340.721 Epidemiologic Inference in Public Health I

ACTIVITY:
Experimental Studies: Vaccine Efficacy

Activities provide experience in applying epidemiologic methods, interpreting findings, and drawing inferences.

This Activity follows from the corresponding set of PRE-Activity Questions that should be completed prior to the start of the Activity. The PRE-Activity Questions prepare you for a productive and collaborative experience during the Activities.

Expectations for the Activities

1. *Individually, read the Activity and attempt to answer all the questions.*
2. *"Meet" with your group and discuss challenging concepts, questions and compare answers*
3. *Formulate group consensus of answers if possible (sometimes there is no right or wrong answer!)*
4. *Post questions to the Discussion Forum if there is disagreement in your group or if there is need for a clarification to answer the question.*
5. *If your group is presenting at the LiveTalk, review your answers with a TA by posting to the Discussion Forum in your Group's Category/Topic by 12PM EST of the Tuesday preceding the LiveTalk*

Questions 1-8 refer to the study by Nichol et al. (Effectiveness of live, attenuated intranasal influenza virus vaccine in healthy, working adults: a randomized controlled trial)

Question 1

Figure 1 depicts the Trial Profile of the study.

a. What was the purpose of excluding persons who had previously received the 1997-1998 inactivated influenza vaccine? Pregnant women? Those who did not provide consent?

b. How were the remaining 4,561 participants randomized to the vaccine or placebo groups? What steps were taken to ensure that the investigators did not bias the assignment of treatment?

Question 2

Compare percentage distributions of the vaccinated and placebo groups by the characteristics given in Table 1. Are they similar or different? Would you expect these to be similar? Why or why not?

Question 3

Table 2 summarizes the follow-up procedures used in the study for evaluating vaccine reactions and the efficacy of the influenza vaccine. How did the investigators monitor the incidence of influenza among their participants during the study period? Was the monitoring of influenza incidence adequate?

Question 4

In the PRE-Activity Questions, you calculated V – P for each symptom (Table 3).

a. What are you estimating when you calculate V – P?

b. How do you explain the occurrence of reactions in participants receiving placebo?

c. Why is it important to have a placebo group when looking at reactions post vaccination? How would your interpretation of the symptoms associated with the vaccine change if a group of participants had not received the placebo?

Question 5

Diagnosis of influenza was not confirmed for the study participants by laboratory testing. Instead, diagnoses of influenza for study participants were made based on clinical evidence from the returned symptom cards. The case definitions that were used by investigators are summarized in Table 4.

a. What would be the result of using only febrile upper respiratory tract illness as your case definition? How would you characterize the *sensitivity* of that case definition?

b. In the PRE-Activity Questions, you calculated the incidence rate difference (P – V) and the efficacy [(P – V) / P] comparing the placebo and vaccine groups for each acute illness (Table 5). Using the information in Table 5, describe the validity of each acute illness as a case definition for influenza. Which acute illnesses would you include in your case definition for influenza? Why?

Question 6

Why is V – P calculated for side-effects, but P – V calculated for efficacy?

Question 7

Do you think that the study population is representative of the general U.S. population? Why or why not? Do you think the results of this trial are generalizable to the general U.S. population? Why or why not?

Question 8

The efficacy of an intervention is determined by how well it works in a trial setting. The effectiveness of an intervention is determined by how well it works in the "real world."

In this article, the authors refer to the effectiveness of the vaccine rather than the efficacy. Do you think that the results of this trial reflect efficacy or effectiveness? Why?

Questions 9-13 refer to study by Hurwitz et al. (Effectiveness of Influenza Vaccination of Day Care Children in Reducing Influenza-Related Morbidity among Household Contacts)

Question 9

What are the advantages and disadvantages of using the population studied (*e.g.*, military, young children in daycare, families) to address the research question?

Question 10

In this single-masked (single- blind) randomized controlled trial, who is masked to the intervention assignment? Why?

Question 11

Based on Table 6, what would you conclude about the efficacy of vaccinating daycare children for influenza in reducing transmission to their household contacts? What was the purpose of stratifying by unvaccinated and vaccinated household contacts?

Question 12

How does this model of vaccination relate to herd immunity? Why might schools and daycare centers require vaccination before enrollment?

Question 13

Effectiveness of a vaccine is not limited to the amount of illness prevented, but also the adverse consequences of having the illness (e.g., missed work, missed school, physician visits, and medication use). What are the economic costs and benefits of vaccinating children? What are the economic costs and benefits of vaccinating adults?

	Children	Adults
Costs		
Benefits		