Research Methodolgy

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A Successful Research proposal

- **A successful research proposal convince the reviewers that:**
- **The proposal address an important issue.**
- **Your proposed experimental plan will answer many of those questions in an efficient and convincing way.**
- **You know the literature in the field.**

A Successful Research Proposal

- **You have access to subjects/equipments to execute in your study.**
- **You will analyze the data in a thoughtful and honest manner.**

Standards of Proposals

- **Title Page**
- **Abstract**
- **Background and significance**
  - **Introduction: (Statement of the Problem, Purpose of Research or Goals, and Significance of Research)**
  - **Literature Review**
- **Project Narrative (Methods, Procedures, Objectives, Outcomes or Deliverables, Evaluation, and Dissemination)**
- **Personnel**
- **Budget and Budget Justification (if applicable)**

Literature Review
The importance of the study for a population

- **Researchers need to emphasis the population that will likely benefit from the results of this study.**

The Purpose Statement

- **Why you want to do the study and what you intent to accomplish. Should be stated clearly.**

The Purpose Statement

- **You should start with the proposed variables for the study:**
- **Independent variables: cause, influence,. (*age, sex, treatment*).**
- **Dependent variable: this is the outcomes or results of the influence of the independent variable (*ex: survival rate*, *mortality rate, pain intensity*).**
- **Control variables: factors that may confound the relationship between dependent and independent variables.**

Example

OBJECTIVE: The aim of this study was to estimate the prevalence and severity of dental caries in the primary dentition of young children in Ajman, UAE, and investigate its association with sociodemographic characteristics and use of dental services. (*Hashim et al, 2006*)

Why Do I Need to Know About Different Methods?

- **As a future practitioner…**
  - **To be able to intelligently participate in research projects, evaluations, and studies undertaken by your institution.**
- **As an educated person...**
  - **To understand the difference between scientifically acquired knowledge and other kinds of information.**

What's the Difference Between "Method" and "Methodology"?

Method:

- **Techniques for gathering evidence**
- **The various ways of proceeding in gathering information**

Methodology:

- **The underlying theory and analysis of how research does or should proceed, often influenced by discipline**

A Review of different research methods

- Case reports
- Cross sectional studies
- Case-control studies
- Cohort studies
- Randomized Clinical trials

Methods
What's The Question?

What is the study hypothesis?

A hypotheses are predictions the researcher holds about the relationship among variables. A hypotheses usually used when comparing groups.

Methods

- **<u>Directional Hypothesis</u>: Women who have mastectomy have poorer QoL than those who have lumpectomy**
- **<u>Non directional hypothesis</u>: Quality of life of women who have mastectomy is different than those who have lumpectomy.**

Methods

- What's the outcome?
- What's the intervention?
- When and for how long?
- For whom?
- How many participants are needed?
- How can we optimize potential benefit (and what we learn) while minimizing potential harm?

Methods
Answering the Question

- **Response variable selection and measurement**
- **Defining the intervention, if any.**
- **Study design (cross sectional, cohort, case-control, randomized clinical trial)**
- **Eligibility criteria (who qualifies to be in your study)**
- **Sample size estimate**
- **Patient management procedures**
- **Monitoring for safety and benefit**
- **Data analysis approaches**

Methods
Response Variable Selection

- **This could be :**
- **a clinical outcome**
- **Patient based-outcome**

Methods
Response Variable Criteria

- **Well defined (i.e. how will you measure it, patient satisfaction, quality of life)**
- **Stable (instrument used before)**
- **Reproducible**
- **Unbiased**
- **Ascertainable in all participants**
- **Adequately address study hypothesis**

Methods

Study Design

The study design should be appropriate to the study question

- **Cross sectional (survey)**
- **Case control (participants are selected based on disease status)**
- **Cohort (participants are selected based on exposure status)**
- **Randomized clinical trial**

Methods
Study Population

Subset of the general population determined by the <u>eligibility criteria</u>

General population

Eligibility criteria

Study population

Enrollment

Study sample

Observed

Methods
Study population

- **Why was the population selected?**

<u>Consider:</u>

External validity

Feasibility

Potential selection bias

Representative of population

Methods
Eligibility Criteria

- State in advance
- Consider
  - Potential for effect of intervention
  - Ability to detect that effect
  - Safety
  - Ability for true informed consent
  - Access

Methods
Sample Size (1)

- Need enough participants to answer the question
- Should not enroll more than needed to answer the question (especially in RCT)
- Sample size is an estimate, using guidelines and assumptions

Methods

Data Collection

- What are the items to be collected?
- How will they be collected?
- How will instruments be validated?

Methods
Regular Follow-up

- **Routine Procedures (report forms)**
  - **Interviews**
  - **Examinations**
  - **Laboratory Tests**
- **Adverse Event Detection/Reporting**
- **Quality Assurance**

Methods

Ethical Considerations

- **All patients must consent to participate in your study.**
- **Obtain ethical approvals.**

Methods
Informed Consent Checklist

- **A statement that the study involves research**
- **An explanation of the purpose of the research**
- **The expected duration of the subject's participation**
- **A description of the procedures to followed.**

Methods
Informed Consent Checklist

- **Identification of any procedures which are experimental.**
- **A description of any foreseeable risks or discomforts to the subjects.**
- **A description of any benefit to subjects or others.**
- **A disclosure of appropriate alternative procedures or course of treatment, if any.**
- **Confidentiality.**
- **Possible compensations**
- **An explanation of whom to contact for answers to questions.**
- **A statement that participation is voluntary.**

Example

The aim of this study was to estimate the prevalence and severity of dental caries in the primary dentition of young children in Ajman, UAE, and investigate its association with sociodemographic characteristics and use of dental services. METHODS: A cluster-sampling approach was used to randomly select children aged 5 or 6 years who were enrolled in public or private schools. Clinical examinations for caries were conducted by a single examiner using World Health Organization criteria. Parents completed questionnaires seeking information on socioeconomic background and dental service utilization. (*Hashim et al, 2006*)

Another Example

- **The purpose of this study was to evaluate periodontal health in young patients with type 1 diabetes mellitus in Serbia. METHODS: Periodontal disease was clinically assessed and compared in 187 children and adolescents (6 to 18 years of age) with type 1 diabetes mellitus and 178 control subjects without diabetes. RESULTS: Children and adolescents with type 1 diabetes mellitus had significantly more plaque, gingival inflammation, and periodontal destruction than control subjects. *(Dakovic, 2008*)**