The Ethics of Double Blind Studies[i]

According to the Centers for Disease Control and Prevention, there are more than 200,000 influenza-related hospitalizations in the United States every year, with influenza-related deaths in the U.S. estimated to be 36,000 people annually.[ii]

The prevailing wisdom among public health officials and epidemiologists is that annual vaccinations are the key to preventing severe illness and death from seasonal influenza. The importance of vaccinations—especially for certain at-risk groups like children and the elderly, as well as their caregivers—is so deeply entrenched, that last week (January 10-16, 2010) was officially recognized as National Influenza Vaccination Week.[iii]

The received view is based largely on an extensive amount of epidemiological data. Cohort studies have consistently shown a dramatic reduction in mortality during the flu season among those who have chosen to get vaccinated. Individuals who are not vaccinated are about twice as likely to die during flu season as those who receive the seasonal influenza vaccine.

However, a vocal minority of epidemiologists has presented a growing body of research that, they argue, shows the prevailing wisdom to be unsupported by the best interpretation of the scientific evidence.

According to these critics, the data is better explained by systematic differences between those who choose to be vaccinated and those who do not. In particular, they argue, the decrease in mortality may be largely (or even entirely) the product of the "healthy-user effect". According to this hypothesis, healthier members of a cohort are more likely to be vaccinated in the first place. Moreover, these critics contend, the healthy-user hypothesis is actually confirmed by studies comparing the mortality of vaccinated versus non-vaccinated individuals outside of the flu season.

Vaccination skeptics contend that the only way to determine whether or not the seasonal influenza vaccine is effective is to conduct placebo-controlled double-blind trials. However, those who accept the prevailing wisdom argue that these studies would pose too great a risk to participants who would not receive a real vaccination; according to their estimates, after all, individuals who receive the placebo would be twice as likely to die that flu season.

Questions for Discussion:

1. A common ethical principle for medical research is that there must be genuine uncertainty within the relevant community about whether or not a new treatment is more beneficial than standard existing treatments (or better than no treatment at all). How should one interpret this principle when the very question in need of answer is whether or not the relevant community's confidence in a standard treatment is warranted? Is it even appropriate to apply this principle in these cases? What other standards of evidence might be (more) appropriate?

2. How should one gauge the risk to participants in medical research? Is it appropriate to use the standard estimates of increased mortality, when it is those very estimates that are in question?

3. The success of a vaccine in reducing serious illness and mortality might depend, in part, on its ability to slow the transmission of a disease through the population. Is it ethical to give some participants a placebo, knowing that this might put those around them—individuals who are not voluntary participants—at greater risk of getting influenza?

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[i] This case is based on information drawn from Shannon Brownlee and Jeanne Lenzer's November 2009 article "Does the Vaccine Matter?" in *The Atlantic*, available online at: http://www.theatlantic.com/doc/200911/brownlee-h1n1 (Retrieved 01/13/10)

[ii] Key Facts About Seasonal Influenza (Flu). Centers for Disease Control and Prevention Website: http://www.cdc.gov/flu/keyfacts.htm (Retrieved 01/13/10)

[iii] National Influenza Vaccination Week. Centers for Disease Control and Prevention Website: http://www.cdc.gov/flu/NIVW/ (Retrieved 01/13/10)