Cytomegalovirus (CMV) Vaccines: Reinfection and Antigenic Variation

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Statistical Design and Power

The primary outcome for the proposed study is increased protective behaviors resulting in a decrease in congenital CMV (cCMV) infection. Based on previous data, the cCMV infection rate in the population is 0.6-1.0%. The outcome for the study was designated as the increased awareness and knowledge of CMV risks for CMV acquisition. Although no data existed on women's CMV awareness in Brazil, CMV awareness in Brazilian women was believed to be similar to US women where less than 15% of women have heard of CMV and even fewer are aware of behaviors that might decrease their risk of acquiring CMV infection. Our previous study in the US using this behavioral intervention found that correct knowledge in the intervention group increased from a mean CMV knowledge score of 7.7 (SD, 3.2) to 11.3 (SD, 2.2) on a 16- point scale. Based on the previous data, a sample size of 200 (100 in each group) was viewed to be adequate to determine a 3-point mean difference in pre and post correct CMV knowledge in the study cohort.

All statistical analyses has included in all participants in the study. Although data on some participants could be missing, all relevant data available from each participant will be used in the analyses. The primary statistical analysis will consist of a simple comparison of binomial proportions. The relative risk and confidence interval will be reported. If the two groups show a difference in cCMV infection rates, knowledge, protective behaviors or risk behaviors, then interactions will be evaluated and subgroup analyses will be conducted to determine whether the effect is found throughout the subgroups of participants. The following factors were considered for subgroup analysis: race and ethnicity, maternal age, and maternal CMV infection. Since many of the data are dichotomous variables, standard statistical methods for rates and proportions was applied. The Wilcoxon rank sum test will be used to compare continuous variables, and survival analysis methodology may be used to compare time-to event variables. Means, standard deviations, and percentages will be collected on the number of intervention sessions attended, the mean length of the intervention session, and implementation fidelity. Descriptive statistics will be calculated for the participant satisfaction about intervention and level of care they received. Intent-to-treat approach will be used for the overall benefits of the intervention. For lost to follow-up, i.e., missing data, we will take into account the type of missing data and use appropriate methods.
For ignorable missing data, we will use multiple imputation method through the SAS MI procedure. For non- ignorable missing data, we will consider selection models and pattern-mixture models. If many participants are lost to follow-up, a sensitivity analysis will be performed including participants lost to follow-up with different assumptions regarding their outcome, to determine whether the results are robust.