An Introduction to Research for Primary Dental Care Clinicians

Part 3: Stage 5. Writing a Protocol

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Introduction

This paper, the third in the series, will address the fifth of the ten stages of a research project suggested in the first paper. The ten suggested stages are:

1. The initial idea (asking a research question).
2. Searching the literature.
3. Refining the research question.
4. Planning the study.
5. **Writing a protocol.**
6. Obtaining ethical approval and funding.
7. Piloting the methodology and project management.
8. Collecting data.
9. Analysing the data.
10. Writing up and disseminating the results.

The previous paper[1] outlined the how to plan a research project. The next stage is to justify the necessity and feasibility of the proposed study and to write a detailed plan in the form of a research protocol. This paper outlines the structure and topics that should be covered when writing a research protocol. It updates a previous publication, *Designing a Protocol*.[2]

Stage 5. Writing a Protocol

This paper is divided into the following sections:

A. What is a protocol and why is a written protocol necessary?
B. The topics that should be covered in a protocol and its layout.
C. Suggested further reading.

A. What is a protocol and why is a written protocol necessary?

A research protocol is a detailed plan of a proposed project that provides written evidence of the need for the proposed study and its feasibility. It is the starting point for all quality research and indicates that the proposers have, as far as possible, considered all relevant points before starting the project.

Research ethics committees, research and development committees, and funding bodies will only consider an application if it is accompanied by a protocol. It allows any individual or organisation the opportunity to make a judgment about the scientific and ethical aspects of a proposed project. It also supplements any application forms that have been submitted and can be used as a resource to provide answers to questions arising from the application form.

The protocol also provides its authors with a reference point during a project as it can (and should) constantly be referred to in order to check that all stages of the project are being satisfactorily completed within the schedule.

Some organisations, such as the Department of Health and the Medical Research Council, issue specific guidelines on the contents of a protocol. Before writing, it is therefore wise to check whether the organisation to which the protocol is to be submitted has such guidelines.

Time spent in designing a protocol is time well spent and will benefit the subsequent stages of the project. Help and advice should be sought before writing it. A wide range of opinion should be canvassed from statisticians, ethics committee chairpersons and clinical colleagues.

A protocol should include justification of the need for the project and a detailed plan that sets out for the investigation:

- What is to be investigated.
- Where and when it will take place.
- Procedures and methods to be used.
- Proposed timetable.
- Resources required (technical, scientific, and financial).

B. The topics that should be covered in a protocol and its layout

The following have been suggested by the Leeds Teaching Hospitals NHS Trust Research and

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Development Department as topics that should normally be covered.[3]

- Title.
- Administrative details and a summary.
- Introduction.
- Aim.
- Statement of the problem.
- Methods.
- Analysis of data.
- Proposed schedule.
- Facilities required.
- Budget.
- Further considerations.
- References.

B1. Title

The title should explain the project. It will usually be longer than the title that will be used if any papers arising from the research are published. The names of the principal investigators and others involved in the study should be included, together with their affiliations and roles in the study. Failure to include these details at this stage has occasionally led to disputes in the past.

Example

A study of complete denture hygiene procedures employed by non-institutionalised, old-age-pensioner patients of a general dental practice in the north of Scotland. Alexander Graham-Bell, Morag Nairn and Rory G MacGregor.

A footnote would show that Alexander Graham-Bell and Morag Nairn are general dental practitioners from Inverness and that Rory G MacGregor is senior lecturer in prosthetics at Dundee University.

In addition to the title, the front page should record the identification number allocated to the protocol, version number and date when the protocol was written or last revised (the version number and date can be updated as and when amendments are made).

B2. Administrative details and a summary

The following administrative details and a summary should follow the title page:

- **Contents page** details relevant sections and subsections and lists page numbers.
- **Signature page** is signed by senior members of the research team and dated to confirm that the version concerned has been approved by them.
- **Contact details** for the research team members listing postal and e-mail addresses and telephone numbers for members of the research team.
- **A summary of the main study issues** includes the title, aims, design, treatment or other schedule, treatment or other groups and end point. A flowchart of the schedule can be added.

B3. Introduction

This should explain why the study is necessary, refer briefly to previous work relating to the problem, and put the proposed research in the context of what has gone before. It should also provide evidence that a literature search has been performed and refer to a few major and relevant studies but should not quote an extensive literature review.

Example

There are no references relating to the denture-cleaning habits of elderly Caledonians but there have been several general studies relating to patients' denture cleaning habits. Details of the key studies are given together with the justification for the study, which in this case is that in Scotland previous studies have only investigated the complete denture cleaning habits of the institutionalised elderly and not those living at home.

B4. Aim

The aim(s) and objectives of the study should be set out clearly, ideally in a single sentence (the difference between aims and objectives has been described earlier[1]). Essentially, the aim is the overall goal to be achieved and the objectives are steps to achieve the aim.

Example

Aim:

To investigate the complete denture hygiene procedures employed by non-institutionalised old age pensioners.

Objectives:

To assess the use of chemical denture cleaners in the study group.

To assess whether or not there are variations related to gender and age.

B5. Statement of the problem

This statement should provide a summary of exactly what the project is trying to achieve. It should provide a more detailed background to the problem than the brief scenario sketched out in the introduction and end with a question.

Example

Fife *et al* (1988) showed that institutionalised elderly patients were frequently unable to clean their complete dentures adequately. The proposed study will address the question of whether or not this finding is also true for the non-institutionalised elderly.

B6. Methods

Having established what the project is trying to achieve, the remaining sections should explain how it is proposed to carry out the necessary work. The methods section should:

- Detail exactly which procedures are to be used.
- Show that the proposals are possible and practical.
- Identify potential problems and suggest solutions to them.
- Detail—most importantly—the proposed methodology for data gathering and processing.

Each project will have its own particular characteristics; for example, there will be differences between the methodologies used for quantitative and qualitative studies. Virtually all will have a 'study population', and details of this population and how it is to be scientifically sampled must be defined. Laboratory methods should be described, if they are used, as should proposals for the use of questionnaires. Prior to writing a protocol, it is wise to discuss proposals for population sampling, data collection and analysis with a statistician, so that they can be justified in the protocol. In particular, the following points should be considered:

(a) **Population to be sampled** describes inclusion and exclusion criteria and how anonymity for individual subjects will be maintained.

(b) **Sample size** explains how the sample size will be calculated, the power of the sample (power calculation will be explained and described in the paper on collecting data, which will appear later on

in this series) and how subjects will be recruited.

(c) **Randomisation** should include the technique used to select subjects randomly and, when appropriate, allocate them to study groups. It should also describe any other factors that were considered and used, and any other factors that were considered during the process. If the study is double-blind, the procedure to ensure that this happens and reasons for breaking the blind (such as not withholding a new life-saving procedure or drug) should be given.

(d) **Informed written consent** should detail the process to obtain it, together with information as to how informed written consent will be obtained from minors or adults who are unable to provide it and may have legal representation.

(e) **Study procedure** describes how the study will be conducted, and if patients are required to make visits during the study, what will happen at each visit, including all examinations and tests.

(f) **Study drug supply** gives details of how drugs will be supplied, packaged and labelled. Applies infrequently to oral research.

(h) **Concurrent medication/treatment** specifies any medication(s) that should not be taken during the study. Applies infrequently to oral research.

Example

A preliminary check of patient records and dental laboratory bills has indicated that during the last year 100 edentulous patients aged over 65 years were seen in each of the six practices that have agreed to take part in this study. A preliminary consultation with a statistician indicates that a sample of 150 subjects should be adequate. Therefore, on the assumptions that not all patients will meet the inclusion criteria and that some will not wish to take part in the study, all edentulous patients who attend these practices over a four-month period will be invited to take part in the study. Those who are unable to clean their dentures because of physical disability will be excluded from the study. The nature of the study will be verbally explained to them and they will be given a patient information sheet (see appendix 1). If they agree to take part, they will give written informed consent using the form at appendix 2.

The patients will be asked about their denture-cleaning habits using the questionnaire (appendix 3). This questionnaire has been piloted on a sample of 20 volunteers. The patients' names will not appear on the questionnaires. Each questionnaire will be given a unique study number. Ethical approval for the study will be sought from the Tayside Local Ethics Committee.

The methods section would then go on to describe proposed data analysis, schedule, facilities required, budget and dissemination of results, as detailed in sections B7-B11 of this paper.

B7. Analysis of data

This section should be written following statistical advice from a statistician, and should detail the methods to be employed in analysing, interpreting and presenting the data.

B8. Proposed schedule

This should set out a timetable for the project and include details of the proposed start and finish dates, as well as the expected hours involved.

B9. Facilities required

Apart from those available in general dental practices, other facilities may well be required. All should be listed, including workspace, equipment, technical help, advisers, computing facilities and transport.

B10. Budget

It is essential to be aware of the costs prior to commencing any project, whether it is self-funded or partly or wholly funded by a private organisation or public body. The budget should be realistic and include the costs of:

- Salaries and wages.
- Purchase and/or hire of equipment.
- Consumables and transport.
- Time taken by all investigators (including dental nurses, administrators and practice staff).
- Telephone calls and photocopying.

If external funding is sought, the budget will have to be justified. If no external funding is sought, or if it is not forthcoming, those taking part in a project should be aware of its costs. If a university department is leading the project, it will almost certainly charge a university overhead to cover the cost of the use of its premises and equipment. Typically, this may be between 30% and 70% of the total budget.

B11. Further considerations

(a) Research governance requires that all research must be fully justifiable and that all those involved are safeguarded.

(b) Approval from an ethics committee will be required if humans or animals are involved in any way, even if only indirectly through the use of patient records.

(c) All research-active National Health Service (NHS) care organisations (including Primary Care Trusts) are required to have local implementation plans. This ensures that any research funded by or involving the NHS, its patients and its employees (including contractors such as general dental practitioners) is conducted within the *Research Governance Framework for Health and Social Care*.[4]

(d) It is recommended that an informal approach should be made to the chairperson and/or secretary of the relevant research ethics committee at an early stage. Furthermore, as mentioned earlier, the ethics committee will request a copy of the protocol and/or require a detailed submission, which may well have to be presented in a prescribed format. This may or may not influence the style in which a protocol is written. General managers of NHS Trusts, Primary Care Trusts and Health Boards should be able to give details of the names and telephone numbers of ethics committees' chairpersons on request. This aspect will be covered in more detail in the next paper in the current series, *Obtaining Ethics Approval and Funding*.

(e) It is also advisable to run a pilot study, as a preliminary to finalising a protocol, to check that problems have been identified. However, even a pilot study may require ethical approval.

(f) The plans for the dissemination of results once the study has been completed should

be outlined. Normally, this will involve presentations at research meetings and publications in scientific journals.

(g) Check that, where appropriate, the protocol addresses the following issues:
- Assessment of efficiency.
- Assessment of safety.
- Subject withdrawal.
- Deviations for the protocol.
- Data recording.
- Statistical considerations.
- Data and document confidentiality.
- Quality control/assurance.
- Ethical considerations.

(h) Finally, give the draft protocol to someone who has had had no involvement in or knowledge of its development and ask them if they feel that they could undertake the study using it as their blueprint.

B12. References and appendices

The protocol should end with a list of references (as appropriate) and be followed by appendices as necessary.

Typically patient information sheets and consent forms, letters from ethics committees, copies of any questionnaires (or draft questionnaires) should be attached to the protocol as appendices.

C. Suggested further reading

- O'Brien K, Wright J. How to write a protocol. J Orthod. 2002;**29**:58-61.
- World Health Organization. *Recommended Format for a Research Protocol*. Accessed (2011 Jan 6) at: www.who.int/rpc/research_ethics/format_rp/en/index.html
- Society of Radiographers. *How to Write a Research Protocol*. London: SoR; 2009. Accessed (2011 Jan 6) via: www.sor.org/public/research/research_getstarted.htm
- Petrie A, Bulman J, Osborn J. Further statistics in dentistry: Part 1: Research designs 1. Br Dent J. 2002;**193**:377-80.*

  * This paper is the first in a series of ten, which appeared in the *British Dental Journal* between October 2002 and March 2003 and has been published in book form: Petrie A, Osborn J, Bulman J. *Further Statistics in Dentistry*. London: BDJ Publications; 2002.

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References

1. Toy A, Santini A, Eaton KA. An introduction to research for primary care clinicians. Part 2: Stage 4. Planning the study. Prim Dent Care. 2011;**18**:16-40.
2. Eaton KA, Santini A. *Designing a Protocol*. London: Faculty of General Dental Practice (UK); 2007.
3. The Leeds Teaching Hospitals NHS Trust Research and Development Department. *Writing a Research Protocol. Guidance Notes for Researchers*. Version 2.0. 2005. Accessed (2010 Dec 12) at: www.leedsteachinghospitals.co/sites/research_and_development/successful.php#Protocol
4. Department of Health. *Research Governance Framework for Health and Social Care*. 2nd ed. London: DH; 2005.

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