Discussion 10:

How Effective is the COVID-19 Vaccine?

The following information is from the article “Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine”. This research was published in the New England Journal of Medicine on December 10, 2020. Link to full article: https://www.nejm.org/doi/full/10.1056/nejmoa2034577

To answer the first three questions you may want to refer to the concepts learned in Module 1 on experimental design.

1) The article states: “participants in the trial were randomly assigned in a 1:1 ratio to receive 30 μg of BNT162b2 (0.3 ml volume per dose) or saline placebo.” Explain what is meant by a placebo and the purpose of a placebo.

2) The article further states: “Site staff who were responsible for safety evaluation and were unaware of group assignments observed participants for 30 minutes after vaccination for any acute reactions.” What is this sentence describing and why would that be considered a good idea in an experiment for a vaccination?

3) The table from the next page was within the article and it contains information about various demographic characteristics of the participants. Explain how this table supports the concept that randomization tends to balance out potential lurking or confounding variables among the treatment groups.

4) The data in the table below shows the proportion of participants in the placebo group and in the vaccine group who developed COVID. Create an appropriate graph to show the difference in the sample proportions.

Treatment	Contracted COVID	Did not Contract COVID	Total Participants
Vaccine	9	18,851	18,860
Placebo	169	18,677	18,846

5) Conduct a complete hypothesis test for comparing two independent population proportions. Be sure to state your final conclusion in context.

Table 1. Demographic Characteristics of the Participants in the Main Safety Population.*

Characteristic	BNT162b2 (N=18,860)	Placebo (N=18,846)	Total (N=37,706)
Sex — no. (%)			
Male	9,639 (51.1)	9,436 (50.1)	19,075 (50.6)
Female	9,221 (48.9)	9,410 (49.9)	18,631 (49.4)
Race or ethnic group — no. (%)†			
White	15,636 (82.9)	15,630 (82.9)	31,266 (82.9)
Black or African American	1,729 (9.2)	1,763 (9.4)	3,492 (9.3)
Asian	801 (4.2)	807 (4.3)	1,608 (4.3)
Native American or Alaska Native	102 (0.5)	99 (0.5)	201 (0.5)
Native Hawaiian or other Pacific Islander	50 (0.3)	26 (0.1)	76 (0.2)
Multiracial	449 (2.4)	406 (2.2)	855 (2.3)
Not reported	93 (0.5)	115 (0.6)	208 (0.6)
Hispanic or Latinx	5,266 (27.9)	5,277 (28.0)	10,543 (28.0)
Country — no. (%)			
Argentina	2,883 (15.3)	2,881 (15.3)	5,764 (15.3)
Brazil	1,145 (6.1)	1,139 (6.0)	2,284 (6.1)
South Africa	372 (2.0)	372 (2.0)	744 (2.0)
United States	14,460 (76.7)	14,454 (76.7)	28,914 (76.7)
Age group — no. (%)			
16–55 yr	10,889 (57.7)	10,896 (57.8)	21,785 (57.8)
>55 yr	7,971 (42.3)	7,950 (42.2)	15,921 (42.2)
Age at vaccination — yr			
Median	52.0	52.0	52.0
Range	16–89	16–91	16–91
Body-mass index‡			
≥30.0: obese	6,556 (34.8)	6,662 (35.3)	13,218 (35.1)

* Table downloaded from: Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine

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