Chapter 03 / Capítulo 03

Evidence-based biomedicine: methodology for research, standardization, and scientific procedural aspects (English Edition)
ISBN: 978-9915-704-43-2
DOI: 10.62486/978-9915-704-43-2.Ch03
Pages: 16-19

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Design and Types of Research Studies: Research Design Model and Structure / Diseño y Tipos de Estudios de Investigación: Modelo-Estructura del Diseño de Investigación

In their daily routine, physicians focus primarily on clinical practice and the studies necessary to apply knowledge to it. Questions often arise about the effectiveness of diagnostic tests, the causes of diseases, the best treatments, and their efficacy. In addition, it is common for patients and family members to inquire about the progression and prognosis of health problems. Historically, these questions were answered empirically, based on the physician's experience or the previous experiences of other professionals. This practice remains common today. For example, a first-year resident might consult a more experienced physician and follow the advice received, assuming it is correct. Another way to respond is through pathophysiological reasoning, such as using high doses of intravenous furosemide for acute pulmonary edema, given its venodilator and diuretic effects. Although these methods have their value and can serve as a basis for new hypotheses, they are not always the most effective.

However, these practices only offer approximations to the truth. The method that comes closest to it is the scientific method, which consists of proposing a theory or hypothesis and evaluating it with objective evidence. One challenge with this method is that it tends to respond efficiently to a single specific question. For example, the question of whether acetylsalicylic acid (ASA) increases survival in acute myocardial infarction may seem simple, but it is actually complex. The question arises in the context of a specific patient and requires consideration of ASA relative to other options. Not only in research but also in the search for evidence, the "PICO" method can be used; it is explained in more detail in another topic.

3.1. Research question

The success of any research lies in asking a good question. Every study, analysis, or investigation begins with the identification of a perceived problem, a situation that causes concern and needs to be explained. This problem persists until a concordance or discrepancy is established between the theoretical explanation of the phenomenon and what is observed in reality. The research question arises from the need to clarify a doubt existing in a population, which the researcher seeks to answer through measurements and observations of the study subjects. There are many possible research questions; the real challenge is not so much finding them as identifying a meaningful one that can be converted into a study plan that is both valid and viable

3.1.1. Sources of a research question

An effective research question often originates from the researcher's personal experience. An experienced researcher generates their own questions based on their discoveries and the challenges observed both in their own studies and in those of colleagues in their field. An excellent starting point is a thorough knowledge of the existing literature in a specific area of study. Another source of inspiration for questions is to remain open to new ideas, which may arise from scientific literature, bibliographic sessions, conferences, and meetings.

It is crucial to adopt a skeptical attitude toward conventional beliefs. Careful observation of patients can also yield rich sources of research questions. To formulate a good question, it is

necessary to keep the imagination active, encouraging creativity by imagining new solutions to old questions and having fun with innovative ideas. Persistence is key to tackling a complicated problem until a satisfactory answer is found. Good ideas can arise at any moment, often when you least expect it. The trick is to keep the problem in mind and prepare for ideas to flow toward it. When selecting an idea, it is helpful to start with a brainstorming session to generate as many options as possible. Then, through critical analysis, you can choose the best one. In this process, teamwork and collaboration can be extremely beneficial.

3.1.2. Requirements for a good research question

An effective research question must first and foremost be feasible. This means having an adequate number of subjects, with a sample size calculation that is practical and the intended subjects achievable, considering possible exclusions, refusals to participate, and losses to follow-up. Often, a pilot study is necessary to adjust these numbers. In addition, to ensure feasibility, the research team must have the technical training necessary to employ the proposed methods, either through their own experience or through collaboration with co-researchers who are experts in other areas. A study must also be affordable in terms of costs and resources. Furthermore, it must be manageable and avoid covering too much ground or asking too many questions.

Second, the question must be interesting. If it is attractive to the researcher, this encourages the dedication and effort necessary to overcome the obstacles and frustrations typical of the research process.

Third, it must be innovative. There is no point in repeating studies that have already established certain facts. However, a question does not need to be completely original; it can seek to confirm previous findings in different populations, apply improved measurement techniques, or overcome limitations of previous studies.

Fourth, it must respect ethical standards. This includes avoiding unacceptable physical risks and invasion of the subjects' privacy. In cases of ethical doubt, it is vital to consult Clinical Research Ethics Committees.

Finally, the question must be relevant. This is evaluated by imagining the possible results of the study and how they could influence scientific knowledge, clinical practice, and future lines of research.

An exceptional research project is characterized by posing important questions that have the potential to yield fundamental observations, generate new knowledge, promote new ways of thinking, and open paths for future research. If these two criteria are met, the other requirements for quality research are generally satisfied.

3.1.3. Development of the research question and study plan

It is essential to draft the research question and a preliminary study outline, covering one or two pages, at the beginning of the project. This process requires self-discipline, but the researcher must clarify their ideas for the study plan and identify specific issues that need attention. Developing the research question and study plan is an interactive process that involves consultation with advisors and colleagues, becoming increasingly familiar with the existing literature, and conducting pilot studies to evaluate recruitment strategies and measurement methods. Although most studies address several research questions, it is crucial to focus on one

main question when designing and conducting the study.

3.2 Study design

The study protocol is developed in four successive phases, each more detailed than the previous one. The first version consists of formulating the research question, a sentence that defines the objective of the study. The second version is a one- or two-page outline that summarizes the key elements of the study and serves as a checklist to remember all the components of the research and detail the steps to be followed. The third version is the study protocol itself, which expands on the previous outline and becomes the main document for study planning and funding applications. Finally, the fourth version is the operations manual, which details the methods, materials, and procedures of the study. This manual aims to establish a consistent and standardized approach to conducting the study with a high level of quality control.

3.3. Types of study

The different types of studies will be described in more detail in later chapters of this course, but here is a summary of their classification and categorization. There are two main approaches to knowledge: qualitative and quantitative. In the qualitative approach, several categories of studies can be distinguished, as described below.

1. Observational studies
2. Interpretive studies: phenomenology, ethnography, grounded theory.
3. Socio-critical studies: action research, feminist research, and critical discourse analysis.

Within the quantitative research paradigm, studies are classified according to two key questions: first, whether the study is based on a pre-established hypothesis; and second, whether it includes a controlled intervention. Studies that are not based on a prior hypothesis and whose purpose is to describe a situation are known as descriptive studies. Examples of these include clinical case series, ecological studies, descriptive research on morbidity and mortality, and prevalence studies. On the other hand, when there is a prior hypothesis, the study is classified as an analytical study. If in these analytical studies the intervention is not controlled, that is, the subjects are only observed, they are called observational, as in cohort and case-control studies. Finally, when a study is based on a hypothesis and the intervention is controlled by the researcher, two main types of studies are identified.

1. Quasi-experimental: assignment is not random
2. Experimental: assignment is random, with scientific evidence indicating that randomized clinical trials have a higher incidence.