Statistical Analysis Plan

EHR-Based Medication Complete Communication Strategy to Promote Safe Opioid Use

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Analysis Plan – Main Manuscript

Descriptive statistics were calculated for all socio-demographic, ED visit, and opioid prescription characteristics. Chi-square, one-way Analysis of Variance (ANOVA), and Wilcoxon rank-sum tests were used, as appropriate, to test for balanced randomization. An inter-cluster correlation assessment was conducted to assess the degree of independence among individuals in the same cluster. We used generalized linear mixed models on all outcomes adjusting for physician clustering. Models were run for dichotomous outcomes (safe demonstrated dosing, safe actual dosing; adjusted odds rations [ORs] reported) and for continuous composite knowledge score (adjusted mean differences reported). Examination for possible associations between patient characteristics and outcome variables revealed significant was conducted, and all models controlled for covariates that related to the outcome. To isolate the effect of the SMS texting portion of the intervention from the EMC^2 EHR embedded tools a generalized linear mixed model was conducted utilizing two dummy variables ("emc2" for patients in both intervention arms, "text" for patients in EMC^2 +SMS arm) rather than the study arms on the primary and secondary outcomes as well as the individual knowledge or behavior questions linked to each text message. Significance for all analyses was set at $p < 0.025$ to adjust for multiple testing.

All analyses were first conducted using an intent-to-treat approach. Subsequently, because some patients did not receive one or more pieces of the intervention, the primary outcome was analyzed per-protocol, where the same methodology described previously was used but applied only to patients who successfully received all patient-facing pieces of the intervention. Patients in the EMC^2 arm were included in the per-protocol analysis if they received the MedSheet and the patient-centered TWS prescription wording on their bottle. Those in the EMC^2 +SMS arm were included in the per-protocol analysis if they received the MedSheet, TWS prescription wording on bottle, successfully enrolled in SMS texting, and received all seven text messages.

The planned enrollment target was for 816 patients to complete the 1-2 week follow-up interval, which would have provided 80% power to detect a difference of 11.8% (from pilot data) between each of the intervention arms and the usual care arm for the primary outcome of any error on the demonstrated dosing task. All analyses were performed using SAS 9.4 (SAS Institute Inc, Cary, NC).