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REVIEW ARTICLE

How to write a research protocol

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A research protocol is best viewed as a key to open the gates between the researcher and his/her research objectives. Each gate is defended by a gatekeeper whose role is to protect the resources and principles of a domain: the ethics committee protects participants and the underlying tenets of good practice, the postgraduate office protects institutional academic standards, the health authority protects provincial resources etc. The protocol must explicitly address the issues likely to be raised by these gatekeepers, demonstrating evidence of a clear understanding of the issues involved and that all components of the research plan have been addressed. The purpose of this paper is to add flesh to the skeleton provided in step six ('write the protocol') of the Biccard and Rodseth paper of 2014, orientated towards the first-time researcher working towards the MMed degree. Although occasional reference will be made to qualitative approaches, it is likely that the majority of these studies will be quantitative designs and these form the focus of this paper.

Keywords: MMed, protocol, protocol design, research, research design

Introduction

The introduction of compulsory research for medical specialist registration with the HPCSA has challenged those institutions that historically used the Colleges of Medicine (CMSA) examinations as a route to specialisation. Without the resources of a fully developed MMed programme (a coursework Masters with a practical research component), some departments have battled to accommodate the increased workload, especially with an inadequate number of experienced research supervisors. Students are faced with the tasks of finding a research area of interest, identifying and developing a research topic, formulating a research question into a suitable protocol, conducting the study, analysing the results and writing the paper or dissertation, against the background of the demands of clinical training, service provision, and preparation for the rigorous examinations of the CMSA.

Biccard and Rodseth examined the research process from the point of view of the novice researcher and presented a nine-step process for taking a research idea to the protocol stage,[1] and provided an invaluable guide to our students. One of the stumbling blocks in the process is the writing of a 'winning' protocol that passes through postgraduate and ethical review with minimum delay and successfully garners research funding. A well-written protocol ensures timely approval and smooth running of the research process, facilitates subsequent writing of the research report, and permits completion within the allotted time.

This paper assumes that the student has a clear idea of what interests him/her, where the knowledge gap lies (from literature review) and has framed either a research question or hypothesis, even if not fully developed (steps 1–4, Biccard and Rodseth[1]). Although requirements for protocol format vary between academic centres, we have kept largely to the structure recommended by Biccard and Rodseth, with slight modification (Table 1).

Introduction and statement of purpose

The introduction is a very brief summary of the literature review consisting of a short paragraph identifying the clinical problem, outlining the areas of equipoise and previous research approaches to them. For example:

> 'Pulmonary aspiration of acid gastric contents has been shown to be an important cause of mortality with general anaesthesia for caesarean section. Efforts to decrease the volume and acidity of gastric contents have included reduced oral intake, active pre-operative gastric emptying and the use of neutralising antacids, with varying degrees of success. One possible method of reducing the incidence of acid aspiration might be the preoperative administration of a histamine H2 receptor antagonist to reduce gastric acid secretion.'

The statement of purpose then outlines exactly *what is to be studied* in the proposed study, *how* it is to be studied, *in whom*, *where* and *when*. Although this normally develops from the subsequent background and literature review, it is a useful initial declarative statement that crystallises the nature of the study in both the reviewer's and student's mind and directs the review to relevant questions that are best addressed by the student beforehand.

For a quantitative study the format (adapted from Cresswell[2]) would be:

> 'The purpose of this … (*observational/descriptive, comparative, correlational, survival, analytical etc.*) study is to … (*explore, describe, compare etc.*) the … (*central focus, i.e. what you are actually measuring*) for/of/in … (*population sampled*) at/in/presenting to … (*location*) from/ over/ for the period … (*Dates, time period*).'

Table 1: Recommended protocol structure

Introduction and statement of purpose
Background to the study
• Clinical problem
• Literature review
• Research question
Aims and objectives
Method
a. Design
b. Setting
c. Sampling strategy: Inclusion and exclusion criteria
d. Outcome assessment and measurements
e. Data collection and statistical analysis. Follow-up.
f. Sample size, statistical power and variable selection
Methodological challenges
• Selection bias
• Loss to follow-up
Feasibility
• Recruitment
• Study team
• Participating centres
• Study funding and progress
Study organisation and ensuring data quality
• Organisation and management
• Investigator responsibilities
• Central coordination
• Ethical considerations
• Ensuring data quality
Ethical considerations
Study significance

Students use this template to create their own purpose statements. For example:

> 'The purpose of this *double blind randomised controlled* study is **to *compare*** the *pH and volume of gastric contents* **in *term parturients*** *presenting for Caesarean section receiving preoperative glopatidine compared to saline controls* **presenting to** *St Elsewhere's Hospital* **for the period** *January to July 2015.*'

The importance of this statement is that it creates boundaries in addition to providing direction. Any further statement or section of the protocol must fall within the limits of purpose; the background/ literature review must demonstrate the research problem and equipoise to which this purpose is the natural consequence. The direction from the statement naturally leads to specific objectives and thence to requisite items within the research instrument (data sheet). It also directs the investigator (and reviewer) to pertinent statistical and research ethics issues. The combination of *purpose* (represented by aims and objectives) and *direction* constitutes a 'golden thread' that binds the protocol together.

If a summary of the proposed research is requested in an institutional protocol format, grant application form, or ethical review application form, this statement is what is required. *Do not* 'cut and paste' the opening sentences of the background; this is not helpful to the reviewer.

Background and literature review

The function of the background and literature review is to encapsulate the clinical problem in such a way that the research question or hypothesis naturally emerges.

- *Clinical problem*. The background declares and explains the clinical problem and summarises existing epidemiological, socioeconomic and health systems knowledge (etc.) globally (from the world literature), and locally (from our regional literature and local audits). In the above example, the background would include evidence of a problem (for example acid aspiration syndrome) in this specific group of patients that is a known cause of morbidity or mortality globally and its relevance to local circumstances (for example as highlighted by enquiries into maternal deaths).
- *The literature review* (again starting globally and reducing to local experience, i.e. contextualisation) is a critical, objective summary of the known extent of the problem and confirms that the research question is appropriate. Reference should be made to the findings of studies performed internationally and locally to address the problem. Novel methods and those particularly suited to local circumstances should be highlighted. By the end of the review it should be clear that the researcher has a thorough understanding of the problem and why the proposed study design has been chosen, based on gaps in knowledge and conflicting results (*equipoise*).

  The protocol literature review should be brief but incisive, and there may be stipulated requirements (e.g. 500 words, and 5 references). However, investigators should develop a more extensive review, kept as a separate document and repeatedly reviewed throughout the study (up to the day of submission of the report, in which a more extensive review is required).
- *The research question (or hypothesis)* should naturally emerge from the background and literature review but must also appear as an explicit statement under a separate sub-heading at the conclusion of this section.

Aims and objectives

Confusion may arise concerning these two terms; semantically they are so close as to be virtually indistinguishable and not all centres will insist on both. However, we value the distinction as it assists in clarifying thought processes within the research design.

Aims are what you hope to achieve in your research project and objectives are the steps you need to take in order to achieve your aims.[3] Aims must directly relate to the research question or hypothesis. Objectives must relate to the aims. For example:

Research question: What are the risk factors for TB in children aged 5–7 years in Limpopo Province?

Aim: To investigate risk factors for TB associated with birthweight, socio-demographic factors and pre-school care in Limpopo Province

Objectives: To determine the relationships between:

(1) birthweight and incidence of TB in 5-year-old to 7-year-old children;
(2) day-care facility, type of caregiver and TB;
(3) socio-demographic factors and TB.