

An Introduction to Research for Primary Dental Care Clinicians

Part 2: Stage 4. Planning the Study

Andrew Toy, Kenneth A Eaton and Ario Santini

Introduction

In the first paper in this series,¹ the ten stages in a research project (listed below) were identified and the first three were addressed. They are the initial idea (asking a research question), searching the literature and refining the question.

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 ethics approval and funding.
7. Piloting the methodology and project management.
8. Collecting data.
9. Analysing the data.
10. Writing up and disseminating the results.

This second paper addresses the tasks involved in the next stage: the study planning.

Introduction to Research in Primary Dental Care

Stage 4. Planning the Study

Having identified a clear research question, it is essential to plan and design an appropriate methodology to answer the question. The adage, ‘failing to plan is planning to fail’ is never more appropriate than in the case of a research study. This fourth stage will be discussed under three headings.

- A. Defining the parameters of a study.
- B. Planning a quantitative study.

C. Planning a qualitative study.

A. Defining the parameters of a study

To ensure the success of any study, it is important to have a clear and accurate definition of the study. The clearer the definition, the more likely it is that the study will be successful. Defining a study is a process of selection and reduction of the ideas and perspectives of those involved into a clearly defined aim and set of objectives.

A1. Aim

The aim expresses the purpose of the study.

- What is the project about in broad terms?
- Who wants it done and why?
- What is its title?

The aim of a study follows from a research question such as ‘Are dental nurses who have been trained in oral health promotion effective smoking-cessation counsellors?’. The aim of a study that sought to answer this question would be ‘To investigate the effectiveness of dental nurses who have undergone training in oral health promotion in helping patients to stop smoking’. While planning the study, it is useful to check each stage in the plan against the aim so that the methodology is focused and does not go off at a tangent.

A2. Objectives

The objectives in the example in the previous paragraph could be:

- To compare success rates in stopping smoking one year after counselling by dental nurses trained in oral health promotion with success rates achieved by other groups of smoking-cessation counsellors.
- To compare the cost of using dental nurses trained in oral health promotion as smoking cessation counsellors with those of other groups of smoking-cessation counsellors.
- To assess patients’ acceptance of dental nurses trained in oral health promotion as smoking-cessation counsellors.

A3. Targets

The objectives set targets within the overall aim. For example:

- What is it to be achieved?
- By when should it be achieved?

- Why are these targets essential to the project?

A4. Methodologies

The methodology for a research project depends on its aims and objectives and may be quantitative or qualitative. Quantitative research should be undertaken to meet the first two of the above objectives in the hypothetical study assessing the use of dental nurses as smoking-cessation counsellors. This relates to discrete variables (numbers stopped after one year and costs).

Qualitative research should be undertaken to meet the third objective because it is subjective and relates to opinion. This could be achieved by interviewing the patients. However, in the same way as pain can be assessed on a scale of from 1 to 10 with descriptors, it would be possible to produce a scale of patient acceptance. This form of psychometric test would enable quantitative assessment of the third objective.

B. Planning a quantitative study

Quantitative research is a formal, objective, systematic process that involves analysis of numerical information based on measurement that is obtained about a subject. It uses the scientific method of observation, measurement, and statistical analysis to test a hypothesis and draw conclusions. The aim is to classify characteristics, count them, and construct statistical models in an attempt to explain what is observed. All aspects of the study are carefully designed before data are collected so that the researcher knows in advance what is being investigated. Tools such as equipment or questionnaires are used to collect numerical data. The objective is to seek precise measurement and analysis of target concepts. Quantitative data are more efficient at testing hypotheses, but may miss contextual detail. The researcher tends to remain objectively separated from the subject matter.

Research designs to determine the relationship between one thing (an independent variable) and another (a dependent or outcome variable) in a population can be either experimental or descriptive (Table 1).

Table 1: The differences between experimental and descriptive studies	
Experimental study	Descriptive study
Measurements before and after intervention	Measurements made only once
Establishes causality	Establishes only correlations between variables
May need only tens of subjects especially when a crossover design (see below) is adopted. The estimate of the relationship is less likely to be biased with a high participation rate in a sample selected randomly from a population	Requires a very large sample size to establish a precise estimate of the relationship between variables
Bias is less likely if subjects are randomly assigned to treatments, and if subjects and researchers are blind to (unaware of) the identity of the treatments	No attempt is made to change behaviour or conditions. Measurements are made to describe the current condition

B1. Experimental studies

The first stage in an experimental study is to define a hypothesis. A hypothesis is a statement that attempts either to explain why certain events occur or to predict what will happen in the future. A good hypothesis makes a specific prediction that can be measured. The hypothesis, which is usually stated as a 'null hypothesis', makes it possible to use statistical tests to analyse the data that have been collected and to assess the probability of the results. In the example quoted above, the null hypothesis (ie the hypothesis that you are trying to disprove) would be 'Training in oral health promotion does not make dental nurses any more effective as smoking-cessation counsellors'.

Experimental studies are also known as longitudinal or repeated-measures or interventions for reasons that are obvious from the above.

Time series study. One or more measurements is/are taken from all subjects before and after a treatment. Time series studies can have multiple participants or, in so-called single subject design, multiple measurements are taken before and after an intervention on only one or a few subjects.

Crossover design. A major problem in any type of time series study is that changes could be due to factors other than the treatment. Subjects might do better on the second test because of their experience of the first test, or they might change aspects of their living conditions between tests, which could influence their subsequent performance. A solution to this problem is found in the crossover design in which subjects are given two treatments, one being the real treatment, the other a control or reference treatment. Half the subjects receive the real treatment first, the other half the control first. After a period of time sufficient to allow any treatment effect to wash out, the treatments are crossed over. Any effect of retesting or anything that happened between the tests can then be excluded by an appropriate analysis. Multiple crossover designs involving several treatments are also possible.

Control group studies. In these studies, which are very common in the medical sciences, all subjects are measured, but only those in the experimental group then receive the treatment. All subjects are then measured again, and the change in the experimental group is compared with the change in the control group. If the subjects are assigned randomly to experimental and control groups or treatments, the design is known as a randomised controlled trial. Random assignment minimises the chance that either group is not typical of the population.

Blind trials. If the subjects are blind to (unaware of) the identity of the treatment, the design is a single-blind controlled trial. The control or reference treatment in such a study is called a placebo: the name that physicians use for inactive pills or treatments that are given to patients in the guise of effective treatments. Blinding of subjects eliminates the placebo effect, whereby people react differently to a treatment if they think it is in some way special. In a double-blind study, the researcher also does not know which treatment the subjects receive until all measurements are taken. Blinding of the researcher is important to stop him or her treating subjects in one group differently from those in another. In the best studies, even the data are analysed blind, to prevent conscious or unconscious fudging or prejudiced interpretation.

Ethical considerations (which will be the subject of a subsequent paper) may prevent experiments from being performed, especially if one group is denied a drug that may be beneficial.

B2. Descriptive studies

Descriptive studies are also called observational, because the subjects are observed without any other intervention. The simplest descriptive study is a case study, which reports data on only one subject. Descriptive studies of a few cases are called case series. In crosssectional studies, variables of interest in a sample of subjects are assayed once and the relationships between them are determined.

In prospective or cohort studies, some variables are assayed at the start of a study (eg toothbrushing habits, gingivitis, and probing pocket depth [PPD]) then, after a period of time, the outcomes are determined (eg reduction in gingival bleeding scores and PPD). Casecontrol studies compare cases (subjects with a particular attribute or condition) with controls (subjects without the condition) and comparison is made of the exposure to something suspected of causing the condition. Case-control studies are also called retrospective because the subjects' history of exposure or other characteristics, or both, prior to onset of the disease, is recorded through interview and sometimes by means of records and other sources. Subjects with the disease or condition under study (cases) are compared to a group consisting of individuals without the disease. Their past history is recorded in the same way as for the cases. The purpose of the control group is to provide an estimate of the frequency and amount of exposure in subjects in the population without the disease being studied. Whereas the cohort study is concerned with frequency of disease in exposed and nonexposed individuals, the case-control study is concerned with the frequency and amount of exposure in subjects with a specific disease (cases) and people without the disease (controls).

B3. Some specific considerations

Deciding which variables to measure

The example of a study of dental nurses and smoking cessation might include such variables (anything that is measured) as:

- The age of the nurses, how long since they started dental nursing, how many patients they counselled during the period of the study.
- The age of the patients, how long the patients had smoked, etc.

Variables may be dependent, independent, or confounding.

- The length of time that a patient had smoked would be independent.
- The ability of a patient to stop smoking would be dependent.
- When there is more than one independent variable influencing a dependent variable, it is always possible that the second independent variable may vary the effect of the first independent variable on the dependent variable. It is then called a confounding variable.

It is essential to select variables that can be measured.

Inclusion and exclusion criteria

The population that is studied limits the extent to which the results of a study can be generalised. Thus if 12-year-old children are examined in an epidemiological study only at one school, their caries prevalence is only valid for that school and not for the town or country. In other words, the results of a study are only valid for the setting (population) that was studied.

It is important to define the population that is to be studied. This is done by defining those who should be included and those who should be excluded. For example, in a mouthwash study, inclusion criteria could be all dentate adult patients aged 18-65 years who attended a dental practice in a two-week period. These inclusion criteria could then be limited by exclusion criteria that could modify the effect of the mouthwash, such as 'have taken antibiotics during the previous three months', 'pregnant', 'smoker', etc. In the example of the dental nurses and smoking cessation, inclusion criteria could be 'all patients counselled over a one-year period' and exclusion criteria could be 'those who did not return for follow-up after a further one year'.

Sampling

It is essential to select a representative sample of sufficient size, and advice should be sought from a statistician. Details of how to sample and how to calculate sample sizes will be given in a later paper in this series that will deal with all aspects of data collection.

Recruitment

A number of ethical issues are associated with the recruitment of participants into a study. All participants must:

- Be given full details in writing of the study into which they are being recruited.
- Give their consent to take part in writing.
- Be free to withdraw from a study at any time.
- Be old enough and intellectually able to give informed consent (if they are not, then informed consent must be obtained from a parent or designated carer).²

If the study concerned involves more than one visit, it is essential to motivate study participants to remain in a study. This may be easier in a dental practice setting than in a hospital or university.

Blinding

It is important to conceal the allocation of treatment in a clinical trial so that the participants are unaware whether they are receiving an active medication or a placebo. This can be relatively easy when pills or potions are being tested but in some dental circumstances, such as the placement of restorative materials, it is impossible because the materials used may look

very different. As described previously, when only the participant is unaware of which treatment he or she is receiving, the study is single-blinded. If both the participant and the clinician/person making the assessment are unaware, the study is referred to as doubleblinded. This consideration needs to be taken into account when planning a study.

Assessment and measurement

It is essential to consider exactly what to assess and measure, how to assess and measure, and how to ensure accuracy and repeatability in assessment and measurement. For example, in a mouthwash study it would be usual to assess plaque and gingivitis, together with other variables such as taste and any side-effects such as staining. The 'how to' would involve the use of any of a number of indices and possibly digital photographs. If traditional indices were used, the assessors would need to train in calibration exercises to apply them consistently, both as individuals (intra-examiner) and within the group of examiners (inter-examiner).

Bias

It is always possible that both researchers and participants in a study can inadvertently be influenced during a study such that they do not record measurements as accurately as they might (researchers) or exhibit selective memory when giving a history (participants). Such bias can skew the results. Bias may creep in at any stage of a research project.³ It is therefore important to bear this in mind throughout a study and to think about how this might occur when the study is being planned.

Risks and hazards

It is important to try to anticipate any problems or hazards that might arise during a study. These could be as mundane as chronic transport problems (traffic jams, transport strikes) that prevent patients from attending for recalls to more serious ones such as adverse reactions to materials and medications.

Data entry and storage

This topic will be covered in a later paper in the series. It will include:

- Designing suitable data collection forms.
- Inputting data to spreadsheets and data banks.
- Analysis, storage and security of data.

The protocol (study plan)

Having considered all the above factors, it should now be possible to write a study plan (better known as a protocol), which lists, describes and documents all aspects of the study. The next paper will explain in detail how to write a protocol. This protocol will evolve and will probably need some amendments after the methodology has been piloted.

C. Planning a qualitative study

Qualitative research involves analysis of data such as words (eg from interviews), pictures (eg video) or objects for exploring complex issues and obtaining insights into them.³ Information for assessing behaviour and attitudes⁴ is frequently gathered by interviews and from focus groups. This may be used to explore new topics and to identify specific issues for subsequent investigation using quantitative techniques.⁵ The aim is a complete, detailed description. The design often emerges as the study unfolds and data are collected. The researcher is the data gathering instrument and interpretation of events is important because the researcher tends to become subjectively immersed in the subject matter.

Qualitative research can be very time-consuming and requires the researcher to possess sufficient interviewing skills and an understanding of the philosophical basis of the methodology. Like the research subjects (those being interviewed or observed), researchers will inevitably carry their own biases and opinions into the research process. This could have a significant effect on the way that the research is conducted. For instance, it would be very easy for untrained or unethical qualitative researchers to conduct the research and find the results that they are looking for, rather than what is actually happening.

To mitigate this, it is imperative that qualitative researchers are trained to assume a non-judgemental interviewing style, and have sufficient emotional intelligence to be aware of their own biases and opinions. These should be recorded before, during, and after the research process and form part of the research report. Consequently, it is not unusual to employ a trained research assistant to gather the data in a research project, with the lead research dental practitioner being involved at the planning and data-analysis phase.

The overall purpose of qualitative research is to gather data on people's opinions and practices and the relationships between individuals and/or social groups. As well as gathering data on 'what' they think or do, it is important to gather data on 'why'. These data can be gathered by a variety of techniques such as interviews, documentary research, observation and questionnaires.

C1. Interviews

Interviews may be carried out either with focus groups or one-to-one in depth. In both cases, the interviewer (who is invariably the researcher) should have a list of predefined questions or discussion points that are put to the group or individual. This is to ensure that the data-gathering session remains focused on the matter under investigation. However, there is also some flexibility, allowing the interviewer to explore new and unexpected areas of enquiry that may arise from the interview.

The interview or discussion is generally audio recorded and analysed later, and may be supplemented by notes taken by the interviewer. It is good practice to write up the session within 24 hours of completion to ensure that the memory is fresh. These notes are then checked with the interviewee to confirm that their opinions have been accurately recorded. Transcriptions must conform to the Data Protection Act 1998.⁶

C2. Sampling

Sampling for qualitative studies is very different to that used in quantitative studies. Several techniques are available.⁷ A very common one is purposive sampling, in which participants are chosen because of their age, gender, ethnicity or other demographic characteristics, attitudes, behaviours and experience.

Sample sizes are invariably smaller but the information obtained from each participant is much richer and of greater depth. After each interview, comments are grouped into themes for further analysis. After a number of interviews, it is frequently apparent that the same comments and themes are emerging when new participants are interviewed. When virtually no new comments or themes emerge, theme saturation has been reached and it is of little value to continue with more interviews.

C3. Observation and documentary evidence

Data gathered from observation enables the researcher to confirm that a practitioner is actually doing what he or she reports doing. Documentary evidence from reports, audits or meetings can also provide confirmation (or not) that the opinions expressed adequately describe the reality under study. Such sources help to 'triangulate' the opinions gathered from interviews or focus groups and allow the researcher to add weight to opinions that have been expressed.

D. Questionnaires

Finally, a brief mention of questionnaires, which can be used in both quantitative and qualitative studies. A questionnaire can be a very time efficient way of collecting a large number of opinions. Indeed, for many in the medical world, questionnaires are deemed to be the only form of qualitative research. It is essential not to underestimate the skill required to compile a questionnaire. They are of little value unless the researcher asks the right questions in the right way to the right audience and knows how to interpret responses. It is helpful to base a questionnaire on an analysis of themes derived from an initial round of interviews or observations and it is important to pilot it to ensure that readers interpret the questions in the way that the researchers intend.

Conclusions

This paper has provided a brief introduction to planning a research study and has identified the wide range of factors that should be considered. Some of these factors will be explored in greater depth in subsequent papers in the series. The next paper (part 3) we explain how to describe the points outlined in this paper in a written study plan (a research protocol).

References

1. Farbey R, Eaton KA, Santini A. An introduction to research for primary care clinicians Part 1: The first three stages in a research project. *Prim Dent Care*. 2010;17:168-72.

2. Department of Health. Research Governance Framework for Health and Social Care. 2nd ed. London: DH; 2005.
3. Bowling A. Research Methods in Health: Investigating Health and Health Services. Buckingham: Open University Press; 2002.
4. Greenhalgh T. How to Read a Paper: The Basics of Evidence-Based Medicine. 3rd ed. Oxford: Blackwell; 2006.
5. Williams AC, Bower EJ, Newton JT. Research in primary dental care Part 3: Designing your study. Br Dent J. 2004;196:669-74.
6. Data Protection Act 1998. London: HMSO; 1998.
7. Silverman D. Qualitative research in health care. Assessing quality in qualitative research. BMJ. 2000;320:50-2.

A Toy MMedSci, BDS, MFGDP(UK). General Dental Practitioner, Loughborough, Leicestershire, UK.

KA Eaton DHC, PhD, MSc, BDS, FFGDP(UK), MGDS, FFPH, FHEA. Editor, Primary Dental Care; National Research Facilitator, Faculty of General Dental Practice (UK);

Visiting Professor, Eastman UCL and King's College London Dental Institutes; Honorary Professor, University of Kent, UK.

A Santini PhD, DDS, BDS, FFGDP(UK), DGDP(UK), DipFMed, FADM. Chair of Research, FGDP(UK); Director Research, Edinburgh Postgraduate Dental Institute,

University of Edinburgh; Visiting Professor, University of Belgrade, Serbia; Honorary Professor, University of Sassari, Italy.

