All About Conducting Research in Five Easy Lessons

Sandra K. Burge, Ph.D.
Professor
Dept Family & Community Medicine
UT Health Science Center
at San Antonio
Five Easy Lessons

1. The Research Question
2. Measurement
3. Bias
4. Sampling
5. Research Design
1. The Research Question
What is the Purpose of Research?

So What?
What is the Purpose of Research?

- To understand "universal laws of nature" 
- AKA "theory"

- More specifically, to systematically answer a question about the relationship between two things.
Research Asks: What Is The Relationship Between Two Things?
Research Question

Are caries outcomes related to variations in tooth surfaces?

- Thing 1: caries
- Thing 2: tooth surfaces

Research Question

- Do dental restoration materials affect children’s growth over 5 years?
  - Thing 1: dental restoration materials
  - Thing 2: children’s growth

Research Question

- Are restorative treatment decisions influenced by caries risk?
  - Thing 1: treatment decisions
  - Thing 2: caries risk

Kakudate N. et al. Restorative Treatment Thresholds for Proximal Caries in Dental PBRN. JDR 2012 vol. 91 no. 12 1202-1208
Research Question

- Is tooth eruption in infants associated with illness symptoms (fevers)?
  - Thing 1: tooth eruption
  - Thing 2: illness symptoms

Research Question

- Also describes a population under study.
Research Question

- Are caries outcomes related to variations in tooth surfaces in a national sample (NHANES)?
  - Thing 1: caries
  - Thing 2: tooth surfaces
  - Population: national sample

Research Question

- Do dental restoration materials affect growth over 5 years in children age 6 to 10 at baseline?
  - Thing 1: dental restoration materials
  - Thing 2: children’s growth
  - Population: children age 6 to 10

Research Question

- Are restorative treatment decisions of Japanese dentists influenced by caries risk?
  - Thing 1: treatment decisions
  - Thing 2: caries risk
  - Population: Japanese dentists

Kakudate N. et al. *Restorative Treatment Thresholds for Proximal Caries in Dental PBRN.* *JDR* 2012 vol. 91 no. 12 1202-1208
Research Question

- Is tooth eruption in infants associated with illness symptoms (fevers)?
  - Thing 1: tooth eruption
  - Thing 2: illness symptoms
  - Population: Infants

Predictors and Outcomes

Predictor: Tooth Surfaces
Outcome: Caries

Independent Variable: Tooth Surfaces
Dependent Variable: Caries
Research Question

Are caries outcomes related to variations in tooth surfaces?

Research Question

- Do dental restoration materials affect children’s growth over 5 years?

Research Question

Are restorative treatment decisions influenced by caries risk?

Kakudate N. et al. *Restorative Treatment Thresholds for Proximal Caries in Dental PBRN*. *JDR* 2012 vol. 91 no. 12 1202-1208
Characteristics of a Good Research Question

- F.I.N.E.R.
  - Feasible
  - Interesting
  - Novel
  - Ethical
  - Relevant
Summary – Research Question

- All studies begin with *curiosity*…
- expressed as a research question which…
  - addresses the relationships between two or more phenomena;
  - Suggests predictors, outcomes, and relevant populations;
  - meets the FINER criteria.
2. Measurement
Measurement = Definition
In research design, “measurement” is the method of defining or assigning numbers to the concepts under study.

Measurement moves the research question from abstract concepts to concrete data.

It organizes data collection to be analysis-friendly.
From the Abstract to the Concrete

Abstract

Concrete

Numerical

Concept-Construct

Operationalization

Variable (Measurement)
We begin with researchable concepts

- Caries
- Gingivitis
- Pain
- Growth
- Anxiety
- Restorative Treatments
- Cultural background
Next, we operationalize the concepts

<table>
<thead>
<tr>
<th>Concept</th>
<th>Operational Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caries</td>
<td># carious tooth surfaces</td>
</tr>
<tr>
<td>Gingivitis</td>
<td>Bleeding gums</td>
</tr>
<tr>
<td>Pain</td>
<td>10-point self report</td>
</tr>
<tr>
<td>Growth</td>
<td>Change in %-ile on growth curve</td>
</tr>
<tr>
<td>Restorative</td>
<td>Composite vs. amalgam</td>
</tr>
<tr>
<td>Treatments</td>
<td>Hispanic versus other</td>
</tr>
</tbody>
</table>
Finally, we assign *numbers* to each concept
- Now called *variables*.

Variables are even more particular than *operational definitions*.

Variables are mathematical representations of research concepts.
From the Abstract to the Concrete

- Abstract
  - Concrete
    - Numerical
- Concept-Construct
  - Operationalization
    - Variable (Measurement)
Variable Scales

- Continuous Scales

- Categorical Scales
  - Nominal Scales
  - Ordinal Scales
Variable Scales

How do you “scale” a concept?
Consider – is it…?
- Present or absent? (a diagnosis)
- A lot or a little? (carious surfaces)
- More or less hazardous? (pain severity)
- More or less pleasant? (patient satisfaction)
- Group membership? (gender, ethnicity, etc.)
Continuous Scales

- Continuous Scales
  - Represented by “real numbers” or “integers”
  - The numbers have a specific meaning – and their fractions or multiples have meanings, too

Examples

- # carious tooth surfaces
- Change in percentile on growth curve
- Blood Pressure
Categorical Scales

- **Nominal Scales**
  - The variable has named categories
  - “Names” or “Definitions,” not numbers
  - Numeric values make no sense whatsoever

- **Examples**
  - *Composite versus amalgam*
  - *Male versus female*
  - *Anglo or African-American or Mexican-American*
  - *Gingivitis: present or absent*
Categorical Scales

- Ordinal Scales
  - The *sequence* of categories is meaningful – it is “ordered”
  - We assign numbers to that value
  - But the intervals between those numbers, fractions, and multiples are not meaningful

- Examples
  - *Pain:* None – some – moderate – high – severe
  - *Often:* Often – sometimes – rarely – never
  - *Poor:* Poor – fair – good – very good – excellent
### Desirable Qualities of a Scale

<table>
<thead>
<tr>
<th>Quality</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reliable</td>
<td><strong>Consistent, Precise</strong>&lt;br&gt;Gives the same value with repeated use.</td>
</tr>
<tr>
<td>Valid</td>
<td><strong>Accurate, True</strong>&lt;br&gt;It represents what it is supposed to represent.</td>
</tr>
<tr>
<td>Sensitive</td>
<td><strong>Subjects with the quality can be identified by the instrument. (rule in)</strong></td>
</tr>
<tr>
<td>Specific</td>
<td><strong>Subjects without the quality can be identified by the instrument. (rule out)</strong></td>
</tr>
<tr>
<td>Adequate Distribution</td>
<td><strong>Variation in responses is good, statistically.</strong></td>
</tr>
<tr>
<td>Objective</td>
<td><strong>Not prone to subject or investigator bias.</strong></td>
</tr>
</tbody>
</table>
Summary - Measurement

- Abstract > Concrete > Numerical
- Concept > Operationalization > Variable
- Variable scales can be:
  - Continuous
  - Categorical
  - Ordinal
- Variable quality is measured by:
  - Reliability, Validity
  - Sensitivity, Specificity
3. BIAS IN RESEARCH
Bias

- Anything that produces systematic (but unexpected) variation in a research finding.
BIAS

Interdental Brush Intervention

- Placebo Effect
- Maturation
- Measurement

Reduce Bleeding Gums

Investigator

Sampling

Publication
Types of Bias

- Investigators have identified enormous lists of biases!
- Bias affects...
  - Study validity
  - Generalizability
  - Measurement
  - Statistical conclusions
BIAS Affecting Study Validity

- Alternative explanations
- Confounding
- History – stuff happens
- Maturation – subjects change anyway
- Testing – subjects improve
- Subjects’ bias + / -
BIAS Affecting Generalizability

- Sample selection
  - Subjects self-select
  - Investigators cherry-pick
- Attrition
- Unique setting
BIAS Affecting Measurement

- Subject error
- Instrument error
- Observer error
- Investigator bias
- Inconsistency in treatments
BIAS Affecting Statistical Conclusions

- Low statistical power
- Violated assumption of statistical tests
- Fishing
- Random irrelevancies in setting
- Random heterogeneity of subjects
Controlling Bias

- Careful sampling
  - Random selection
  - Large-enough sample
  - Persistent followup

- Comparison Groups
  - Similar to Experimental Group

- No fishing!
  - State your hypotheses before starting.
Controlling Bias

- **Blinding**
  - Blind subjects and clinicians to Tx

- **Consistency**
  - In measuring concepts
  - In delivering interventions

- **Accounting for alternative causes**
  - Measure and analyze it
  - Exclude subjects with the condition (cause)
Summary - Bias

- Many forces are at work when you conduct research!
- And they may affect...
  - Study validity
  - Generalizability
  - Measurement
  - Statistical conclusions
4. SAMPLING
What is a sample?

Sample:

A subset of people who are studied to gain information about a larger population.
What is “random sampling”? 

Random Sampling: 

- *The method of drawing a portion (or sample) of the population such that each member of the population has an equal chance of being selected.*
Why is random sampling important in research?
Type I and Type II error

Research goal: to know true relationships between predictors and outcomes

<table>
<thead>
<tr>
<th>Sample:</th>
<th>Population: $T_1 \rightarrow T_2$</th>
<th>Population: $T_1 \nrightarrow T_2$</th>
</tr>
</thead>
<tbody>
<tr>
<td>$T_1 \rightarrow T_2$</td>
<td>POWER! 1 - $\beta$</td>
<td>Type I error $\alpha$</td>
</tr>
<tr>
<td>$T_1 \nrightarrow T_2$</td>
<td>Type II error $\beta$</td>
<td>1 - $\alpha$</td>
</tr>
</tbody>
</table>
Sampling Strategies

- Probability Sampling
  - Simple random sampling
  - Systematic sampling
  - Stratified sampling
  - Cluster sampling
- Nonprobability Sampling
What is “probability sampling?”

Probability sampling:

- Refers to methods that use random techniques to select samples.
Types of probability sampling

Simple random sampling

- Each member of the study population has an equal chance of being selected.
Types of probability sampling

Systematic sampling

- Given a list of the population,
  - randomly choose a starting place,
  - randomly choose an interval to sample.
Types of probability sampling

Stratified sampling:

- Identify “strata” in the population
- Select a simple random sample from each stratum

Examples of strata:

- Anglo/Hispanic
- Male/Female
- Old/Young
- With Gingivitis/ Without Gingivitis
Types of probability sampling

- Cluster sampling:
  - Identify clusters in the population
  - Select clusters at random
  - Include every member in the cluster
What is “nonprobability sampling?”

Non probability sampling:

- Refers to methods that do not use random techniques to select samples
Types of nonprobability sampling

- Convenience sampling
- Quota sampling
- Purposive sampling
- Snowball sampling
Other Sampling Considerations

- Appropriate comparison group
- Inclusion criteria
- Exclusion criteria
- Generalizability
Summary: Sampling Strategies

- **Probability Sampling**
  - Simple random sampling
  - Systematic sampling
  - Stratified sampling
  - Cluster sampling
  - Multistage sampling

- **Nonprobability**
  - Quota sampling
  - Convenience sampling
  - Purposive sampling
  - Snowball sampling
5. Research Design
What is the Purpose of Research Design?

- To systematically answer questions…
- While controlling bias…
- And ruling out alternative explanations.
Bias

Interdental Brush Intervention

Reduce Bleeding Gums

Placebo Effect
Maturation
Measurement

Investigator
Sampling
Publication
Alternative Explanations

Interdental Brush Intervention

- Reduce Bleeding Gums
- Dietary Changes
- Oral Rinses
- Vitamin C
- Chewing Gum
- Lower Stress
Design Decisions

- Balance these issues:
  - Rule out alternative explanations
  - Control bias
  - Control costs
  - Ensure feasibility
  - Be ethical
  - Enhance generalizability
Design Features

- Retrospective vs. Prospective
- Observational vs. Interventions
Retrospective vs. Prospective

- **Retrospective:**
  - Use existing records or information

- **Prospective:**
  - Generate new information
Retrospective vs. Prospective

- Retrospective:
  - Examine children’s dental and health records to find evidence of growth curve changes over 5 years and dental interventions.

- Prospective:
  - Identify children with caries and randomly assign them to receive composite or amalgam materials for tooth repair. Follow them for five years.
Advantages
- Less expensive
- Data is more accessible
- Some data not available otherwise
- Dropout rates not a problem

Disadvantages
- Critical data may be absent
- Some biases are hard to rule out
- Measurement is limited
Prospective Designs

- **Advantages**
  - Measurement of data is consistent with study goals.
  - Easier to control bias.
  - Easier to show causation.

- **Disadvantages**
  - You are dependent on subject cooperation.
  - Some prospective designs are unethical.
  - Following subjects is staff-intensive, and very expensive.

The risk factors for dental caries do not necessarily exert their effects uniformly across all tooth surfaces. We identified 5 distinct groups of tooth surfaces that differ with respect to caries. *We examined these clusters in a national dataset (NHANES 1999-2000, N = 3,123).* Caries outcomes were defined as the number of carious tooth surfaces within each cluster. Some cluster-based caries outcomes were associated with potential risk factors such as age, sex, educational attainment, and toothbrushing habits. These results suggest permanent dentition can be subdivided into groups of tooth surfaces that are useful for understanding the factors influencing cariogenesis.
Prospective Design

**Comparing the Interdental Brush to Dental Floss**

Many people find dental floss difficult to use and do not floss daily to maintain oral health. The interdental brush may be easier to use, motivating people to use it daily. The purpose of this study is to determine if the interdental brush is just as effective at removing plaque and reducing bleeding gums as dental floss. Study subjects will be 32 healthy adults with bleeding gums. They will use the dental floss or the interdental brush for 12 weeks. Plaque and bleeding scores will be measured before the study begins (week 0), midway (week 6), and at the end of the 12 weeks. All study subjects receive a teeth cleaning prior to the first measurements.
Observation vs. Intervention

Observation

- Descriptive
- Analytic
  - Cross Sectional
  - Case Control
  - Cohort

Intervention

- Pretest-Posttest
- Experimental vs. control
- Experimental vs. Placebo
- Crossover
Observation vs. Intervention

Observation
- Descriptive
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  - Case Control
  - Cohort

Intervention
- Pretest-Posttest
- Experimental vs. control
- Experimental vs. Placebo
- Crossover
Observational Designs

- The investigator *does not* intervene.
- The investigator *does not* alter events or situations under study
- Study can be prospective or retrospective
Observational Designs

- Descriptive Studies
  - Generally a “one-pass” collection of data
  - Examines one key phenomenon
  - Does not examine correlations
  - Useful for prevalence studies

- Example:
  
  Examine and describe tooth surface-level caries data in 1,068 Appalachian adults, grouping subjects into 5 clusters (types).
Cross-Sectional Studies

- Generally a “one-pass” collection of data
- Correlates a predictor & outcome
- Demonstrates association, not causation

Example:

Japanese dentists were shown radiographic images of interproximal caries and asked to indicate the lesion depth at which they would surgically intervene in both high- and low-caries risk scenarios.

Thing 1 = treatment decision; Thing 2 = caries risk
Observational Designs

- Case-Control Studies
  - Retrospective Design
  - Identify “cases”
    - Presence of a specific outcome/problem
  - Select “controls”
    - Absence of the outcome/problem
    - Match on other demographic or clinical characteristics
  - Good choice for studying rare problems
Case-Control Studies: Example

Dental amalgams containing mercury have recently been suggested as a possible risk factor for multiple sclerosis (MS). In a case-control study, we interviewed a total of 143 MS patients (cases) and 128 controls, to obtain information on socio-demographic characteristics and the number of dental amalgams and the time since installation based on dentists' records. Neither the number nor the duration of exposure to amalgams supported an increased risk of MS, even after adjusting for age, sex, smoking, and education.

Cohort Studies

- Investigator follows groups of subjects over time
- Prospective
- Not suited to...
  - disorders of low prevalence
  - long latency periods between cause & effect
Many symptoms are attributed to teething in infants. We investigated relationships between tooth eruption, fever, and teething symptoms. **In a prospective cohort study**, we enrolled 21 children 6 to 24 months old attending suburban day care centers and **followed them for 7 months**. **Measures.** 1) Daily recording of tooth eruption, temperature, and other symptoms. **Results.** Child temperatures were similar on toothdays (5 days preceding eruption) and non-toothdays (28 days away from eruption) (temp: 36.21 vs 36.18). Parent-reported loose stools were significantly associated with tooth eruption. All parents retrospectively reported that their children had teething symptoms. **Conclusions.** This study did not confirm the expected associations between tooth eruption and teething symptoms in children.

Observation vs. Intervention

**Observation**
- Descriptive
  - Cross Sectional
- Analytic
  - Case Control
  - Cohort

**Intervention**
- Pretest-Posttest
- Experimental vs. control
- Experimental vs. Placebo
- Crossover
Intervention Designs

- Investigator intentionally does something “to” the subject or alters a situation
- Prospective
- Analytic
Intervention Designs

- Pre/Post Intervention studies
- Experimental versus Control
- Experimental versus Placebo
- Crossover
Intervention Designs

- Pre/Post Intervention Study

Time marches on...

Pretest → Use Interdental Brush → Post-test
Intervention Designs

- Experimental versus Control

Time marches on...

Tx Group Pretest → Use Interdental Brush → Tx Group Post-test

Control Group Pretest → Do nothing → Control Group Post-test
Intervention Designs

- Experimental versus Comparison

Time marches on...

- Tx Group Pretest
  - Use Interdental Brush
  - Tx Group Post-test

- Control Group Pretest
  - Use Dental Floss
  - Control Group Post-test
Intervention Designs

Experimental versus Placebo

Time marches on...

- Tx Group Pretest
- Use Interdental Brush
- Tx Group Post-test

- Control Group Pretest
- Use (Ineffective) Device
- Control Group Post-test
Crossover Design

Time marches on...

Group 1
Pretest

Brush

Group 1
Mid-test

Placebo

Group 1
Post-test

Group 2
Pretest

Placebo

Group 2
Mid-test

Brush

Group 2
Post-test