

Biost 590:
Statistical Consulting
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**Statistical Classification of
Scientific Studies;
Approach to Consulting**

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Lecture Outline
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- Statistical Classification of Scientific Studies
- Statistical Tasks
- Approach to a Consulting Problem

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Scientific Method
.....

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Stages of Scientific Studies
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- Observation
 - Hypothesis generation
 - Confirmatory studies
 - Disadvantages:
 - Confounding
 - Limited ability to establish cause and effect

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Stages of Scientific Studies

.....

- Experiment
 - Intervention
 - Elements of experiment
 - Overall goal
 - Specific aims (hypotheses)
 - Materials and methods
 - Collection of data
 - Analysis
 - Interpretation; Refinement of hypotheses

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Scientific Method

.....

- A well designed study discriminates between hypotheses
 - The hypotheses should be the most important, viable hypotheses
 - All other things being equal, it should be equally informative for all possible outcomes
 - But may need to consider simplicity of experiments, time, cost

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Addressing Variability

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- Outcome measures rarely constant
 - Inherent randomness
 - Hidden (unmeasured) variables

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Probability Models

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- Probability models are used as a basis for variability
 - Distribution of measurements
 - Summary measure for scientific tendency
 - (Signal and noise)

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Role of Statistics

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- Statistics is used to
 - Describe tendencies of response
 - Quantify uncertainty in conclusions
 - “Statistics means never having to say you are certain” (ASA sweatshirt)

Statistical Classification of Scientific Questions

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General Classification

.....

- Prediction of individual observations
- Clustering of observations
- Clustering of variables
- Quantification of distributions
- Comparing distributions

1. Prediction

.....

- Focus is on individual measurements
 - Point prediction:
 - Best single estimate for the measurement that would be obtained on a future individual
 - Continuous measurements
 - Binary measurements (discrimination)
 - Interval prediction:
 - Range of measurements that might reasonably be observed for a future individual

Example: Continuous Prediction

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- Creatinine clearance
 - Creatinine
 - Breakdown product of creatine
 - Removed by the kidneys by filtration
 - Little secretion, reabsorption
 - Measure of renal function
 - Amount of creatinine cleared by the kidneys in 24 hours

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Example: Continuous Prediction

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- Problem:
 - Need to collect urine output (and blood creatinine) for 24 hours
- Goal:
 - Find blood, urine measures that can be obtained instantly, yet still provide an accurate estimate of a patient's creatinine clearance

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Example: Continuous Prediction

.....

- Statistical Tasks:
 - Training sample
 - Measure true creatinine clearance
 - Measure sex, age, weight, height, creatinine
 - Statistical analysis
 - Regression model that uses other variables to predict creatinine clearance
 - Quantify accuracy of predictive model
 - (Mean squared error?)

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Example: Discrimination

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- Diagnosis of prostate cancer
 - Use other measurements to predict whether a particular patient might have prostate cancer
 - Demographic: Age, race, (sex)
 - Clinical: Symptoms
 - Biological: Prostate specific antigen (PSA)
 - Goal is a diagnosis for each patient

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Example: Discrimination

.....

- Statistical Tasks:
 - Training sample
 - “Gold standard” diagnosis
 - Measure age, race, PSA
 - Statistical analysis
 - Regression model that uses other variables to predict prostate cancer diagnosis
 - Quantify accuracy of predictive model
 - (ROC curve analysis?)

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Example: Interval Prediction

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- Determining normal range for PSA
 - Identify the range of PSA values that would be expected in the 95% most typical healthy males
 - Age, race specific values

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Example: Interval Prediction

.....

- Statistical Tasks:
 - Training sample
 - Measure age, race, PSA
 - Statistical analysis
 - Regression model that uses other variables to define prediction interval
 - (Mean plus/minus 2 SD?)
 - (Confidence interval for quantiles?)
 - Quantify accuracy of predictive model
 - (Coverage probabilities?)

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Comment About Prediction

.....

- For me to consider a problem to be purely a prediction problem, interest must lie solely in the predicted value, and not in the way that value was obtained
 - E.g., in weather prediction, we might just want to know the weather tomorrow
 - We won't be trying to impress upon our audience the way it should be predicted
 - I do not think this is very often the case

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2. Cluster Analysis

- Focus is on identifying similar groups of observations
 - Divide a population into subgroups based on patterns of similar measurements
 - Univariate, multivariate
 - Known or unknown number of clusters
 - (All variables treated symmetrically: No delineation between outcomes and groups)

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Example: Cluster Analysis

- Potential for different causes for the same clinical syndrome: Glucose in urine
 - Identify patterns of measurements that separate subpopulations of patients with diabetes
 - Age of onset
 - Symptoms at onset (e.g., weight)
 - Auto-antibodies
 - Characteristics of epidemics

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Example: Cluster Analysis

- Statistical Tasks:
 - Training sample
 - Measure age, change in weight, auto-antibodies, etc.
 - Statistical analysis
 - Cluster analysis
 - Summarize variable distributions within identified clusters
 - (Attach labels?)

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3. Factor Analysis

- Identifying hidden variables indicating groups that tend to have similar measurements of some outcome
 - Interest in some particular outcome measurement
 - Predictors that imprecisely measure some abstract quality
 - Desire to find patterns in predictors that more precisely reflect the abstract quality

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Example: Factor Analysis

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- Identifying barriers to patient compliance in clinical trials
 - In the Health Behavior Questionnaire, multiple variables might be used to measure
 - Self-perceived health; social support; depression
 - Desire is to
 - Find subset of questions that would suffice
 - Identify hidden variables that affect compliance

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Example: Factor Analysis

.....

- Statistical Tasks:
 - Training sample
 - Measure response to questionnaire
 - Statistical analysis
 - Factor analysis (principal components)
 - Report contribution to factors, factor loadings
 - (Attach labels?)
 - (Draw conclusions about importance of latent variables?)

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4. Quantifying Distributions

.....

- Focus is on distributions of measurements within a population
 - Scientific questions about tendencies for specific measurements within a population
 - Point estimates of summary measures
 - Interval estimates of summary measures
 - Quantifying uncertainty
 - Decisions about hypothesized values

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Example: Estimate Proportions

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- Proportion of women among patients with primary biliary cirrhosis
 - Serious liver disease often leading to liver failure
 - Unknown etiology
 - Characterizing types of people who suffer from disease may provide clues about causes
 - (About 90% of patients with PBC are women)

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Example: Estimate Proportions

.....

- Statistical Tasks
 - Sample of patients (from registry?)
 - Measure demographics, etc.
 - Statistical analysis
 - Best estimate of the proportion
 - Quantify uncertainty in that estimate
 - Compare to the known proportion of women in the general population (approximately 50%)?

Example: Estimation of Median

.....

- Median life expectancy of patients newly diagnosed with stage II breast cancer
 - Want to know prognosis
 - Patients' planning
 - Judging public health risks

Example: Estimation of Median

.....

- Statistical Tasks
 - Sample of patients with newly diagnosed with stage II breast cancer
 - Follow for survival time (may be censored)
 - Statistical analysis
 - Best estimate of the median survival (K-M?)
 - Quantify uncertainty in that estimate
 - Compare to some clinically important time range (e.g., 10 years)

5. Comparing Distributions

.....

- Comparing distributions of measurements across populations
 - 5a. Identifying groups that have different distributions of some measurement
 - 5b. Quantifying differences in the distribution of some measurement across predefined groups (effects or associations)
 - 5c. Quantifying differences in effects across subgroups (interactions or effect modification)

5a. Identifying Groups

.....

- Identifying groups that have different distributions of some measurement
 - Focus is on some particular outcome measurement
 - Identify groups based on other measurements
 - E.g., quantifying distributions within subgroups
 - E.g, stepwise regression models
 - (cf: Cluster analysis where all measurements are treated symmetrically)

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Example: Identifying Groups

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- Chromosomal abnormalities associated with ovarian cancer
 - Cytogenetic analysis of dividing cells identifies regions of the chromosomes with defects
 - Cancer is caused by some defects, and cancer causes other defects
 - Approximately 370 identifiable regions
 - Which of the regions are the most promising to explore in more focused studies?

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Example: Identifying Groups

.....

- Statistical Tasks:
 - Sample of cancer tissues
 - Measure type of cancer (ovarian, melanoma, etc.)
 - Measure chromosomal defects
 - Statistical analysis
 - Stepwise regression models of chromosomal abnormalities predicting cancer type
 - (Use p values to rank interest in particular regions?)

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Example: Identifying Groups

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- Risk factors for diabetes
 - Variables most associated with diabetes risk may give clues about etiology and eventual prevention

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Example: Identifying Groups

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- Statistical Tasks
 - Sample subjects to measure risk factors and disease prevalence
 - Cohort study
 - Case-control study
 - Statistical analysis
 - Stepwise model building
 - (Rank most interesting variables by p value?)

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5b. Detecting Associations

.....

- Associations between variables – distributions of one variable differ across groups defined by another
 - Existence of differences
 - Direction of tendency of effect
 - First, second order relationships in a summary measure
 - Characterization of dose-response in a summary measure

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Example: Detecting Association

.....

- Effect of blood cholesterol levels on risk of heart attacks
 - Understanding etiology of heart attacks may lead to prevention and/or treatment strategies

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Example: Detecting Association

.....

- Statistical tasks
 - Measure risk factors, MIs on sample
 - Cohort or case-control sample
 - Statistical analysis
 - Regression model (possibly adjusted)
 - Cohort: Incidence of MIs across cholesterol levels
 - Case-control: Cholesterol levels across MI status
 - (Comparison can be at many levels of detail)
 - Quantify estimates, precision, confidence in decisions

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Detecting Effect Modification

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- Quantifying differences in effects across subgroups (interactions or effect modification)
 - Existence of interaction
 - Direction of interaction (synergy, antagonism)
 - Quantification of exact relationship of interaction

Example: Effect Modification

.....

- Identifying whether effect of cholesterol on heart attacks differs by sex
 - Comparing association between blood cholesterol level and incidence of heart attacks between sexes
 - Quantify association in men
 - Quantify association in women
 - Compare measures of association

Approach Common to #4 & #5

.....

- In answering each scientific question, statistics typically provides four numbers
 - Best estimate
 - “Best” can be defined by frequentist or Bayesian criteria
 - Interval describing precision
 - Confidence interval or Bayesian credible interval
 - Quantification of belief in some hypothesis
 - P value or Bayesian posterior probability

Statistical Tasks

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Statistical Tasks

.....

- Statistical considerations come into play in all stages of scientific studies
 - Study Design
 - Data analysis
 - Descriptive statistics
 - Inferential statistics
 - Interpretation and reporting of results

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Statistical Tasks

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Study Design

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Scientific Hypotheses

.....

- Usual statement:
 - The intervention when given to the target population will tend to result in outcome measurements that are

{ higher than,

{ lower than, or

{ about the same as

}

{ an absolute standard, or

{ measurements in a comparison group

}

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Refining Scientific Hypotheses

.....

- Statistical hypotheses precisely define
 - the intervention
 - the outcome
 - advise on precision of measurement
 - the target population(s)
 - covariates
 - “tend to” (the standards for comparison)
 - summary measures
 - relevance of absolute or relative standards

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General Methods

.....

- Choosing a general method for collecting data
 - Observational
 - Intervention

Sampling Time Frame

.....

- Time frame
 - Cross-sectional sampling
 - Real time
 - Event time (e.g. at diagnosis or birth)
 - Longitudinal sampling
 - Prospective
 - Retrospective

Common Study Designs

.....

- Cross-sectional studies (surveys)
- Cohort studies
- Case-control studies
- Interventional studies

Cross-sectional Studies

.....

- Surveys of subjects sampled from a population
- Real or event time
- Efficient for examining
 - Common outcomes and risk factors
 - Associations (not cause and effect)

Cohort Studies

.....

- Groups defined by risk factor
 - Identified prospectively or retrospectively
- Followed longitudinally for outcome event(s)
- Efficient for examining
 - Common outcomes
 - Many different outcomes for same exposure
 - Associations (not cause and effect)

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Case-Control Studies

.....

- Groups defined by some outcome event
- Characterize prior exposures
 - Longitudinal study into the past
- Efficient for examining
 - Rare outcomes
 - Many different risk factors for same outcome
 - Associations (not cause and effect)

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Interventional Studies

.....

- Subjects assigned to some intervention
 - Ideally controlled, randomized
- Followed longitudinally for some outcome
 - So a special case of a cohort study
- Efficient for examining
 - Common outcomes
 - Cause and effect

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An Aside:

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Ability to
Detect Associations

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Definition of an Association

- The distributions of two variables are not independent
 - Independence: Equivalent definitions
 - Probability of outcome and exposure is product of
 - Overall probability of outcome, and
 - Overall probability of exposure
 - Distribution of exposure is the same across all outcome categories
 - Distribution of outcome is the same across all exposure categories

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Mathematical Definitions

- Independence: Equivalent definitions
 - Joint probability of outcome D and exposure E
 - $\Pr(D = d_1, E = e_1) = \Pr(D = d_1) \cdot \Pr(E = e_1)$
 - Conditional probability of outcome given exposure
 - $\Pr(D = d_1 | E = e_1) = \Pr(D = d_1 | E = e_2)$
 - Conditional probability of exposure given outcome
 - $\Pr(E = e_1 | D = d_1) = \Pr(E = e_1 | D = d_2)$

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Establishing Independence

- Consider all events defined by the two variables
 - For each choice of d_1, d_2, e_1, e_2 show either
 - $\Pr(D = d_1, E = e_1) = \Pr(D = d_1) \cdot \Pr(E = e_1)$,
 - $\Pr(D = d_1 | E = e_1) = \Pr(D = d_1 | E = e_2)$, or
 - $\Pr(E = e_1 | D = d_1) = \Pr(E = e_1 | D = d_2)$
 - It takes an infinite sample size to prove equality

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Detecting Associations

- Instead, we detect associations by showing that two variables are not independent
 - Thus, we show that two distributions are different

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Summary Measures

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- Generally we consider some summary measure of the distribution
 - E.g., when we use the mean, we show an association by showing either
 - $E(D \mid E) \neq E(D) \neq E(E)$,
 - $E(D \mid E = e_1) \neq E(D \mid E = e_2)$, or
 - $E(E \mid D = d_1) \neq E(E \mid D = d_2)$

Justification

.....

- This works, because if two distributions are the same, ALL summary measures should be the same
 - If some summary measure is different, then we know the distributions are different

Impact of Study Design

.....

- To establish an association
 - Cohort studies must examine whether
 - $\Pr(D \mid E = e_1) \neq \Pr(D \mid E = e_2)$
 - Case-control studies must examine whether
 - $\Pr(E \mid D = d_1) \neq \Pr(E \mid D = d_2)$
 - Cross sectional studies can examine either of the above, as well as whether
 - $\Pr(D, E) \neq \Pr(D) \neq \Pr(E)$

Statistical Tasks

.....

Study Design
(cont.)

Treatment of Variables

- Measure and compare distribution across groups (response variable in regression)
- Vary systematically (intervention)
- Control at a single level (fixed effects)
- Control at multiple levels (fixed or random effects)
 - Stratified (blocked) randomization
- Measure and adjust (fixed or random effects)
- Treat as “error”

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Materials

- Subjects used for measurement
 - Inclusion criteria
 - Exclusion criteria
- Independent subjects versus matched groups
 - “Repeated measures” designs
 - “Cross-over” designs

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Statistical Hypotheses

- Selection of summary measure from distribution
 - Characterize measurements within a population
 - Characterize differences between groups
- Selection of groups
 - Covariates in a regression model
- Hypotheses in terms of summary measure

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Univariate Summary Measures

- Many times, statistical hypotheses are stated in terms of summary measures for the distribution within groups
 - Means (arithmetic, geometric, harmonic, ...)
 - Medians (or other quantiles)
 - Proportion exceeding some threshold
 - Odds of exceeding some threshold
 - Time averaged hazard function (instantaneous risk)
 - ...

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Comparisons Across Groups

.....

- Comparisons across groups then use differences or ratios
 - Difference / ratio of means (arithmetic, geometric, ...)
 - Difference / ratio of proportion exceeding some threshold
 - Difference / ratio of medians (or other quantiles)
 - Ratio of odds of exceeding some threshold
 - Ratio of hazard (averaged across time?)
 - ...

Based on Type of Data

.....

- Binary or dichotomous:
 - mean (proportion); odds
- Nominal (unordered categories):
 - frequencies; odds
- Ordinal (ordered categories):
 - median (quantiles); odds; ? mean
- Quantitative (addition makes sense):
 - mean; median; proportion > c; hazards, ...

Joint Summary Measures

.....

- Other times groups are compared using a summary measure for the joint distribution
 - Median difference / ratio of paired observations
 - Probability that a randomly chosen measurement from one population might exceed that from the other
 - ...

Criteria for Summary Measure

.....

- In order of importance
 - Scientifically (clinically) relevant
 - Also reflects current state of knowledge
 - Is likely to vary across levels of the factor of interest
 - Ability to detect variety of changes
 - Statistical precision
 - Only relevant if all other things are equal

Probability Models

- Parametric
 - E.g., Poisson, exponential, Weibull
- Semiparametric
 - E.g., proportional hazards, ? quasilikelihood
- Nonparametric
 - E.g., Kolmogorov-Smirnov, ? quasilikelihood

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Statistical Models

- Dimension of response variable
 - univariate, bivariate, multivariate
- Summary measure
- Relationship among observations
 - Independent (uncorrelated) vs dependent (correlated)
- Number of groups
 - One, two, K, infinite (regression)

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Statistical Precision

- Choose sample size to ensure adequate precision to answer question
 - Width of interval estimates (best)
 - Statistical power

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Sample Size Calculation

- Choose sample size to ensure adequate precision to answer question
 - Width of interval estimates (best)
 - Statistical power

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Sample Size Calculation

- Sample size formulas used in wide variety of statistical settings

$$n \approx \frac{z_{\alpha/2}^2 V}{(\mu_1 - \mu_0)^2}$$

- n is the maximal sample size
- $z_{\alpha/2}$ is the alternative for which a standardized form of a level α test has power $1 - \beta$
- $1 / V$ is the average statistical information contributed by each sampling unit

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Logistical Constraints

- When sample size is constrained, either
 - Determine power to detect a specified alternative
 - Determine alternative detected with high power
 - When using 95% CI, the alternative discriminated from the null is the alternative for which we have 97.5% power

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Statistical Tasks

Data Analysis

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Descriptive Statistics

- Description of a sample
 - Identification of measurement or data entry errors
 - Characterize materials and methods
 - Validity of analysis methods
 - Assess scientific and statistical assumptions
 - (Straightforward estimates of effects-- inference)
 - Hypothesis generation (inference-- estimation)

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Inference

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- Generalizations from sample to population
 - Estimation
 - Point estimates
 - Interval estimates
 - Decision analysis (testing)
 - Quantifying strength of evidence

Inference: Point Estimation

.....

- Identification of clusters
- Individual observations (predictions)
 - Continuous measurements
 - Categorical measurements (discrimination, classification)
- Summary measures of distributions
 - Within a population
 - Across populations

Inference: Interval Estimates

.....

- Quantifying uncertainty
 - Individual observations
 - Prediction intervals (continuous measurements)
 - Accuracy (discrimination, classification)
 - Summary measures
 - Frequentist confidence intervals
 - Bayesian credible intervals

Inference: Decision Analysis

.....

- Hypothesis testing
 - Quantification of strength of evidence for a decision
 - Frequentist p values
 - Bayesian posterior probabilities
 - Decision

Approach to a Consulting Problem

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Start at the Beginning

.....

- Understand the scientific question
 - Overall goal
 - Current state of knowledge
 - Specific aims of this experiment
 - Scientific relevance of the experiment
 - “Why do we care?”
 - What will we do with the results
 - If positive
 - If negative

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Can Statistics Help?

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- Litmus Test # 1:

- If the scientific question cannot be answered by an experiment when outcomes are entirely deterministic, there is NO chance that statistics can be of any help.

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Can Statistics Help?

.....

- Litmus Test # 2:

- If the scientific researcher cannot decide on an ordering of data distributions which would be appropriate when measurements are available on the entire population, there is NO chance that statistics can be of any help.

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Classify the Statistical Goal

.....

- Type of question
 - Prediction: point, interval
 - Cluster analysis
 - Factor analysis
 - Quantifying distribution within group
 - Comparing distributions across groups
- Level of detail
 - Existence, direction, first order trends, precise dose response

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Thought Experiment

.....

- Think about ideal study design
 - It is very useful to imagine what you would like to do (unconstrained by practicality or ethics) as a starting point
 - This can then serve as a reference to help decide what can be done within the limitations of the actual problem

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Where Are We in the Study

.....

- Hypothesis generation
 - (Interpretation of literature)
- Study design
- Statistical design
- Quality control
- Analysis of data
- Interpretation of results
- Response to reviewers

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Describe Sampling Methods

.....

- Source of data
 - Location, time
 - Selection criteria (inclusion, exclusion)
- Sample sizes specified by design
 - Overall and within prespecified strata
 - Sampling scheme may have specified number of smokers and nonsmokers in a cohort design
 - Sampling scheme may reflect random process
 - incidence of events is then estimable

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Scientifically Classify Variables

- Demographic variables
- Measures of exposure
- Measures of concurrent disease
- Measures of severity of disease
- Measures of clinical outcomes
- etc.

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Statistical Role of Variables

- Outcome (response) variable(s)
- Predictor(s) of interest
 - (main grouping variable(s))
- Subgroups of interest
 - for effect modification
- Potential confounders
- Variables that add precision to analysis
 - Often these are potential confounders, because they may be associated with predictor(s) of interest in sample

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Descriptive Statistics

- Tables, plots
 - Identification of measurement or data entry errors
 - Characterize materials and methods
 - Available data
 - Validity of analysis methods
 - Assess scientific and statistical assumptions
 - (Straightforward estimates of effects-- inference)
 - Hypothesis generation (inference-- estimation)

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Select Inferential Methods

- Cluster analysis
- Factor analysis
- Prediction, quantifying, or comparing distributions
 - Summary measures
 - Comparison measures
 - Probability models
 - Statistical models, covariate adjustment
 - Measures of accuracy and precision of analysis

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Results of Analyses

.....

- For each scientific question
 - Point estimate
 - Interval estimate
 - Quantification of strength of evidence

Interpretation

.....

- Statistician as collaborator
 - Contribution to manuscript
 - (Introduction)
 - Statistical methods
 - Results
 - Analysis
 - Clarity of presentation
 - Discussion
 - Especially where statistical limitations play a role