Designing Clinical Research Studies: Part I

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In laying the groundwork for "Demystifying Nursing Research" we examined the importance of defining the problem to be studied (Colling, 2003a) and the vital aspects of the literature review (Colling, 2003b). The third major step of the research process is selecting and describing the research design in detail. It is the overall plan for the study. Using the travel analogy as we have previously in describing the research process, just as there are a number of routes and methods of travel to reach a destination, there are a number of research design strategies which can be employed to answer the research question you have posed. Table 1 and Figure 1 provide a summary of the most common research designs which are useful to examine research questions in nursing.

The decisions you make about design provide the specific directions to guide you successfully through the study and to maximize the possibilities of achieving accurate information in the results. This two-part article will present a series of design issues and components which are common to many clinical studies. It is not possible within the scope of this article to cover all aspects of research designs; however, the reference material will direct you to further detail. In addition, a glossary of commonly used research terms is included. Design issues for the setting of the study will be discussed in Part 1. Part 2 (December 2003) will entail sample size issues and other considerations needed to complete a research proposal.

Research Question/Problem Statement: Quantitative and Qualitative Designs

Your research question or problem statement is the primary guide for the design of the study. A clearly stated research question/statement, refined through a thorough literature review, will aid in design decisions. Begin the design section by writing an overview. (This is also the place to state your theoretical or conceptual framework, if you are using one, but don't get bogged down in its construction.) Essentially the overview is an extension of your research question. The overview states how, where, and whom you are going to study and also how you will evaluate (measure) the study question(s). For example, a study question is: Do patients with fibromyalgia who have urge incontinence show similar improvement with drug and exercise treatment as other patients with urge incontinence? An example of an overview statement is:

> To determine if fibromyalgia patients with urge incontinence (UI) improve similarly to other patients with UI, Caucasian post-menopausal women will be recruited from physician practices, newspaper ads, and fibromyalgia support groups to participate in a 16-week treatment program consisting of Ditropan® and daily Kegel exercises. Potential subjects will be screened for inclusion using standardized instruments and progress will be evaluated at baseline, 8 and 16 weeks using 24-hour pad weights, biofeedback EMG measurements, the Symptom Check-List Instrument, and the UI Satisfaction Measure.

Now you are ready to state specific research questions or hypotheses such as: Is the improvement in leakage volume in patients with fibromyalgia significantly correlated with leakage volume improvement in patients without fibromyalgia? For the study overview stated above, several specific research questions would be written. Stating them clearly provides the direction needed to later analyze findings to determine if the original research question has been answered.

A study may be exploratory in nature such as: What factors influence compliance or noncompliance with self-catheterization? While this question could be answered using a structured interview guide which would make it a descriptive study, the study question could also be approached using unstructured interviews with patients over a period of time to learn to evaluate their self-catheterization experience. This type of study is *qualitative* while the fibromyalgia example is a *quantitative* study (see Glossary). The design of qualitative studies is not specified in advance as it is in quantitative research; instead the design tends to evolve over time during the study. Thus, decisions about the best way(s) to gather data, how to schedule and record data, and how many subjects will be used in the study are all

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Table 1.
Quantitative Research Designs

Design Type	Definition	Major Characteristics
Description or Exploratory	Provides information about a person, place, or thing.	1. Only one sample at one point in time. 2. No manipulation of variable(s). 3. Used to answer "what" questions. 4. Describes frequency of occurrence.
Comparative Description	Type of descriptive design that examines differences between two or more groups.	1. No manipulation of variables. 2. Answers "what" questions. 3. Can use descriptive and inferential statistics in analysis.
Case Study	Descriptive design that intensively studies single case or small number of subjects.	1. Sometimes used in qualitative research. 2. Examines large number of variables that may affect a particular situation. 3. Answers "what" questions.
Correlational or Ex Post Facto	Examines relationships among variables; can be descriptive, predictive, or test theory relationships.	1. No manipulation of variables. 2. No control over independent or dependent variables. 3. Used to collect large amount of information about small number of variables. 4. Answers "what" questions.
Quasi-Experimental	Examines why certain effects occur.	1. Answers "why" questions. 2. Independent variable is manipulated. 3. Lacks randomization of groups. 4. Sample and setting are controlled.
Experimental/Clinical Trial	Examines causes of certain effects.	1. Answers "why" questions. 2. Independent variable is manipulated. 3. Groups randomized. 4. Sample and setting are controlled.

decisions made during the study. This has been called an *emergent* design — one that becomes clear during the study as the researcher makes decisions about what he/she has learned.

It may seem easier to choose a qualitative study. However, qualitative studies, if done properly, have scientific rigor equal to quantitative studies. Thus, do not be lulled into thinking that qualitative research is easy!

Considerable advance planning is necessary to conduct a successful project. If this type of research appeals to you and if your study question has received little exploration in the literature, consult specific references on qualitative research or/and find a mentor who can guide you through your study.

Finally, research is not value free; that is, the background and biases of the researcher have an influence on study outcomes. In quantitative studies, the researcher strives to control as much bias as possible through design decisions. But, because qualitative studies involve researchers directly and personally, and the design emerges during the study, the biases of the researcher must be carefully examined before the study begins. Understanding what biases influence you in making certain design decisions can be useful in the data analysis phase of your study.

Setting

The setting is more than a passive place to collect data. It is an important consideration when planning your study, because the setting and the dynamics within the setting can greatly influence

Figure 1.
Outline for Research/Study Proposal

1. *Title of study.* Make it short but clear.
2. *State the problem to be studied.* This can either be in a question or a statement. Begin by saying, "The purpose of this study is to..." Say it in one sentence. Follow this sentence by one or two others describing the study in greater detail. Say, "Specifically, this study will identify, measure, describe..." Use action verbs and list each variable to be measured.
3. *Give a brief review of the literature.* If you have funding agency limits on the length of this review, be clear and give a summary of the most important studies to support the *need* for you to do your study. If there has been a recent review article, this is gold, because someone else has gone to a lot effort to summarize the literature. This should not be a substitute for examining the most important articles yourself. Much can be learned from the literature review, which will help make your own study better. *Emphasize why getting an answer to your study question is important for nursing practice.*
4. *Theoretical framework.* If you have one, state what it is, but don't construct one unless your funding agency demands it.
5. *Describe the design of the study.* State the overall study plan:
   a. Setting and sample.
   b. Intervention (if applicable). Describe protocol of intervention.
   c. Describe what you are using to measure or evaluate your study question(s) in detail (if you have done a pilot test, describe it here).
   d. Describe the procedures you will use to gather the data you will need. For example, "The investigator will interview each subject using a guided interview sheet."
   e. Describe the way in which data will be evaluated (usually using statistics such as mean, median, Chi-square, etc.).
   f. Present a timeline for key steps in the process. For instance, subject recruitment – 3 weeks.
6. Provide a short but detailed budget.
7. Briefly state your qualifications for doing the study.

the outcomes. Settings can be *natural* — no attempt to control any aspect of the setting; *partially controlled* — modified in some way which strengthens your research design; and *highly controlled* — usually a laboratory setting such as when animal research is conducted. Many nursing research studies use quasi-natural settings such as hospitals, clinics, or other care facilities, but it is important to ensure access to the settings that you plan to use. Obtain letters of assurance or support from facilities to ensure cooperation for your study.

It is not necessary to describe how you will approach individual subjects at this stage as that is usually described in a later *procedures* section. But subject inclusion and exclusion criteria should be listed next. You must obtain a person's permission to be included in the study. Each study participant must read and sign a *consent to participate letter* which gives full disclosure of the nature of the research, and benefits and possible adverse consequences for participation. This can be appended at the end of your proposal (see Figure 2).

Figure 2.
What Should Go into an Informed Consent Letter

Letter to Prospective Subjects

1. Describe what you are going to do in the study and why it is important to nursing.
2. Describe potential risks and benefits to potential subjects.
3. Describe procedures for minimizing or eliminating risks to potential subjects.
4. Describe how you will maintain the privacy and confidentiality of subjects.
5. If warranted, state that you will provide for medical treatment for any adverse effects from the intervention.
6. Discuss why risks are reasonable given the potential for patient benefits as well as for increasing knowledge about the particular subject/topic.

Summary

Research study design requires careful planning and key decisions. While these steps may seem tedious, they will save time and perhaps aggravation later. In addition, if you plan to seek funding for the study, you must provide a detailed description of how you plan to conduct it. Part 2 of study design (December 2003) will include how to determine the number of subjects, how to select measures for the variables, and what should be included in the procedures and the plan for data analysis sections. ◙

References

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Additional Readings

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Glossary

Attrition – loss of participants during the course of a study for any reason such as voluntary withdrawal from the study or illness, death.

Beneficence – an ethical principle of research which seeks to prevent harm or exploitation of subjects.

Case study – an influence within the study that distorts the study outcomes.

Chi-square test – a statistical test to test the significance between two variables.

Clinical research – studies which are designed to increase knowledge for nursing practice.

Concept – a name given an abstraction of an observed behavior or characteristic (fatigue, jaundice, etc.).

Conceptual or theoretical framework – interrelated concepts used together in some manner to explain phenomena.

Consent form – a written agreement between the researcher and the subject about the terms of what the subject voluntarily has agreed to do within the study.

Control – holding constant possible influences on the dependent variable in the study.

Convenience sampling – selecting the most available persons or units for inclusion in the study.

Correlational research – studies which explore relationships between or among variables which do not involve an active intervention by the researcher.

Data – pieces of information gathered in the study.

Dependent variable – a variable that is expected to depend or be caused by another variable in the study. The outcome variable of interest in an experimental study.

Descriptive statistics – statistical ways of summarizing and describing data such as mean, median, mode, and standard deviation.

Effect size – a statistical expression of the magnitude of the relationship between two variables.

Experimental research – a study where the investigator manipulates one of the variables and randomly assigns subjects to different conditions (the experimental group or the control group).

External validity – the generalizability of the study of other settings or groups which are not in the study.

Findings – the results of the study analysis.

Hawthorne effect – the effect on the dependent variable caused by the subject's awareness that they are being studied.

Independent variable – the variable that is believed to cause or influence the dependent variable. In experimental research, this is the variable that is manipulated.

Informed consent – a written process of informing subjects what the study is about to gain their voluntary participation.

Instrument – technique or device used to collect data (questionnaire, observation sheets, machines, etc.).

Internal validity – the degree to which the independent variable is truly due to the experimental treatment and not to extraneous factors.

Intervention – the variable the researcher manipulates in experimental research.

Literature review – critical examination and summary of relevant research and other literature on the topic for further investigation.

Manipulation – an intervention or treatment such as an educational program or new drug which the investigator introduces in an experimental or quasi-experimental study. Also called the independent variable.

Mean – a control tendency descriptive statistic. It is computed by summing all the scores and dividing by the number of subjects or units.

Median – a central tendency descriptive statistic. It is the exact middle score; that is, 50% or the scores are above the median and 50% are below.

Methods – the steps for gathering and analyzing data in a study.

Mode – a central tendency descriptive statistic. It is a score or value that occurs most often in a set of scores or values.

Nominal measure – lowest level of classification of a characteristic (1 = female; 2 = males).

Operational definitions – defining a concept so that it can be measured in a study (hypertension: a systolic reading 140 and above and a diastolic reading of 90 and above as taken by the Derry Dell BP cuff).

Participant observation – a method of collecting data in which the investigator is a member of the group or organization which he/she is studying.

Pilot study – a trial run using a small sample done prior to undertaking a major study.

Population – the entire universe of persons or units which have common characteristics (for example, all SUNA members).

Power – the ability of a research design to show existing relationships among study variables.

Power analysis – a mathematical procedure for determining sample size requirements for a study.

Problem statement or question – identifies key variables, the population to be studied, and may say how the variables are to be measured.

Proposal – a written document stating in detail what is proposed to be studied, the significance of the problem, how the problem is to be addressed in the study, the analysis plan, and often how much the study will cost.

Qualitative data – non-numerical information collected in a study such as that from interviewing a subject.

Quantitative data – numerical information collected in a study.

Quasi-experimental study – random assignment is not possible for subjects, but the investigator manipulated the independent variable.

Randomization – subjects assigned to experimental or control groups by a method of chance alone. Uses a table of random numbers.

Random assignment – sample selection in which each person in a population has an equal chance of being selected for a study.

Relationship – a connection between two or more variables.

Results – answers to the research questions posed in the study.

Sample – a subset of the entire population to be studied.

Self-report – any means of collecting data involving the direct report of the person being studied. Usually interview or questionnaire.

Statistic – the calculation of a sample's characteristic(s) which is obtained from gathered data.

Subject – an individual who provides data for a study.

Theory – a constructed abstraction or statement that gives an explanation about relationships among phenomena.

Treatment – the condition or variable being manipulated in an experimental or quasi-experimental study.

Validity – the degree to which an instrument measures what it is intended to measure.

Variable – an attribute or characteristic of an individual or object that has different values within a population (for example, blood pressure, age, weight).