

Analysis Plan/Project Proposal

As they arrive, meet the people in your group for today. Find out their names (and pronunciation) and something about where they come from (country, state, college, neighborhood, major).

Read and discuss the first two paragraphs of the analysis plan for this project. Comments/questions? Would this answer the client's primary subject matter question? Why or why not?

Read and discuss the last paragraph of the analysis plan for this project. Comments/questions? Would this answer the client's secondary subject matter question? Why or why not?

Skim over the remaining sections of the project proposal. Perhaps have each person in your group read a different section and report back. Comments/questions?

Project Proposal

Assessing the coagulation ability of dogs with septic peritonitis
for Client Name, DVM
College of Veterinary Medicine

University of Minnesota Statistical Consulting Center
Aaron Rendahl, PhD
February 4, 2015

Background and Goals

This study concerns the coagulation ability of dogs with septic peritonitis. This condition refers to contamination within the abdomen due to loss of integrity of GI tract, foreign body penetration, or surgery complications; it is a serious condition for which immediate surgery is needed. It is unknown if the coagulation ability of these dogs is limited, or if their coagulation ability makes the surgery more or less likely to be successful.

To measure coagulation, four platelet indices are used: platelet count, MPV (mean platelet volume), PDV (platelet distribution width; a measure of how uniform they are), and PCT (platelet crit; a measurement of mass). Three are directly related (one is product of other two). These platelet measures are important because platelet are involved in clotting (coagulation); either low or high values can be concerning, as either trouble clotting or complications due to clotting can add to the seriousness of the condition.

The primary aim of this study is to characterize coagulation abnormalities in dogs with septic peritonitis. The secondary aim is to determine if there are differences in these abnormalities between survivors and non-survivors of the surgery.

Project Design and Data

The data for this retrospective study comes from cases in the Veterinary Clinic database from 2009 to 2014. To be included, dogs must have met certain inclusion and exclusion criteria. The data set consists of 48 animals. The variables are the four platelet indices and whether or not the dog survived the surgery (or, if surgery was not performed), and also the age, breed, sex, and weight of the dog.

To determine abnormalities in the four measurements, we also have reference intervals (the range within which 95% of normal dogs are) with 95% confidence intervals for each measurement. This was done for an earlier study, though the data remain available if needed. The reference intervals were computed from 43 normal dogs, also from the Veterinary Clinic database. These normal dogs met strict inclusion/exclusion criteria. Reference intervals were created using the normal approximation and confidence intervals were computed using bootstrap simulations.

Analysis Plan

We will first graphically explore the data by plotting the data; for each measure separately, we will plot the values against the group (survived/died/no surgery), with the reference intervals and associated confidence intervals shown on each plot.

Then to answer the first question, we will calculate the percent of dogs with septic peritonitis that are above and below the given reference intervals, for each of the four measures separately. Using a one-sample proportion test, we will test if this percent is statistically significantly different than the expected 2.5%; we will also calculate 95% confidence intervals for these proportions, using the Agresti-Coull method.

To check for sensitivity to the endpoints of the reference intervals, these calculations will be repeated using the higher and lower bounds of the 95% confidence intervals. Hopefully, results will be similar. If not, we will discuss with you additional methods to assess the reliability of the results.

To answer the second question, we will compare the proportions that are above and below the reference interval between the dogs that survived and the dogs that died, using a chi-squared test. We expect that using a version of the chi-squared test that is better for small sample sizes will be appropriate; options including simulation, the Fisher-Irwin test, and the $N - 1$ correction. This test will be performed separately for each of the four measures. We will again check these results for sensitivity to the endpoints of the reference intervals by repeating using the endpoints of the confidence intervals.

Outcomes/Deliverables

The desired final deliverable is a written report with text suitable for placing into a journal article, with sections for the statistical methods used and for the results, and including a publication-quality graphic showing the data in comparison with the reference intervals. Additional text about the sensitivity analyses will also be included.

This report will be provided in advance of our final meeting, at which we will explain in person all the procedures and results and answer any additional questions that have not been answered during the process.

Additionally, all calculations will be performed in R and both code and output will be available.

Expectations about Publications If the text is used in a publication, it is expected that the two statisticians who worked on this will be given co-authorship, and that they will be given a chance to read and approve the final draft before it is submitted, as well as any revisions that are made as part of the review process.

Data Confidentiality Data will be kept confidential and only copied to official University computer systems. All data and results will be deleted from our systems after the conclusion of the project. Data will not be used for class examples or in any other publications beyond those referred to in this proposal.

Communication We will email a progress report at least weekly. These may contain additional questions that need answering or clarifying before work can continue. We will respond to any emails from you within 24 hours. If phone conversations are desired by either you or us, they will be arranged by email first.

Personnel and Responsibilities Aaron Rendahl, PhD, will supervise all work and write the final report text. A graduate student working under his supervision will perform the calculations and create the graphics. Biosketches for each are attached.

Tasks, Timeline, and Cost

1. Graphically explore the data by plotting the four measures for each group, showing the reference intervals. This graphic will not be publication quality. 5–10 hours estimated time; about 1 week to complete.
2. Compute the percent of dogs outside the reference interval and perform further analyses including confidence intervals and chi-squared tests. 5–10 hours estimated time; 1–2 weeks to complete.
3. Check these results for sensitivity to the endpoints of the reference intervals. 3–5 hours estimated time; about 1 week to complete.
4. If results are sensitive to endpoints, meet in person to discuss possible next steps. This is likely to increase both the time and costs beyond that specified in this proposal.
5. Write a report containing the results and create a publication-quality graphic. 5–10 hours estimated time; 1–2 weeks to complete.
6. Final meeting. 1–2 hours estimated time

The consulting service charges \$80/hour for internal work. Given the above schedule, we expect the final cost to not exceed \$3000, and the time to completion to be no more than seven weeks. As specified above, if complications arise, additional time and costs may be needed.

Name: _____

Your next assignments will be to write a project proposal for a new case that we will begin introducing on Friday. I'll have you write this in sections over the next few weeks. How ready do you feel to do that? Anything in particular that you do not feel ready for?

Please leave this sheet, your nametag, and your playing card on the tables by the door when you leave. The other sheet is for you to keep; this sheet will not be returned except by request.