# **PubH 7430: Group Project**

### Results

Length: 1-2 single-spaced pages, not including tables and figures

#### Overview

The results section of your report should be relatively easy to write if you have a good statistical analysis plan. A results section does more than recite a sequence of estimates, confidence intervals, and p-values; rather, it follows the path laid out in the analysis plan to tell the story of the data.

#### Details

You are strongly encouraged to follow the **Results** section of the CONSORT (<a href="https://www.consort-statement.org/">http://www.consort-statement.org/</a>) or STROBE (<a href="https://www.strobe-statement.org/index.php?id=available-checklists">https://www.strobe-statement.org/index.php?id=available-checklists</a>) checklist appropriate for the type of data you are analyzing (CONSORT: randomized trial; STROBE: cohort, case-control, and cross-sectional studies). The following items may also be relevant to your results section:

- 1. A flow diagram showing how you went from the "full" data set to the analysis population. While a CONSORT diagram (<a href="http://www.consort-statement.org/consort-statement/flow-diagram">http://www.consort-statement.org/consort-statement/flow-diagram</a>) is specific to randomized trials, a similar diagram can sometimes be useful in other study designs.
- 2. A table of baseline data (often referred to colloquially as "Table 1"). The baseline table should summarize participant characteristics for each study group. For a randomized study, I do not recommend performing a statistical test to compare subject characteristics across treatment groups at baseline. This is because we know that the null hypothesis (that characteristics are randomly distributed between groups) is true before we even perform the test. For more on this issue, see Senn, Stephen. "Testing for baseline balance in clinical trials." Statistics in medicine 13.17 (1994): 1715-1726.
- 3. The results from the models or plots used to answer the main scientific questions. There are many different styles for presenting results, but most journals (and readers!) like it if you organize results according to the scientific questions of interest. So, for example, if your study's primary question is about the (main) effects of treatment, with secondary questions relating to possible variables which interact with treatment, then your results section should contain at least two separate parts relating to these questions. If you fit several related models to address the same question (e.g., GEE with different working correlations), it is often helpful to summarize the results from these models in table form.
- 4. The results (models/plots) from any other analyses you carried out.

# General tips and recommendations

- 1. Be **disciplined** and try to stick with your original analysis plan. If things seem to be working out as expected, great! If not (fitting problems, results that don't seem right, etc.), you can note this and describe the alternative approach you used instead.
- 2. Use plots and tables judiciously; again, think about what information they convey and how they fit into the story you are trying to tell. Also, make sure to label your tables and plots so they can be understood!
- 3. Estimates from regression models should be interpreted scientifically, using appropriate units and accompanied by confidence intervals and p-values wherever possible.

- 4. Even though you (hopefully) described the models you fit in detail in the statistical analysis plan, it is still a good idea in the Results section to briefly remind the reader which model each result is coming from. **Example:** "Fitting a Gaussian GEE with exchangeable correlation structure, we concluded that subjects who drank 3 pints of beer per day had mental task scores 4 points lower after 1 week than those who drank water (95% CI: 1 point lower to 7 points lower, p = 0.01)." is better than the equally correct but less helpful "We concluded that subjects who drank 3 pints of beer per day had mental task scores 4 points lower after 1 week than those who drank water (95% CI: 1 point lower to 7 points lower, p = 0.01)."
- 5. No direct model output from statistical software (e.g., screenshots of SAS or R output) should be included in your write-up. Table and figures should be of publication quality.

## Submission details

One member of your group should submit your Results on Canvas. Please name the **PDF file** using the following scheme: **"PubH7430 GroupX Results.pdf"** where X is your group number.

## Example

The following is an extract from the Results section of the *New England Journal of Medicine* article (the full article is available at http://www.nejm.org/doi/pdf/10.1056/NEJMoa0910087). It is a good model to follow.

Figure 2 shows average FEV1 values for firefighters and EMS workers before and after 9/11 and the percent of the predicted FEV1 at 6-month intervals, stratified according to smoking status. FEV1 values were adjusted for race (with white workers as the reference group), age on 9/11 (centered at age 40), height (centered at 179 cm), weight (centered at 200 lb), and sex (with men as the reference group). Average FEV1 values were higher for firefighters than for EMS workers (P<0.001) and tended to be highest for workers who had never smoked (P = 0.06) and lowest for smokers after 9/11 (P<0.001), with a trend toward widening differences over time. The percent of the predicted FEV1, which is adjusted for an expected age-related decline, was significantly lower at year 1, a decline that persisted during the following 6 years, with a trend toward a steeper decline among workers who continued smoking after 9/11.

Figure 3 compares changes in FEV1 values over time on the basis of the arrival time at the World Trade Center for workers who had never smoked. Among firefighters, we noted a large decrease in the mean adjusted FEV1 (355 ml; 95% CI, 352 to 359) during the first 6 (P = 0.004) months and a decrease of 439 ml (95% CI, 408 to 471) during the first year (P = 0.003). The firefighters with the heaviest dust exposure, those arriving at the World Trade Center site on the morning of 9/11, had significantly larger declines of 371 ml (95% CI, 362 to 380) during the first 6 months and 585 ml (95% CI, 515 to 656) during the first year than did those arriving at later times. EMS workers had smaller declines, averaging 272 ml (95% CI, 268 to 276) during the first 6 months and 267 ml (95% CI, 263 to 271) during the first year, without apparent influence of arrival time. We noted similar declines in the percent of the predicted FEV1 (Fig. 3B).