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Research Fundamentals: II. Choosing and Defining a Research Question

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Abstract. This is the second in a series of articles developed by members of the SAEM Research Committee to describe a stepwise approach to the research process. This series is aimed at junior academic emergency physicians (EPs), as well as nonacademic EPs with an interest in the research process. This article describes the development of a testable research hypothesis. While a multitude of sources provide interesting questions for consideration, choosing and refining the research question, so that it can be tested adequately and answered completely, are difficult tasks. **Key words:** research question; research concepts; fundamentals of research. ACADEMIC EMERGENCY MEDICINE 1998; 5: 1114–1117

THE GOAL of medical research is to establish facts or principles that ultimately will have a positive impact on a population's overall health status, through careful and systematic investigation in a laboratory or clinical setting. The first step in this process is the definition of the research question. Research questions often fall into two categories: descriptive questions not involving an intervention, which may be answered by observational studies (e.g., what is the prevalence of undiagnosed hypertension in elder patients presenting to the ED?); and experimental questions regarding the effect of interventions, which ideally are answered using data from prospective interventional studies (e.g., what is the impact of thrombolytic therapy on 90-day mortality in patients with acute myocardial infarction?).

CHOOSING A RESEARCH QUESTION

Basic Criteria. The primary criterion for choosing a research question is to consider whether it will likely lead to useful information. Any research question should be able to pass the "so what" test[1]; the answer to the question should be important, interesting, and meaningful. A project does not have to have far-reaching consequences to be important, but it must have relevance to medical practice or theory and not have an obvious or undisputed answer. For example, a study designed to answer the following question: "Do patients in the ED prefer a quiet or noisy environment?" will not provide much useful information because the answer is intuitive. However, if noise is an accepted problem, then the question: "Can the level of unnecessary noise in the ED be reduced by periodic interdisciplinary inservice sessions?" may be useful.

Another important characteristic of a research question is that finding the answer should be realistic, given the investigator's expertise and professional environment. In other words, a research question must be answerable. Unless it can be translated into an operational study plan, it is not worth pursuing.

Sources of Questions. The practice of clinical medicine is a problem-solving process that seeks answers to given situations. When dilemmas arise, so does the opportunity to develop a research question. Although the development of an area of research interest requires time and effort, it begins by finding one good research idea. This first idea can come from several common sources. Clinical experiences provide many opportunities to develop research questions. Topical areas include the testing of new interventions for a specific clinical problem, proving or refuting the value of an accepted but untested clinical practice, or the trial of an available intervention for a new indication. Observational studies are also well suited to clinical practice. Examples include epidemiologic studies that prospectively or retrospectively document the incidence or prevalence of particular diseases or outcomes in defined populations.

Published funding opportunities such as requests for proposals or foundation announcements can stimulate interest in particular research ques-

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tions and provide possible funding sources for the project.

The medical literature frequently suggests new research questions. The discussion sections in many articles often indicate unresolved areas and additional experiments or studies that should be done.[2] One could also replicate a study to validate its results, especially if there is controversy regarding the conclusions or the generalizability of the results to another practice setting. A thorough review of the medical literature is mandatory when formulating a new research question, to ensure that the proposed question has not already been answered or become irrelevant.

Discussion with colleagues is another important source of new research ideas. This can occur at academic meetings following scientific presentations or even through direct correspondence with the author of a particularly interesting paper. These contacts also may provide new opportunities for collaboration.

Quality improvement activities will often identify clinical issues that can be transformed into research questions. A pertinent example is the "door-to-drug" time for administration of thrombolytic therapy for patients with acute myocardial infarction. If a department's time interval exceeds the national norm, a study could be designed to determine the factors that contribute to delay in drug administration. If the study were properly designed, the resulting information would be useful not only at that particular institution but also at other institutions that experience similar time delays.

Characteristics of a Good Research Question. The characteristics of a good research question can be summarized by the mnemonic FINER as described by Cummings et al.[3] FINER stands for feasible, interesting, novel, ethical, and relevant.

1. *Feasible.* There are many issues that must be addressed prior to initiating a study that will determine whether the project can be completed successfully. It is essential to determine whether the research question can be answered in a specific environment and in a reasonable time frame. For instance, to prospectively study the effectiveness of a new nasal tampon for treating anterior nosebleeds, how long will it take to recruit the required number of patients?

The next important question addresses the availability of adequate time and resources. Depending on the type of study and data collection methods, time commitments can be quite variable. If the investigator is planning on performing a retrospective chart review, there is some flexibility in scheduling time. However, if the study design requires recruiting patients prospectively within a fairly narrow time frame, the time commitment will be much greater and scheduling less predictable. Often co-investigators or research assistants will be needed to recruit patients successfully.

Financial resources are also very important. Hidden costs (e.g., clerical support, statistical consultation, supplies) can have a significant impact on a project's overall budget and must be estimated accurately prior to study initiation to ensure that adequate support will be available.

2. *Interesting.* To successfully complete a project, the investigator must have a genuine interest in the question being asked. Otherwise, it will be very difficult to maintain an adequate level of enthusiasm throughout the (often prolonged) research process.

3. *Novel.* Any research question worth pursuing produces new information. Occasionally, replicating a previous study is important when its results are not widely accepted or if particular aspects of the design can be improved upon. Many studies also will suggest new questions, related to the original research question, that need to be answered.

4. *Ethical.* A study's objectives and design must meet the ethical standards of the scientific community. Although the acceptable benefit/risk ratio will vary with the disease process being studied, prudent standards have been developed and almost all studies require review and approval by an institutional review board (IRB), by an animal use and care committee, and/or other review bodies.

5. *Relevant.* As previously stated, the major purpose of medical research is to discover new information that will improve overall health status. Such information can take many different forms. However, unless the results or possible outcomes of the research project will produce such information, the project is not worth pursuing and it will not pass the "so what" test.

Investigator Issues. One of the most important issues that an investigator must determine prior to choosing and initiating a research project is the amount of time he or she has available and is willing to devote to the study. This will realistically determine the type of project that can be pursued. For instance, a longitudinal study examining the impact of gun control legislation on ED firearm-related injuries would not be appropriate for someone who desires to complete a project in a one-to-two-year period. In addition, identifying a senior investigator (within or outside emergency medicine) who can provide the necessary mentorship will improve the chances of successfully completing the project.

Departmental Issues. Individual departments have differing levels of experience and commit-

ment to research. The available resources, including intramural funding, are also variable. Thus, the appropriateness of undertaking an investigation of a research question will depend heavily on existing expertise, commitment, and the potential for support. Many departments have a research committee or research director who can provide advice regarding the feasibility of a project and the availability of funding.

Institutional Issues. Academic medical centers generally have a greater research emphasis than community hospitals, although the availability of adequate technical expertise, space, personnel, and financial support must be determined separately for each project. The opportunities for interdisciplinary research also tend to be greater at larger academic centers. Since many study participants for clinical research studies are recruited or identified during their ED stays, there is a tremendous potential for collaboration with investigators from other clinical departments at such centers. Such partnerships will often lead to ongoing exchange of research ideas and additional opportunities for interdepartmental research projects.

REFINING THE RESEARCH QUESTION

Objectives. The research question drives the development of the study protocol. After the question has been developed and the potential clinical or scientific relevance identified, it must be shaped and narrowed into an answerable format. Research questions should be expressed in simple, straightforward language that an intelligent layperson can understand.[2] For experimental or analytic studies, the research question must be refined further into a precise, testable statement known as the hypothesis (see below). However, regardless of the type of study, the research question must be unambiguous and as specific as possible. For example, the question "Do prophylactic antibiotics reduce the incidence of wound infection?" is poorly defined, broad, and unanswerable. In contrast, "Does the use of ciprofloxacin reduce the incidence of infection associated with puncture wounds to the foot in healthy, nondiabetic patients? is more precise and more likely to yield useful information.

Several issues must be considered when refining a research question. Typically, research questions start out broad and must be modified several times to yield a specific testable question. Returning to the example regarding prophylactic antibiotics and the incidence of wound infection, several additional questions must be answered before the question is truly testable. What age groups will be studied (children, adults, elders)? What age wounds will be studied (less than 6 hours, less than 24 hours)? How long will the antibiotic be administered? As can be seen from this example, what seems like a simple straightforward question actually must be refined and modified until a testable hypothesis is reached.

Once a precise, clinically important research question has been developed, the next step is to determine whether it is worth investigating. Performing a thorough literature search is a good place to start.

Evaluating the Literature. The primary objectives of performing a literature search are to determine whether the question already has a well-accepted answer and to obtain a broad and thorough knowledge of the subject matter. One will also be able to determine who is actively doing research in the field and what types of study designs have already been used. Ideally, the literature search should be performed when the investigator is determining the feasibility of pursuing the research question.

The U.S. National Library of Medicine's MEDLINE database is the largest medical bibliographic database available, and several user-friendly programs have been developed to search it efficiently. They all use the Medical Subject Headings (MeSH) vocabulary.[4] Most medical librarians are facile in its use. However, investigators, when doing their own searches, have the advantage of refining the search online as they process the large volume of information that is available for most subject areas. For this reason, it is essential that junior investigators become familiar with the use of MEDLINE and the MeSH vocabulary to maximize the quality of their literature searches. *Index Medicus* can also be manually searched in the library. However, this process can be very time-consuming and is probably best reserved for searching very specific subject areas.

Since electronic searches do not typically identify every relevant article, secondary references of original research and review articles are also an important source of information, especially for locating articles that predate 1966, which are not part of the computerized MEDLINE database. When reviewing reference or review articles, it is important to obtain any original references that are cited and read them completely.

Once the research question has been refined and a review of the literature completed, the process of transforming the research question into a hypothesis can begin.

HYPOTHESIS DEVELOPMENT

Objectives. For experimental or analytic studies, the research question must be translated into the

form of a hypothesis. A hypothesis is an assumption of the relationship between two or more variables. It is the researcher's best guess or prediction of the outcome. The hypothesis is developed after the research question has been formulated and refined and guides the development of the research protocol.

A well-written hypothesis should be very specific, easy to understand, and testable in terms of measurable variables. The hypothesis will guide the collection and analysis of data.

Variables. A variable is merely a characteristic of a study subject that can be measured. Descriptive studies evaluate individual variables one at a time. In contrast, experimental or analytic studies analyze relationships between two or more variables.

The *dependent* variable is the outcome that is measured. An *independent* or *predictor* variable is a factor that may affect the dependent variable or outcome. In an experimental study, the investigator manipulates the independent variable (the intervention) and observes the effect on the dependent variable (the outcome).[1]

Confounding variables are other factors or predictors that may affect the outcome of a subject (e.g., age, gender, comorbidities) that must be considered and/or measured during the study.

Null and Alternative Hypotheses. The null hypothesis states that there is no association between the dependent and independent variables in the study population (there is no difference between the experimental and control groups). If accepted at the conclusion of the study, the null hypothesis suggests that any difference noted between the study groups was due to chance and not due to the intervention or independent variable.

The alternative hypothesis usually states the investigator's true expectation, that there is a difference between the study populations with respect to the variable of interest and it is not merely due to chance. The alternative hypothesis also must define the size of that difference, which, in turn, has a large effect on the required sample size for the study.

Primary and Secondary Outcomes. The primary outcome measure is the major variable of interest in a study design. For example, in a study designed to measure the effect of thrombolytic therapy for acute ischemic stroke, the primary outcome variable could be mortality at 90 days. A secondary outcome might be functional outcome at 90 days or rate of intracerebral hemorrhage at 24 hours. Both the primary and secondary outcome measures should be stated in writing at the outset of the study. The interpretation of hypotheses that are formulated after examination of the data is difficult and subject to question.

CONCLUSION

Every research project begins with an idea that is subsequently refined into a research question. There are many sources of research questions, including clinical experiences, the medical literature, discussion with colleagues, and quality improvement activities. Junior investigators should identify a mentor who can assist them in formulating a good research question.

The mnemonic FINER summarizes the characteristics of a good research question—feasible, interesting, novel, ethical, and relevant. Other factors will influence the types of research questions that can be realistically considered, including the investigator's interests, departmental expertise, and institutional resources.

Once a research question is chosen, the investigator must refine it and determine whether it is worth pursuing. This requires a thorough search and understanding of the relevant literature.

Experimental or analytic studies require the development of a hypothesis from the study question. The hypothesis must contain both the dependent (outcome) and independent (predictor) variables. Every study should list a primary outcome measure. In addition, many studies will also identify secondary outcome measures. All outcome measures, whether primary or secondary, should be specified prior to the initiation of the study.

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