Emalee Schuler
LSC 541
14 October 2023

Homework Assignment #1

1. Population and Sample:

- Population: The population in this clinical trial includes all adults aged 18 years and older who are at risk of SARS-CoV-2 infection.
- Sample: The sample is the subset of this population who participated in the clinical trial. The sample size mentioned in the study is 30,000 participants.

2. Confounding Variables:

- Viral Variants of SARS-Cov-2: The emergence of viral variants can potentially affect the results of vaccine efficacy.
- Pre-existing medical conditions: Participants with pre-existing medical conditions may have different responses to the vaccine compared to healthy individuals. Failure to account for these conditions can confound the assessment of vaccine efficacy and safety.
- Unknown history of SARS-CoV-2 infection: Individuals with a prior history of SARS-CoV-2 infection may have pre-existing immunity, which could affect their response to the vaccine. Failure to account for this can confound the evaluation of the vaccine's effectiveness.

3. Potential Effects of Confounding Variables:

- If not handled correctly, confounding variables can introduce bias or incongruities into the study results. For example:
    - Viral Variants of SARS-Cov-2:
        - Viral variants may have mutations in the spike protein or other antigenic regions, potentially affecting the binding of vaccine-induced antibodies. This can lead to variations in vaccine efficacy, with some variants showing

reduced susceptibility to the vaccine. Furthermore, emergence of vaccine-resistant variants may result in a higher incidence of breakthrough infections among vaccinated individuals, especially if the variants become dominant in the population which ultimately will skew efficacy results of the vaccine.

- **Pre-existing Medical Conditions**:
  - Participants with pre-existing conditions may experience vaccine-related adverse events that are unrelated to the vaccine. These events could be mistakenly attributed to the vaccine if not properly controlled. Participants with underlying health conditions may have compromised immune systems, affecting their vaccine response. These events could be mistakenly attributed to the vaccine if not properly controlled.
- **Unknown History of SARS-CoV-2 Infection**:
  - Since SARS-Cov-2 infection can present without symptoms, some participants may not be able to report their prior infection.
  - Individuals with prior infection may already have some level of immunity, which can influence the perceived effectiveness of the vaccine. Furthermore, participants with a history of infection may exhibit different immune responses to the vaccine compared to those without prior exposure, potentially affecting the assessment of vaccine safety and effectiveness.