Title of Study: Heparin Prophylaxis Dosing for Antepartum Hospitalizations (HEPDOSE)

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Document: Statistical Analysis Plan

Traditional univariate analysis was performed for our primary and secondary outcomes with Chi-square or Fisher exact test for categorical variable and t-test or Wilcoxon rank-sum test for continuous variables. A logistic regression analysis was performed to further assess the association of elevated aPTT with gestational age-based dosing of unfractionated heparin relative to standard dosing. We also performed a multivariate logistic regression to adjust for confounders. Confounders included in the model were a priori covariates that potentially could affect the response to unfractionated heparin along with baseline characteristics from our univariate analyses comparing study arm groups that had a p value < 0.2. Via a stepwise regression, none of the variable demonstrated a significant effect on our primary outcome. However, for our final model we elected to adjust for creatinine and obesity based on clinical relevance and a priori knowledge of these factors being potential confounders that may not have been detected in our study cohort due to the small sample size.

Statistical significance was defined as a p-value of < 0.05 or non-overlapping 95% confidence intervals (CI). All analyses were conducted using Statistical Analysis Software (SAS), version 9.4 (Copyright 2013, SAS Institute, Inc. Cary, NC).