# Quantitative Research Methodology in the Health Sciences

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## CHAPTER ONE

# FUNDAMENTALS OF THE SCIENTIFIC METHOD AND RESEARCH PARADIGMS

#### Introduction

One of the fundamental aspects of health sciences is selecting a methodology that can adequately respond to the study's research question or objective. This initial step will be based on the theoretical orientation, i.e. on the selected research paradigm, from which the methods and techniques for analysing the data collected during the study of a given phenomenon will be defined.

Scientific research has a great variety of approaches or modalities. Each one is theoretically supported by a paradigm, from which the researchers will contemplate what they have to investigate. However, a paradigm underlies all scientific research, even when researchers do not explicitly report it.

This perspective of a problem or phenomenon will mark the researcher's theoretical position or the health sciences professional responsible for developing the steps based on a specific methodology. For this reason, health professionals must know the principles that define the positioning within one methodology or another and use its instruments and techniques to develop their research.

Therefore, the way we approach problems and seek answers determines how we investigate. Our assumptions, interests and purposes lead us to choose a methodological vision, which will determine our position before the phenomenon under study as researchers.

Thus, this module aims to bring the professionals closer to different approaches from the paradigms of knowledge to study a given phenomenon framed in health sciences.

#### Subject and objective of the research

Science applied to the social and human world constitutes a practice in which different actors intervene, and the subject that seeks to know or cognitive subject is one of them. Depending on the research paradigm considered, this subject occupies one place within the phenomenon under study. This subject establishes an intimate and necessary relationship with the object of research or cognisable objective. With its forms, living beings, theories, models, and situations, the whole universe can be the object of investigation.

Knowledge is the result of the relationship between the cognitive subject and the cognisable objective that gives rise to scientific interpretation through the result obtained from qualitative and quantitative characteristics (1).

There are two generically opposite positions with the generated knowledge: materialism and idealism as explained in the following block diagram 1.

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- •Determination of the objective and the subject from an objective and material perspective.
- The object of the phenomenon under study determines the research process.
- The object is independent of the subject's knowledge.

#### Idealism

- •Reality is not known as it is in itself.
- The object of knowledge is preconfigured or constructed by cognitive activity.
- •The subject recreates the object through abstractions and is not independent of the subject.

#### Scientific knowledge

If we look at the modern perspectives on how scientific knowledge is constructed, Popper already criticised the classical ideas. He considered the importance of variability by deconstructing the idea that all scientific theories are not verifiable even if it can be demonstrated that they are not true or cannot occur, referred to as falsificationism. Kuhn also later demonstrated that numerous social conditions influence the behavior of scientists, which changes over time.

Paul Feyerabend also criticised the limiting idea that we can find in a series of methodological rules on carrying out scientific research. Based on historical examples, he affirmed that science has only advanced when researchers have disobeyed the rules defended by methodologists. According to him, these rules tend to favor previously established theories, hindering new ideas. He proposed the only methodological rule that favors scientific progress, the "anything goes" rule, and hence his thesis is known as "methodological anarchism".

Lakatos developed a version of Popper's falsificationism, in which the basic units of scientific activity were not theories but research programs. He proposed that researchers should be aware of whether their research program can generate correct predictions and be progressive or, on the contrary, be degenerative if it is permanently forced to transform itself. These programs are formed by a nucleus of hypotheses and not eliminated, even if anomalies are found in the empirical investigation. Also, a protective belt formed by a set of hypotheses and added to the strong nucleus generates new predictions, which are substituted by other hypotheses when they are not confirmed. Lakatos confirmed that the best scientific theory would explain the greatest number of historical events (2).

Thus, we can affirm that empirical concepts are imprecise and uncertain; they are produced by preconceived ideas, tend to accept metaphysical explanations, and are dogmatic. However, empirical knowledge serves as a basis for scientific knowledge, as it is extracted from reality. More specifically, empirical knowledge is derived from experience; it is the knowledge that allows man to interact with the environment; it is generational, although it does not criticise the procedure for obtaining it, nor the sources of information.

Scientific knowledge must resist comparison with reality, eliminate metaphysical explanations, and use first-hand sources. Scientific knowledge must go beyond the empirical tradition to proceed to its generalisation or transferability in parallel realities.

#### **Contextualisation of research paradigms**

We can consider a paradigm as the perspective or vision analysing phenomena. It is a set of norms that define a style, a method, a worldview or vision from a macrostructure used by human subsystems and systems. It is more than a theoretical framework that allows us to observe phenomena from one point of view or another (3).

A paradigm answers three fundamental questions:

- (1) Ontological question: what is the form and nature of reality, what can we know about it?
- (2) Epistemological question: what is the nature of the relationship between the one who knows or seeks to know and what can be known? Conditioned by the above.
- (3) Methodological question: how can the researchers manage to determine if what they believe can be known?

Denzin and Lincoln (4) consider paradigms as human constructions, i.e., they respond to a more informed and sophisticated point of view than they have been able to reach, subject to human error, as they are inventions of the human mind.

Following these considerations, the authors present a differential analysis between the different research paradigms, which are clarified in Table 1.

Fundamentals of the Scientific Method and Research Paradigms

Table 1. Differential analysis of ontology, epistemology, and methodology based on the research paradigms (5)

	PARA	<b>PARADIGMS OF KNOWLEDGE</b>	/LEDGE	
	Positivism	Postpositivism	Critical Theory	Constructivism
Ontology	Realism: reality	Critical realism:	Historical realism:	Relativistic: more or
	driven by natural	apprehension of	reality that, due to	less informed and/or
	laws and forces free	reality as	social, political,	sophisticated
	of temporality and	faithfully as	cultural, ethnical and	information, not true.
	context.	possible.	gender factors,	
			becomes real over	
			time.	
Epistemology	Dualistic and	Dualist and	Transactional and	Transactional and
	objectivist:	modified	subjectivist:	subjectivist:
	Independence	objectivist: an	researcher and object	Investigator and object
	between researcher	extreme ideal	interact.	interact so that the
	and object without	regulator of		findings are created as
	mutual influence.	objectivity. False		the research
		hypothesis.		progresses.
Methodology	Experimental and	Modified	Dialogic and	Hermeneutics and
	manipulative:	experimental	dialectic: a dialogue	dialectics:
	hypotheses in the	manipulation:	between researcher	Constructions are
	form of propositions	proven false of the	and research.	refined and compared
	to be empirically	hypothesis.		in the interaction
	verified.			between researcher and
				object of response.
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From analysing Table 1, the following conclusions can be drawn.

There appears a gradual process from an immutable reality of positivism to a multiple social reality that changes with dialogue and information in constructivism in Ontology.

Knowledge is considered real or an interaction between the researcher and the object under investigation from positivism to constructivism in Epistemology.

We move from positivism by verifying the hypothesis to constructivism by reconstructing the different previous perspectives in methodology.

These paradigms will generate a series of practical difficulties for their application, which will be summarised in (6):

#### 1) What is the objective or purpose of an investigation?

- a) Positivism and Postpositivism: The researcher is considered an expert from an explanation that predicts and controls phenomena.
- b) Critical theory: transforming social, political, cultural, economic, ethnic, and gender structures that limit humanity through conflict. The investigator is an instigator and facilitator.
- c) Constructivism: reconstructing the initial social discourses of the people and the researcher by improving information and sophistication. In this case, the researcher is defined as participant and facilitator.

#### 2) What is the nature of knowledge?

- a) Positivism: research hypotheses are verified by facts or laws.
- b) Postpositivism is based on a hypothesis that has not been proven to be false as a fact or law.
- c) Critical theory: they start from a series of "insights" transformed over time through dialectical interaction.
- d) Constructivism: critical constructions are generated of which there is a relative consensus among competent people.

#### 3) How is the knowledge accumulated?

a) Positivism and Postpositivism: knowledge is generated from a fact after the research is generalised or linked to clinical practice.

- b) Critical theory: knowledge grows and develops through a dialogue of the historical review, generating transferable facts when social circumstances are similar.
- c) Constructivism: knowledge is generated through more informed and sophisticated constructions with case studies.
- 4) What are the appropriate criteria for judging the quality or validity of an investigation?
  - a) Positivism and Postpositivism: criteria of rigor, internal and external validity, veracity and objectivity.
  - b) Critical theory: criteria of historical placement of research, degree of erosion of ignorance and misconceptions, a stimulus for action and transformation of the existing structure.
  - c) Constructivism: reliability of credibility criteria, transferability, trustworthiness and confirmability.

#### 5) What is the role of researchers ' values?

- a) Positivism and Postpositivism: excluded and free of values.
- b) Critical theory and Constructivism: values cannot be excluded.

#### 6) What is the place of research ethics?

- a) Positivism and Postpositivism: important but irrelevant with the use of committees and codes.
- b) Critical theory: intrinsic towards the transformation of misconceptions.
- c) Constructivism: intrinsic with the participation of values without hiding the researcher's intention.
- 7) What "voice" is reflected in the activities of the researcher, those oriented to change?
  - a) Positivism and Postpositivism: a disinterested researcher explains actions and policies to change proposals.
  - b) Critical theory: transforming intellectual.
  - c) Constructivism: passionate participant committed to facilitating reconstruction.

#### 8) What are the implications for the novice researcher?

- a) Positivism: technical in quantitative methods.
- b) Postpositivism: quantitative with qualitative aggregate.

c) Critical theory and constructivism: resocialisation and mastery of qualitative and quantitative methods. Knowledge of the research environment.

#### 9) Should these paradigms conflict?

- a) Positivism and Postpositivism: all can be accommodated with disagreements.
- b) Critical theory and Constructivism: incompatibility, either when there is reality or not.

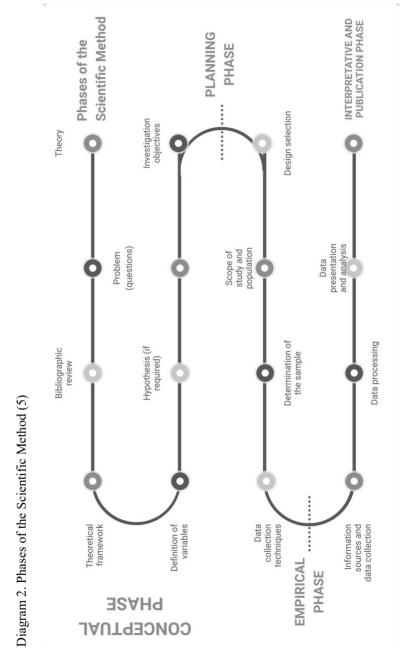
#### 10) Is there hegemony of some over others?

- a) Postpositivism is placed above Positivism since it resolves some criticisms raised about positivism.
- b) Critical Theory and Constructivism are under construction, and the hegemony of one over the other is not established. Critical Theory reflects on social phenomena, while Constructivism is based on relativism or critical naturalism.

In conclusion, we can see how qualitative research will be in Critical-Social Theory and Constructivism paradigms, further away from Positivism and Postpositivism's postulates due to its ontological and epistemological nature.

#### The scientific method

The scientific method or research process is structured in four fundamental phases, including the steps necessary for developing research in health sciences. In diagram 2, we can see each of the phases and sub-phases that assist in the following modules to structure and define our research proposal in the clinical setting.



Fundamentals of the Scientific Method and Research Paradigms

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#### **Types of Research**

We have established different types of research based on a series of criteria, and two main types have been then finally indicated based on their method and analysis. The types of research are summarised as follows:

#### Depending on the purpose, they can be:

- 1) Basic research: it aims to obtain new knowledge and research fields without a practical and applicable purpose, only to create a methodological body. Positivist paradigm.
- 2) Applied research: it aims to solve practical and immediate problems and improves the conditions and quality of documentary services.

#### Depending on the temporal scope:

- 1) Cross-sectional research (synchronic): it analyses one aspect of the development of the phenomenon at a given time.
- 2) Longitudinal research (diachronic): it involves studies over the years at different times.

#### Depending on the depth or objective:

- 1) Exploratory research: it is the first approach to the situation and is usually provisional.
- 2) Descriptive research: it is the first level of scientific knowledge and describes a situation or phenomenon.
- 3) Explanatory research: it explains the phenomena, their components, and dynamics.
- 4) Experimental research: it establishes cause-effect relationships to control the phenomena and actively intervenes in the phenomena under study through experimentation.

#### Depending on the framework in which they are carried out:

- 1) Laboratory research: usually, it recreates artificial conditions.
- 2) Field research: it is conducted at the place where the phenomenon occurs.

#### According to the time dimension:

- 1) Historical research: it orients to the past and studies phenomena that have already occurred. It mainly uses archive documents.
- 2) Experimental research: it is based on changes introduced in a variable to analyse the effects over time.

#### According to the orientation, it assumes:

- 1) Verification-oriented research: it focuses on testing and contrasting theories and explaining phenomena.
- 2) Discovery-oriented research: it aims to generate knowledge from what is observed. It usually uses interpretive methods to understand the studied phenomenon for the discovery of new events.
- 3) Application-oriented research: it attempts to respond to specific phenomena.

#### According to the source of information:

- 1) Documentary research: The source for this research will be documents such as medical records, nursing records, comments, etc.
- 2) Field research: the source of information for this research will be collected directly from the scope of the study.

The following are two classifications useful for the development of this book, and the classification of research is based on the level of research as follows:

- 1) Primary Research: It contains new and original information resulting from the fieldwork. It is based on the direct study of primary sources, which require a great deal of dedication and are carried out over a medium to a long time. This is the classic concept of research.
- 2) Secondary Research: The extraordinary and progressive increase in the number of scientific publications indicates the need to carry out reviews of the scientific literature to synthesise the results achieved in a given topic. It is a process of reviewing the scientific literature based on fundamentally methodological and experimental criteria that select quantitative studies, although also qualitative, to provide an answer to a problem by synthesis as approached from the primary research. The fundamental objective of this research is to identify what is known about the topic, what has been researched, and what aspects remain unknown. To summarise/synthesise information on a topic or problem. The studies conducted with this research are reviews. Literature reviews can be defined as the process of searching for information, analysing it, and integrating the results to update knowledge and/or identify the scientific evidence available on a topic.

#### Chapter One

The last and very important classification refers to the type of methodology used to develop the research. It refers to a primary type of research, and it could be:

- 1) Quantitative research: It uses empirical-analytical methodology and statistics. It has the characteristics that respond to the positivist or post-positivist paradigm.
- 2) Qualitative research: In this research, non-quantifiable aspects are measured. The analysis of subjects' perceptions, opinions, beliefs, and values through discourse analysis, interviews, and other qualitative techniques are important. It responds to the characteristics of a critical-social or constructivist paradigm.

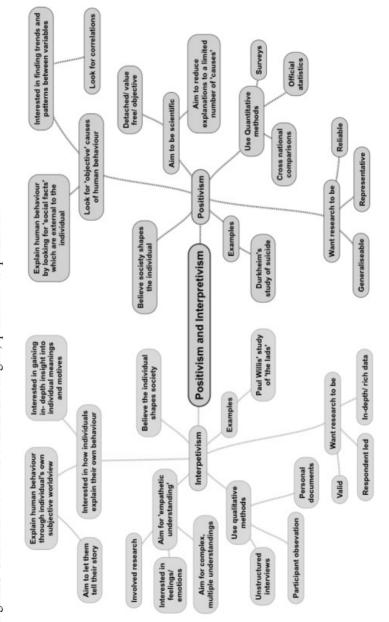
In this course, the focus is on our efforts towards primary research. In the next module, we will talk more about secondary research and its usefulness. However, it will be the distinction in planning, analysis, and interpretation of qualitative and quantitative methodology that we will develop throughout the course.

# Differences between qualitative and quantitative methodology

From the above classifications, connecting it with the theoretical positions through one paradigm or another, we can indicate, as noted above, that analysing a phenomenon from one view or another determines which type of research methodology would be the most appropriate (Table 2).

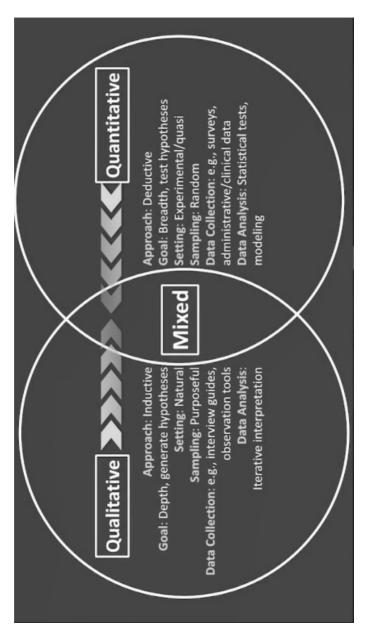


Diagram 3. Differences between both methodologies, qualitative or quantitative



# Chapter One

In Table 2, the differences between both methodologies, qualitative or quantitative, in each of the phases of the research are indicated.



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## CHAPTER TWO

# FUNDAMENTALS OF EVIDENCE-BASED PRACTICE

#### **Introduction to Evidence-Based Clinical Practice (EBCP)**

Throughout the 1980s, the term "Evidence-Based Medicine" appeared to describe an approach to medical practice based on scientific evidence to determine the best available clinical practice.

Subsequently, the term became the more generic "Evidence-Based Practice" from the moment when other professionals, apart from doctors, began to recognize the importance of scientific evidence when making clinical decisions.

The EBCP arises from the following aspects:

- a) An enormous amount of scientific information exists in the health sciences.
- b) Health professionals do not have enough time to read the average of 19 articles that would allow them to be up to date on topics related to their exponentially growing area of work.
- c) A way of identifying the most current information on a topic of interest, obtaining the appropriate references, and organizing to archive all the information handled.
- d) The need to offer the highest quality of care.
- e) Limitation of resources allocated to health care.

In Oxford, the English government first established a review centre, the socalled Cochrane Centre, which gave the final impetus to the EBCP.

#### **Definition and characteristics of EBCP**

Different definitions of Evidence-Based Clinical Practice (EBCP) emerge in the literature as the phenomenon has evolved. One of the most widely used is elaborated by Sackett, Rosenberg, Gray, Haynes, and Richardson (1), who define EBCP as "the conscious, explicit and judicious use of current best evidence to make decisions about patient care".

In order to build a culture of evidence-based decision-making, it is necessary to have better scientific information systems, the presentation of critical and comparative studies, and a system that offers decision-makers better syntheses of that evidence obtained through research or comparative studies of data generated in the Institution. Therefore, both the way of obtaining scientific information as well as applying it are the fundamental elements to be considered in developing clinical protocols and procedures.

Scientific information has undergone exponential growth in recent years, indicating that the more the information is, the more difficult it is to access (2). Gálvez Toro (3) is pointing out this as the information paradox, a phenomenon for which terms such as "information explosion", "information saturation", or the neologism "infoxication" have been coined (4-6).

A correct bibliographic search based on the appropriate documentary techniques will facilitate and optimize the available information resources and provide methodological rigour and avoid documentation selection biases in the research work.

Traditionally professionals are up to date only by subscribing to journals in their speciality or other journals of general interest. However, this seems to be an inefficient option. Not everything that is published is relevant to the work of each professional. Based on this aspect, one of the main contributions of EBCP is the consensus on the hierarchy of evidence. Certain study designs with a lower risk of bias are assigned a higher value. Even if we consider only the highest-ranking studies as the only source of updates, the situation remains unapproachable. For example, MEDLINE, the main database of biomedical journals, has more than 18,000,000 articles, as well as 700,000 new additions each year (7). Continuing with the example of the MEDLINE database alone, more than 18,000 Randomized Clinical Trials and 2,600 Systematic Reviews have been published in recent years (8). To this large volume of information must be added the difficulty of many professionals (particularly those who are not involved in research)

to critically analyze the information from a methodological point of view, and the difficulty of reading what is published in English (9). It should be pointed out that EBCP is not restricted only to research results, improved quality of care, or nursing research itself. It is about going beyond that, although it is implicitly related to the processes mentioned above. Each of their results and actions may have effects and consequences on the rest.

In this regard, it is worth noting the differences between quality improvement projects and research projects since both may be similar for practical purposes in the clinical field. However, they differ in terms of participants, the selection of subjects, the methods of analysis, and the use given to the results obtained.

### The importance of patient participation

These days, professional practice must be approached not only from the perspective of patient participation itself but also in terms of autonomous decision-making on the part of the patient. Given the exponential access to information, it is common to find patients with enough information to question any of our practices.

Technological development makes the patients become increasingly disoriented in our clinical environment. One of the reasons could be that the professionals have not developed the ability to explain clearly what and how we will apply our care. Patients attend as passive spectators to the study or treatment of their own body, each time in charge of more and different personnel, hardly questioning the many transgressions of personal dignity. They have answered as many times as they have been asked all types of questions, even the most intimate ones. Confidently, they see their data and life experiences recorded in documents and files that are vulnerable to possible indiscretions.

As in the rest of society, our healthcare organizations have a long democratic road ahead of them. The vested interests, pressure groups, and the existing cultural bias hinder a transparent and rational relationship between the healthcare system and citizens.

The predominant and monolithic view of health practice about what constitutes a good life inevitably contrasts with the myriad and diverse views of multiethnic and multicultural populations in many Western countries. Professional biomedical and healthcare practice must adopt a respectful and tolerant perspective when attempting to respond to the needs expressed by a wide variety of citizens.

The number of human groups proclaiming their right to health is growing, and all claim to choose their own lifestyles, illness, and death. The generalization of knowledge is beginning to break the classic patterns of paternalism prevalent in our field, where the relationship between the professional and the patient is often established, sometimes abusively. This important cultural change implies moving away from the false authority provided by the patient's misunderstanding, lack of knowledge or ignorance of the process that affects them to the true authority of knowledge per se.

The asymmetry in the professional-patient relationship derived from a different level of knowledge, both professionals and the healthcare system, entails a type of agency relationship that cannot be ruled out, even in a future of better-informed clients or users. Informed consent and full justification need to be obtained to give a new drug in a clinical trial setting, but not to administer it to all of them when it is decided in routine clinical care. Paradoxically, clinical decisions that truly condition the future of our patients' illnesses or diseases are not subject to mechanisms that sufficiently guarantee that the best and most appropriate decisions are made for the patients.

Thus, few studies, for example, Molina Mula (10), reveal that the patient is not autonomous in making decisions about their due care, first, to a certain institutionalization of care, which sets the pace of decisions; and second, to the characteristics of interprofessional relationships and the relational dynamics established between professionals, particularly between the nurse and the patient and family. These elements describe the current situation in a hospital environment, the ability of the patients to make their decisions regarding what type of care they want.

There continues to be a crossroad between a model of protective paternalism and a model of informed choice, as indicated by few Anglo-Saxon studies (11-17). A restrictive conception of patient decision-making dominates in our clinical setting. The nurse constantly justifies any care decision for the benefit of the patients, without leaving any room for patients' autonomy. The professional's decision based on scientific evidence and expert knowledge prevails, and only sometimes, taking into account the preferences of the patients as long as they coincide with those of the professional, as revealed by the studies of Epstein and Peter (18), Nelson, Han, Fagerlin, Stefanek and Ubel (19) and Dowie (20).

Despite the dominance of the restrictive model, certain discourses emerge among nurses, which emphasize the need to involve the patient, advising on the different possible care alternatives. However, still, there is a long way to go since it has not yet been extended in the specialized care setting, where the relationship between nurse and patient, although characterized by trust, continues to be fixed and marked by the roles that each one assumes in this relationship, as defined by Emmanuel (21). Thus, the limitations of practical operationalization of a more open-minded model of inpatient decisionmaking proposed by Cribb and Entwistle (11) are evident.

It has been demonstrated that the relationships established between the nurse and the patient and family, the members of the team and the healthcare system shape the self-determination of patients. Likewise, the historicalsocial context of healthcare institutions explains the degree of autonomy that the patients acquire in the clinical setting.

In conclusion, changes must occur in the internal structures of the healthcare organizations, replacing the standardization of professional practice and the instrumentalization of the patient, based on resistance strategies, with actions aimed at promoting the self-determination of the values of patients.

#### **Sequence for Evidence-Based Clinical Practice**

Evidence-based clinical practice is structured in a cyclic sequence of five well-defined steps (22).

STAGES OF SCIENTIFIC EVIDENCE		
Stages	Characteristics	
First	The question arises from the problem, doubt or uncertainty that we want to solve. Identify the person or population or problem situation, the usual intervention against the problem, the new intervention to be considered, and the expected effect or result. It must be translated into a search strategy that finds a quick and appropriate response.	
Second	Search for the best answer to the question in the sources of information within our reach, which would be the books and texts also called stable knowledge; periodicals, electronic bibliographic bases, specific EBP information bases, and finally, the internet to be used by analyzing the quality of the sites visited and the information contained in them. It also includes clinical practice guidelines, which recommend professionals and users to make intervention decisions according to the clinical condition presented.	
Third	Critical evaluation of the evidence found. Classify each piece of evidence found in the information sources into the different levels of evidence.	
Fourth	Implementation of the evidence in practice aims to improve the quality of care delivered to users and their families. The act of care must be a thoughtful, deliberate, and autonomous activity.	
Fifth	The consequences of applying the chosen intervention should be evaluated. Permanent feedback between research and clinical practice.	

In the first step, the research questions are formulated using the PICO method of question design. The different research elements are structured based on a predefined guideline that facilitates the sequencing of the bibliographic searches.

The second step of the sequence corresponds to the basic bibliographic search strategies. Utilizing descriptors extracted from the previous formulation, the relevant publications for the subject of the study are identified.

The third step involves critically reviewing the identified articles in the previous phase through key reading tools of checklists, which makes it possible to discern the degree of quality and scientific rigour of different publications.

The fourth and fifth steps relate to implementing the reviewed evidence in clinical practice and evaluating it to verify that it represents a positive and relevant change in daily clinical practice.

#### **Fundamentals of EBCP**

The four fundamental elements of the EBCP are (23):

- 1) Evidence
- 2) Experience
- 3) Preferences and values
- 4) Resources

Evidence is derived from research studies, clinical trials, and qualitative studies. It is important to consider the available evidence to decide to reduce uncertainty and variability in clinical practice, i.e., it acts as a support for deciding or helping the patient make a decision. This is the external evidence, i.e., evidence taken from others.

The professional's experience encompasses the body of knowledge a professional acquires over the years of practice. It allows the adoption of sound decisions in complex situations despite the uncertainty of the decision itself. This is the internal evidence arising from rigorous professional practice.

The patient's preferences and values should have the same status as the other pillars of EBCP, and in any case, they should prevail over others or be the starting point of the entire decision-making process. This implies that the professionals should evaluate the patient's state of health, issuing a clinical judgment and some recommendations or treatment proposals. Also, they act as advisors, allowing the patients to make the therapeutic decision with their help.

The resources available condition EBCP while specific conditions must be met to make it possible. With the limited available health and social resources, it is necessary to have the instruments at one's disposal.

#### Hierarchy and quality of scientific evidence

In general, the selection of sources and tools is given by the type of evidence or proof we need. Factors such as time, accessibility, or the environment or speciality where we operate must be added. Following this reality, Haynes (7) proposed a hierarchical and pyramidal model searching for evidence, referred to as the 5S model.