**Laryngoscope Case Study**

**Teaching Resource Overview**

**Brief Description**

This case study on the Portal’s Laryngoscope dataset includes a background presentation, two assignments (statistical analysis plan and statistical analysis report), and two guideline documents (statistical analysis plan description and statistical analysis report guide). These five files are intended to be employed in the following order: (1) Background presentation, (2) Statistical analysis plan assignment with statistical analysis plan description, and (3) Statistical analysis report assignment with statistical analysis report guide. This activity is appropriate for graduate students in statistics or biostatistics, or advanced undergraduate students with prior coursework in survival analysis.

*Background Presentation*:

This introductory presentation provides an organized summary of the study’s background, design, and objectives. Many of the slides contain information taken almost directly from the Laryngoscope dataset introduction on the Portal, supplemented in places by definitions of vocabulary that may be unfamiliar to students. Other slides contribute additional terminology and figures helpful to students’ understanding of the study’s context.

*Statistical Analysis Plan (SAP) Assignment*:

The first assignment asks students to construct a 1-page (single-spaced) statistical analysis plan based on the Portal’s Laryngoscope dataset. Students are then to peer-review another’s SAP and engage in class discussion covering everyone’s SAPs. The goal is to lay out a detailed strategy for addressing research questions using statistical analysis, written so that anyone with a sufficient background in statistics should be able to understand and follow it. For this Laryngoscope case study, students may propose various linear regression or survival analysis methods in their SAPs. Whether they suggest a t-test, a multiple linear regression model, a Cox proportional hazards model, or some other method, a clear justification of their choice is necessary. An effective SAP will contain enough information to replicate the analysis. Key components include descriptions of how exploratory analysis, handling of missing data, and data visualization will be conducted. Any software (including version number) intended to be used should also be mentioned.

*Statistical Analysis Plan (SAP) Description*:

The *Statistical Analysis Plan Description* accompanies the SAP assignment. It serves not only to guide the construction of a student’s SAP, but also to specify valid criteria for peer review. The first section summarizes the general contents of an SAP and other practical considerations, such as appropriate verb tense. The second section gives an example of an effective SAP structure, adapted from an article excerpt by Aldrich et al., “Lung Function in Rescue Workers at the World Trade Center after 7 Years” (<https://www.nejm.org/doi/pdf/10.1056/NEJMoa0910087>).

*Statistical Analysis Report Assignment*:

The second assignment asks each student to carry out the analysis proposed in their SAP and write a statistical analysis report based on their results. The laryngoscope case study is centered around two research questions: Whether the Pentax AWS is easier *and* faster than the standard Macintosh laryngoscope with a #4 blade. Students’ statistical analysis reports should address both questions in the interpretation of their chosen statistical analyses. Unlike an SAP, a statistical analysis report is generally written for an audience of non-statisticians (e.g. client, scientific community). Its opening section should summarize key findings that directly address the primary research question(s); supporting details are left to the remainder of the report. These details are to be organized in a comprehensible manner, beginning with enough of the study’s scientific background to allow the questions to be specified and answered, then an overview of the methods used, and concluding with a discussion of results and future directions. Ideally, the statistical analysis report should be about 5 pages or less (single-spaced).

*Statistical Analysis Report Guide*:

The sections of a statistical analysis report are explicitly broken down in the *Statistical Analysis Report Guide*. This includes the intuition behind each section’s purpose, as well as its detailed components. Because statistical analysis reports vary depending on their purpose and the analyses carried out, the directions of the Statistical Analysis Report Guide should be taken contextually.

**Statistical Concepts**

Multiple linear regression, Kaplan-Meier analysis, Cox proportional hazards regression

**Learning Objectives**

*Statistical Analysis Plan (SAP)*:

1. Plan exploratory data analysis to inform choice of statistical methods
2. Choose appropriate statistical methods for addressing data problems (e.g. recognition and handling of missing data, data transformation)
3. Choose appropriate statistical methods for addressing research questions (e.g. modeling, data visualization, variable interaction and adjustment)
4. Recognize statistical assumptions and their implications
5. Communicate intended statistical analysis to an audience with background in statistics

*Statistical Analysis Report*:

1. Choose a level of statistical significance
2. Execute planned statistical analysis
3. Compute *p*-values and confidence intervals
4. Prepare appropriate tables and figures
5. Interpret statistical results
6. Write a statistical consulting report in the proper structure, with header, background, statement of research question(s) to be addressed, research methods, statistical methods, results, final comments, and references
7. Communicate the answer to the research question to a non-statistician audience

**Dataset**

Laryngoscope (Portal)

**Teaching Resource Files**

Laryngoscope Case Study Background Presentation.pptx

Assignment 1\_Statistical Analysis Plan.docx

Statistical Analysis Plan Description.docx

Assignment 2\_Statistical Analysis Report.docx

Statistical Analysis Report Guide.docx

**Notes to Instructor: How to Use this Resource**

Before introducing this case study to a class, the instructor should prepare two Google Drive folders accessible to students through emailed links or an online course management system (e.g. Moodle, Canvas, Blackboard, etc.). Students will post their SAPs in one of these folders, and their statistical analysis reports in the other. The shared nature of Google Drive is conducive to the case study’s assignment structure.

In addition, the instructor should edit both assignment documents as needed to match the timing of their particular class.

The two assignments are to be implemented in three parts each: (1) Drafting and submission, (2) Peer review, and (3) Class discussion. For the SAP assignment, students begin by submitting their own SAP, then proceed to peer review another student’s SAP (using the comment feature in Google Drive). The assignment is concluded with a class discussion addressing the strengths and weaknesses of each SAP and any other relevant considerations. The statistical analysis report assignment follows a similar format.

Below is a general idea of how this assignment structure can be implemented over three class periods.

During the first class period, the instructor uses the Background Presentation to provide both an overview of the Laryngoscope study and a description of what a statistical analysis plan should contain. Once familiarized with the study and the idea of an SAP, students are given the SAP assignment. (Note that the instructor does not provide the Laryngoscope dataset itself until the second class period.) Students are responsible for completing the first two parts of the assignment (drafting and submission, then peer review) before the next class period.

By the second class period, the instructor has reviewed and graded all students’ SAPs, and guides the class discussion based on the omissions and misunderstandings s/he observed. The direction of this discussion will vary depending on the students, but may include topics such as covariate adjustment, and the pros and cons of proposed statistical methods. The instructor then transitions into covering what a statistical analysis report should contain, and presents the statistical analysis report assignment and the Laryngoscope dataset. Students are responsible for completing the first two parts of the assignment (drafting and submission, then peer review) before the next class period. Graded SAPs are handed back at the end of class.

By the third (final) class period, the instructor has reviewed and graded all students’ reports, and guides the class discussion based on the omissions and misunderstandings s/he observed. Again, the direction of this discussion will vary depending on the students, but may include topics such as why a Table 1 is needed, what exactly should go into a Results table, or how to more clearly explain results to a non-statistician. Graded statistical analysis reports are handed back at the end of class.