Resources for Grant Applicants

CONSORT - Consolidated Standards of Reporting Trials.
Provides detailed checklists and reporting standards for randomized controlled trials and useful to follow when designing trials.

EQUATOR Network - Enhancing the QUAlity and Transparency Of health Research.
Provides detailed checklists and reporting standards for all study types and useful to follow when designing any kind of study.

Center for Evidence-based medicine on advantages and weaknesses of various study designs.

Mini research design and methods course on the Unite for Sight website.
This is an excellent 5 module mini course covering the key issues for designing a solid research project.

BMJ – 13. Study design and choosing a statistical test.
One in a series of excellent and easy to follow stats and methods articles from the BMJ. The article on data display and summary is also indispensable for presenting results.

The STAR Data Reporting Guidelines for Clinical High Altitude Research.

NIH guidance on grant writing.
WMS uses the same criteria as the NIH in grant scoring, so this guide contains helpful information on what makes a successful grant, even if not all details apply.

The Anatomy and Art of Writing a Successful Grant Application: A Practical Step-by-Step Approach.

Fundamental Principles of Writing a Successful Grant Proposal.

Grant-Writing Advice and Sample Applications from NIH-NCCIH.

Writing a Scientific Paper Prior to the Research

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The traditional approach to preparing a research report for publication is to begin writing after the study has been completed. We propose another approach—to write a "zeroth" draft before the study is begun. This approach helps to focus the investigator's attention during the planning stage on critical aspects of the study. The discipline of writing down the rationale, the methods, and the variety of possible outcomes and their significance helps to clarify the logic on which the study is based. If these are acceptable to all authors and colleagues in the zeroth draft, it is likely that the research questions posed will be answered in a definitive way and that the final draft will be scientifically sound.

The notion of writing a paper before doing the research may raise concerns of prejudice, preconception, or even academic dishonesty. How could one possibly know what to write until after the study is completed? However, if one considers the actual content of a scientific paper or research report, it becomes clear that most of the report can be drafted before the first data are collected. The process is in many ways similar to that of preparing a formal proposal to a funding agency. Indeed, a grant application may borrow heavily from the zeroth draft of the paper, and vice versa.

The content of the zeroth draft is only the first of a series of approximations to the final form. Yet, it can be a very useful beginning. Authors often procrastinate when faced with writing up the results of completed research projects and may find it much easier to write at the beginning of a project when enthusiasm is at its peak. Most importantly, there may be no better way to prepare the mind, anticipate pitfalls, and avoid wasted time, effort, and money than to write a zeroth draft.

THE INTRODUCTION: DEFINING STUDY OBJECTIVES

Every scientific study seeks to answer a question, whether explicit or implied. A well-designed study answers specific, important questions. A poorly designed study is often the product of vague objectives from the outset. Our encouragement of specific questions is not intended to inhibit the spirit of inquiry and curiosity or discourage the scientist from thinking, "What if. . . ." Preliminary experiments in pursuit of curiosity are an important part of the investigative process—the chance to chase rabbits or take advantage of opportunity. However, after the initial feasibility studies or preliminary experiments are completed, it is most helpful to define the specific objectives or questions to be addressed by the full study that will be submitted for peer review.

Before irreversibly expending effort and resources on the planned investigation, the questions to be answered should be specified in writing. The result will contain key words with which to begin a literature search. Has the question already been answered by someone else? Is it an important question? These issues can be resolved by placing the proposed questions into the context of current knowledge reported in relevant books and journal articles. If the goal is original research, it is important to establish that the proposed study has not already been done definitively by others. One may discover that the proposed question has already been answered quite satisfactorily. If so, one may then be in a position to address the next question of importance in the area.

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We submit that the best practical test of a proposed research objective is its successful incorporation into a zeroth draft of an introduction to the final paper. A good introduction orients the reader to the question addressed by the study. The first sentences should convey the general problem addressed by the study in language that can be understood by a reader generally familiar with the field but not with the specific area of the study. Subsequent sentences should further define and limit the topic and demonstrate the need for this particular investigation. The most relevant findings of others that set the stage for the work about to be presented should be described briefly. The final sentences of a good introduction will clearly state the objective of the study—the questions to be answered, whose appropriateness and reasonableness are obvious from the background painted by the preceding paragraphs of the introduction.

Observe how these elements are skillfully blended together in the introduction by Boenning, Fleisher, and Campos, which appeared in AJEM.[1]

> Dog bites constitute a major public health problem in the United States. The Center for Disease Control (CDC) estimates that nearly one million people are bitten annually.[1] The majority of the victims are children; 40% are between the ages of 5 and 14 years.[2] Victims may comprise as many as 1% of all pediatric emergency department visits during summer months.[3]
>
> Infection is reported as a common complication following dog bites. In some studies that have included both children and adults, between 5% and 30% of wounds presenting for medical care develop infections, depending on such factors as patient age, wound type, wound location, and treatment delay.[4-6] The relatively high incidence of this complication has encouraged the use of prophylactic antibiotics. To date, no investigation in children has properly evaluated this practice or established the incidence of infection following adequate local care. Therefore, we designed a prospective controlled study with three purposes in mind, 1) to further define the epidemiology of dog bites in children; 2) to evaluate the role of antibiotic prophylaxis following dog bites; and 3) to determine whether initial wound cultures would predict subsequent infections.

Notice that the first sentence in the introduction is understandable to any reader, clearly introduces the clinical problem to be discussed, and stresses its importance. The next sentences limit the topic to children, focus on infection as the most important complication, and identify gaps in present knowledge. The final sentence lists specific objectives. Thus, in only nine sentences the authors have seized the reader's attention and focused it on the specific topic of the study. Notice that this entire introduction could have legitimately been written before the study was actually conducted.

THE METHODS SECTION: PLANNING THE EXPERIMENTAL PROTOCOL

This is the time to face the crucial details of experimental design and analysis. What animal model will be used, or what population of patients will be studied? Where will they come from? What data will be required, and how will it be collected? What equipment will be needed? Who will perform the study? How many subjects will be needed? What control groups are needed? All of these questions can be addressed by writing a detailed protocol before beginning data collection. This is the methods section of the zeroth draft. With such a written protocol in hand, one can efficiently obtain a variety of useful suggestions from colleagues by giving them copies of the introduction and methods sections of the zeroth draft and asking for their constructive criticism.

Details in the methods sections of good scientific papers are often organized by means of subheadings, a practice we strongly recommend. A subsection on "Experimental Design" can serve as an overview of the strategy of the study. Such an overview sets up the framework to which the subsequent details of the methods section can be attached. A "Subjects" subsection is almost always pertinent to biomedical studies. Complicated special techniques may deserve separate subsections, for example, "Radioimmunoassay," "Microsphere Technique," or "Electron Microscopy." A sketch of the experimental apparatus or a diagram of the sequence of treatments is often helpful at this stage to clarify thinking. Professional renditions of these may appear in the final manuscript as well. A discussion of "Data Analysis" is best placed at the end of the methods section to prepare the reader for the upcoming results section. If one has trouble writing parts of the methods section straightaway, the task is often made easier after some attention is given to hypothetical results.

THE HYPOTHETICAL RESULTS: PLANNING THE DATA ANALYSIS

During the planning stage, an excellent way to visualize the experimental design and its consequences is to plot hypothetical data. Thought experiments have a long and fruitful tradition in physical science, where exact calculations of expected outcomes can be made from theory. Although precise predictions may not be possible in the biological sciences, a thought experiment will at least help one realize exactly what kinds of data are needed to demonstrate a detectable effect of the experimental treatment.

If the results themselves will consist of images, such as electron micrographs or computed tomographic scans, then sketches of these can serve as hypothetical

results. It is especially important to anticipate the need for photographs at the beginning of a study, as the opportunity to obtain them may vanish after the study is completed. In most instances, however, the result of such a thought experiment will be sketched graphs of hypothetical data. Visualizing results in this way is helpful even if one later elects to present the data in tabular form.

From such hypothetical graphs one can easily compose the headings of the corresponding tables that must be filled in to generate the kind of results that have been sketched. Precisely typed and ruled, these blank tables become data collection sheets for the study. The sheets can be copied as necessary and help to impose discipline on the investigators to record all necessary data during the study itself.

The plotting of hypothetical data may also help clarify the correct design of the experiment. By pondering sketches or tables of hypothetical results and their possible interpretations, one can often anticipate the control groups needed to validate the conclusions. One should examine the hypothetical data and ask: If the results came out like this, would I be convinced? What additional controls would be necessary to make a truly convincing presentation? It is much better to discover these before the study is undertaken than when pondering real data months later.

Hypothetical data also provide an excellent opportunity to consider the statistical tests to be applied. What groups are comparable statistically? How will data from different subjects be combined, normalized, or averaged? Are equal numbers required in the design for each group? Would paired observations be more convincing? These dry, technical questions come alive and are easy to answer with reference to a hypothetical set of data. If one is not certain of the answers, it is an appropriate time to consult a statistician. Statisticians are most at home in the domain of hypothetical data and are most grateful to be consulted *before*, rather than after, the actual data have been collected.

THE DISCUSSION SECTION: CONSIDERING POSSIBLE OUTCOMES

A well-designed study will lead to meaningful conclusions for any reasonable outcome. One should go back to sketches of hypothetical data and consider all possible outcomes. For example, consider the results of a positive effect of treatment, a negative effect of treatment, or no effect of treatment. What would be the significance of the study in each case? What would be the conclusion and how would it relate to what is already published on the subject? Writing a brief discussion paragraph in advance for each possible outcome will help the investigator detect experimental design faults that permit no meaningful conclusions or only weak conclusions for certain outcomes. Once convinced that the results will be meaningful and important regardless of the outcome, the investigator will have no temptation to bias the data as they are obtained and can approach the investigation as a truly openminded search for the truth. If certain outcomes would be wonderful but others would be worthless or hard to interpret, it is time to consider recasting the design of the study.

Drafting the discussion section also forces the investigator to carefully read related reports of others with which the results will eventually be compared. It may become apparent, for example, that the experimental design should be modified to allow strict comparison with another study. One may learn of an important methodological detail that was missed or a variable that should have been accounted for or measured. As the investigator ponders the significance of certain outcomes, an interesting theoretical possibility that could be tested with additional measurements may come to mind. All of this intellectual preparation can be done with only preliminary or hypothetical data in hand.

THE CONCLUSION: OVERALL STUDY SIGNIFICANCE

Finally, it is necessary to face the ultimate question: So what? This question should be answered in what we call the "punchline" of the paper. The punchline is a brief statement of the results of a study and their significance. An operational definition of the punchline of a research study is one or two sentences that can be quoted in a review article or book dealing with the topic. Here are two examples of "punchlines" quoted from Yakaitis in a monograph on resuscitation[2]: "Calcium salts are not peripheral vasoconstrictors," and "Because of the early release of norepinephrine from myocardial nerve endings, bretylium has a positive inotropic effect on the myocardium, both *in vivo* and *in vitro*."

At the zeroth-draft stage one may need to write several possible punchlines, depending on each possible outcome. Some may be more exciting than others, but all punchlines that could conceivably be written as a result of research should be meaningful contributions that are quotable in a textbook or review article. The investigator may conclude that the study will likely not lead to a "quotable" conclusion. In that case one should consider redesigning the study to ensure that any reasonable outcome will be important. We submit that a study for which one may not be able to write a good punchline may not be worth doing in the first place.

SUMMARY

We propose that many potential pitfalls of a research study can be brought to light through the exercise of

writing a zeroth draft of the paper before beginning formal data collection. Further, because the zeroth draft of the paper contains the elements required in most research proposals—background, rationale, approach to data analysis, methods, and significance—it may serve as a generic grant application that can be easily recast in the style required by a specific funding agency. Moreover, the task of preparing the final report after completing the study is a shorter, less painful process if one has only to revise the zeroth draft rather than face the blank page. In these ways writing the scientific paper before gathering the data can help an investigator plan, fund, execute, and report a study that asks and answers specific and important questions.

REFERENCES

1. Boenning DA, Fleisher GR, Campos JM. Dog bites in children: Epidemiology, microbiology, and penicillin prophylactic therapy. Am J Emerg Med 1983;1:17–21.
2. Yakaitis R. The pharmacology of cardiopulmonary resuscitation. In Jacobson S. Resusitation. New York: Churchill Livingstone, 1983:69–81.