

# Conducting and publishing clinical research

## *Reflexões sobre elaboração e publicação de pesquisas clínicas*

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**L**earning how to devise and conduct clinical studies can be an ambitious goal, but it is perfectly feasible. The most important step in this learning process is perhaps the initial reflection, which is the basis for planning each step of the training requirements, bearing in mind that even the great researchers have not learned overnight<sup>(1)</sup>.

Even if the ultimate goal (learning to research) is intimidating, the challenge becomes more manageable if it is taken in steps. Thus, a novice researcher must first get organised in order to set and meet his/her learning tasks, which can be further divided into mini-tasks.

Completing each mini-task is a rewarding experience, providing immediate satisfaction for a long-term task. The human brain prefers activities that are immediately rewarding, such as hunting, to long-term rewards, such as saving firewood. Therefore, we have a tendency to postpone tasks that will provide a distant benefit (for example, studying for a test) in favour of those providing instant pleasure (for example, going out with friends)<sup>(2,3)</sup>.

Thus, to achieve the ultimate goal, we suggest that training should be broken down into tasks, and these into mini-tasks that are objective and easy to perform, as follows:

1) The first task is to learn how to find articles in electronic databases, which can be subdivided into mini-tasks: finding a local library and scheduling a practical training with a librarian (main databases, keywords, search tools, etc.); searching for papers on topics related to your area of expertise; checking the bibliography of papers found in your search in order to identify recently-published, relevant studies not found in the initial search, and then determining and correcting the reasons why these articles were not found initially.

2) The next learning task would be to critically analyse the literature in order to determine which of the articles found in your electronic search are methodologically correct and therefore reliable. The mini-tasks in this case would include: reading books and texts on scientific methodology, with particular attention to chapters on systematic errors (bias); carefully reading the Methods section of papers published in scientific journals, practicing how to identify the methodological qualities of some papers and the biases of others<sup>(4)</sup>.

After completing these two tasks you will feel more confident, especially when you realise that you can now continuously update your medical knowledge through scientific publications, determining the subject of articles to be searched and discarding studies that are methodologically inadequate. Furthermore, setting smaller tasks that are easy to perform and provide immediate rewards (readily apparent benefits) while keeping the focus on your main goal helps to optimise the learning process and to make it more enjoyable.

3) The next step would be to choose a research topic. Its mini-tasks would include: choosing, within a sub-specialty of your choice, a topic that is viable to study, considering the available human and physical resources in your institution; searching databases for articles related to that topic; critically evaluating the articles you've found; looking for a gap in scientific knowledge that can be filled with a study you can conduct at your institution. Questions only arise for those who study. If your knowledge is limited, you cannot even have doubts. Thus, carefully reading scientific papers on a specific theme will certainly raise a number of issues that have not yet been explained by science; additionally, articles often suggest ideas for future studies. Not all studies aimed to find solutions to these open questions will be feasible in every institution, but some may be. The importance given to your study will depend on the relevance of the question to be answered.

At this point of the planning process it is important to approach an advisor who can gauge the relevance of the chosen topic, provide access to surgical and diagnostic devices, and, especially, supervise the subsequent tasks.

4) Finally, it is time to design the study. Determining and standardising how the data will be collected is called the study design, which should be described in the Methods section of your article. It is the strategy that will be used to conduct the study. Its sub-tasks would include: identifying the target population and extracting a representative sample; determining the exclusion criteria; considering what is the most appropriate type of study to answer the research question (prospective, retrospective, cross-sectional, observational, interventional, case-control, cohort, randomised, etc.); selecting and standardising interventions and tests to measure results. At this stage it would be useful to write the Methods section to ensure compliance with the rules for conducting the study.

By now, the team that will help conducting the research project can be formed.

After the experiment is conducted, with the help of an advisor and possibly a statistician, the data are tabulated and the article is written<sup>(5)</sup>.

We believe that the main requirements for conducting high-quality clinical studies include: 1) Involvement of

an experienced advisor and a motivated team; 2) access to patients and diagnostic and therapeutic technology, usually available in university hospitals and large clinics; 3) diligent work by the principal researcher, who should study the literature to devise and design the study, organise and delegate tasks, and overcome logistical barriers.

When it comes to publishing the article, although international journals tend to be more prestigious, the quality and visibility of Brazilian journals are progressively improving. Good quality national scientific journals allow authors to publish and disseminate articles on relevant topics using appropriate methods, even if they are only relevant to the local context<sup>(6,7)</sup>.

I had the opportunity and the pleasure to work in this area as the Editor-in-Chief of the Brazilian Journal of Ophthalmology. In order to advance the journal's mission and meet my responsibilities as Editor-in-Chief, I had to rely on my previous experience as a **researcher** (author of 83 articles published in scientific journals, with a h-index of 8 [ISI] and 10 [Scopus]; research productivity fellow [CNPQ]), **advisor** (Professor at the post-graduation programme of the Medical School of the São Paulo University [USP], with three students having defended their theses and three more students undergoing their Ph.D. studies), **supervisor** (member of the Research Ethics Committee of the USP University Hospital; CNPQ reviewer of grant applications for research projects), **reviewer** (*Journal of Cataract and Refractive Surgery*, *Journal of Refractive Surgery*, *Brazilian Archives of Ophthalmology*), and **scientific editor** (Associate Editor of the *Clinics* journal and Co-Editor of the *Brazilian Journal of Ophthalmology*).

My main activities as head of the Brazilian Journal of Ophthalmology (RBO) have included:

1) Encouraging and teaching beginning researchers to conduct high quality clinical studies by writing a series of 12 editorials teaching how to conduct the most important steps of clinical research and organising three symposia for beginning researchers in ophthalmology congresses (Congresses of the Brazilian Society of Ophthalmology in Foz do Iguaçu [2013] and Rio de Janeiro [2014] and the Congress of the Ophthalmology Society of the North-Northeast in Fortaleza [2014]).

2) Implementing a system whereby Section Editors are responsible for distributing articles for reviewers and approving them for publication. By delegating scientific functions, the Editor-in-Chief is thus in a better position to perform the initial screening of submitted articles and supervise all stages of the editing process.

3) Contributing to preparing authors by improving the design and writing of articles submitted for publication through a team of scientific reviewers trained to guide the authors of articles with good potential, teaching them how to refine their research and thus investing in improving clinical research and researchers.

4) Providing the translation of all published articles into English at no cost to the authors, thus improving the international visibility of studies and the journal itself.

5) In order to form partnerships with other national journals and optimise the process of scientific review, we organised a Fast Track system to speed up re-submissions and/or take advantage of the reviews of submissions to the *Brazilian Archives of Ophthalmology* or the *Ophthalmology in Focus* journals.

I had the opportunity and the privilege of continuing the excellent work of the editors who headed the journal before me, and I believe I have contributed to its continuing improvement.

With the knowledge I acquired coordinating the Brazilian Journal of Ophthalmology and participating in scientific editing congresses (Congress of the Brazilian Association of Scientific Editors [ABEC] and the Scielo Congress) I was able to keep in close contact with other science editors and to reflect deeply on the subject, thus taking an important step in my academic career.

My next action aimed at contributing even further to the training of beginning researchers will be the publication in 2015 of a book on Introduction to Clinical Research, a manual for young researchers in which I will have the opportunity to present my suggestions and reflections on the subject.

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