## Organizing Your Approach to a Data Analysis

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- I. Before looking at the data
  - A. Identify overall goal of the study
  - B. Identify specific aims and how they relate to overall goal
    - 1. Identify the current state of scientific knowledge
    - 2. Identify the competing hypotheses that the study is designed to discriminate between
    - 3. (Often dictated by available data)
  - C. Refine scientific hypotheses into statistical hypotheses
    - 1. Identify type of question
      - a. Prediction, estimation, or testing
      - b. Identifying groups, quantifying distributions, or comparing distributions
    - 2. Where appropriate, specify statistical hypotheses in terms of a summary measure for the distribution of measurements
      - a. e.g., mean, median, proportion above a threshold, event rate
  - D. Consider design of ideal experiment
    - 1. Ignore practical, ethical limitations in order to be able to later compare how close the actual situation is to the ideal
      - a. Who/what would be the sampling units
      - b. What would be the intervention
      - c. How would subjects be assigned to the intervention
      - d. What would be the variables measured
  - E. Available data
    - 1. Sampling scheme
      - a. Retrospective vs prospective
      - b. Observational vs intervention
      - c. Inclusion, exclusion criteria
    - 2. Variables in the data set
      - a. Names
      - b. Relationship to real world quantities
      - c. Conditions under which they were measured
      - d. Units of measurement (limitations)
        - e.g., qualitative vs quantitative, continuous vs discrete, patterns of missing data
    - 3. Categorization of variables according to use in analysis
      - a. Response (outcome) variables
      - b. Predictor variable of interest (variable identifying groups)

- c. Variables identifying subgroups to explore effect modification
- d. Potential confounders
  - Association with response variable (in truth)
  - Association with predictor of interest (in the sample)
  - Not in causal pathway of interest
- e. Variables which allow increased precision
  - Variables predictive of response, but not associated with predictor of interest
  - Questions about effects within such groups can be answered with more precision than questions about effects in the larger population (e.g., adjusting for age)
- f. Surrogates for response
  - Variables in the causal pathway of interest
  - Variables measuring a later effect of the response
- g. Irrelevant
- II. Univariate descriptive statistics

#### A. Goals

- 1. Identify errors in the data
  - a. Particularly unusual measurements (out of range)
  - b. Unusual combinations of measurements
- 2. Verify your understanding of the measurements
- 3. Identify patterns of missing data
- 4. Identify exact population used in study (Materials and Methods)
- 5. Identify aspects of the data that may present technical statistical issues
  - a. Ideal: allows easiest, most precise statistical inference with smaller sample sizes
    - equal information about all groups being investigated (? equal sample sizes)
    - measurements of response within each group distributed symmetrically with no 'long tails' (outliers)
    - no missing data
  - b. Potential problems suggesting possibility of problematic scientific interpretation (problems which can not necessarily be solved with the available data)
    - missing data patterns
  - c. Potential problems suggesting less generalizable statistical analysis (problems not necessarily indicated by the measures of statistical confidence)
    - 'Outliers' in distribution of grouping variables (predictors): i.e., low sample sizes in some groups that are far away from the rest of the data (e.g., trying to determine an age effect in a sample in which most are between 10 and 20 years old, but one subject is 80)
  - d. Potential technical problems suggesting possibility of less precise inference (problems that will tend to lower our reported level of statistical precision)
    - 'Outliers' in distribution of response
    - Too little variation in the distribution of the grouping variables (e.g., trying to de-

- termine an age effect from a sample in which everyone is between 20 and 21 years old)
- Too much association among the different grouping variables (e.g., trying to determine an age effect when all the young subjects are male and all the old subjects are female)
- e. Potential technical problems which suggest we might need to use more complicated statistical methods
  - Repeated measurements on the same sampling unit (correlated response)
  - When comparing means: unequal variability across groups being compared
  - When comparing time to events: lack of proportional hazards
  - When adjusting for covariates: nonlinear effects; interactions

## C. Order of investigation

- 1. Potential confounders
- 2. Predictor of interest
- 3. Response

### D. Tools

- 1. Frequency tables
- 2. Mean, median, standard deviation, etc.
- 3. Box plots, histograms

## III. Bivariate and trivariate descriptive statistics

### A. Goals

- 1. Identify confounding relationships
  - a. Associations between other variables and predictor of interest
  - b. Associations between other variables and response
- 2. Identify important predictors of response
  - a. Univariate effects
  - b. Effect modification (interactions)
- 3. Identify surrogates of response
- 4. Characterize form of functional relationships (linear, etc.)

## B. Ideal

- 1. Predictor of interest has no association with any other predictors
- 2. Only a few variables are markedly associated with response
- 3. All associations look like a straight line relationship
- 4. No interactions (effect modification)

## C. Order of investigation

- 1. Relationships among other predictors
- 2. Relationships between predictor of interest and other predictors
- 3. Relationships between response and other predictors
- 4. Relationships between predictor of interest and response overall
- 5. Relationships between predictor of interest and response within subgroups

### D. Tools

- 1. Contingency tables
- 2. Stratified means, medians, standard deviations, etc.
- 3. Stratified box plots, histograms, etc.
- 4. Scatterplots
- 5. Stratified scatterplots
- 6. Correlations

## IV. Defining a suitable context for modeling

### A. Goals

- 1. Choosing appropriate form for response variables
  - a. Selection of measure of response
    - Transformations of available data
  - b. Summary measure to use as basis for statistical model
- 2. Selection of groups to be investigated / compared
  - Form for predictor of interest
  - Identification and form of interactions (effect modification)
  - Identification and form of potential confounders to be modeled
  - Identification and form of precision variables to be modeled
- 3. Choosing analysis method (type of regression)

### B. Methods

- 1. Ideal: Statistical model dictated entirely by scientific question (before looking at the data)
- 2. Practical: Model building
  - a. Educated guess for first models
  - b. Fit models
  - c. Evaluate validity of necessary assumptions

### V. Model Building to Address Primary Question

- A. Goals (in order of importance)
  - 1. Selection of variables to address scientific questions (main effects and interactions)
  - 2. Selection of variables to minimize bias (address confounding)
  - 3. Selection of variables to maximize precision
  - 4. Selection of models which are easiest to implement (usually: have the least technical requirements on the distribution of response)

## B. Methods

- 1. Addressing scientific question: Thinking about the problem
- 2. Addressing confounding: Adding or removing variables and observing effect on other regression parameters relative to findings in bivariate description of data
- 3. Addressing precision: Determining which variables tend to predict response (many difficult issues here)
- 4. Evaluate extent to which data meets technical requirements of statistical procedures

- VI. Exploratory Analyses for Hypothesis Generation
  - A. Modeling of exact form of predictor-response relationship (e.g., dose-response)
  - B. Identification of other predictors of response
  - C. Subgroup analyses: Compare effect of predictor of interest on response within subgroups (effect modification)
- VI. Reporting Results and Interpretation
  - A. Scientific Background and Hypotheses
  - B. Materials and Methods
    - 1. Sampling scheme
    - 2. Most basic descriptive statistics
  - C. Results (more objective first)
    - 1. Descriptive statistics
    - 2. Results of analyses about primary question
      - a. Estimates of effect
        - Point estimates (single best estimate)
        - Interval estimates (range of estimates indicating precision)
      - b. Decisions about hypotheses
        - Binary decision (yes or no)
        - Measure of statistical confidence in precision
    - 3. Results of analyses about prespecified secondary questions or questions which demonstrate consistency (or lack of same) across alternative approaches
    - 4. Results of analyses about questions that arose during analysis and that the vast majority of readers would agree could and should be answered by the data
  - D. Discussion (subjective, including particularly data-driven analyses)
    - 1. Elaboration on ways that these analyses address the overall goal of the study
    - 2. Results of the most speculative analyses of the data