STAT 301 HW11 due Wed Oct 21

You may work with one partner on this assignment, submitting one report with both names, provided that both students contribute substantially to the work. Word-processed reports are preferred to hand-written ones. Please copy/paste relevant computer output into your report as appropriate.

Botox for back pain?
A study published in the journal *Neurology* (2001) examined whether the drug botulinum toxin A (botox) is helpful for reducing pain among patients who suffer from chronic low back pain. The thirty-one subjects who participated in the study were randomly assigned to one of two treatment groups: 16 received a placebo of normal saline and the other 15 received botox. The subjects' pain levels were evaluated at the beginning of the study and again after eight weeks. The researchers found that 2 of the 16 subjects that received the saline experienced a substantial reduction in pain, compared to 9 of the 15 subjects who received botox.

a) Organize the data into a 2×2 table, with the response variable in rows.

	Botox	Placebo	Total
Substantial reduction in back pain	9	2	11
No substantial reduction	6	14	20
Total	15	16	31

b) Explain the importance of using the "placebo treatment" of saline in this study.

We need to have a group to compare the botox results against, so we can isolate the effect of botox as opposed to the possibility that the passage of time might naturally lead to reduction in pain, or that the placebo effect might lead to a reduction in pain.

c) Is this an observational study or a randomized experiment? Explain how you can tell.

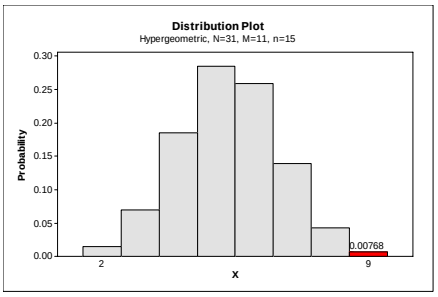
This is a randomized experiment, because the 31 subjects were randomly assigned to a treatment group (botox or placebo).

d) Describe the null model for this study.

The null model asserts that there is no difference in back pain reduction rates between botox and placebo. In other words, the null model says that there is no effect of botox on back pain, as compared to a placebo.

e) Determine the p-value for Fisher's exact test applied to these data. Feel free to use Minitab, but be sure to indicate which probability distribution you use, what its parameter values are, and what region you find the probability of.

The exact p-value is $\Pr(X \geq 9)$, where X has a hypergeometric distribution with N = 31, M = 11, and n = 15. Minitab reveals this probability to be .00768, as shown here:



f) Interpret what this p-value means (i.e., it's the probability of what?).

This is the probability of getting such an extreme result (so many with pain reduction in the botox group) if in fact there were no difference between botox and placebo.

g) Is the observed difference between the groups statistically significant at the $\alpha = .05$ level? Explain how you know.

Yes, because the p-value is less than .05.

h) Summarize your conclusion. Be sure to address whether it's valid to draw a cause-and-effect conclusion between botox and reduction in back pain.

This study provides very strong evidence that botox does provide greater reduction in back pain than a placebo. A cause/effect conclusion is warranted because this was a randomized experiment.