**Laryngoscope Case Study**

**Statistical Analysis Plan Description**

**Length:** ~1 single-spaced page

**Overview**

A *statistical analysis plan* should describe the methods and techniques you plan to use to analyze your data. It is particularly important that you state the statistical model underlying your analysis approach. It might be as straightforward as a normal theory two independent groups comparison (two-sample t-test). Or it may be more complex, such as a normal theory mixed model for cluster randomized studies.

The goal of a statistical analysis plan is to give enough information so that someone with a good understanding of statistics would be able to replicate the analysis. Therefore, in the analysis plan you should describe and justify:

1. The main statistical methods that will be employed to address the primary research question and any secondary research questions (e.g. – analysis of variance, mixed-model regression, Cox Proportional Hazards regression, etc.).
2. The preliminary (descriptive) analyses that will be conducted.
3. Any non-trivial techniques that will be used to visualize the data (e.g., histograms/boxplots need no explanation, but you may want to mention if you plan to use a scatterplot smoother to visualize a trend).
4. Any transformations (e.g., log) that will be applied to the data prior to carrying out the main analyses, and why.
5. What observations, if any, will be excluded from the analysis, and why.
6. What potential confounder, effect modifier, or precision variables will be explored and the criteria you will use for their retention in the final model.
7. How missing data will be handled.
8. What null hypotheses will be subject to statistical significance testing.
9. The confidence intervals that will be computed for all other associations.

It is also conventional to report the software (including version number) that will be used to carry out your analysis.

Since a statistical analysis plan is written *before* data analysis has been performed, it is typically written in the future tense (“We will analyze…”, “We will plot…”).

[Creative Commons License](http://creativecommons.org/licenses/by-nc-sa/4.0/)Furthermore, since the statistical analysis plan is written before the analyst has seen the data, it may not be possible to completely describe some details of the analysis methods. For example, you may not know if the outcome of interest will require transformation until you have looked at the data. However, the statistical analysis plan should state how you will decide, based on the data, whether transformation is needed.

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**Example**

The following is adapted from the Statistical Analysis section from an article in the *New England Journal of Medicine* (the full article is available at http://www.nejm.org/doi/pdf/10.1056/NEJMoa0910087). The text has been modified to be written in the future tense so that it more closely resembles an analysis plan. It provides a good guide to the basic structure of an analysis plan, although due to space limits imposed by the journal it is less detailed than what you should provide as part of your report.

[Creative Commons LicenseCreative Commons License](http://creativecommons.org/licenses/by-nc-sa/4.0/)We will compare individual characteristics between firefighters and EMS workers, according to smoking status and arrival-time group, using Pearson’s chi-square test, the Mann–Whitney test, Student’s t-test, or analysis of variance, as appropriate. All reported P values will be two-sided. We will use linear mixed models to estimate weighted average values for FEV1 and percent of the predicted FEV1 for each 6-month period from March 12, 2000, to September 11, 2008, for all workers and separately for arrival-time groups and for firefighters and EMS workers. We will also use the linear mixed models to assess changes during the first 6 and 12 months after 9/11, during the 7 years after 9/11, and during the 6 years between September 12, 2002, and September 11, 2008. FEV1 will be adjusted for age on 9/11, sex, height, and race and adjusted both the FEV1 and the percent of the predicted FEV1 for weight, smoking status, arrival time, and duration of work. The models will allow for the acute decrement in spirometric measurements that we expect to be observed in the first year after 9/11. We will include all predictors in the models as fixed effects. We will use a random intercept to take into account the heterogeneity across subjects and the correlation induced by having repeated observations on the same subjects. We will perform a similar analysis with the last FEV1 value taken during the final 2 years of follow-up as the outcome but without the random effects. For white workers and black workers, at each 6-month interval, we will use marginal logistic regression models, fit with generalized estimating equations, to estimate the percentage of FEV1 values that fell below the lower limit of the normal range and the percentage that fell below 70% of the predicted value. Both the linear mixed models and the marginal logistic-regression models take into account that individuals could contribute unequal numbers of repeated correlated observations to the analyses over time. All data analyses will be performed with the use of SAS software, version 9.1.

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