]

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FINER Criteria

Research questions should be feasible, interesting, novel, ethical, and relevant (FINER).[12] The FINER criteria provide guidance for developing the research question. The question should be feasible in that there is the ability to investigate. There are several aspects to consider for feasibility including subjects, technical expertise, and resources.[12] Feasibility includes assessing the number of subjects needed to ensure an acceptable sample size. Studies that include a very small number of subjects from a single center are difficult to generalize compared to a study with a larger number of subjects from multiple centers.

Feasibility also includes having the necessary skills, equipment, and technical expertise to complete the proposed study. It would not be feasible to conduct an in vitro study of aerosol therapy without the required supplies and equipment to collect and analyze samples or the knowledge to operate the machinery. Financial resources to conduct the research as well as the time needed to fulfill study obligations should also be considered when developing the research question. Cost for supplies, equipment, and personnel are all factors to consider. Other aspects of feasibility include institutional and departmental support.[3] This should be addressed prior to planning a study versus discovering the research cannot be completed due to lack of support after study activities have been initiated.

The research question should be interesting. Consider the audience for the research question. Would the topic be of interest to other clinicians that provide care to the patient population in question? Although a topic may be interesting, if it is not applicable to clinicians it is not likely to be of importance to the general audience. The research question should be novel and provide new insights to existing knowledge on the topic, contribute to what is known through improved methodology, or fill a gap in areas where the literature may be lacking.[8] Duplication of an existing study using the same exact methods would confirm what is already known, whereas improving upon flawed methodology or applying different approaches could be innovative. Importantly, confirming prior study results is often overlooked as a well-designed study should be reproducible.

The question must be ethical and comply with all local, state, and federal regulations. Approval from an institutional review board or ethics committee is required before conducting any study that includes human subjects. There are also guidelines governing animal studies that must be followed. The research question should be relevant, generate new knowledge, and improve clinical practice. Implications for clinical practice should be considered when contemplating relevance of the research question. An example of how FINER criteria was applied in a publication regarding home CPAP cleaning practices is provided in Table 1.[13]

Table 1. Application of Feasible, Interesting, Novel, Ethical, and Relevant for Cleaning Home CPAP Equipment

Feasible	Interesting	Novel	Ethical	Relevant
The study aimed to identify cleaning practices of home CPAP equipment through a survey. Prior to study initiation, the authors had to assess the number of potential subjects needed for an adequate sample size, develop the questionnaire, and determine how subjects would be recruited.	The population involved children with obstructive sleep apnea prescribed home CPAP. The topic and patient population may be of interest to sleep medicine and home care clinicians as well as others who work with the patient population.	A limited number of case reports have described infections associated with inadequate care of home CPAP equipment. No literature was available describing cleaning practices for children prescribed home CPAP when the research protocol was developed.	Since human subjects were involved, approval was required by the local institutional review board prior to administration of the survey.	The research generated new knowledge, as there was not a similar published study. It had clinical relevance as the results highlighted that cleaning practices often varied from recommended instructions.

Adapted from Reference 13.

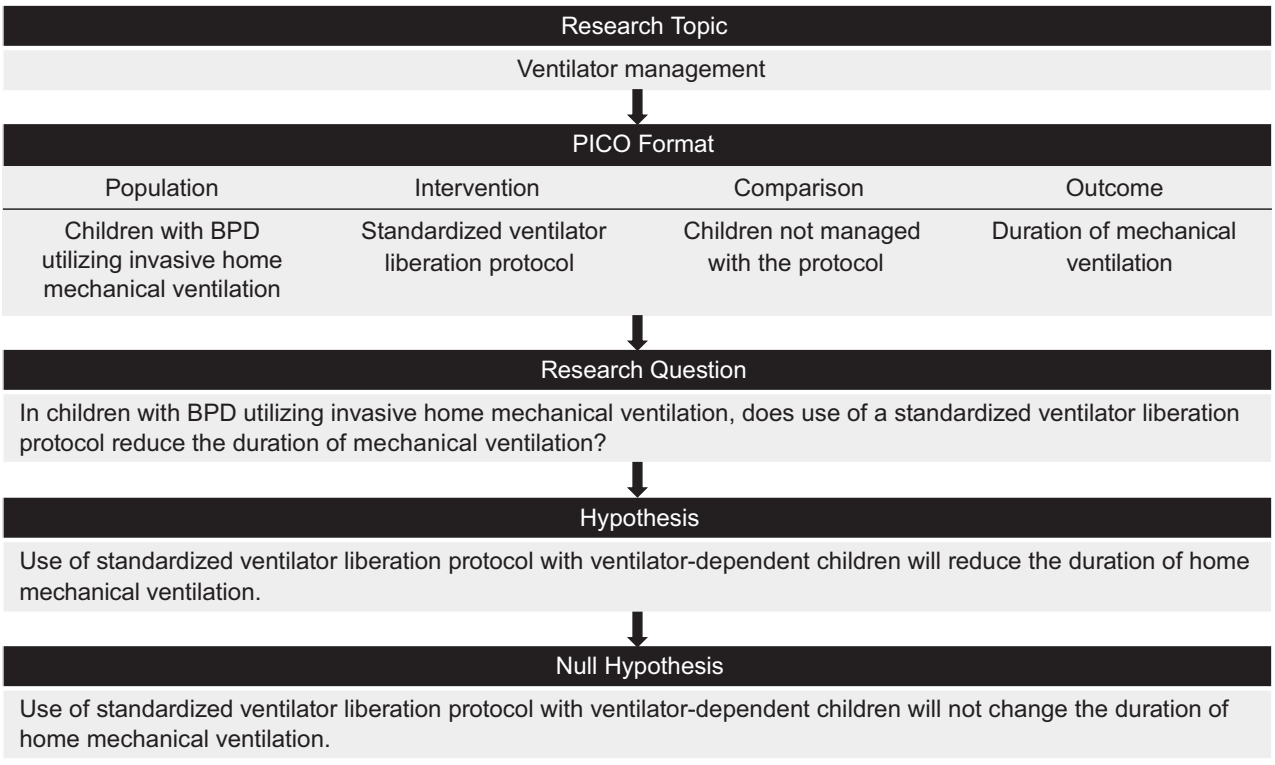

Fig. 1. An example of a broad research topic structured in population, intervention, comparison, and outcome format to formulate the research question and develop a hypothesis. PICO = population, intervention, comparison, and outcome; BPD = bronchopulmonary dysplasia.

PICO Framework

Identifying the elements for population, intervention, comparison, and outcomes (PICO) provides a framework for proper structure and format of the research question.[14] The PICO process helps focus on the single most important issue and outcome while keeping the question focused and narrow. The PICO process also helps identify key terms for the literature search.[15] American Association for Respiratory Care clinical practice guidelines published since 2021 utilize PICO questions for writing evidence-based guidelines.[16]

Table 2. Elements of the Population, Intervention, Comparison, and Outcome Framework

Question	Population	Intervention	Comparison	Outcome
How do blood gas and pH results from a blood sample obtained from a capillary site differ from results obtained from venous or arterial sites?[17]	Neonatal and pediatric patients who required blood gas sampling	Capillary blood gas sampling	Venous and arterial blood gas sampling	Blood gas results (eg, pH, P_{CO_2}, P_{O_2})
Should artificial airway suctioning be performed using open or closed systems?[18]	Neonatal, pediatric, and adults with an artificial airway	Artificial airway suctioning	Open versus closed suction systems	Physiologic outcomes (eg, heart rate, blood pressure, S_{pO_2}), development of hospital-acquired infection, ventilator-associated events
In adult patients requiring supplemental oxygen does heated or non-heated humidification of oxygen improve patient outcomes, improve patient comfort, and reduce adverse events versus no humidification?[19]	Adults in the acute care setting treated with supplemental oxygen	Humidified supplemental oxygen	Heated versus nonheated humidification	Comfort level, nasal, throat, and mouth dryness; nasal bleeding; infections; liter flow; device temperature

Adapted from References 17–19.

The first step of PICO is to determine the patient, population, or problem related to the question, including the characteristics of the patient population and the disease or condition. Age, sex, race, and ethnicity are other factors that may be relevant to the question and help further narrow the focus.[15] Intervention or exposure is what will be done or what happens to the population such as a treatment, test, or observation. The comparison or control parameter of PICO articulates the standard or alternative to the intervention. This may involve comparing one group to another or comparing different interventions. Outcomes refer to the measured results. Examples of potential outcomes are admission rates, length of stay, respiratory scores, ventilator days, mortality, cost, and other similar measures depending on the nature of the study.

Consider the topic of ventilator management and apply the PICO format. Assume the specific interest is ventilator liberation for children utilizing invasive mechanical ventilation in the home setting. This patient population includes children with many different underlying diagnoses, some of whom are not candidates for ventilator liberation, such as progressive neuromuscular disease. The focus might be narrowed to a specific diagnosis such as bronchopulmonary dysplasia, as the need for ventilator support commonly resolves in this group of children. In this hypothetical case, a ventilator liberation protocol was developed. The research proposal aims to compare duration of home ventilation in children managed with and without the protocol (Fig. 1).

Three clinical practice guidelines were published in RESPIRATORY CARE in 2022.[17-19] Each guideline included a set of PICO questions used to develop evidence-based recommendations. Table 2 includes a question from each guideline along with examples of the PICO elements for each question.

Hypothesis

The hypothesis is an educated prediction of the expected outcome based on existing knowledge and assumptions.[20] It is developed from the research question and is a declarative statement rather than a question. Both the research question and the hypothesis are developed prior to study initiation. The hypothesis is data driven in contrast to the research question, which is hypothesis driven. The hypothesis can be tested and is used to determine what information or data are needed to answer the research question. In the example of using a standardized protocol for ventilator liberation in children receiving invasive home mechanical ventilation, a potential hypothesis may be that use of the protocol reduces the duration of ventilator support.

An additional step of the research process is stating the null hypothesis, which is a restatement of the hypothesis to one that postulates there is not a difference in outcome

variables or a relationship between the compared groups or interventions.[20,21] The null hypothesis is the basis for the statistical analyses used to test the collected data for significance. If the findings demonstrate statistical significance, meaning there was a difference in outcomes between the groups, the null hypothesis is rejected.[8] Contrarily, if the analyses do not identify statistically significant differences, the null hypotheses cannot be rejected. Figure 1 includes an example of taking a broad research topic, using the PICO format to structure and develop the research question, and formulate a testable hypothesis.

It is important to note that as the research progresses the question and hypothesis may evolve throughout the process before a study protocol is finalized.[6] A literature search may provide information that changes the focus or further refines the research question, which could lead to a different hypothesis than initially planned. Additional questions may also emerge during the process that generate further research ideas and other potential studies. However, the hypothesis and study question should not be changed post hoc to fit the data collected.

Research Aims and Objectives

A research protocol should include study aims and objectives. These elements identify the overall purpose or intent of the research and specifically state how the purpose will be achieved. Although aims and objectives are related, and the terms often used interchangeably, each serves a different purpose. Study aims are broad, overarching, and focus on the overall intent of the research. Examples of aims are to predict outcomes, increase knowledge, measure change, and test or generate new ideas.[22] In contrast, objectives are specific and focus on how the aim(s) will be accomplished.

Studies can have both primary and secondary aims and objectives, but all should be closely linked with the research question.[22] To demonstrate the relationship between aims and objectives, consider the survey of cleaning practices for home CPAP equipment.[13] The primary aim of the study was to identify cleaning practices and compare with provided instructions, whereas the objective was to identify the practices through a survey of caregivers of children with obstructive sleep apnea who were prescribed home CPAP.[13] The secondary aim was to determine if respiratory-related symptoms were associated with inadequate cleaning practices, and the objective was to inquire about specific respiratory symptoms that occurred or increased with CPAP use.[13]

Common Pitfalls

The ultimate goal for any research study is dissemination of findings and publication. It is rewarding to submit abstracts, have them accepted for presentation at conferences, and see all the hard work and effort come to fruition. Writing a full-length manuscript and submitting for publication is the final step of the research process.[23] There are several considerations for the early stages of research to help avoid problems that may arise during presentation of research findings or prevent publication.

Formulating the research question is one of the most critical steps in the research process and provides the foundation for the hypothesis. Problems associated with importance of the topic and study design are directly related to development of the question and hypothesis. Issues with topic importance include rehashing established facts, an insignificant research question, irrelevant or unimportant topic, little clinical relevance, and not being generalizable.[1] Utilization of FINER criteria to construct the research question can help avoid problems with topic importance. Lack of a hypothesis has been described as one of the common issues with study design.[1] The PICO process can assist with developing a structured research question used to create a testable hypothesis.

Summary

The research question is the foundation of the research process and guides the development of the hypothesis. The hypothesis is a declarative statement developed from the research question and used to determine the information needed to answer the question. Both the research question and hypothesis should be identified prior to the start of the study. Utilizing tools such as FINER criteria and the PICO process can help avoid some of the common problems encountered with research questions and study design. The FINER criteria can be helpful to ensure the research question is feasible, interesting, novel, ethical, and relevant. The PICO format provides a structured framework to refine the question and guide the literature search. The research question may evolve throughout the process and may lead to additional questions and stimulate ideas for further research.

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