WRITING A RESEARCH PROPOSAL

*FAISAL MOEEN, BDS, MSc
**RUBINA MUMTAZ, BDS, MPH
***AYYAZ ALI KHAN, BDS, MSc, PhD

ABSTRACT

As researchers in dentistry, we have a quest to learn more, to look beyond what is written and to contribute a little to the field we plan to dedicate our lives to. For a beginner, writing a research proposal is probably one of the most challenging and arduous tasks, especially since research is a new area for the majority of Pakistani dentists. This article provides the necessary guidelines for the inexperienced potential researcher to produce a standard research protocol. It is outlined in a comprehensible, easy-to-grasp and systematic manner. Obtaining a grant for a research project generally determines the academic and administrative success of any project. Therefore the quality of a research protocol is of paramount importance for viable competition.

Despite the uphill daunting task of producing a protocol of high quality, it is nonetheless one of the most interesting and satisfying part of research. Conquering this arena opens the door to an exciting, unending world of knowledge yet to be discovered.

Key words: *Research protocol, Dentistry*

INTRODUCTION

Research in general is a quest for knowledge through diligent search, investigation or experimentation[1]. It is aimed at discovery and interpretation of new knowledge or at resolving debatable existing knowledge. It involves a systematic body of procedures and techniques for explorations targeted at obtaining new knowledge.

At the level of professional education, especially in the field of dentistry, we have a quest to learn more, to look beyond what is written and to contribute a little to the field we plan to dedicate our lives to. As a beginner, one is usually unsure of how exactly to go about research. It is also seen that academic success in health care largely depends on the quality and quantity of received grants[2]. Grant money brings prestige to the writer and his institution. However, writing a research proposal can be a challenging task especially for the inexperienced researcher. As research budgets are being reduced by many funding agencies, and more researchers are competing for it, it is becoming increasingly important to be able to write a research proposal of high quality and relevance.

The purpose of this article is to outline the main steps in producing a standard protocol for a research project. It intends to provide the necessary guidelines for the potential researcher who hopes to carry out a research project and, consequently, to maximize chances to obtain the desired funding. None ofthese ideas is our own; they are a condensation of those derived from several readily available sources.

STARTING POINT – IDENTIFY A RESEARCH IDEA

It is generally thought within the scientific community that the difference between good and poor research is the distinction between asking a good or poor

* Assistant Professor, Departments of Dental Materials and Prosthodontics, Islamic International Dental College, G-7/4, 7th Avenue, Islamabad

** Assistant Professor, Department of Community Dentistry, Islamic International Dental College, G-7/4, 7th Avenue, Islamabad

*** Professor and Dean, Islamic International Dental College, G-7/4, 7th Avenue, Islamabad

Correspondence: Dr.Faisal Moeen, Smile Works, 5B, Plot 16-G. Lower Ground, Aghaz Plaza, F-8 Markaz, Islamabad

question[3]. Good research starts with a good idea! The idea will help you define the problem that needs to be addressed and formulate a research question. A well-crafted research question can help you to design a study properly so as to arrive at a precise conclusion[3]. Subsequently, you need to ask yourself if that question is already answered[4]. A thorough literature review is therefore mandatory[5]. If you have a truly good idea, you might find out that you are not the first one having it. You do not want to spend a lot of time and energy into a project only to find out later that there have been already a substantial number of trials, quantitative studies, systemic reviews or a meta-analysis already performed and your research question is answered.

It is not only important to know how much was already published on that topic, but also what the quality of the current evidence is. Rarely in dentistry does a question have a definitive answer. If you are trying to compare two interventions for a certain condition, after performing a thorough literature search, you have to ask yourself the following questions: 1) Are there already multiple case series published on that topic? If yes, then it might not be worth it to add another case series to the literature. However, this may be your chance for the first comparative study (cohort study or randomized controlled trial). 2) Are there already multiple comparative studies? If yes, are they cohort studies or randomized controlled trials (RCT)? If there are no RCTs maybe you should do one. 3) Are there already multiple RCTs published? If yes, what are the results and what is their sample size? Maybe they were underpowered? If yes, you might consider doing a meta-analysis of the existing RCTs and, subsequently, a larger trial.

The idea that leads to your research question not only needs to be novel as mentioned above, but also needs to be feasible with the availability of adequate subjects, technical expertise, time, money and most importantly scope[6]. The idea most definitely needs to be interesting to the investigator, relevant to scientific knowledge and future research directions and last but not least, ethical.

Identifying a good research topic

The inexperienced researcher who is having problems identifying a pertinent topic needs to have a prepared mind and be alert to new ideas[7]. He or she can draw inspiration from other researchers and exploit similar ideas, rather than absolutely unique ones. Also, one can repeat or reproduce what someone else has done. For example, one can challenge the hypothesis of certain studies or confirm if the study is true for a population of a different ethnicity. A topic which has been studied on a small scale can be studied again on a larger study group or with a longer duration of follow-up[8]. A study can be conducted on the same topic sometime later, especially for efficacy of drugs[8]. For example, one can study whether an anti-microbial drug, with previously proven efficacy, is still efficacious against a particular micro-organism after a certain period of time.

Identify an area of importance in your country. The prevalence of diseases is different in different countries e.g. Pakistan has one of the highest occurrences of oral sub-mucous fibrosis. Also, for example, the need to draft a national oral health policy incorporating issues such as the need for routine check-ups, early replacement of missing teeth, basic oral hygiene, adequate sterilization procedures to avoid contraction of Hepatitis B and C and awareness regarding the consequences of consuming antibiotics and water with a high fluoride content during pregnancy etc can play a crucial role in educating the public on a national level.

Choosing a research guide

It is a good idea to do your first project under the guidance of an academic faculty member, who has prior research experience and is willing to invest adequate time for the project. Alternately, you could assist a faculty member in an ongoing research project to get "hands-on" experience.

WHAT IS A PROTOCOL AND WHAT MAKES IT IMPORTANT?

A protocol is a document that explicitly states the reasoning behind and the structure of a research project. The reasons for preparing a protocol are: [9-10]

It states the question you want to answer

It encourages you to plan the project in detail, before you start

It allows you to see the total process of your project

It acts as a guide for all personnel involved in the project

It acts as a "reminder" to you and your supervisor (or co-workers) of the initial structure and aims of the project

It enables you to monitor the progress of the project

It is necessary if you need to apply for funding and/or ethical approval

Research Protocols usually have the following components[11-12]:

Project title and investigator

Abstract

The research question

The hypothesis

Introduction (including the literature review).

The aims and objectives

Materials and methods:

i. Study design

ii. Sample size calculation

iii. Data collection

Statistical analysis

Resources required

i. Work plan

ii. Budget

References

Major funding agencies usually have their individual protocol requirements which must be strictly adhered to.

The Project title

The investigators for the project should be selected for their expertise and contributions. The project title is one of the most important features of the protocol because it attracts the attention of the potential reader[10, 13]. It is, therefore, necessary to make it as short and to the point as possible. It may need to be revised after completion of the writing of the protocol to reflect more closely the sense of the study.

Abstract or project summary

The abstract is the first page that a reviewer reads. Reviewers of granting agencies may make their opinion based on the abstract alone. It may be difficult to overcome a bad first impression and, conversely, there may be a lot to gain with a good first impression. The purpose of the abstract is to describe succinctly every key element of the proposed project. It should give a clear idea to the reader of the central question that the research is intended to answer, its significance and justification[14]. It should specify the hypotheses (if applicable) and the research objectives. In addition, the abstract should briefly describe the methods and procedures laid out in the section on methodology. Although the abstract will come first in the presentation of your application, it is best written last, after the protocol itself is written. Most application forms place restrictions on the amount of space or number of words the abstract can contain. Make sure your abstract conforms to these restrictions.

The research question

This should be described precisely and concisely. It is going to be the basis of designing the project. Define the problem in such a way that a reader can at once grasp the essence of it, e.g. “while preparing teeth to receive full coverage crowns it is generally believed that as the gingivo-occusal height of the preparation is reduced and as the total occlusal convergence or taper is increased the retention form of the preparation is proportionally diminished.” The important question here is; “is the alleged association between preparation height and taper and a loss of retention form true or false.” A well-thought-out and focused research question leads directly into your hypotheses[14]. What predictions would you make about the phenomenon you are examining? This will be the foundation of your application.

Hypothesis

The general purpose of a hypothesis is to guide scientific inquiries, and often follows directly with the question being asked or theory being tested. It provides direction to the research design and assists in the collection, analysis and interpretation of data. A hypothesis is a tentative prediction or explanation of a relationship between two or more variables and describes the results the researcher expects to obtain[15]. The hypothesis that you are trying to prove should be stated in the simplest form possible. It is general practice that hypotheses are stated in the null form, because they have their basis in inferential statistics, as a statement that expects that no relationships or differences to exist. You challenge the hypothesis of no significant difference. The result of statistical testing gives the probability that the hypothesis of no difference is true. For example, the nulls hypothesis states

that "There is no significant effect of varying tooth preparation height and taper on its retention form". The alternative hypothesis would therefore be decreasing the height and increasing the taper of a tooth preparation will reduce its retention form.

Back ground and literature review

This section is your opportunity to convince reviewers that your research is essential. In other words, the background section should be a carefully constructed and subtle argument for the fact that your research simply *must* be done. The literature review shows the reviewers that you understand your field and have the base knowledge to perform the tasks you propose. Make sure your review includes the most recent publications in the field. As a general rule, citations more than 10 years old should not be used unless they are absolutely necessary in making the case for the proposed study. A literature search should be done even before any research begins. In fact, the topic of the research is selected only after you have reviewed the literature and found some gap in it. At this stage of preparing a protocol, a more extensive and critical review of the existing knowledge about the research problem is essential. You must find out whether or not others have investigated the same or a similar problem. This is important because[16-17]

It helps further understanding the problem proposed for the research and may lead to improving the "statement of the problem".

Study variables can be better understood and their relationship conceptualized.

A research hypothesis can be formulated.

It helps in finding out what others have reported on the issue by analyzing relevant literature, including highlights of ongoing research and gaps in existing knowledge.

One would become familiar with various other methods, which could be used in the research topic. The parameters to be assessed and various end points to be observed during a study can be finalized in the protocol only after one has studied the methods of previous workers in the field.

A literature search can be done using the Internet. Some common databases are Index Medicus/MEDLINE, Web of Science, EMBASE, CAB, Cochrane, etc - these provide information and research services in areas of biomedicine, healthcare and related topics[18]. These are databases can be searched using their own interfaces such as Entrez PubMed for PubMed or even through the general search engines such as Google. One can also look through scientific journals. Sources of literature have improved drastically during the last decade. However, data obtained at the national or state levels may be needed in some epidemiological searches and these may not be available in Medline or PubMed.

Aims and objectives

Begin this section with a brief description of the overall short- and long-term goals and the importance of your research project, and then state the specific aims in terms of measurable, time-phased objectives. Numbering or bulleting each specific aim can be an effective way of "walking the reader through the proposal". Objectives/aims should be simple and not complex, specific and not vague, and stated in advance and not after the research is done[19]. After statement of the primary objective, secondary objectives may be mentioned. Investigators doing research for the first time are advised to resist the temptation to put too many objectives or over-ambitious objectives that cannot be adequately achieved by the implementation of the protocol.

Make sure your specific aims lead logically into, and are consistent with, the long-term objectives. For projects completed in two phases, indicate how the activities performed in Phase I lead directly into the activities planned for Phase II.

MATERIALS AND METHODS

How should I do a study? This question is undoubtedly uppermost on a researcher's mind. The study would be futile and lead to insignificant findings if conducted using incorrect methodology. Conversely, the research question can only be answered satisfactorily if proper study methodology is adopted. The selection of research methodology is based on certain assumptions regarding the subject matter, the nature of the phenomena under investigation, the most appropriate means of inquiry into the phenomena and the end results sought. [20]

i. Study design

The study design is the researcher's overall plan to obtain the answer(s) to the hypothesis being tested. The design spells out strategies for developing information that is accurate, objective, and meaningful, and explains the methods that will be used to collect and

analyze data[21]. Appropriateness of the research question, lack of study bias, precision of the study and power of the study to change practices are characteristics of a well-designed study. There are a number of different forms of medical research, some of which are considered to be more valid than others[22-23]. The two main types of research are experimental/intervention trials and observational trials[24]. An experimental/intervention trial is a study which intentionally administers a particular treatment, procedure or regime to determine if the intervention is beneficial. However, these types of trials are not suitable for testing all hypotheses. For instance, it would be unethical to conduct an experimental/intervention trial to determine whether a particular treatment might increase the chances of periodontitis when the patient is already suffering from the disease. Therefore, observational studies are used to investigate research questions of this type. Observational studies are designed to observe a group of people from a particular point in time and report on what happens to them.

The choice of study design whether experimental/interventional or observational is based on the proposed objectives and the availability of resources, however, you must show the reviewers that you know what you are doing and talking about by explaining why you chose the methodology you *have* chosen rather than alternative methodologies that you elected *not* to use. To the greatest extent possible, the reviewer should see your decision as one that was based on scientific merit and factors rather than on the basis of convenience or simplicity.

Once the study design has been finalized it is necessary to mention the sampling methods, including sampling frame, study settings and sample size, the criteria for inclusion or exclusion, anticipated sampling list, method of selection[25]. The investigator also needs to state the strategies and mechanisms that will be used to reduce or eliminate threats to the validity of the results, i.e. the confounding factors in the selection and assignment of subjects, the loss of cases, and the control of instruments and observers, etc.

ii. Sample Size calculation

Medical researchers primarily consult bio-statisticians for two reasons. Firstly, they want to know how many subjects should be included in their study (sample size) and how these subjects should be selected (sampling methods). Secondly, they desire to attribute a p value to their results to claim significance for the results. Both these bio-statistical issues are interrelated. If a study does not have an optimum sample size, the significance of the results in reality (true differences) may not be detected. This implies that the study would lack power to detect the significance of differences because of inadequate sample size[25]. Whatever outstanding results the study produces, if the sample size is inadequate then validity would be questioned.

There are numerous ways to calculate the sample size such as use of formulae, readymade tables, nomograms, and computer software[26-28]. We do not intend to describe the various methods as these are adequately covered in most statistical textbooks[29-30]. The sample size depends primarily on the study design and the main outcome measure of the study. However, if the sample size is too small, even the most rigorously executed study may fail to answer its research question, may fail to detect important effects or associations, or may estimate those effects or associations too imprecisely. Similarly, if the sample size is too large, the study will be more difficult and costly, and may even lead to a loss in accuracy, as it is often difficult to maintain high data quality. Hence, it is necessary to estimate the optimum sample size for each individual study[31-33].

iii. Data Collection

The investigator should write up the procedures that will be used[34-35] (population survey, in-depth interviews, non-participant observation, focus group dynamics, content analysis, etc.), how and when the procedures will be used, and the measurement instruments/tools that will be used to collect information (questionnaire, interview guide, observation recording form, guide for a focus group moderator, content analysis guide, etc.). Procedures or techniques that are standardized and/or documented in the literature should be described briefly, and bibliographic references should be given to sources where the details of these procedures and techniques can be found. You must describe in detail the procedures that will be used to control the factors that undermine the validity or reliability of the results (controls for observers or persons responsible for compiling the information, and controls for the measurement instruments).

If the use of secondary data is required, the investigator will describe their sources, content, and quality so that it will be clear that the information required for the study is available. If use is made of historical, journalistic, or other similar types of documentary

sources, an indication should be provided of the sources and techniques that will be used to collect and analyze the information. The protocol should have an annex containing the instruments that will be used (questionnaires, interview guides, moderator guides, registration forms, etc.), and it should indicate their stage of preparation.

When the research involves human subjects the known benefits and risks or disadvantages for the subjects in the study should be made clear[36-38]. When appropriate, indicate any special incentive or treatment that subjects will receive through their participation in the study. If there is any type of remuneration, specify the amount, method of delivery, time, and reason why payment is required. Incentive/participatory fees must be a modest amount to avoid ethical dilemma. Indicate how the information obtained from participants in the study will be kept confidential. List the drugs, vaccines, diagnoses, procedures, or instruments to be used, whether they are registered, unregistered, new, or currently in use in the country. Moreover, in studies where personal information will be obtained from the subjects, indicate how the information will be kept confidential. For studies involving the participation of subjects in an experiment, information should be provided on the free and informed consent of the participants and the strategy that will be used to obtain it. Gender and minority representation must be discussed, and a justification provided if adequate representation is not applicable or not possible[39]. Remember, reviewers can reject applications that do not represent all relevant groups appropriately. All reasonable steps should be taken to guarantee representation of women, children, and members of racial and ethnic minority groups.

Statistical analysis

Statistics is a mathematical science pertaining to the collection, analysis, interpretation or explanation, and presentation of data. Statistical measurements are techniques that render data meaningful and intelligible. These techniques enable researchers to reduce, summarize, organize, evaluate, interpret and communicate information collected during a research study.[30]

The basic idea of statistics is simple: you want to extrapolate from the data that you have collected to make general conclusions about the larger population from which the data sample was derived. As mentioned before, data are collected about the sample in an observational or experimental setting. The data are then subjected to statistical analysis, which serves two related purposes: description and inference. Descriptive statistics can be used to summarize the data, either numerically or graphically, to describe the sample. Basic examples of numerical descriptors include the mean and standard deviation. Graphical summarizations include various kinds of charts and graphs. Inferential statistics is used to model patterns in the data, accounting for randomness and drawing inferences about the larger population. These inferences may take the form of answers to yes/no questions (hypothesis testing), estimates of numerical characteristics (estimation), descriptions of association (correlation), or modeling of relationships (regression). Other modeling techniques include analysis of variance (ANOVA), time series, and data mining[40].

There exists an exhaustive list of statistical tests to analyze medical data[41-44]. The choice of statistical analysis is dependent on the purpose of investigation, mathematical characteristics of the variable involved, the method of data collection and the statistical assumptions made about these variables. It is generally advisable to seek guidance from experts in the area of research and a biostatistician on the methodology and the statistical interpretation of the proposed research. Valuable insight and suggestions should be critically looked upon and suitable changes made.

Resources required

Finally, you should make a precise list of all the resources that you are likely to require to successfully complete your investigation and don't assume that the reviewers will know you have all the necessary research equipment. If these resources have cost implications, you should also note the potential cost of the investigation. These two will come under the headings of 'work plan' and 'budget'

i. **Work plan**: A work plan is an outline of activities of all the phases of the research to be carried out according to an anticipated time schedule, for each phase as well as for the complete project. A time outline must be given for the phases of questionnaire preparation, pilot testing, sampling of subjects, training, logistics and data collection, data analysis and writing up of results. It might be a good idea to describe your institution here. A stronger case may need to be made for certain institutions with typically less resources and facilities, including nonprofit organizations. Reviewers need to be convinced that the institution has

extensive experience in conducting large-scale projects or has considerable expertise in the field. You may include a brief statement of the physical location or history of the organization, other kinds of contracts or grants the organization has previously had, facilities for focus groups or conferences, access to transportation for research participants, library collections, facilities or equipment for media production, and so forth.

ii. **Budget plan:** If your research has cost implications, each individual cost must be mentioned as a separate item of expenditure. It should be presented along with a justification of the expenditure relevant to your research aims and objectives. In addition, other expenditures that are often forgotten at this stage include logistics, personnel/staff, clinical/laboratory, communications and publications. Therefore the budget plan should be made after the work plan to avoid such mistakes. Generally budget plans are created in Microsoft excel document and submitted as such.

REFERENCE SYSTEM

Referencing is the standard way of acknowledging information and ideas that you have taken from other peoples' work. A proper citation or reference should provide the details necessary to easily identify a work so that your readers are able to follow up any reference of interest. References are always listed at the end of the research protocol.

Plagiarism refers to claiming someone else's ideas as your own and is considered a criminal action. Failure to reference an idea that you have found in your research, or to acknowledge the work of other team members in a team assignment falls under the category of plagiarism.[45] Therefore referencing is an extremely important aspect of your research protocol. The two most commonly used citation systems in medical writing are the Vancouver system and the Harvard system.[46]

In the Vancouver system, also known as the author-number system, references are numbered consecutively in order of appearance in the text and identified by Arabic numerals in parenthesis (1), square brackets [1], superscript[1], or a combination.[1] The references are then listed numerically at the end of the protocol.[46] The structure of a journal article citation under the Vancouver system is author's' surname/s, initials, title of article, abbreviated name of journal, year, volume, issue (if applicable) and page numbers. If there are more than six authors, the names of the first six are mentioned and followed by "et al". The structure of a book citation is author's' surname/s, initials, title of book, edition, city, country, publisher and year. If the city is internationally recognized e.g. London, then the country need not be mentioned. If chapters are authored, then the author/s of the chapter and its title is mentioned before the author/s of the book. The remaining sequence remains the same. Citation of electronic material is structured as homepage on internet, title of material with date of latest update, date of your access to this site with the full website address.[45,46]

Under the Harvard referencing system, also known as the author-date system, a brief citation (authors name and year of publication) to a source is given in parentheses within the text of an article e.g. (Khan 2004). More than one citation is listed using either "and" or "&" e.g. (Khan 2005 & Ahmed 1999). An unknown date is cited as "no date" e.g. (Khan n.d.).[46] The full citations are then listed in alphabetical order at the end. The structure of the full citation of a journal article under the Harvard system is author surname, initials, year, title of article, full name of journal, volume, issue (if applicable) and page numbers. The usage of "et al" applies after three authors. If an author published twice in a year say 2005, the first publication is referenced as 2005a and the second as 2005b, in both the text and in the full citation. Citation structure of a book is author's' surname/s, initials, edition, year of publication, city, country (if necessary) and publisher.[45,46]

The choice of referencing system depends on the funding agencies or organization you are submitting your research protocol to. They usually specify their preferred system of referencing and this should be adhered to strictly.

CONCLUSION

If your research involves human subjects, approval from the ethical review committee of your organization/college is pertinent before you submit your protocol for funding. Preparing and presenting a protocol is one of the most difficult parts of carrying out a research project. It can also be the most interesting and satisfying. The result of this process should be a short yet comprehensive document that clearly outlines your research project. If the protocol is poorly prepared and not adhered to, it is unlikely that the project will yield

the information that you hope for and in all probability the chances of selling your idea to the reviewers of a granting agency would be less.

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