Comparison of immune response to the influenza vaccine in obese and non-obese healthcare workers

Background:

Influenza viruses cause significant but potentially preventable morbidity and mortality. Influenza epidemics were associated with more than 450,000 deaths in the United States in the ten-year span of 1989-1999. The Advisory Committee on Immunization Practices (ACIP) to the Centers of Disease Control and Prevention (CDC) in 2010 expanded the recommendations from a stratified vaccination scheme to vaccination for all patients over the age of 6 months without contraindications.

There are special populations which have shown a decreased response to vaccinations and theoretically could be less protected. These populations currently include the elderly, patients with low pre-vaccination antibody titers and those with certain co-morbidities. Obesity maybe another population as evident by a prior study conducted by the senior investigator in which obese healthcare workers (HCW) demonstrated lower responses to the hepatitis B vaccine compared to non-obese HCWs (unpublished data). According to 2009 CDC data West Virginia had the third highest rate of adult obesity in the nation, at 31.1 percent. During the 2009 Influenza A (H1N1) pandemic, there was an increased mortality in morbidly obese individuals. The current practice is to administer normal doses of influenza vaccine to obese individuals, despite not being studied to determine if there is a decrease response to the influenza vaccine. The combination of the decreased response to other vaccines and a higher rate of mortality and morbidity with the pandemic 2009 influenza A (H1N1) invites the question of the effectiveness of the influenza vaccines at the current dose in the obese population.

Objectives and Hypothesis:

The objectives of this mentored junior investigator clinical study are to determine the pre-vaccination antibody titers, to quantify antibody response, functionality and to compare the pre-vaccination and post-vaccination antibody titers in response to the 2011/2012 influenza vaccine between obese and non-obese HCWs. The hypotheses for this project are that HCWs with a high BMI will have a decreased seroconversion and lower overall levels of influenza antibodies compared to non-obese HCWs.

Methods:

This study will be conducted at the West Virginia University Hospitals' annual influenza vaccination campaign (2011/2012 season) during which a total of greater than four thousand HCWs received influenza immunization during 2010/2011 season. The four week follow up blood collection will be taken in the Employee Health department and incentivized by giving the employees a $25 gift card upon completion of the follow up collection.

The junior investigator and co-investigators will recruit 100 HCWs with a BMI > 30 and 100 HCWs with a BMI < 30 for this study. The inclusion criteria will be all HCWs receiving inactivated influenza vaccine by intramuscular administration. After consent, the initial serum antibody titers will be obtained to determine the current concentrations to the influenza strains in the 2011 vaccine (presumably H3N2, H1N1, B) will be taken by a nurse or nurse practitioner and then the HCW will receive recommended influenza vaccine by a nurse or pharmacist. The follow up blood collection will be performed four weeks later. HCWs who do not return for follow up will be contacted to encourage retention.

Specimens will be collected and sent to the clinical laboratories for centrifugation and -70°C and frozen storage. Once all samples are collected, they will be sent to St. Jude Children's Research Hospital for analysis using the hemagglutination inhibition (HI) and mirconeutralization assays. Seroconversion will be defined as a fourfold increase in titer. Using the primary outcome of seroconversion, a total of 200 patients will achieve a power of 89% with an alpha of 0.5. Geometric mean titers (GMT) of pre- and post-influenza vaccine sera will be determined. Fischer's exact or chi-square will be used for comparison of HI antibody titers and categorical variables. Continuous variables will be analyzed using the student's t-test.

Results:

Outcome measures will include baseline pre-vaccination antibody titers and post-vaccination antibody responses to the influenza vaccine in obese and non-obese HCWs during the 2011/2012 influenza season.