



Revista Española de Cirugía Ortopédica y Traumatología

www.elsevier.es/rot



EDUCATION

How to start a research project[☆]

Cómo iniciar un proyecto de investigación

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Introduction

One of the goals of undergraduate education should be the acquisition of a scientific attitude, determined by affective dimensions, and whose traits or characteristics should include: curiosity, objectivity, open-mindedness, flexibility, critical thinking, intellectual honesty, investigative energy, creative daring and social participation. In short, the "university essence": creating and transmitting knowledge and attitudes.

Understanding the professional life of a doctor as a "continuous training", both during specialised studies and during the rest of a professional career, that university essence will be obtained through the scientific method. This method should represent the basis of the entire profession, not only of research activity, but of all clinical activities.

It is important to note that knowledge must be framed within a theoretical field and a practical field in which theory will be a tool to be used and as an interpretation field. There are two principles to be kept in mind in the field of science: the first is uncertainty and the second is controversy.

The researcher

A researcher should be a creative individual, understanding creativity as the "act, idea or product that changes

or transforms an area of knowledge or culture" (Csikszentmihalyi, 1997), or else the "way of thinking which results in things that have both novelty and value" (Romo, 1997). Regarding creativity, it has been said that it is a privilege of youth, that the main creative peak appears in the third decade of life and that fewer than 10% of creative contributions occur after the age of 60 years. However, although this may perhaps be true in the arts, with some major exceptions (Mozart or Picasso, who were below the lower limit, or Picasso, Segovia and Verdi, who were above the upper limit), it does not seem to hold true in the field of science, in which creativity is maintained between the ages of 30 and 70 years.

As for the appearance of an idea, an initial observation, a question, these often arise from personal experiences, demands in an area of knowledge, environmental pressures, other existing questions, the curiosity of researchers, the surroundings, clinical problems, etc.

The creative process has two main parts, one of anticipation, the vision of a problem ("being able to see where others just look"), and one of tenacity, commitment to pursue it. This process consists of several phases, one is preparation (in order to see it is necessary to look and know the terrain), and another involves incubation and insight, followed by evaluation and, finally, development. Sometimes, questions arise at a time of apparent indolence, when there is an abstraction from other problems or issues, often by a subconscious association of ideas. However, we must not forget that the creative process consists of 10% inspiration and 90% perspiration; in the words of Pablo Picasso "let the arrival of inspiration find me hard at work". A researcher can direct his interest towards clinical trials or experimental trials.

[☆] Please cite this article as: Gil Garay E, et al. Cómo iniciar un proyecto de investigación. Rev Esp Cir Ortop Traumatol. 2013;57:78–82.

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Clinical trials usually entail studies conducted to evaluate a therapy involving humans. They may also be defined as clinical intervention studies, prospective, with recurrent controls and random assignment. Experimental trials involve the kind of scientific experience in which a change is deliberately proposed in order to observe and interpret its results with some cognitive purpose.

Neither case is conducted within a theoretical vacuum. They are scientific constructs which involve theories, hypotheses, etc. Scientific knowledge is conceptual, it is built on systems of interpreted concepts. A concept is a unit of thought (Bunge, 1969). Some of the generalities presented below are based on this author.

The scientific method

The scientific method is a procedure for treating a set of problems. It consists of a series of phases which must be followed in correlation and involves a series of peculiarities in clinical medicine and experimental medicine, with a number of limitations. Research must stem from questions such as: what is it? or how is it?; it is largely based on observation. Observation is the basic empirical procedure. The product of observing an event is a fact.

Observation of facts

Observing means examining carefully; the object is a specific fact or set of facts and there should be no room for impressions arising from feelings; scientific attitude should exclude subjective speculation. Observation should include a series of objective actions:

- a. An accurate definition of the problem: "formulate the right question and the answer will often become apparent". Articulate well-founded and fruitful questions. Formulate the problem clearly. Minimise vagueness of concepts.
- b. Determination of the relevant facts or circumstances. Highlight the assumptions and unknowns. Describe budgets.
- c. Analysis of the problem defined (question): what is the difference with current knowledge? How can it be approached? For what purpose? What will the applications be?
- d. Review of prior information.
- e. Selection of specific objectives. Normally, a work should not have more than two objectives.
- f. Design of an approach. This step is very important because it defines the quality of the work.
- g. Design of a suitable method to achieve the objectives.
- h. Criticism of what is already known through information. This involves addition of new questions, some of which might help to decide:
 - iv. If the problem can be approached in the light of new findings.
 - v. If someone else is working on it.
- i. If the problem has already been solved correctly (the most frequent).
- ii. If the problem has already been solved, but poorly.
- iii. If the problem is entirely new (exceptional).

- iv. If the problem can be approached in the light of new findings.
- v. If someone else is working on it.

The problem is the source of science and requires a significant cognitive load in its formulation:

- a. What is the problem?: stock of ideas.
- b. What is the background?: stock of information.
- c. What are the assumptions?: stock of concepts (or paradigms) within a theoretical framework.
- d. What are the means?: stock of procedures.

The continuity or not of the work will be the result of the above.

Hypothesis

A hypothesis must be born from the attempted correlation between events that may explain an observation and facts which are already known. It should be based on an assumption from which a conclusion may or may not be drawn, if it can be verified. A hypothesis has a function and a characteristic.

The first consists in a critical analysis until the interpretation of the selected facts. Therefore, it is a natural consequence of observation from which more than one hypothesis usually arises. Out of these, the most logical and coherent will be identified. The characteristic of a hypothesis is that it may be tested, both by the observer and by others.

There are several mechanisms for constructing a hypothesis, including:

- a. Analogue hypotheses: inferred by analogy arguments.
- b. Inductive hypotheses: composed on the basis of case by case analysis.
- c. Intuitive hypotheses: those whose introduction has not been considered.
- d. Deductive hypotheses: obtained by deduction of propositions.

A work is usually based on a single hypothesis. A hypothesis can be specified into one or two objectives and this will affect the conclusion. A hypothesis with a single goal will have a single conclusion. When writing an article, this translates into: one article – one hypothesis – one objective – one conclusion.

Results

This is the most important section in each work, along with the hypothesis and method. These are the sections in which those who are truly interested in a work will read more closely. It is common for newcomers to a field to pay less attention to these paragraphs when reading their first scientific works, whilst, on the other hand, they usually highlight the introduction and discussion sections with abundant colours. The results should not be understood as a "completed definition", but rather as science undergoing a construction process.

The manner of evaluating results determines the type of work being done, and must be taken into consideration during the approach to a work. Thus, the results may be:

- a. Descriptive, qualitative or observational.
- b. Quantitative.
- c. Comparative.
- d. Functional.

Verification

The main concern should be the practical feasibility of the experiment, considering not one but several alternative experimental models based on the availability of resources. After deciding and checking the approaches, these must be translated into a protocol in terms of planning, integrating observation, construction and formulation of the hypothesis and execution of the experiment. The planned protocol or approach must contain a summary of the problem, reference to prior knowledge and the question or questions, clearly expressed as objectives of the study. The next phase will be the research plan in terms of material and methods, including the technical means available and any which could be incorporated; personal resources and collaborations with other researchers or centres, benefiting from a multidisciplinary approach. The last component should be a programme correlating the various stages of the work in terms of time and space, the financial budget considered and the facilities available or requested.

Interpretation of results

This is expressed in the discussion section. Prior to this, it is necessary to conduct a quantifiable analysis of the observations of the experiment. In biomedical sciences it is not always possible to obtain an accurate measurement, so sometimes the discussion must rely on indirect assessments, such as comparison, in order to distinguish between different variables. However, quantitative data are more valid when they are classified and measured in statistical terms. This requires:

- a. Specific and clear definition of dependent and independent variables within the project.
- b. Avoiding distortion of results by other variables.
- c. Anticipation of evaluations, measurements, etc., before concluding the experiment.
- d. Allowing the mathematical calculation of the significant versus the casual.

As it can be seen, statistical analysis represents a means to obtain knowledge in cases of uncertainty, to estimate the validity of the observations introducing an appreciation of probability in each situation according to the levels of significance.

Finally, it is necessary to distinguish between evident findings, circumstantial evidence and signs or indications, in a decreasing scale of objectivity. Contrasting experimental observations and previous knowledge (discussion) will help to draw conclusions which, as required by a scientific

attitude, should be accurate, humble, objective, inherently non-definitive and, inevitably, leading to new hypotheses and questions.

As mentioned earlier, the scientific method has certain limitations. Being confined to the limits of observation, its validity depends on the validity of the initial observation and only trial and error may support it. Furthermore, the main objection is the lack of absolute certainty intrinsic to medicine, as it was designed for less complex areas of knowledge which do not have to account for the individual variability present in this field.

When writing the discussion section of a work, it is important to avoid transcribing the results. Readers are interested in the critical analysis of the work, the framework or paradigm within which they are included, understanding as such a model of resolution. Forceful assertions should be avoided, as they will be cancelled by the uncertainty principle. It is more advisable to express that results "suggest" certain conclusions. It is prudent to avoid an excessive use of possessive pronouns (although they may be used occasionally), and instead use: "the results show", etc.

Writing of a project

Certain observations or "advice" should be taken into consideration when developing and drafting a project for submission to any institution, be it a Research Foundation at a centre (research committee or clinical research ethics committee), university (doctoral committee, for example if the project is a PhD thesis, animal ethics committee or experimental practice control committee), collaborating centre or funding agency.

As a general rule, full documentation and curricula of researchers should be provided, deadlines should be met and all limits should be clearly specified, such as the hours of dedication of each researcher, as these are sometimes involved in more than one project. This is because there tends to be a relationship between the formal quality (presentation) and intrinsic quality of a project.

The background (introduction and justification) and references should be expressed briefly and directed towards the hypothesis. Moreover, "self-citations" should be avoided insofar as possible.

The assumptions and objectives of a project should be specific and expressed in clear language. The project must be evaluated and the objectives must be feasible, consistent with the background and well justified. The originality of a project and its relevance, as well as any direct or potential applications to the practical field should be clearly highlighted.

A project must have scientific interest, that is, increasing knowledge, having validity in itself, but may also have a social and healthcare interest. In other words, it may be applicable to solving a clinical problem with varying social significance. In any case, its relevance should be clearly specified.

The method must be carefully developed and described. The population and sample should be described and delimited as much as possible. The design of the experimental

or clinical model should be carefully delineated and should describe any measurements to be made, the method and validation of instruments used and the controls required in each series or measurement to ensure quality. If any pilot studies have been carried out, these should also be noted. Finally, the statistical method to be used must be reflected in the initial project as precisely as possible.

Although it does not critically affect the evaluation, the financial budget does give an indication of seriousness and viability. Any available and requested material, as well as any consumables used, should be referenced and "inventoried". Staff employed for the project (interns), as well as their workload and, eventually, the need for training and eventual cost should be referenced. Finally, travel and subsistence expenses (learning a practical skill, presentation of results, etc.) must also be included. The proportion of the last paragraph should always be "appropriate".

Another important aspect of a project is ethical standards. Studies involving patients must exercise an exquisite respect towards individuals, as well as confidentiality. This last point will be legally regulated. Any type of expected gains, directly or indirectly related to the project, should be clearly spelled out. The project must have the approval of the ethics committee of the centre where it will be conducted. Finally, a civil liability insurance policy must be obtained for studies involving patients. Animal studies should follow the legal standards published in Royal Decree RD 1201-2005, on the protection of animals used for experimental and other scientific purposes, issued by the Ministry of Agriculture, Fisheries and Food, arising from a directive of the EU Council (86/609, 24/11/86).

Work on clinical cases is the most common. We advise some of the following general guidelines to be considered:

- a. The authors should be at least two professionals. It is advisable for there to be several authors (anecdotally, works by a single author are the least cited in international literature).
- b. Specific identification of the problem to be studied.
- c. Comprehensive literature review. Do not forget classical authors.
- d. Hypothesis (one hypothesis).
- e. Objective (one or two objectives).
- f. Approach.
- g. Definition of the reference population.
- h. Definition of the sample selection.
- i. Definition of inclusion and exclusion criteria.
- j. Definition of variables to be included in the study. Literature references, when appropriate.
- k. Measuring instruments to be used. It is important to include commercial references. Do not forget semiology.
- l. Choosing the type of study. Do not call upon statistics, or otherwise do not perform statistical design *in rigor mortis*, that is, at the end of the study. This should be taken into account during the approach to the work. Otherwise, the result may require rethinking the entire work.
- m. Use subjective assessment models of patient outcomes.
- n. Prepare reports for Ethics Committees.

Notes and acknowledgements

This is not a "typical" article, but rather a contribution to the training of younger readers on the principles of research and, therefore, of scientific publication. The authors have had the inspiration and influence of their teachers; some phrases and thoughts remind of Prof. Luis Munuera, as some readers may infer, as well as Dr. Emilio Delgado Baeza, who also reviewed the manuscript and added some of his own ideas, developed during a career dedicated to research in Orthopaedics and Traumatology, and who has been the main source of inspiration for the authors.

The bibliography is not described in the text: this would be very difficult since many concepts have been simultaneously collected from various authors*. Neither does this work follow the rule of five applicable to original articles. Almost all quotes are "old", in keeping with the concepts presented and which are still applicable.

Level of evidence

Level of evidence V.

Conflict of interests

The authors have no conflict of interests to declare.

Further reading

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