REACH P2: Communication Coaching to Improve Patient and Clinician Satisfaction in Cardiology Encounters

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Analysis Plan

F.2 Aim 1 analyses**:**

*Hypothesis 1a***:** As compared to the control group, clinicians randomized to the intervention will have a **greater mean number objective measures of communication quality** in encounters with both Black and White patients combined and in each race subgroup.

The goal of the primary Hypothesis (1a) is to determine the efficacy of the clinician communication coaching intervention versus usual care on an objective measure of the quality of communication from baseline to post-training. Additionally, we are interested the intervention effect within Black patients and White patients separately. The quality of communication will be assessed at both baseline encounters and post-training encounters by a summary of clinician encounter counts derived from the audio recordings. We plan to use mixed-effects models[27] as our primary analytic strategy because they will appropriately account for the intracluster correlation of multiple patient encounters for each clinician. The mixed-effects model for Hypothesis 1a will have the following form:

$\log(\lambda_{ik}) = \beta_0 + \beta_1(\text{int}) + \beta_2(premean_k) + \beta_3(\text{clinsex}_k) + \beta 4(\text{clintype}_k) + b_{0k}$, where Y_{ik} is the number of quality communication statements for patient *i* in the post-period clustered within physician *k*, and Y_{ik} is assumed to be Poisson with mean and variance equal to λ_{ik}. The fixed effects in the model include indicator variables intervention group (*int*), each clinician's mean number of quality communication statements per conversation prior to the intervention, and the clinician stratification variables. The random intercept, b_{0k}, is normally distributed and accounts for dependence of encounters within clinicians. PROC GLIMMIX (with the quadrature option) in SAS (SAS Inc., Cary, NC) will be used to fit the mixed-effects Poisson model and test the primary hypothesis (1a). Specifically, if β_1 is positive and significantly different than zero, this provides evidence of greater communication quality among patients and clinicians in the intervention group as compared to the control group.

The analysis for Hypothesis 1a will also be conducted for encounters with white and black patients separately.

Hypothesis 1b: Black patients and White patients seen by clinicians in the intervention group will report **higher mean quality of patient-centered care** compared to patients seen by control group clinicians.

The secondary outcome, quality of patient-centered care, is a continuous measure assessed at baseline and post-training. However this is a patient-centered outcome (i.e., the patient's perception) and the same patients are not being followed longitudinally. Therefore, the patients' data collected in the baseline period will not be incorporated in the analysis.

$Yik = \beta_0 + \beta_1(\text{int}) + \beta_3(\text{clinsex}_k) + \beta 4(\text{clintype}_k) + b_{0k}$, where Y_{ik} is the IPC score for patient *i* clustered within physician *k*, and Y_{ik} is assumed to be normally distributed. The fixed effects in the model include indicator variables intervention group (*int*) and the clinician stratification variables. The random intercept, b_{0k}, is normally distributed and accounts for dependence of patients within clinicians. PROC MIXED in SAS (SAS Inc., Cary, NC) will be used to fit the mixed-effects model and test hypothesis (1b). Specifically, if β_1 is positive and significantly different than zero, this provides evidence of greater IPC among patients of clinicians in the intervention group as compared to the control group.

Hypothesis 1b will be repeated within Black and White patients separately with the goal to ensure that the intervention is effective in each subgroup (as an overall treatment effect can sometimes mask important heterogeneity). Relative differences in the intervention effect on reducing disparities will be addressed in Aim 2.

F.3 Aim 2 Analyses**:**

Hypothesis 2a: Racial disparities in objective measures of the quality of communication will be **lower** in encounters with clinicians in the intervention group as compared to encounters with clinicians in the control group.

Hypothesis 2b: Racial disparities in patients' perceptions of the quality of patient-centered care will be **lower** among those seen by clinicians in the intervention group as compared to encounters with clinicians in the control group.

A mixed-effects Poisson model will again be the primary modeling strategy for the objective communication outcome Aim 2 analyses. For this Aim, however, the model will include patientrace interaction terms and will have the following form: $\log(\mu_{ik}) = \beta_0 + \beta_1(Black_i) + \beta_2(int_k) + \beta_3(Black_i*int_k) + \beta_4(premean_k) + \beta_5(clinsex_k) + \beta_6(clintype_k) + b_{0k}$, where Y_{ijk} is the number of quality communication statements for patient *i* in the post-period clustered within physician *k*, and Y_{ik} is assumed to be Poisson with mean and variance equal to μ_{ik}. Again, the random intercept b_{0k} is normally distributed and account for dependence of encounters within clinicians. In this model, $Black_i$ is the indicator variable for whether a patient is Black (value of 1) or White (value of 0).

Post-treatment, the Black-white mean difference among patients seen by usual care group clinicians is $BWuc = \exp(\beta_0 + \beta_1) - \exp(\beta_0)$, **this represents the racial disparity in communication quality**. The B-W mean difference among patients seen by intervention group clinicians is $BWint = \exp(\beta_0 + \beta_1 + \beta_2 + \beta_3) - \exp(\beta_0 + \beta_2)$.

Hypothesis 2a will be tested by β_5 being significantly greater than zero, indicating a greater mean number of quality communication statements for the intervention group versus the control group for Black patients as compared to White patients (i.e., the intervention group reducing the racial disparity). The estimated incident rate ratio, p-value, and 95% confidence intervals will be calculated via estimate statements in PROC GLIMMIX.

A similar linear mixed-effects model (rather than a Poisson) model will be used to examine the reduction in racial disparities of quality of patient-centered care and test Hypothesis 2b. Note that in a linear model framework, the coefficients will represent differences in means rather than rate ratios.

Power and Sample Size Considerations: The effect of interest for Aims 1 and 2 is the relative difference in the post-period between the intervention and usual care groups; Aim 1 focuses on the overall difference and the difference within Black and White patients separately, while Aim 2 on the difference within Black patients compared to White patients. The sample size requirements are greatest for Aim 2; as discussed by Leon and Heo (2009)[29], the needed

sample size for the patient race-by-intervention group interaction is 4 times that needed for the overall test. For Hypotheses 1a and 2a, our sample size calculations are based upon the difference between two Poisson rates (incident rate ratio) in a cluster randomized design (i.e., patients clustered within clinician).[30]

Based on preliminary studies, the baseline mean number of quality communication statements is 1.0, and a conservative range of coefficients of variation (CV) is 0.2 to 0.5 to account for patients clustered within clinician. With a **sample size of 240 patients in the post period (6 per clinician)** and a type-I error of 5%, we will have 80% power to detect incident rate ratios of 1.5 to 1.8 for Hypothesis 1a in the overall test, 1.6 to 1.9 for Black or White patients separately, and 1.8 to 2.5 for Hypothesis 2a.

For hypotheses 1b and 2b, our sample size calculations are based upon the difference between two means in a cluster randomized design. We present a conservative range of intraclass correlation coefficients (ICC) to account for patients clustered within clinician.[30] With a **sample size of 240 patients (6 per clinician)** and a type-I error of 5%, we will have 80% power to detect mean differences of effect size 0.37 to 0.44 for Hypothesis 1b in the overall test, 0.52 to 0.56 for Black or White patients separately, and 0.65 to 0.91 for Hypothesis 2b. PASS 15 was used for all calculations.[31]

	Number of clinicians	Number of patients in the postintervention phase (number per clinician)	Hypothesis 1a and 2a: Incident Rate Ratio		Hypothesis 1b and 2b: Mean Effect Size	
			CV	Pre-post Relative Rate	ICC	Pre-post Difference
Aim 1: Overall intervention versus usual care	**40 (20 in each treatment arm)**	**240 (6 per clinician)**	0.2 0.35 0.5	1.5 1.6 1.8	0.01 0.05 0.1	0.37 0.41 0.44
Aim 1: Racial subgroup intervention versus usual care	40 (20 in each treatment arm)	120 (3 per clinician)	0.2 0.35 0.5	1.6 1.8 1.9	0.01 0.05 0.1	0.52 0.54 0.56
Aim 2: Racial differences in intervention versus usual care	40 (20 in each treatment arm)	Effective sample size is 60 (1 or 2 per clinician)	0.2 0.35 0.5	1.8-2.2 1.9-2.3 2.1-2.5	0.01 0.05 0.1	0.65-0.91 0.66-0.91 0.67-0.91