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Statistical Analysis Plan

The CMSL sites will be clustered-randomized based on clinic location, patient volume and patient to provider ratio to the intervention and control arm. Baseline characteristics (e.g. sex, age, race, ethnicity, insurance plans etc.) will be collected and compared between groups to ensure consistency for the investigation of all aims and sub-aims. Where applicable, statistical tests will be 2-tailed. T-tests will be used to measure the statistical significance of continuous data between groups. Chi-Square tests will be used to measure the statistical significance of categorical data.

All primary and secondary outcomes will be assessed using a GLM model and appropriate link and distribution, e.g. multivariate Poisson/Linear regression with robust standard errors. We will check model assumptions and power to produce constructive analysis and determine the effects of the interventions on the final outcomes. All analyses will be two-tailed and results will be reported both as effect estimates (with standard errors and p values) as well as effect estimates with 95% confidence intervals. We will estimate average treatment effects (ATEs) to mitigate biases in intervention-control group comparisons. These biases arise from permanent differences between the groups as well as biases in pre-post comparisons resulting from secular trends unrelated to the intervention. In the simplest case, program effects are assessed by comparing pre-post differences in outcomes between practices exposed (Y12–Y11) and not exposed (Y22–Y21) to the BPA, i.e. (Y12–Y11)–(Y22–Y21). We will calculate program effects on practice-level outcomes using a semi-parametric, causal analysis if required. We will compare differences in outcomes between intervention and control practices. Multiple periods will be examined, when possible, to assess potential "burn-in" (effects of the intervention). Demographic variables that are significantly different between groups ($p < 0.05$) will be included in a multivariable (adjusted) model.

The analysis will be conducted based on the principle of "intention-to-treat (ITT)." All patients who consented and met the inclusion criteria will be included in the analysis per the group they were recruited into. For missing data via survey collection inclusion of only patients who completed all 3 sets of questionnaires could bias results toward improvement. To minimize this potential bias, a last observation carried forward (LOCF) technique will be applied. Results from the LOCF technique will be further compared to those from the measured data to assess the impact of loss to follow u