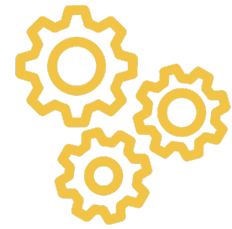# Analysis Plan

Project Name: Increasing flu vaccine uptake at Atlanta VA's through the use of a provider report card

Project Code: 1904

Date Updated: December 18, 2019

This document serves as a basis for distinguishing between planned (confirmatory) analysis and any unplanned (exploratory) analysis that might be conducted on project data. This is crucial to ensuring that results of statistical tests will be properly interpreted and reported. In order that the Analysis Plan fulfill this purpose, it is essential that it be finalized and date-stamped before we begin looking at the data — ideally, before we take possession of the data. Once this plan is finalized, a date is entered above, and the document is posted publicly on our team website.

Project Description

The Office of Evaluation Sciences is collaborating with the Atlanta VA Health Care System to increase seasonal flu immunizations among veterans. The intervention targets physicians, advanced practice providers, and nurses. It includes a behaviorally informed performance report card that compares the vaccination rates for the recipient patient aligned care team (PACT) to the top ten percent of PACTs in the Atlanta VA Health Care System. Report cards will be delivered via email. They also include an attached PDF leaflet with evidence-based actionable recommendations for PACTs and a link to frequently asked questions on the intervention, data used and why providers are receiving the report card email. The intervention will be delivered to PACTs monthly in four rounds, from early November through early February. Final, patient-level outcomes data will be pulled from Atlanta VA's electronic health record system one month after the final delivery of the intervention.

Data and Data Structure

This section describes variables that will be analyzed, as well as changes that will be made to the raw data with respect to data structure and variables.

The raw dataset will be pulled from Atlanta VA's electronic health record (EHR) system one month after the final delivery of the intervention. That dataset will be at the individual patient level and will, in sum, include records of (1) patients empaneled to a PACT and (2) records of flu vaccination for those patients through the end of the study period (2/29/2020). More specifically, it includes the following variables:

- Patient SID (a unique identifier, but not linkable to personal identity without VA crosswalk)
- Assigned provider SID and title (PCMMProviderIEN, PCMMProvider, and PCMMTitle) - these refer to the provider to whom the patient is empaneled (i.e., assigned for primary care)

- Patient-aligned care team (PACT) to whom the patient is empaneled (Team)
- Patient characteristics include age range, race/ethnicity, rurality and gender
- Date when the patient last received a flu vaccine that was either delivered at the VA or reported to the VA (ImmunizationDateTime)

We also aim to obtain
- An indicator that gives the date of flu shot receipt if one was received in the 2018-2019 flu season (i.e., between 9/1/2018 and 5/1/2019), and
- An indicator that gives the date of flu shot receipt if one was received in the 2019-2020 flu season (i.e., between 9/1/2019 and 5/1/2020)

Outcome Variable to Be Analyzed:

Receipt of influenza vaccine during the study period (11/4/2019 -- 2/29/2020, inclusive): We will use a patient-level outcome variable representing whether the patient received the influenza vaccine during the study period, as identified by the patient's influenza vaccine timestamp. We will count influenza vaccine obtained at the Atlanta VA, as well outside of the VA system and reported to the VA (which results in a date-time-stamped record of vaccination in the VA's EHR system).

Transformations of Variables: We will calculate whether the flu vaccine was received in the study period by using the "ImmunizationDateTime" variable. If a patient was vaccinated within the study period, he/she will be coded as vaccinated (i.e., "1"). If the patient was not recorded as having a vaccination he/she will be coded as not vaccinated (i.e., "0"). Those who were recorded as having received vaccination outside of the study period but within the 2019/2020 flu season (e.g., in October 2019) will be filtered out (i.e., not included in the analysis) because at the beginning of the study period, they were not candidates for the intervention.

Imported Variables: To minimize the probability of treatment contamination because a provider works for two PACT teams, we included only those PACT teams without provider overlap between other teams in the study. In this respect, 82 teams were randomly allocated to treatment and control conditions - a treatment identifier will be merged with the data provided by VA Atlanta (using provider name as the matching variable).

Treatment of Missing Data: We expect no true missing values. On the vaccine receipt and other medical indicator variables, missing values will be interpreted as absence of an influenza vaccination or other event or condition.

Statistical Models & Hypothesis Tests

This section describes the statistical models and hypothesis tests that will make up the analysis — including any follow-ups on effects in the main statistical model and any exploratory analyses that can be anticipated prior to analysis.

Statistical Models:

Randomization Test

Before continuing with analysis, we will check the initial randomization by conducting balance tests which account for cluster assignment using observable demographic characteristics of patients (e.g., age, rurality). Balance tests will involve regressing these characteristics on treatment assignment, using cluster corrected HC2 standard errors. We will conduct these randomization tests on the full dataset. Since these patient and facility characteristics are likely correlated with our outcome, we will adjust for them regardless of whether we find significant imbalance in the dataset; we will report average treatment effects both with and without adjustment for covariates.[1]

Treatment Effects

We will estimate the causal effect of the treatment (more specifically, intent to treat) using differences of means calculated using ordinary least squares (OLS) regressions of a binary outcome (vaccine receipt) on treatment assignment. The primary question of interest is: Was the report card feedback effective in increasing flu vaccination coverage among veterans?

In the primary specification, the outcome will be regressed on treatment assignment. A patient's treatment status is determined by the treatment or control status of the PACT that patient was assigned to at the study baseline (i.e., on 10/27/2019 when the first data for the report card was pulled).[2] In a second specification, we will use covariate adjustment to increase the precision of the treatment effect estimate, based on: patient's race/ethnicity, age range, rurality and gender; prior PACT-level pre-treatment vaccination rates during the 2019-2020 flu season prior to the first email sending date; and whether a patient was vaccinated (in flu season 2018-2019).[3] Patient-level treatment assignment will be defined as:

- 'treatment' if the patient was assigned to a treated PACT or

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[1] Throughout the document, we refer to covariate adjustment as adjustment following Lin's estimator (2013; "Agnostic Notes on Regression Adjustments to Experimental Data: Reexamining Freedman's Critique." *The Annals of Applied Statistics* 7 (1): 295–318).

[2] For instance, if a patient moves PACTs after randomization, and moves from a control to treatment PACT, the patient's treatment status will remain "control" and vice versa.

[3] For the indicator for whether or not a patient was vaccinated in the previous season, conditioning on it will depend on data availability. For patients who have newly joined the Atlanta VA system during the 2019-2020 season, we will test the robustness of: (1) counting them as "0" for vaccination during the previous season, versus (2) excluding them from the model for this second specification.

- 'control' if a patient was assigned to a control PACT.

For patient i:

$$Y_i = \beta_0 + \beta_1 T_i + \beta_2 X'_i + \varepsilon_i$$

The purpose of including a covariate in vector X' is to enhance the precision of our estimate of the treatment effect by adjusting for pre-treatment differences in patient characteristics and provider characteristics. We will also adjust for whether a patient received an influenza vaccine in the previous flu season (2018-2019) (pending data availability), which is known to be a strong predictor a flu shot uptake in the current season and should enable a gain in precision of our treatment effect estimate.

In our primary analysis, we will estimate cluster-corrected HC2 standard errors.

Inference Criteria, Including Any Adjustments for Multiple Comparisons:

We will use two-tailed tests and a significance level of 0.05.

We will not perform any adjustment for multiple comparisons when analyzing our primary outcomes, since we expect just one outcome (receipt of the influenza vaccine). We may apply some adjustment for multiple comparisons in any exploratory analyses, depending on the form these analyses take.

Limitations:

We anticipate the following limitations:

- Patients can get influenza vaccinations from other sources, and these are sometimes, but not always, recorded in the VA's EHR. This will constitute unavoidable measurement error. If providers in the treatment group disproportionately make strong vaccine recommendations to patients who end up getting vaccinated outside the VA then this is something we will account for by classifying these as 'vaccinated.'

- Patient cross-over between PACTs during the study period; we propose a series of robustness tests to find out whether this introduces any bias. In addition, we have conceptualized our outcome measure as ITT at the study baseline, so that it captures treatment assignment in round 1.

- Staff cross-over between PACTs during the study period. We will request the most current PACT staff composition data prior to implementing each round (starting from round 3 onwards) and target report cards to the most recent PACT staff members so that the flu vaccination report card will be sent to the most current PACT staff members.

- Though we have tried to minimize spillover by clustering physicians, advanced practice providers, and nurses in random assignment, there are still some forms of spillover that might occur:
    - Providers could talk with one another, so those in the control condition might hear something about the report card and respective recommendations to increase vaccination rates from providers in the treatment condition.

Exploratory Analysis:

We will examine the heterogeneity of the treatment effect for the first three intervention rounds. For the first round (fielded in early November) we will look at data through November, for the second round we will look at data through December, and for the third round through January (using one day before the implementation of the next data round as cut-off point). The final outcome data includes cumulative vaccination rates for the entire study period; these snapshots look at the short-term dynamics (1 month) of each additional round of the intervention (independent of the performance feedback's content). We will do this by OLS regression on these sub-periods, with and without covariate adjustment. This will yield insights into habituation effects.

In addition, we will examine whether we can observe a displacement effect where we may see an increase in vaccinated patients in the first (or second) period, but a decrease in a later period (equivalent to the prior increase). For such an analysis, we will construct non-cumulative datasets (i.e., net vaccination rates within a given month) for each of the four rounds (or time periods). We will do this by OLS regression on these sub-periods, with and without covariate adjustment.

We further plan to explore potential heterogeneity of treatment effects for different subgroups of patients (e.g., by age range, gender, race/ethnicity, rurality, PACT's 2019 pre-study period vaccination rates, PACT's 2018-2019 flu season vaccination rates (pending data availability), as well as the specialization (if any) of the provider clinic). In addition, we will examine whether being classified as a "Top 10% PACT" versus the rest in any of the four intervention rounds has heterogeneous effects on the treatment. We will do this by OLS regression on these subgroups, with and without covariate adjustment.

To account for potential PACT staff movement during the study period, we will re-estimate our primary model specification, including a covariate of whether a PACT has remained stable throughout the study period (i.e., the PACT staff remained the same) versus those that experienced fluctuations, new staff members, or staff attrition. We will do this by OLS regression, with and without covariate adjustment.

As a final set of robustness tests, we will limit the sample to patients who do not move between PACTs during the study period, as well as those who do not move plus those who move across

PACTs but within experimental conditions[4]. Finally, we will re-conceptualize patients' treatment status as "ever treated", thereby only including those patients who have ever been empaneled to a treatment PACT at any point in time during the study period. We will do this by OLS regression, with and without covariate adjustment.

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[4] For example, if a patient would move form a treatment PACT to another treatment PACT, we would include him/her - same goes for a patient who moves from a control PACT to another control PACT. however, if a patient would move from a treatment PACT to a control PACT (or vice versa) at any point in time, we would exclude him/her.