Required Information for a Biostatistical consultation

Instructions

RSAP faculty will assist residents in developing a research and analyses plan when needed. In order to maximize the efficient use of the RSAP resources, we will require that residents seeking biostatistical assistance prepare a summary of their project that contains the information needed to best support their needs. Please complete this form once the research question and study design of the project are clear. Residents that need assistance clarifying these issues should contact the RSAP faculty to schedule an appointment.

Hypothesis

Whenever possible the hypothesis should be presented as a quantifiable outcome (examples: treatment A has 10% higher incidence of X than treatment B or the prevalence of Y will be 20% higher among subjects w when compared to subjects Z). This is usually based on preliminary data or previously reported data. When no data available on a particular hypothesis, try to select a difference that is clinically relevant but at the same time possible. For example, a hypothesis of a mortality difference of 30% would seem unrealistic unless preliminary data supports the presence of such a large difference.

Specific Aims

Present as a measurable difference or outcome. Examples: Determine if patients who received treatment A had higher incidence of X than patients treated with B , or determine if the Hispanic patients have a higher rate of UGIB during admission to the ICU when compared to white patients, or evaluate if cases of X are more frequent during the summer months compared to winter months, or explore if variable X (eg. low health literacy) is associated with outcome x (e.g. lower follow up rates after admission).

Methods

Emphasize and explain in your own words the study design you envision and support this with a brief description of the general procedure of your study. Describe the outcome variables, other variables to be collected, if variables are continuous, categorical, and nominal or ordinal and method of data collection (chart review, collection in clinic, etc). If variables are not continuous and not obviously categorical (examples of obviously categorical variables are gender, smoker/non smoker, yes/no variables, etc) like a score or a variable with several options, please provide a description of the variable. If comparisons between groups will be made, please provide an expected difference between the groups and the assumed dispersion or variance of the variable for example mean and standard deviation of the outcome variable in one group. (e.g. if the outcome variable is blood pressure, you could provide de expected mean blood pressure and standard deviation from either preliminary data you already have or from the literature). If not sure about how to get the variance of a variable please contact Dr. Palacio or Dr. Tamariz for advice. If no real data is available, find one or more published articles that have used a similar variable. If no comparisons between groups will be made, provide an estimate of the effect size

or in other words, the size of the impact that a variable has over the outcome (e.g. low health literacy is associated with a 10% higher Hba1c compared to Moderate and high health literacy). Either the difference between groups or the effect size (depending on the study design) plus the variance of the variable are key for power and sample size calculations.

Define the population to be studied, where it will be recruited from and if a comparison group is desired based on your aims. If that is the case describe as best as you can what possible comparison groups are available and how these groups could be identified. When you think about selecting and collecting data for different groups, keep in mind minimizing possible biases.

RSAP Project Information Form

1**. Main Hypothesis**

2. Specific Aims

3. Study Design or description of study

Cross-sectional

Case control: Please describe how the cases and controls were/would be selected and how you would ascertain the exposure.

Retrospective cohort: Please provide the shortest follow up time after an exposure present in your dataset, if no data available yet, think about what would be the minimum follow up time needed to observe the outcome.

Prospective Cohort (same as above regarding the time)

Diagnostic (cross sectional measure against a gold standard) Describe if everyone or only a sample will use the test being evaluated, for example a new screening survey for alcohol abuse against the gold standard. If only a sample, explain how you would select the sample to avoid biases and describe the process of comparing to the gold standard (objective/subjective, blinding, who will do it, when, who would administer the gold standard).

4. Main outcome variable

Continuous Dichotomous Ordinal Nominal

If continuous, do you expect it to be normally distributed? YES NO

(See if has been reported as a normally distributed variable before. Can check in the literature to see what types of tests have been done using this variable, if not sure about the test, attach/bring a reference of a study using this variable. If you have preliminary data or already have a dataset can check mean and median, if both measures are similar, the data may be normally distributed, can also do a histogram to look at the distribution. This is important to help you decide if you need to do parametric versus non parametric tests (which are needed when data is skewed).

4. Difference between groups or effect size as appropriate

5. Main predictor variable (if study design is about describing a correlation or a predictive model) and similar description as main outcome variable. For example, race/ethinicity, laboratory value, depression, primary language, etc)

6. List of other variables. Think about variables you would need to adjust for.

7. Graphs you may like to have for poster or publication. It is important to think early on how you like would to present your results.

Survival curves histograms box-plots Linear regression plots

(If not sure which graph is appropriate, describe what would you like to show in a graph, for example show the difference in smoking cessation between two groups)

Do you have time/date of the main outcome for all subjects who had one? Yes No

8. How you are going to collect data:

Existing dataset

Chart review (retrospective)

De novo data collection (prospective),

Creating a dataset from already collected data

The purpose of this is to have a clear understanding of your expectations of the project so we can help you accomplish those expectations or revise them if needed. If not sure about the required information, please make an appointment with one of the RSAP directors to discuss your study.

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