Methods

The Methods section of a proposal will provide readers with an overview of whom you are studying and the statistical methods you will use to answer the question or test the hypothesis posed in the problem to be addressed.

Study designs and reasons for choosing a particular design

- Observational
  - Cross-sectional
  - Case-control
  - Cohort (retrospective or prospective)

Proposal Abstract Methods Section

In one paragraph, present the information that best describes your study in terms of:

- Study design
- Population
- Variables to be examined
  - Outcome(s)
  - Exposures (or Interventions)
  - Covariates
- Statistical analysis

Study Designs and Choices

- Experimental
- Clinical trial
- Community intervention trial
Whom do you plan to study?

- Population
  - From what population were subjects recruited or selected—target (AKA source or reference) or accessible population?
  - Were the subjects obtained consecutively, by random sampling, or as volunteers?
  - When were the participants enrolled in the study?

What are you measuring?

- Outcomes
- Exposure
- Covariates (Confounders, effect modifiers, or mediator variables)

As a review...

- Measurement can be:
  - Continuous
  - Discrete
  - Categorical
    - Two values—dichotomous
    - More than two values
      - Nominal—Unordered
      - Ordinal—Ordered

Outcome

- How was the information to define the outcome collected?
- How was the outcome measured?
- How will you define the outcome?
- Will you have to do any recoding?
- If defined as categorical, how many levels does the outcome variable have?

Exposure(s)

- How was the information to define the exposure(s) collected?
- How were the exposure(s) measured?
- How will you define the exposure(s)?
- How many levels do your categorical exposure variables have?
- Will you recode?
  - Collapse categories
  - Set cutpoints for continuous variables
  - Develop an index or scoring system for combined exposures
Covariates

- Why might the covariate be a - Confounder?
  - Effect modifier?
  - Mediator?
- How is the covariate defined?
- Is the covariate associated with the exposure?
- Can the covariate cause the outcome?
- Does the exposure/outcome relationship vary with levels of the covariate?
- Can the exposure cause the covariate?

Statistical Analysis

- Descriptive
  - Continuous
  - Categorical
- Bivariate analyses
- Multivariable approaches
- Any additional information

Nature of your Outcome: Continuous

- Normal?
  - Yes
    - One Group
      - Mean (SD)
    - Two Groups
      - t-Test
      - Mann-Whitney or Wilcoxon
    - 3+ Groups
      - ANOVA-One-way or Repeated
      - Kruskal-Wallis
  - No
    - Median
    - Range
    - t-Test Unpaired or paired

Problem to be addressed:

In 3-5 sentences state the research question. Make sure you include information about the study regarding person, time and place. For example, to investigate the association between smoking and cancer the study would include smoking status, smoking habit, and cancer. Please list any other approved among master's students in the Department of Epidemiology, MPhil, Fall 2002.

Background and significance:

In one paragraph, define the problem, why it is important, what is known about it, what gaps in knowledge your study is intended to fill, why it is innovative and how it will contribute to public health. In other words, DELL YOUR IDEA.

Hypotheses:

Your hypotheses (at least one, no more than three) should be closely related to the research question. If you have more than one hypothesis, they should be independent from one another. Make sure you include the direction of the association or effect you expect to observe (i.e., increase, decrease or no change). For example, taking the master's thesis course will be associated with a decrease in time to approval of master's thesis proposal for all Epidemiology master's students during the Fall 2002. This decrease will be independent of students having a dataset.

Methods:

In one paragraph present the information that best describes your study design (i.e., observational, experimental), population (i.e., sample) (i.e., the criterion of the population, characteristics of the population in term of age, sex and smoking are defined exclusion criteria and exclusion criteria), outcomes to be examined and their characteristic risks, exposure(s), and statistical analysis (i.e., descriptive i.e., mean, frequencies, proportions, etc.), bivariate (i.e., Chi-square, correlation, etc.) and multivariable analysis approach (i.e., logistic, linear, Cox, Pearson). BE BRIEF BUT CLEAR AND SPECIFIC.
Statistical Analysis
- Descriptive
  - Categorical
- Bivariate analysis

Nature of your Outcome: Categorical
- Survival time?
  - Yes
    - Kaplan-Meier
    - Log-Rank
    - Cox Proportional Hazards
  - No
    - Proportion Frequency
    - Chi-Square
    - McNemar’s

Bringing it all together: Outcome and Exposure
- Two Variables
  - Both continuous
    - Correlation
    - Linear Regression
  - One continuous-
    - One dichotomous
    - ANOVA
    - Linear Regression
    - Logistic Regression
    - Cox Proportional Regression
  - Both dichotomous
    - Chi-Square Logistic Regression
    - Cox Proportional Hazards
    - Survival Analysis

Any additional information
- Test for interaction
- Test for trend
Example

- To examine the association between head trauma and seizures and epilepsy before and after controlling for age, gender, family history, physical and mental health, alcohol, drug
- Hypothesis:
  - Head trauma increase the probability of head trauma and seizures and epilepsy after controlling for all covariates
  - This association will depend on age, with younger people having a stronger association

Example...

- Individuals seeking medical care in Iceland over a 4 years period
  - Cross-sectional
  - Cohort
  - Case-control
    - Matched
    - Unmatched

Back to our Example

- To examine the association between head trauma and seizures and epilepsy before and after controlling for age, gender, family history, physical and mental health, alcohol, drug
- Hypothesis:
  - Head trauma increase the probability of head trauma and seizures and epilepsy after controlling for all covariates
  - This association will depend on age, with younger people having a stronger association

Example...

- Outcome: Febrile seizures, other provoked seizures and epilepsy
  - Binary (yes/no)
- Exposure: Head trauma
  - Binary
  - Number of trauma

Example...

- Covariates:
  - Age-Continuous and categorical
  - Gender-Categorical
  - Family history-Categorical
  - Physical and mental health-Summary score
  - Alcohol-Categorical
  - Drug-Categorical

Statistical Analysis

- Descriptive
  - Continuous- t-tests, ANOVA
  - Categorical- Chi-square tests
- Bivariate analysis
  - Continuous-continuous/categorical- r
  - Categorical-categorical-OR, RR
Statistical Analysis

- Multivariable approaches
  - Continuous-continuous/categorical: Linear regression
  - Categorical-categorical/continuous: Logistic regression/Cox Proportional Regression

- Any additional information

Then...

- The population for this study represents a random sample of individuals 16 to 28 years of age seeking medical care in 4 clinics during 1992 and 1996 in Iceland. The outcome for this study will be defined as the first diagnosed seizure, febrile or due to other causes, after a head trauma. Individuals seeking care for a head trauma will be considered as exposed and those seeking care for other traumas not involving the head as unexposed. Age, gender, family history, self-rated physical and mental health, alcohol and drug consumption will be included as covariates.

Then...

- Descriptive statistics will be presented for all covariates by the outcome and the exposure status. t-, ANOVA, and chi-square tests will be used to assess significant differences between groups. In addition, Pearson and Spearman correlation coefficients will be used to determine the association between the outcome and all other covariates included in the analyses. Logistic regression will be used to assess the strength of the association between seizures and head trauma before and after controlling for all covariates in the analysis. An interaction term between head trauma and age will be tested to determine whether the association between head trauma and seizures varies with age.