"You can, for example, never fortell what any one man will do, but you can say with precision what an average number will be up to. Individuals vary, but percentages remain constant. So says the statistician."

Sherlock Holmes, The Sign of Four

From the BBC website (9/25/09) comes the following report:

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An experimental HIV vaccine has for the first time cut the risk of infection, researchers say. The vaccine - a combination of two earlier experimental vaccines - was given to 16,000 people in Thailand, in the largest ever such vaccine trial. Researchers found that it reduced by nearly a third the risk of contracting HIV, the virus that leads to Aids. It has been hailed as a significant, scientific breakthrough, but a global vaccine is still some way off. The study was carried out by the US army and the Thai government over seven years on volunteers - all HIV-negative men and women aged between 18 and 30 - in parts of Thailand.

The vaccine was a combination of two older vaccines that on their own had not cut infection rates. The vaccine is based on B and E strains of HIV that most commonly circulate in Thailand not the C strain which predominates in Africa.

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Half of the volunteers were given the vaccine, while the other half were given a placebo - and all were given counselling on HIV/Aids prevention. Participants were tested for HIV infection every six months for three years.

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Question 1: This study is what is called a Phase III Clinical Trial, but in terms of what you have learned in MA 2611, what kind of study is this?

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Answer: A controlled experiment.

# The data are:

| Group   | Infected | Uninfected | Total |
|---------|----------|------------|-------|
| Placebo | 74       | 8124       | 8198  |
| Vaccine | 51       | 8146       | 8197  |

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Question 2: How would you analyze these data using the estimation techniques you've learned in MA 2611?

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More specifically, since we are trying to see if the vaccine is effective, we would like to estimate their difference,  $p_p - p_v$ .

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The point estimate of  $p_p - p_v$  is

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As the interval estimate, let's construct a 95% confidence interval for  $p_p - p_v$ .

Note that we could use the large sample interval, since the numbers of HIV cases and non-cases are large in both groups, but I will construct an approximate score confidence interval, since it works for both large and small samples and is what I have asked you to use for all your MA 2611 work.

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$$\tilde{n}_p = 8198 + 0.5 \times 1.96^2 = 8199.92$$

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$$\tilde{p}_p = (74 + 0.25 \times 1.96^2) / \tilde{n}_p = 0.00914,$$

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$$\tilde{n}_v = 8197.92 + 0.5 \times 1.96^2 = 8198.92,$$

$$\tilde{p}_{v} = (51 + 0.25 \times 1.96^{2})/\tilde{n}_{v} = 0.00634,$$

And the CI is

$$ilde{p}_p - ilde{p}_v \pm z_{0.975} \sqrt{rac{ ilde{p}_p(1- ilde{p}_p)}{ ilde{n}_p}} + rac{ ilde{p}_v(1- ilde{p}_v)}{ ilde{n}_v}$$

= 0.00914 - 0.00634

$$\pm 1.96 \sqrt{\frac{0.00914(1-0.00914)}{8199.92} + \frac{0.00634(1-0.00634)}{8198.92}} \\ = (0.00012, 0.00548)$$

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5. Results and Interpretation:

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This means the vaccine could potentially prevent the infection of between  $1\times10^9\times0.00012=120,000$  and  $1\times10^9\times0.00549=5,490,000$  individuals over a seven year span.

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That would be quite an achievement.