

Final project
BIOST 515

This project is worth 25% of your final grade.

A randomized, double-blinded clinical trial was conducted of four anti-retroviral treatments for HIV. The goal of these treatments is to reduce or eliminate HIV replication which hopefully leads to an increase in immune function and in the time until progression to AIDS or death. The main study included 391 subjects who were randomized to four anti-retroviral treatments (A, B, C and D). The participants had baseline measures of immune function (CD4 cell count) and HIV replication (viral load or the amount of virus circulating in the system). Of the 391 subjects, 272 were still in the study 8 weeks later when CD4 count and viral load were measured again.

The investigators have come to you with data from the subset of 272 subjects who had both the baseline and 8 week measures of CD4 count and viral load. They have data consisting of two repeated baseline measures of CD4 count and viral load along with some other baseline measures of interest (these are listed in the data description file) and time to progression to AIDS or death (whichever happens first). They have two primary questions of interest. First, they would like to know how change in CD4 count and viral load between baseline and 8 weeks is related to treatment group and if this change is different depending on race/ethnic group, history of IV drug use, homosexuality or previous history of anti-retroviral use. Second, they are interested in how treatment affects time to progression to AIDS or death within this group that has been event free for the first 8 weeks (note: the event time in the data set is from randomization (start of treatment, when the baseline measures are taken), not the 8 week visit). They are also interested in knowing if baseline viral load and CD4 count, 8 week viral load and CD4 count, or the change in viral load and CD4 count are better predictors of time-to-event. In the data set, viral load is reported in copies/ml. It is customary to work with the log base 10 of viral. You will need to transform viral load. However, many of the viral load values are 0. This does not mean that there was no virus present, but that the amount of virus was below the lower limit of detection. Because of the zeros, you can transform viral load by taking the log base 10 of viral load plus one.

The investigators have asked you to write a report to answer their questions of interest. You should be able to answer these questions well using the statistical techniques you have learned in BIOST515. Your report should be no longer than 5 pages including all figures and tables. The report should also be neatly organized and typed. Remember, this report is written for the investigators. You need to explain the techniques you used and the results with that target audience in mind.

Your report will be graded on three sets of criteria:

1. Statistical aspects (did you use appropriate techniques and interpret the results correctly)
2. Scientific aspects (did you address the scientific question of interest in a sensible way)

3. Presentation (is your report clear and well-written; are appropriate graphs and tables presented, well-labeled and clearly explained).

The reports are due at noon on Friday, March 19. You may either hand the reports to Elizabeth or e-mail a pdf or postscript file of your report to Elizabeth. I will not accept word files as there is too much risk of something being lost in translation from one platform to another.

Guidelines:

1. You must work independently. Unlike the homework, you are not permitted to work together or seek statistical or scientific advice from another individual on this project. It is to be treated like a take home exam. The only exception to this rule is that you may have someone proofread your project. This person, however, may not give you any scientific or statistical feedback about your work. They may only give you feedback on issues of clarity and grammar.
2. Any questions you have about the project should be asked of Elizabeth or Xuesong who will determine if the question is appropriate to answer.